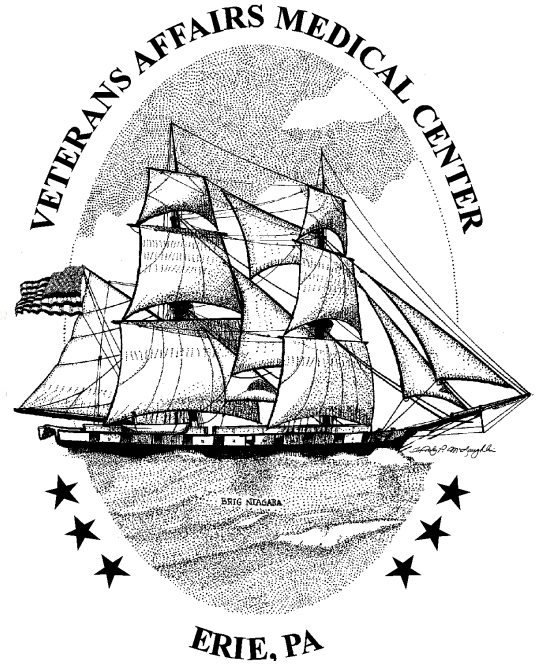
CLINICAL and ANATOMIC LABORATORY MANUAL



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Pathology & Laboratory Medicine
VA Medical Center, Erie, PA 16504

VETERANS AFFAIRS MEDICAL CENTER
Erie, Pennsylvania

CLINICAL LABORATORY MANUAL
May 2010

Pathology & Laboratory Medicine

This manual has been prepared by the staff of Pathology & Laboratory Medicine in order to apprise you of general policies and procedures for procurement of specimens and services provided by the Laboratory. No part of this manual may be altered without the consent of the Medical Director, Pathology & Laboratory Medicine.

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I. General Information and Services

Pathology & Laboratory Medicine

I. General Information and Services

The Pathology & Laboratory Medicine performs a comprehensive range of Laboratory tests with our goal being to provide accurate and timely Laboratory test results in a cost effective manner.

A. LOCATION

Pathology & Laboratory Medicine is located on the first floor, east wing, E1-1A.

B. PEOPLE WHO CARE

The Laboratory is directed by a Pathologist and staffed by qualified Medical Technologists and support staff who are committed to provide the highest level of quality and service. The staff has broad based knowledge and technical expertise to assist with information regarding significance of test results, unusual cases, and technical matters.

C. SERVICES PROVIDED

Pathology & Laboratory Medicine provides Clinical and Anatomic Services.

- The Clinical laboratory offers a wide variety of testing being performed with sufficient rapidity to support emergency, inpatient acute care, outpatient services, outreach clinics and long-term health care monitoring. The departments in the Clinical Laboratory include Chemistry, Special Chemistry, Therapeutic Drug Monitoring, Hematology, Coagulation, Blood Bank, Microbiology, Serology/Immunology, Urinalysis, and Blood Gases. Each department provides a comprehensive menu of testing.
- Anatomic Pathology includes surgical pathology, intra-operative consultation, cytopathology, and post-mortem examination.
- Ancillary Testing Program Services includes establishing policies, standards, operation, quality management and medical appropriateness for all bedside laboratory testing within the Medical Center and its outreach functions.

D. LABORATORY HOURS OF OPERATION AND STAFFING

Laboratory technical coverage is available 24 hours per day, assuring adequate coverage to meet the demands of the inpatient and outpatient services provided. The hours of operation are as follows:

1. Clinical Laboratory

Sunday – Saturday…….Technologist on-site 24 hours

Holidays…….12:00 AM to 4:30 PM

The full range of technical services, including inpatient phlebotomy, are provided on all three shifts. Outpatient phlebotomy is provided during first shift only, Monday – Friday. Second shift holiday coverage (4:30 pm – 11 pm) is provided by a standby/on call technologist. During these holiday hours, the MAA must be notified to phone the covering medical technologist. The MAA will be provided a schedule of technologists covering the designated hours. After completing the work from the call back, the technologist will contact the AOD/PCF on duty to clearly establish that there is no requirement to stay longer.

2. Anatomic Pathology

Weekdays (Monday - Friday)	Surgical Pathology, Cytopathology, and Autopsy Pathology

On weekends and holidays, autopsy services are also available, if necessary.

E. KEEPING YOU INFORMED

The Laboratory will provide you with up-to-date information regarding current developments, new in-house tests, and any changes in test procedures.

F. ACCREDITATION

Pathology & Laboratory Medicine is accredited by Joint Commission and the Food and Drug Administration (FDA).

G. QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)

Quality Assurance (QA) and Quality Control (QC) are an integral part of daily operation. The internal and external proficiencies are utilized to monitor the accuracy and precision of each patient run for every assay performed.

Laboratory Standard Operating Procedures (SOP's) have been written to include when to repeat testing to assure that reported test values are accurate and precise.

H. DEDICATION TO EXCELLENCE

The Laboratory has state of the art, automated and computerized equipment and an efficient and motivated workforce to provide services that are of high quality and customer focused.

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CLINICAL LABORATORY

Laboratory tests contribute vital information about a patient's health. Correct diagnostic and therapeutic decisions rely, in part, on accuracy of test results. Adequate patient preparation, specimen collection, and specimen handling are essential prerequisites for accurate testing. The accuracy of test results depends on integrity of specimens.

This section provides information on the following:

A. Ordering of Laboratory Test(s)
B. Specimen Collection and Handling
C. Criteria for Handling/Rejecting Unacceptable Specimen(s)
D. Turnaround Time of Test Results
E. Reporting of Test Results
F. Specimen Retention
G. Reference Laboratory Testing

A. ORDERING OF LABORATORY TESTS

1. ORDERS - GENERAL INFORMATION

a. ***"Electronic" test(s) requests:***

- All requests for Clinical Laboratory tests are made electronically into the CPRS computer system by authorized healthcare providers. The Laboratory personnel are not authorized to place orders for Laboratory testing except under situations such as:
  - Lab test orders that are cancelled and are required to be recollected.
  - Patients designated by the Coumadin Clinic who require protime testing.
  - Patients coming to the Laboratory with standing orders from another VA facility.
  - Reflex testing as designated per policy.
  - During emergency situation (e.g., Code Blue or Surgery)

- The following requests for testing should be **phoned** to the Laboratory in addition to electronically ordered:
  - STAT test requests
  - "Immediate Collect" orders
  - Blood culture requests

- Blood Bank testing – the physician CPRS order and a completed SF518 form for each unit requested must be submitted.

- Special Procedure(s) requests: The following tests should be scheduled with the Laboratory.
  - Glucose tolerance tests – Chemistry (x2182)
  - Bone marrow procedures – Histology (X2189/x2176)
  - Therapeutic phlebotomies – Blood Bank (x2190)
  - Frozen sections – email to P&LM program assistant and P&LM supervisor.

- HIV testing is considered routine testing and no longer will require a written consent (documented verbal patient consent only). Laboratory service staff will not request, require or verify consent per VHA DIRECTIVE 2009-036 dated 8-14-2009.

b. ***Verbal/telephone test requests***:

- Telephoned or verbal orders for laboratory tests are not authorized except in emergency situations. Providers are required to enter the order into CPRS and then contact the lab to have the lab test collected or completed using previously drawn specimens.
- In the event of an emergency request, the P&LM staff taking the verbal or telephone order for laboratory tests should write down the patient's full name/identification and complete order or enter it into the computer. The order should be read back to the provider to ensure accuracy. The P&LM will document in VistA under comment section for patient test accession number that "read back was performed for the test order."

c. The Laboratory test order must be accurate and include the following information:

- Patient's full name and full social security number

- Test(s) required
- Type of material to be analyzed (e.g., blood, urine, cerebrospinal fluid, etc.)
- Ordering provider
- Date, and when relevant, time of specimen collection
- Any special handling required.

NOTE: The correct information is of paramount importance. Incorrect or incomplete information causes unnecessary delays, as all discrepancies must be resolved prior to processing the specimens.

2. LABORATORY TEST ORDERING URGENCY

An urgency status is defined as the priority given to each laboratory test that will indicate how quickly Laboratory personnel must perform that test.

The urgencies for the Laboratory tests are as follows:

Test Ordering Urgency	Definition	Turnaround Time (TAT)
STAT	The "STAT" as applied to Laboratory test requests means a request for information that has immediate implications for patient care. The key elements of the definition are: * Patient's condition requires immediate action * Results of the test are required before a decision about the type of action to be taken can be made The category should be confined to life threatening situations.	One (1) hour for most tests. List of approved tests on STAT list is attached.
IMMEDIATE COLLECT	"Immediate collect" applies to test requests that need to be collected at a specific time or right away, other than normal inpatient rounds. * The lab needs to be called/ notified and a order needs completed. * Immediate collect may also be used for outpatients; however, it would not be the recommended choice. This ordering urgency should be used for special circumstances to include timed specimen collection for drug or stimulation testing or serial cardiac monitoring.	Up to two (2) hours.
ROUTINE	The "routine" category includes test request(s) that are required for routine treatment/follow-up of patients. NOTE: If no urgency is given, the order will be entered as "routine".	Dependent on test complexity
PRE-OP	The "pre-op" status applies to pre-operative laboratory work-up for an elective surgery. NOTE: Any delay in writing the order will not be considered enough justification to place it in the "STAT" category.	One (1) to two (2) hours
PATIENT WAITING	The "patient waiting" category applies to outpatients who are waiting for the test results. The tests will be performed ASAP.	Two (2) hours for routine tests

3. LABORATORY TEST ORDERING DURING COMPUTER DOWN

In the event of a computer scheduled downtime or failure, the following procedure should be implemented:

PHLEBOTOMY:

INPATIENT:

1. If phlebotomy collection rounds are pending:

    A. Contact all ward locations for identification of patients needing phlebotomy.
    B. Request that the attached Laboratory Request Form (Computer Back-Up Sheet) be filled out for each patient with pending blood work. These sheets will be kept at the nurses' station until the phlebotomist arrives. The phlebotomist will use these sheets to properly identify the patients and tests required.
    C. Specimens will be hand-labeled with patient's full name, full social security number, date and time of draw and phlebotomists' initials in the presence of the patient.

    NOTE: All nursing locations should routinely print a list of lab orders to be collected each morning to assist with scheduled and unscheduled computer downtimes.

OUTPATIENT:

1. Patients with lab order number only:

    A. Contact patient's originating clinic to obtain lab test(s) associated with the order number.
    B. Fill out Laboratory Request Form (Computer Back-Up Sheet) with appropriate test requests, lab order number and complete patient identification.
    C. Obtain specimen and label with patient's full name, full social security number, date and time of draw and phlebotomists' initials in the presence of the patient.

2. Patients with Laboratory Request Form (Computer Back-Up Sheet):

    A. Obtain specimen and label with patient's full name, full social security number, date and time of draw and phlebotomists' initials in the presence of the patient.

Save all Lab Request Forms with ward collection sheets. Deliver specimens to appropriate lab departments.

*When using the manual "computer back up" form for test requests, complete the following information on the Lab Request Forms:

1. Date of test
2. Patient's full name
3. Patient's full social security number
4. Provider ordering the test(s)
5. Laboratory test(s) requested
6. Request Date
7. Collection time/date
8. Person collecting the specimen

For further information, see department specific computer downtime procedures in the Computer Downtime Log.

LABORATORY REQUEST FORM
(Computer Back-up Sheet)

TEST DATE: _____ ROUTINE TESTING UNLESS INDICATED

Laboratory Tests:

HEMATOLOGY

_____ CBC & DIFF □ STAT
_____ HGB & HCT □ STAT
_____ ESR (Westergren/Sed Rate)
_____ Retic Count
_____ Other

COAGULATION

_____ PTT □ STAT
_____ ProTime □ STAT
_____ Other _____

SEROLOGY

_____ RPR
_____ RA
_____ Other _____

URINALYSIS

_____ Routine □ STAT

MICROBIOLOGY

_____ Culture & Sensitivity
Site: _____
Use regular micro form #10-2129

BLOOD BANK

Use regular form SF 515

MISCELLANEOUS

_____ Test: _____
_____ Test: _____

UNIT: _____

Patient ID Stamp:

CHEMISTRY

_____ Glucose □ STAT
_____ Lipid Profile
_____ Liver Profile □ STAT
_____ Chem 8 □ Fasting □ Nonfasting □ STAT
_____ Chem 14 □ Fasting □ Nonfasting □ STAT
_____ Cardiac Profile □ STAT
(CPK/CK-MB, Troponin)
_____ Troponin-I □ STAT
_____ Magnesium □ STAT
_____ Lipase □ STAT
_____ Amylase □ STAT
_____ Calcium □ STAT
_____ Other _____

THERAPEUTIC DRUGS

_____ Digoxin (monitor/random) □ STAT
_____ Theophylline (monitor/random) □ STAT
_____ Dilantin □ STAT
_____ Phenobarbital □ STAT
_____ Valproic Acid □ STAT
_____ Lithium (sent out) □ STAT
_____ Other _____
_____ Vancomycin PEAK time _____
_____ Vancomycin TROUGH time _____
_____ Gentamycin PEAK time _____
_____ Gentamycin TROUGH time _____
_____ Tobramycin PEAK time _____
_____ Tobramycin TROUGH time _____
_____ Other_____PEAK time _____
_____ Other _____ TROUGH time_____
_____ Dose to be given at _____ over
_____ hours.

DOCTOR: _____

REQUEST DATE: _____

COLLECTION TIME: _____

COLLECTION DATE: _____

COLLECTED BY: _____

4. ***SPECIMEN COLLECTION AND HANDLING***

An adequate specimen properly timed, collected, identified, preserved and stored is critical in achieving an accurate test result.

a. Patient Identification

Accurate patient identification, specimen labeling and maintaining the integrity of identification from specimen collection to accessioning within the Laboratory is essential. Each section of the Laboratory will maintain the identity of each specimen during testing and reporting of test results. For complete identification procedure, refer to "Patient Identification for Phlebotomy."

b. Specimen Collection

All specimens will be collected using proper collection technique and appropriate specimen requirements for the test(s) requested.

5. PHLEBOTOMY SERVICES - GENERAL INFORMATION

The Laboratory provides phlebotomy service for all inpatients and outpatients. The phlebotomist will routinely perform venipunctures on the hand and arm. Phlebotomies in the foot can be performed with provider permission. Nursing personnel or physicians may draw blood specimens from in-line catheters.

a. Service Hours

Outpatients:

Phlebotomy service will be provided to outpatients in the Laboratory phlebotomy area from 6:30 a.m. to 5:00 p.m. Monday through Friday. Laboratory personnel are available for phlebotomy on the weekends and holidays for STAT and critical timed tests.

Inpatients:

An electronic order must be placed by the provider, or other authorized personnel, prior to scheduled phlebotomy rounds.

Pathology & Laboratory Medicine will routinely perform inpatient phlebotomy rounds at the following times:

Timing for Phlebotomy Rounds

6:00 AM
10:30 AM
3:00 PM
6:00 PM (**Not on Holidays)**
8:30 PM (**Not on Holidays)**

STAT, timed and Immediate Collect specimens will be collected as ordered. STAT requests should be limited to life threatening situations.

b. Blood Sample That Cannot Be Obtained by Phlebotomist

Pathology & Laboratory Medicine will make two (2) attempts to draw a blood specimen on a patient. The phlebotomist will not attempt more than two (2) venipunctures on the same patient. After two attempts, an alternate phlebotomist will be requested to draw the patient. If the alternate phlebotomist is unable to obtain the specimen, the attending physician will be contacted for further direction.

c. Vacutainer Tubes

All Laboratory tests require different Vacutainer tubes containing anticoagulants and preservatives. For information, refer to "Vacutainer Chart & Other Test Collection Information." For any Laboratory test(s) not listed or requiring special collection procedures, and/or special transportation, call the specific Laboratory section.

d. Other Specimens (Urine, Sputum, Stool and Swabs)

- Prior to each collection, review the laboratory's specimen requirements, including proper specimen to be collected, the amount, the procedure, collection materials, and the handling requirements.

- Preparing the patient: Provide the patient in advance with appropriate collection and instructions when necessary. **NOTE: Some 24-hour urine specimen containers may contain hazardous chemicals such as hydrochloric or boric acid. Collection containers containing these preservatives will be labeled accordingly in order to inform the patient of its content.**

- The specimens should be delivered to the Laboratory after collection. The specimens (urine, sputum, stool, and swabs) that are collected after 11:00 p.m. on weekdays and after 4:30 p.m. on weekends and holidays should be kept in the ward refrigerators. These specimens should be delivered to the Laboratory the next morning.

e. Specimen Labeling

All specimens collected by Laboratory and hospital personnel should be labeled in the presence of the patient and contain the following information:

- Patient's full name and full social security number
- Date and time (if applicable) collected
- Initials of person collecting the specimen

"AVOID COMMON ERRORS DURING SPECIMEN COLLECTION"

Careful attention to routine procedures can eliminate most of the errors. The complete blood collection system and other collection materials provided by the Laboratory can maintain the integrity of the specimens only when they are used in strict accordance with the instructions provided.

Types of errors include:

- Failure to label a specimen correctly and to provide all pertinent information
- Insufficient quantity of specimen to run test or QNS (quantity not sufficient)

- Failure to use the correct container or appropriate specimen preservation
- Inaccurate and incomplete patient instructions prior to collection
- Failure to tighten specimen container lids resulting in leakage and/or contamination of specimen

NOTE: Refer to the Specimen Rejection section of the General Lab Manual for detailed criteria for acceptance/rejection of Laboratory specimens.

VACUTAINER CHART & OTHER TEST COLLECTION INFORMATION

NOTE: Minimum sample volumes are provided to minimize unnecessarily large blood draw volumes. Questions or concerns about minimum blood volumes or turnaround times may be answered by contacting the appropriate Laboratory section or reference laboratory.

IN-HOUSE TESTS				
Tube	***Turnaround Time** (*offered as STAT with TAT ≤ 1 hour)*		***Test***	***Minimum Sample Volume***
Red/gray speckled with gel separator OR Gold top with gel separator OR Red top/Silicone coated/no additive 10 ml/7 ml	*	Daily	Acetone	2 ml
		Daily	Albumin	
	*	Daily	Alcohol (no alcohol on arm)	
		Daily	Alk. Phos. Isoenzymes	
		Daily	Alkaline Phosphatase	
		Daily	ALT (SGTP)	
	*	Daily	Amylase	
		Daily	AST (SGOT)	
		Daily	B12	
	*	Daily	Bicarbonate (CO2)	
		Daily	Bilirubin, Direct	
		Daily	Bilirubin, Total	
	*	Daily	BUN	
	*	Daily	Calcium	
		Daily	CEA	
		Daily	Chem 14	
	*	Daily	Chem 8	
	*	Daily	Chloride	
		Daily	Cholesterol	
	*	Daily	CPK	
	*	Daily	Creatinine	
		Daily	Ferritin	
		Daily	Folate (protect from light)	
		Daily	Free T4	
		Daily	GGT	
	*	Daily	Glucose	
		Daily	HDL	
		Daily	Iron	
	*	Daily	LDH	
		Daily	LDL Cholesterol (calculated)	
	*	Daily	Lipase	
		Daily	Lipid Profile	
	*	Daily	Liver Profile	
	*	Daily	Magnesium	
		Daily	Osmolality, calculated	
		Daily	Phosphorus	
	*	Daily	Potassium	
	*	Daily	Pregnancy	
		Daily	PSA	
	*	Daily	Sodium	
		Daily	T3	
		Daily	T4	
		Daily	TIBC	
		Daily	Total Protein	
		Daily	Triglycerides	
		Daily	TSH	
		Daily	Uric Acid	

Tube		***Turnaround Time*** *(*offered as STAT with TAT ≤ 1 hour)*		***Test***	***Minimum Sample Volume***
Pink Top K_2 EDTA		*	Daily	Blood Bank Specimens	4 ml
			2 hrs	Direct Coombs	
Red top Silicone coated/no additive		*	Daily	Digoxin	2 ml
		*	Daily	Gentamicin	
		*	Daily	Phenobarbital	
		*	Daily	Theophylline	
		*	Daily	Phenytoin (Dilantin)	
Lavender 5 ml EDTA		*	Daily	CBC/Diff	
			2-4 hrs	Eluate	
			Daily	HBA_1C (Glycated HGB)	
		*	Daily	Platelet Count	
			Daily	Reticulocyte	
Black 3.2% Sodium Citrate Streck ESR Vacuum Tube			Daily	Sed Rate	Tube Full
Blue 3.2% Sodium Citrate 4.5 ml		*	Daily	PT	Tube 2/3 Full
		*	Daily	PTT	
Dark Green Top Lithium Heparin 4 ml	Light Green Top PST gel Li Hep 4 ml	*	Daily	CK-MB	Tube 2/3 Full
		*	Daily	Troponin	

NOTE: *** Cardiac Profile: (1) Dark Green Top, (1) Light Green Top and (1) Gold Top

OTHER IN-HOUSE TESTS				
Test	**Turnaround Time (*offered as STAT with TAT ≤ 1 hr)**		**Collection Device**	**Collection Device**
Manual Differential (Peripheral Blood Smear)		2-4 hrs	Microscope Slide	1 drop of capillary blood from EDTA tube
CSF: Body Fluid Cell Count		2 hrs	CSF plastic vials (numbered in order of collection)	1 ml
Other Source Body Fluid Cell Count		2-3 hrs	Plastic collection container with lid OR Vacutainer tube/purple top	1 ml (clot free)
Urinalysis, Diabetic Urinalysis, Microalbumin/ Creatinine Ratio	*	2-4 hrs	Plastic collection cup with lid OR Special collection system vials	5 ml
Urine Culture		1-2 days	Special collection system – gray top tube	1 ml
Blood Gas	*	15 min	Heparinized syringe – drawn by RTs or physician only	1 ml arterial blood
Occult Blood		Daily	Special test card with sticks	Thin smear of stool
Culture and Sensitivity OR Other Microbiology Tests		2 days	Sterile culture swab OR Other sterile collecting device and/or media	Refer to Microbiology Dept. section in General Lab Manual
Surgical Pathology/Cytology Tests		Daily/Weekly	Refer to appropriate section in General Lab Manual	Refer to appropriate section in General Lab Manual

6. SPECIMEN REJECTION CRITERIA AND SUBOPTIMAL TEST REQUESTS

1. CRITERIA FOR ACCEPTANCE/REJECTION OF SPECIMENS FOR LABORATORY TESTING

The criteria for accepting or rejecting laboratory specimens for analysis to limit the number of pre-analytical variables in testing and ultimately to ensure an uncompromised reliable sample for testing. The following are the criteria for acceptance/rejection of specimens for Laboratory testing;

a. Incorrect/Inadequate Specimen Identification:

The Laboratory personnel will not assume the responsibility for identification of unlabeled specimens. All specimens not properly labeled with full patient name and full patient social security number will not be processed until positive patient identification is made by the collector. If identification cannot be secured, the specimen will be rejected.

Specimen cups must have the identification label affixed to the side of the specimen container, not the lid.

Each individual specimen container (tube, cup, swab, etc.) must be properly labeled.

b. Inadequate Volume (QNS):

Certain minimum volumes are required for test analysis. Also, the amount of additive placed into a tube is intended for a defined volume of blood. If less blood is drawn, the excess additive has the potential to adversely affect the Laboratory results. The following criteria will apply for the rejection of "short draw" samples when the optimum volume is difficult to obtain:

- Blood Bank specimens not containing at least 5 ml of clotted blood will be rejected.
- Coagulation specimens (drawn in blue sodium citrate tubes) must show 90% or greater expected fill or they will be rejected. FSP (Fibrinogen Split Products) tubes must contain 1-2 ml of blood. This tube cannot be overfilled and is obtained from the Coagulation department.
- Hematology specimens must contain at least 1 ml of blood. Westergren Sed Rate tubes (black top) must be full or they will be rejected.
- Urine specimens for routine Urinalysis must contain at least 1.5 ml of urine or they will not be accepted for analysis.

Please refer to specific test procedures for additional sample requirement information.

c. Hemolyzed Specimens:

Hemolysis can result from a difficult venipuncture or from improper handling of specimens. Hemolysis can also occur within the patient as a result of intravascular erythrocyte destruction caused by a disease state. Certain tests will be inaccurate when the specimen is "moderately" hemolyzed in vitro. The presence of a visible red pigmentation also interferes with spectrophotometric analysis and interpretation of blood banking procedures. Therefore:

- Blood Bank specimens that are hemolyzed will be rejected.
- Chemistry determination (especially LDH, K+, AST, ALT, Iron, and T4) showing moderate to gross hemolysis will be rejected.
- Specimens exhibiting slight hemolysis will be accepted for analysis. Results will be entered with a comment reflecting the presence of slight hemolysis.

d. Clotted Specimens:

EDTA (Lavender) and sodium citrate (Blue or Black) tubes for Hematology and Coagulation that arrive in a clotted condition will be rejected.

e. Delays or Error in Transport:

Specimens must be transported in as short a time as possible. Unopened specimens for coagulation studies can remain uncentrifuged for up to 24 hours.

Tubes of blood are to be kept stoppered at all times and be transported in a vertical position when possible. Specimens requiring special transport include but are not limited to:

- Ammonia-- Placed on wet ice and transported to lab immediately.
- ACTH-- Draw into chilled lavender top (EDTA). Transport on wet ice, separate and freeze plasma.
- Alcohol-- Arm must not be prepped with alcohol. Use Betadine, green soap or phisohex.
- Blood cultures--Require special preparation to ensure a sterile venipuncture.
- Fibrinogen Degradation (Split) Products: Use special tubes kept in chemistry refrigerator.
- Carotene-- Draw serum; protect from light.

Further instructions can be obtained from the appropriate Laboratory department.

All samples arriving in the Laboratory not meeting specific sample transport requirements will be rejected.

f. Improper Collection:

- Wrong collection tube: specific specimen requirements must be considered as indicated in the test chart section of the General Laboratory manual. In particular, tubes with additives cannot be used indiscriminately. An additive can interfere with the analyte to be determined.

  EXAMPLE: (1) Sodium Fluoride interferes in BUN testing (urease method)
  (2) Plasma collected when serum is needed (Amylase)

  Specimens arriving in the wrong collection tube will be rejected. Notification of specimen rejection will be made to the collecting location.

- 24 hour Urine: Improper collection of 24 hour urine specimens, i.e., wrong preservative, wrong timing, wrong pH, and lack of patient information regarding volume, height, weight, will be rejected. Date and time period of collection must be noted.

g. Gross Contamination/Unsafe Submission of Specimens:

- Specimens arriving in the Laboratory in an unsanitary condition will be discarded and a second specimen requested. Laboratory associates will notify appropriate collecting location when recollection is necessary.

  EXAMPLE: (1) Gross contamination of the outside of the container with the specimen.
  (2) Leakage of specimen from the container.

- Specimens that arrive with needles attached will be returned to the collecting location for proper submission or recollection.

2. PROCEDURES FOR HANDLING SUBOPTIMAL TEST REQUESTS AND SPECIMENS

For detailed procedures for Handling of Suboptimal (Unsatisfactory) Test Requests and Specimens, refer to Pathology & Laboratory Medicine Operations Policy 115-06.

D. TURNAROUND TIME OF LABORATORY TESTS

- The turnaround time (TAT) of Laboratory tests is the interval between specimen receipt in the Laboratory and reporting of test results. The TAT of each test depends on the urgency requested, complexity and testing location (in-house versus reference laboratory testing).
- The TAT of routine in-house testing is defined in each section of Laboratory and updated as necessary (Attachment A).
- The TAT for tests sent to reference laboratories is listed in the section "Reference Testing."

Notification of Providers When Testing is Delayed: When unexpected delays in test resulting occurs due to situations such as computer down or instrument malfunction, providers will be notified based on the following criteria:

Delay in Testing	Notification Procedure
• STAT Testing (TAT >1 hour)	Providers notified by section technologist of the reason for the delay. The STAT testing may be sent to local reference laboratory as necessary.
• Routine Testing (instrument malfunctioning or computer down-time)	Notification of all providers via computer email or telephone by the Supervisor, P&LM or designee. The Supervisor, P&LM/Medical Director, P&LM, will make the decision to send specimens to reference laboratory depending upon the reason and expected length of delay.

TURNAROUND TIME OF ROUTINE IN-HOUSE LABORATORY TESTS

Tests	*Turnaround Time*
Chemistry • Chem 8 • Chem 14	2-4 hours
Special Chemistry/Toxicology • Troponin	60 minutes
Hematology • CBC	2-3 hours
Coagulation	2-3 hours
Urinalysis	2-3 hours
Microbiology	2-3 days
Blood Bank	1-2 hours
Serology	1-2 hours

E. REPORTING OF TEST RESULTS

1. ***GENERAL INFORMATION***

The Clinical Laboratory test results are entered into the patient's electronic record via the VistA computer system upon verification. STAT test results will be reported as specified in MCM 115-04 "STAT Laboratory Testing." Critical values will be called to patient's healthcare provider and documented as specified in MCM 115-05 "Communication of Critical Values for Laboratory Tests."

2. ***REPORTS***: All Laboratory results will have adequate pertinent information and are available via the VistA computer (electronic record), which can be accessed by all appropriately privileged providers.

a. Interim Reports:
The interim reports are printed immediately at all inpatient and outpatient oncology-ordering locations after verification of the test results. The providers may also access all interim reports in the patient's VistA and CPRS chart. The interim reports should not be charted.

b. Cumulative Reports:
The cumulative summary reports are no longer printed and distributed. Cumulative reports are found in CPRS under the Laboratory Section, which could be accessed by all privileged providers.

c. Anatomic Pathology Reports
The tissue and cytology reports are sent by the Laboratory Program Support Assistant to the inpatient units, Ambulatory Surgery, and the File Room. A copy is also sent to the appropriate healthcare provider.

d. Reference Lab Reports
The copies of all reference laboratory test results are retained in the Laboratory. All reference laboratory test results are entered into VistA upon receipt without alterations that would affect clinical interpretation. Exceptions to this would be complex test results, such as electrophoresis. These more complex reports are scanned into VistA Imaging. These results have a comment attached stating "*SEE SEPARATE REPORT IN VISTA IMAGING*" to indicate original test results appear on the patient chart.

PENDING TEST RESULTS

The inquiries concerning pending in-house Laboratory test results should be directed to the specific sections of the Laboratory.

3. CORRECTION OF ERRONEOUS RESULTS:

- The Laboratory technical staff discovering the error is responsible for communicating the error to the Supervisor, P&LM or designee.
- The error should be IMMEDIATELY communicated to the healthcare provider responsible for the patient.
- The error should be corrected in the patient's report as "corrected result."
- All errors, including major and minor errors, will be documented in P&LM as a part of Performance Improvement activity with investigation of results and corrective action taken.

F. SPECIMEN RETENTION

SPECIMEN RETENTION CHART

Specimens are retained for a clinically acceptable period as defined below:

Specimen Type	***Retention Time***	***Storage Requirements***
Chemistry	2 days (at least 48 hours)	Chemistry refrigerator
Special Chemistry Toxicology Serology	2 days (at least 48 hours) 30 days (for Urine Drugs)	Special Chemistry refrigerator
Hematology • CBC's • Peripheral Blood Smears/Body Fluid Smears	 48 hours 1 month	 Room temperature in Hematology Section
Coagulation	48 hours	Room temperature
Urinalysis	24 hours	Room temperature
Body Fluids	48 hours	Room temp/refrigerate
HIV	12 months	Chemistry freezer
Blood Bank	2 weeks	Blood bank refrigerator
Blood Gas	48 hours	Room temperature
Microbiology • Culture plates • Permanently Stained Microbiology Slides (e.g., gram, trichrome, etc.)	 1 week 1 month	 Room temperature in Microbiology section
Histology Gross Specimens	2 weeks after reporting	Room temperature in preservative
Cytology • CSF/Body Fluids • Urine	 48 hours 24 hours	 Refrigerate Room temperature

Reference: JCAHO comprehensive Accreditation Manual for Laboratory 2004, Appendix E.

G. REFERENCE TESTING – CLINICAL LABORATORY

The tests that cannot be performed in-house are sent to fully accredited (CLIA 88 certified) reference laboratories.

SELECTION OF REFERENCE LABORATORY:

- The reference laboratory(ies) are selected for VISN 4 based on evaluation criteria which focuses on quality, turnaround time and customer satisfaction.
- The selected reference laboratories are approved by the Medical Executive Council.

REFERENCE LABORATORIES CURRENTLY BEING USED

Non-VA/VA Reference Laboratories	***Reference Laboratories***	***Type of Tests Sent***	***Turnaround Time***
Non-VA Reference Laboratories	Laboratory Corporation of America, Columbus, Ohio	Used for esoteric send out tests that cannot be performed in-house or by VAMC Pittsburgh	• One (1) to two (2) days for routine specimens • One (1) to five (5) days for special routine tests, e.g. 5HIAA, ACTH.
	ACL/Quest Erie, PA	• STAT tests not done in-house • Back up for instrument malfunction	• 2-3 hours for STATs
	Hamot Medical Center, Erie, PA	• Back-up for arterial blood gases	• STATS within one (1) hour
VA Reference Laboratories	VAMC Pittsburgh	• Routine tests with TATs ≥24 hours. • HIV • HCV RNA-PCR • HIV RNA, viral load • CD4-CD8 Subset • Pap Smears	• 2-3 days, usually • 2-3 weeks • 3-10 days
	VAMC Kentucky	• Mycoplasma • Epstein Barr • Farmers lung panel • Toxoplasma • Herpes Simplex Ag Titer • HCV Genotyping	• 1-2 weeks
	VAMC, Philadelphia, PA	• Vitamin D Testing • Drug Screen Confirmations (GC/MS)	• 2-3 days

III. Department Information
CLINICAL LABORATORY

A. Chemistry

B. Special Chemistry

C. Toxicology

D. Hematology

E. Coagulation

F. Microbiology

G. Urinalysis

H. Serology

I. Arterial Blood Gas

J. Blood Bank

K. Ancillary Testing (Point of Care Testing – Waived Testing)

A. CHEMISTRY

1. General Information
2. Test Information
3. Specimen Collection and Storage
4. Reference Ranges
5. Additional Information

Attachments:
Instructions for the Chemistry Special Tests

A. CHEMISTRY

1. GENERAL INFORMATION

a. In-house Automated Tests: All automated chemistry procedures are performed during normal duty hours.

b. Reference Laboratories: Tests not performed in-house may be sent to Laboratory Corporation of America, Associated Clinical Laboratories or another VAMC for testing if approved by the Chief, Pathology & Laboratory Medicine Service. It may take a week or more to receive results for these tests. Contact the Laboratory Chemistry Department (x2182) for turnaround times of specimens sent to a Reference Lab.

c. All body fluid testing in chemistry is sent to a local reference lab for testing.

2. TEST INFORMATION

a. STAT TESTS**:** The following tests are available on a STAT basis (24 hours a day, 7 days a week). The turnaround time is approximately one (1) hour:

Chem 8
Chem 14
Electrolyte Panel
Liver Profile
CPK, LDH
Amylase
Magnesium
Lipase
Alcohol (Ethanol)

b. ROUTINE TESTS:

- TEST PROFILES: (NOTE: Any test may be ordered as a single analyte).

Liver Profile (Hepatic Function Panel)
Albumin
Total bilirubin
Direct bilirubin
Alk Phosphatase
Total Protein
ALT
AST

Lipid Panel
Cholesterol, total
HDL cholesterol
Triglycerides
LDL cholesterol, calculated

Chem 8 (fasting/nonfasting)
(Basic Metabolic Profile)
Sodium
Potassium
Chloride
CO2
Glucose
BUN
Creatinine
Calcium

Electrolyte Panel
Sodium
Potassium
Chloride
CO2

Cardiac Profile
CPK
CPK-MB
Troponin I

Chem 14 (fasting/nonfasting)
(Comprehensive Metabolic Profile**)**
Creatinine
BUN
Sodium
Potassium
Chloride
CO2
Albumin
Total protein
Calcium
Total bilirubin
Alk phosphatase
AST
ALT
Glucose

TPN Panel (for hyperal patients)
Chem 8 (fasting)
Total Protein
Albumin
Cholesterol
Triglyceride
ALT
Alkaline phosphatase
Magnesium
Phosphorus

Anemia Profile
Iron
TIBC
Transferrin
B12
Folic Acid
Ferritin

NOTE: Serum amylase, lipase, LDH, GGT, Ammonia, and uric acid are available for testing, but are not included in any profile.

- CHEMISTRY SPECIAL TESTS:

  24 Hour Urine Testing
  In-house testing: Sodium, Potassium, Chloride, Creatinine, Creatinine Clearance, Protein, Glucose, Calcium and Microalbumin.
  Glucose Tolerance Test – must be scheduled with Laboratory.
  Serum Acetone
  Ethanol

(See attachment "Instructions for the Chemistry Special Tests" for specific instructions for these tests)

3. SPECIMEN COLLECTION AND STORAGE

a. Except for metabolic studies, blood specimens should be obtained after an overnight fast of 8 or more hours or at least 4 hours after a solid meal. Lipid profiles and triglyceride analysis should be collected after a 12-14 hour fast.

b. Serum or plasma should be free of hemolysis and separated from the clot ASAP or within 2 hours of collection. If there is marked hemolysis, lipemia or icterus, the specimen should be noted as such on the final report. If gross hemolysis is present, a new specimen may be requested at the physician's discretion.

c. 24-hour urine should be collected with the appropriate preservative and preferably refrigerated during the collection period. See attachment “Instructions for the Chemistry Special Tests” regarding list of tests requiring preservatives.

d. Cerebrospinal fluid and other body fluids should be analyzed promptly or refrigerated at 2-8°C. All body fluid testing is sent to a local reference lab for testing. Normal ranges are not available for most body fluid testing.

4. REFERENCE RANGES

Chemistry Routine, Glucose Tolerance Tests and Special Tests: *Refer to "**Test and Reference Range Chart**"(Section IV).*

5. ADDITIONAL INFORMATION

Drug Effect on Blood Chemistry:

It is important for the physician and laboratory technologist alike to be aware of the possible effect of drugs on laboratory test results. Communication between those concerned with patient care is essential since many of the drug interferences have been discovered through such cooperation.

Drugs may have physiological or pharmacological actions in addition to those for which they are prescribed; they may cause idiosyncrasies or hypersensitivities, which could lead to unusual test values; they may have toxic effects particularly on the liver and kidneys; and finally they may interfere in test procedures. In most cases, the association between the drug and unexpected test results may be readily identified. Results become abnormal after the drug is given and return to normal after it is discontinued.

Please contact the Laboratory with any specific questions regarding drug interferences.

INSTRUCTIONS FOR THE CHEMISTRY SPECIAL TESTS

A. 24 Hour Urine Collection

INSTRUCTIONS FOR NURSING

1. General Information:

a. Schedule 24-hour urine with the Laboratory. Collection is normally taken between 7AM to 7AM the following day.

b. Specimen bottle may be obtained from the Laboratory.

c. The patient is carefully instructed to empty his bladder at 7:00 AM and discard this urine. He collects all subsequent urine up to and including that voided at 7:00 AM the following morning.

d. Label specimen with name, social security number, order number, and the date test started and date finished.

e. Keep specimen bottles refrigerated and away from direct sunlight.

f. For Outpatient urine collection, the patient should be given a copy of the collection instructions entitled Instructions for 24 Hour Urine Collection (attachment).

2. Creatinine Clearance:

24-Hour Urine

I. PRINCIPLE:

Creatinine Clearance is a means of quantitatively expressing the rate of excretion of creatinine by the kidney glomeruli. The clearance of normal levels of endogenous creatinine by the kidneys appears to be a valid measure of the glomerular filtration rate since there is neither tubular excretion nor tubular reabsorption.

II. SPECIMEN:

A. Patient preparation:

1. Hydrate the patient with at least 600 ml of water.
2. Tea, coffee, and drugs should be withheld the day of the test.
3. Have patient void and discard the urine. Note the time and from then on, collect all urine passed for 12 or 24 hours. Keep patient well hydrated during the collection period in order to ensure a urine flow rate of 1 to 2 ml/min or greater.
4. Collect a blood specimen for serum creatinine anytime during the urine collection period.
5. A height and weight of the patient must be submitted with the request.

B. Specimen collection:

1. 12 hour urine specimen (8:00 PM to 8:00 AM) or a 24-hour urine specimen (7:00 AM to 7:00 AM). Note the time of collection on the request slip and on the container. Collect urine without preservative and keep refrigerated or on ice during collection.
2. A blood specimen collected on the day the urine specimen is received is necessary for a serum creatinine.

III. QUALITY CONTROL:

A. Biorad Liquichek Urine Controls, Level 1 and 2.
B. Beckman Triad Nysspath Quality Control, Levels 1, 2, and 3

IV. PROCEDURE:

A. Measure and record the volume of the urine.
B. Centrifuge an aliquot of the urine.
C. Creatinine tests are done on the urine and the blood following the methods outlined for these under serum and urine creatinine procedures.
D. Program the urine specimen as a "timed" urine in the LX, and input the volume, collection time, height, weight and serum creatinine. The LX will automatically calculate the surface area, and the calculated creatinine clearance.

V. CALCULATIONS:

The creatinine clearance, corrected to the average body surface of 1.73 sq. mm. is calculated as follows if not using the capability of the LX:

$$C = \frac{UV}{P} \times \frac{1.73}{A}$$

U = mg/dl of urine creatinine

P = mg/dl of serum creatinine

V = Urine flow in ml/minute = total volume in ml ÷ collection time in minutes (1440 minutes for a 24 hour specimen; 720 minutes for a 12 hour specimen)

A = Body surface are in sq. mm. calculated from the height and weight of the patient by Dubois formula (see attached table)

EXAMPLE:

- 24 hour urine volume = 2500 ml
- Blood creatinine result = 1.0 mg/dl
- Urine creatinine result = 46 mg/dl
- Patient's height = 6.0 feet
- Patient's weight = 220 pounds

U = 46 mg/dl
P = 1.0 mg/dl
V = 2500 ml ÷ 1440 min = 1.74
A = 2.21

$$C = \frac{46 \times 1.74}{1.0} \times \frac{1.73}{2.21}$$

C = 62.7 ml/min

VI. NORMAL VALUES:

Age (Years)	Males		Females	
20-30	88 – 146	117	81 – 134	107
30-40	82 – 140	110	75 – 128	102
40-50	75 – 133	104	69 – 122	96
50-60	68 – 126	97	64 – 116	90
60-70	61 – 120	90	58 – 110	84
70-80	55 – 113	84	52 – 105	78

VII. SOURCES OF ERROR:

A. Error in recording timing of collection period, loss of a portion of the urine during collection, including the first void in the time collection, and urinary retention are the most common sources of error.
B. Vigorous exercise during the urine collection may alter clearance.
C. Proper hydration of patients to ensure urine flow rate of 2 ml/min or greater improves the accuracy of the measurement of filtration rate and tends to eliminate retention of urine in the bladder as a source of negative error.

VIII. REFERENCES:

A. Tietz Textbook of Clinical Chemistry, Second Edition, c. 1994, p 1536.
B. Beckman Synchron LX Chemical Systems Chemistry Information Manual

3. 24-Hour Urine Testing: Preservative Quick Reference Chart

Collection is normally taken between 7:00 AM to 7:00 AM the following day.

24-HOUR URINE TESTING: PRESERVATIVE QUICK REFERENCE CHART

Collection is normally taken between 7:00 AM to 7:00 AM the following day.

Analyte	Collection Time	Preservative	Storage	Preservative Also Acceptable	Comments
Aldosterone	24 hours	Boric acid	Refrigerate		
Aminolevulinic acid (ALA)	24 hours or random	Acetic acid	Freeze		Protect from light; pH must be <6.0
Amylase	Random or 24 hours	None	Refrigerate		
Arsenic	Random or 24 hours	None	Room temp.		
Calcium	24 hours	6N HCl	Refrigerate		pH must be ≤4.0
Catecholamine, fractionated	24 hours	6N HCl	Refrigerate		Final pH must be 1-3
Chloride	Random or 24 hours	None	Refrigerate (do not perform on urine to which acid has been added)		
Citrate	24 hours	6N HCl	Refrigerate		Final pH must be 1-3
Copper	Random or 24 hours	None	Room temp.		
Cortisol, free	24 hours	Boric acid, 1 g	Refrigerate	6N HCl	
Creatine	24 hours	None	Freeze		
Creatinine	Random or 24 hours	None	Refrigerate		
Creatinine Clearance	24 hours	None	Refrigerate		Need height and weight of patient.
Cystine	Random or 24 hours	6N HCl	Freeze		Final pH must be 1-3.
Glucose	Random or 24 hours	Boric acid	Refrigerate		
Heavy metals	Random or 24 hours	None	Room temp.		
Homovanillic acid	24 hours or random	6N HCl	Refrigerate		Final pH must be 1-3
Hydroxy-corticosteroids	24 hours	Boric acid, 1 g	Refrigerate	6N HCl	
Hydroxyindo-leacetic acid	24 hours	None	Refrigerate	Boric acid or 6N HCl	
Hydroxyproline	24 hours	6N HCl	Refrigerate		

Immuno-electrophoresis	Random or 24 hours	None	Refrigerate		
Ketogenic steroids	24 hours	Boric Acid	Refrigerate	6N HCl	
Ketosteroids	24 hours	Boric Acid	Refrigerate	6N HCl	
Lead	24 hours or random	None	Room temp.		
Magnesium	24 hours	6N HCl	Refrigerate		Final pH must be 1-3
Mercury	Random or 24 hours	None	Room temp.		
Metanephrines	24 hours or random	6N HCl	Refrigerate		
Microalbumin	Random or 24 hours	None	Refrigerate		
Myoglobin	Random	None	Refrigerate		
Osmolality	Random or 24 hours	None	Freeze		
Oxalate	24 hours	6N HCl	Refrigerate		Final pH must be 1-3
Phosphorus	24 hours or random	6N HCl	Refrigerate		
Porpho-bilinogen	Random or 24 hours	Acetic Acid	Freeze	Sodium carbonate	Protect from light.
Porphyrins	24 hours	Sodium carbonate	Refrigerate		Protect from light
Potassium	24 hours	None	Refrigerate		Do not perform on urine to which acid has been added
Protein	24 hours	None	Refrigerate		Do not perform on urine to which acid has been added
Protein electrophoresis	Random or 24 hours	None	Refrigerate		
Sodium	Timed or 24 hours	None	Refrigerate		Do not perform on urine to which acid has been added
Urea nitrogen	24 hours	None	Refrigerate		
Uric acid	24 hours	None	Refrigerate		
Vanillyl-mandelic acid (VMA)	24 hours	6N HCl	Refrigerate		Final pH must be 1-3
Zinc	Random or 24 hours	None	Room temp.		

INSTRUCTIONS FOR 24-HOUR URINE COLLECTION

Obtain the one-gallon plastic urine collection container from the Laboratory. DO NOT remove any tablets or other preservatives that may be in the bottle. Note any warnings or instructions posted on the outside of the urine collection container.

For 24-hour urine collections with ANY type of warning labels or ANY additions to the container, DO NOT URINATE DIRECTLY INTO THE CONTAINER. A small urine cup will be provided to urinate into and then transfer the contents into the large container.

For 24-hour urine collections without additives or warning labels, you may urinate directly into the container.

URINE COLLECTION

1. In the morning (for example 7AM), completely empty the bladder and discard the urine specimen.

2. All urine that is voided subsequently, including the final specimen voided at the end of the 24-hour collection period (i.e., 7AM the following day) is collected and added to the plastic container.

3. Keep the 24-hour urine collection bottle in a cool place, preferably in the refrigerator.

4. The container must be labeled with the patient's name, social security number and date/time collection started and finished.

5. Return the 24-hour urine collection bottle as soon as possible to the Laboratory.

NOTE: It is essential that this procedure be followed without any deviation, since the results provided to the physician depend upon the accuracy of timing and the collection of the entire 24-hour specimen.

Pathology & Laboratory Medicine
VA Medical Center, Erie, Pennsylvania

B. GLUCOSE TOLERANCE TEST

I. PRINCIPLE:

The glucose tolerance test measures the body's ability to metabolize glucose. Glucose is the sugar that the body uses for energy. Patients with untreated diabetes have high blood glucose levels. Glucose tolerance tests are one of the tools used to make the diagnosis of diabetes. The oral GTT is also used to screen pregnant women for gestational diabetes.

II. SPECIMEN:

A. Patient prep: A 10-14 hour fast is recommended; no beverages containing caffeine or smoking just prior to or during the test. All non-essential medications should be discontinued. A diet of average intake should precede the test for at least three days.

B. Test is scheduled with the Lab Monday through Friday to start at 7:00 AM.

C. Serum or plasma.

D. Urine.

III. REAGENTS:

Sun-Dex 100 Orange Carbonated Glucose Tolerance Test Beverage; catalog #TG 30006 Fisher Brand.

IV. QUALITY CONTROL:

A. Beckman Triad Nysspath Controls, Levels 1, 2 and 3.

V. PROCEDURE:

Special Instructions:

1. Collect a fasting specimen of blood and urine.
2. The recommended usual dose of the glucose tolerance beverage is 7.5 oz for nonpregnant adults; 10 oz. for pregnant women. Administer the recommended dose. Start timing when the patient begins to drink the SUN-DEX 100 (drink in about 5 minutes).
3. Collect subsequent blood and urine specimens at the following times: before glucose administration, 1/2 hour, 1 hour, 2 hours and 3 hours (or the maximum specific time period of the request) after glucose administration.
4. **NOTE: It is strongly recommended that a fasting and post prandial glucose be tested prior to any glucose tolerance testing and that the fasting glucose is less than 160 mg/dl before proceeding with the tolerance test.**

VI. REFERENCE RANGES:

Normal Values:

For a 75-gram oral glucose tolerance test used to check for Type II diabetes, normal (nondiabetic) blood values are:

- Fasting: 60-110 mg/dl
- 1 hour: less than 200 mg/dl

- 2 hours: less than 140 mg/dl. Between 140-200 mg/dl is considered impaired glucose tolerance or pre-diabetes. This group is at increased risk for developing diabetes. Greater than 200 mg/dl is diagnostic of diabetes mellitus.

For a 50-gram oral glucose tolerance test used to screen for gestational diabetes, normal blood values at 1 hour are less than 140 mg/dl.

For a 100-gram oral glucose tolerance test used to screen for gestational diabetes, normal blood values are:

- Fasting: less than 95 mg/dl
- 1 hour: less than 180 mg/dl
- 2 hours: less than 155 mg/dl
- 3 hours: less than 140 mg/dl

VII. LIMITATIONS:

Interfering Factors:

- Acute stress (for example, from surgery or an infection)
- Vigorous exercise

Several drugs may cause glucose intolerance, including the following:

- Thiazide diuretics (e.g., hydrochlorothiazide)
- Beta-blockers (e.g., propranolol)
- Oral contraceptives
- Corticosteroids (e.g., prednisone)
- Some psychiatric medications

Before having the test, let your health care provider know if you are taking any of these medications.

VIII. REFERENCE:

A. Beckman Synchron LX Clinical Systems Chemistry Information Manual

B. **Update Date: 8/12/2004:**
Updated by: Aniket R. Sidhaye, M.D., Division of Endocrinology and Metabolism, Johns Hopkins University School of Medicine, Baltimore, MD. Review provided by VeriMed Healthcare Network.

C. Acetone, Iron, TIBC and Alcohol:

a. No special preparation for acetone.

b. Iron and TIBC should be drawn fasting in the morning and prior to administration of therapeutic iron or blood transfusion. Iron determinations in patients who have had blood transfusions should be delayed at least four (4) days.

c. Alcohol should be collected after cleansing the venipuncture site with a non-alcohol based cleanser.
Back

B. SPECIAL CHEMISTRY

B. SPECIAL CHEMISTRY

1. GENERAL INFORMATION

Most Special Chemistry testing is performed on a random access automated analyzer using a Chemiluminescent Methodology. Hemoglobin A1c testing is performed on an automated analyzer using High Phase Liquid Chromatography (HPLC).

2. TEST INFORMATION

In-House Testing	***Frequency of Testing***
• CK-MB • Troponin I	Routinely performed on each shift. STAT testing available.
• TSH/Free T4 • PSA/Free PSA • B12/Folate • Ferritin • Hemoglobin A1c	Routinely performed daily.

3. SPECIMEN COLLECTION AND STORAGE

a. Sample Collection: Most specimens require serum with the exception of Hemoglobin A1c, CK-MB and Troponin I. A1c requires whole blood drawn in a lavender top tube while CK-MB and Troponin I require plasma drawn in a Lithium Heparin green top tube.

b. Storage of Specimens: Most assays will be performed daily if received before 4PM. A1c specimens should be stored at 2-8ºC for no longer than seven (7) days. (Specimen must be free of clots and fibrin.)

The following requirements apply to all assays with the exception of folate, free PSA and Troponin I:

- Within two hours of centrifugation, remove serum or plasma from cells.
- Store samples at room temperature for no longer than eight hours.
- If not analyzed within eight hours, refrigerate at 2-8ºC
- If not analyzed within 24 hours, freeze at -20ºC.

Folate specimens should be protected from light to prevent deterioration. If the assay will not be completed immediately, store at 2-8ºC. If the assay will not be completed within eight (8) hours, store at -20ºC.

PSA specimens that will potentially be used for free PSA testing should be centrifuged and refrigerated within three (3) hours of blood draw.

Troponin I specimens, if not analyzed immediately, should be separated from cells and stored at 2-8ºC. If the assay will not be completed within 24 hours, store at -20ºC.

4. REFERENCE RANGES

Refer to *"**Test and Reference Range Chart**"(Section IV)* f or a list of Special Chemistry reference ranges.

C. TOXICOLOGY

1. General Information
2. Test Information
3. Specimen Collection and Storage
4. Reference Ranges
5. Additional Information

C. TOXICOLOGY

1. GENERAL INFORMATION

The Toxicology testing is performed on a random access automated analyzer. Only therapeutic drugs listed below and Urine Drug Screens are analyzed in-house. Testing is performed on a STAT or timed basis, depending on the urgency determined by the ordering provider. All critical results are immediately phoned to the ordering physician.

2. TEST INFORMATION

a. In-House Testing:

In-House Testing	***Frequency of Testing***
• Urine Drug Screen (Amph, Barb, Benzo, Cocaine Met., THC, Methadone, Opiates, Oxy, Propoxyphene) • Digoxin • Theophylline • Phenytoin (Dilantin)	Performed daily as ordered. STAT testing is available during regular and off duty hours, and result turnaround time is approximately one (1) hour.
• Phenobarbital • Gentamicin, Random • Gentamicin, Peak • Gentamicin, Trough	Performed daily as ordered.

b. Definitions

TROUGH: The trough is the lowest concentration of drug observed during the dosing interval and is usually measured just prior to the next dose. For most therapeutic drug monitoring requests, a trough concentration, drawn just prior to the next dose, is recommended to ensure that a therapeutic concentration of drug is maintained throughout the dosage interval.

PEAK: During the drug-dosing interval, the peak is the highest concentration obtained and may occur immediately after an intravenous dose or may require 0.5 to 2 hours or longer after oral dosage.

NOTE: Measurement of both peak and trough concentrations may be indicated for some drugs (e.g., aminoglycoside antibiotics and Vancomycin); however, peak concentrations may be useful only for intravenous therapy due to the variable rates of absorption following oral dosages.

c. Indications for TDM:

Although the need for therapeutic drug monitoring varies, the primary indications are summarized as follows:

●Drugs with a relatively low margin of safety (i.e., serum concentrations required for therapeutic effect are in the same range as the toxic effects).
●Drugs with large differences in pharmacokinetics between patients.
●Drugs administered concomitantly (especially if one is known to induce or inhibit drug metabolism.

●In presence of disease or clinical conditions, which may alter drug kinetics (e.g., renal, hepatic, cardiovascular disease; prepubescence; pregnancy.
●For nonresponders to drug therapy (to identify patient non-compliance or alter the drug dosage regimen).
●As part of the differential diagnosis if symptoms consistent with drug toxicity are observed.

3. PROCEDURE FOR ORDERING AND COLLECTION OF TIMED DRUG DRAWS

The timing of blood sampling in relation to dosage is critical for correct interpretation of the serum concentration results. Collection time should be based on the pharmacokinetic properties of the drug, the dosage form (i.e., IV, IM, oral, etc.), the dosing protocol and the clinical reason for assaying the sample. For this process to work, it is necessary to have close communication between pharmacy, nursing and the laboratory.

a. Medication order entered in GUI.
b. Clinical Pharmacist/Provider orders peak and trough lab draws by "Immediate Collect" option.
c. Immediate Collect order prints out on designated lab printer and to nursing printer on units.
d. The person ordering sends email to g.lab staff to notify us of this order. Lab pulls the immediate collect order off printer and files in the correct day of week bin.
e. Lab draws blood at designated time and informs nursing staff prior to leaving unit.
f. Lab enters timed lab draw into lab through "Accessioning Tests Ordered by Ward Order Entry" option in VistA, entering the exact time the specimen was drawn.
g. Nursing staff is to call and inform lab staff of any discontinued orders and/or time of draw changes due to any problems.
h. Lab processes the test and enters timed lab result into the computer.

4. SPECIMEN COLLECTION: Specimens should be collected in a plain red top tube. DO NOT USE serum separator tubes. If the specimen is a timed draw (i.e., peak or trough), the exact time of draw must be entered into the computer. See chart for recommended drug draw times.

TEST		DRAW TIME
Theophylline		½ - 1 hr before dose
Digoxin		½ - 1 hr before dose
Phenytoin		½ - 1 hr before dose
Phenobarbital		½ - 1 hr before dose
Valproic Acid		
Gentamicin, trough		½ - 1 hr before dose
Gentamicin, peak (IV)		½ hr after dose infused
Vancomycin, trough		½ - 1 hr before dose
Vancomycin, peak (IV)		1 hr after dose infused
Carbamazepine (Tegretol)		½ - 1 hr before dose

NOTE: To facilitate interpretation of peak concentrations, the recommended sample time is usually 0.5 to 2.0 hours after the end of an intravenous infusion. This allows for the expected differences in distribution and is less sensitive to small errors in sampling time. In setting the recommended time for blood collection, the following should be considered:

●Length of time patient has received the drug (at the same dose)

- Expected half-life of the drug
- Time of last dose
- Time of next dose
- Whether peak and/or trough concentration is required.

5. REFERENCE RANGES

Refer to **"*Test and Reference Range Chart*"** *(Section IV)* for a list of Therapeutic Drug reference ranges.

6. ADDITIONAL INFORMATION

REPORTING OF RESULTS: Each report generated will contain the following:

- Type of request (i.e., random, peak/trough)
- Time of collection specific to test results
- Test results and related units
- Expected ranges for type of request
- Notation in "comments" of critical values – to whom and time phoned.

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D. HEMATOLOGY

D. HEMATOLOGY

1. GENERAL INFORMATION

a. Complete Blood Counts (CBC) and Reticulocyte Counts are performed on an automated Hematology Analyzer. Differentials are either reported from the automated instrument or manually performed according to the preset instrument flagging.
b. Test Frequency: CBC with differential and CSF available routine and STAT. All other testing is available routine.
c. Physician Coverage: A Pathologist is available for consultation (x2177).

2. TEST INFORMATION

Test	Test Includes
CBC Profile with Automated Five Part Differential	WBC, RBC, HGB, HCT, Platelet, MCV, MCH, MCHC, RDW, MPV, Neut %, Lymph %, Mono %, Eos %, and Baso %
Manual Differential Count	Performed when specifically request by the physician and/or if any abnormalities are identified by instrument flagging or after scanning.
Reticulocyte Count	Automated reticulocyte count expressed as a percentage in a total of 30,000 RBCs.
Sedimentation Rate	Sedimentation rate measured in mm/hr.

3. SPECIMEN COLLECTION

Tests	Specimen Requirement
Complete Blood Counts Manual Differential Counts	For CBC and differentials and platelet count, 4.5 ml of blood must be collected in a lavender tube with EDTA anticoagulant.
Sedimentation Rate	For sedimentation rate, collect a putple top tube with EDTA as anticoagulant.
Reticulocyte Count	4.5 ml EDTA whole blood.
Body Fluids	The pleural, peritoneal, synovial, and ascitic fluid specimens for cell count must be submitted in lavender top tubes. The type of body fluid must be identified on the requisition.

4. REFERENCE LABORATORIES: Tests not performed in-house may be sent to Laboratory Corporation of America, Associated Clinical Laboratory or another VAMC for testing, if approved by the Medical Director, Pathology & Laboratory Medicine. Contact Hematology Department (ext 2181) for turnaround times of specimens sent to a Reference Laboratory.

5. REFERENCE RANGES: Refer to *"Test and Reference Range Chart"(Section IV)* f or a list of Hematology reference ranges.

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E. COAGULATION

E. COAGULATION

1. GENERAL INFORMATION

   a. Coagulation testing for Partial Thromboplastin Time (PTT) and Prothrombin Time (PT) are performed on an automated instrument by using a stainless steel ball and an electromagnetic field to measure the increase in viscosity.
   b. Test Frequency: PT and PTT are available routine and STAT. Bleeding times are available routinely.

2. TEST INFORMATION

Test	Test Includes:
Protime (PT)	Protime (PT) INR
Partial Thromboplastin Time (PTT)	PTT

3. SPECIMEN COLLECTION

Test	Specimen Requirement
Protime (PT)	3.2% Sodium Citrate tube
Partial Thromboplastin Time (PTT)	3.2% Sodium Citrate tube

NOTE:

A. 3.2% Sodium Citrate tubes must be filled to maximum volume for proper 9:1 blood to anticoagulant ratio.

B. Plasma Storage: Specimens for PT assays uncentrifuged or centrifuged with plasma remaining on top of the cells in an unopened tube kept at 2-4ºC or 18-24ºC should be tested within 24 hours from the time of specimen collection. If the testing is not completed within 24 hours for PT specimens, plasma should be removed from the cells and frozen at -20ºC for up to two weeks or -70ºC for up to six months. A frost-free freezer should not be used. Frozen plasma samples should be rapidly thawed at 37ºC while gently mixing and tested immediately; if testing cannot be performed immediately, the sample may be held for a maximum of two hours at 4ºC until tested.

C. Plasma Storage: Specimens for routine APTT assays on *nonheparinized* patients uncentrifuged or centrifuged with plasma remaining on top of the cells in an unopened tube kept at 2-4ºC or 18-24ºC should be tested within four hours from time of specimen collection. Specimens for APTT assays suspected to contain *unfractionated heparin* kept at 2-8ºC or 18-24ºC should be centrifuged within one hour of collection and the plasma tested within four hours from time of specimen collection. If agitation of the specimen is likely after centrifugation, such as transportation to a remote-testing site, the plasma should be removed within one hour of collection and tested within four hours from the time of specimen collection. If the testing is not completed within four hours for APTT's, plasma should be removed from the cells and frozen at -20ºC for up to two weeks or -70ºC for up to six months. A frost-free freezer should not be used. Frozen plasma samples should be rapidly thawed at 37ºC while gently mixing and tested immediately; if testing cannot be performed immediately, the sample may be held for a maximum of two hours at 4ºC until tested. The APTT may be affected on specimens that have been frozen.

4. REFERENCE LABORATORIES: Tests not performed in-house may be sent to Laboratory Corporation of America, Associated Clinical Laboratory or another VAMC for testing, if approved by the Medical Director,

Pathology & Laboratory Medicine. Contact Coagulation Department (ext 2181) for turnaround times of specimens sent to a Reference Laboratory.

5. REFERENCE RANGES

Refer to *"**Test and Reference Range Chart**"(Section IV)* f or a list of Coagulation reference ranges.

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F. MICROBIOLOGY

1. General Information

2. Test Information

3. Specimen Collection and Storage

4. Additional Information

Attachments:
Microbiology Test List
Microbiology Test Chart

F. MICROBIOLOGY

1. GENERAL INFORMATION

Quality results in Microbiology depend on both the client and the Laboratory. The many factors contributing to the successful isolation of potential pathogens range from specimen selection and collection to proper transport and timely delivery to the Laboratory. Specific plating media and procedures depend on proper specimen handling for pathogen isolation. It is extremely important to refer to specimen collection and submission instructions to ensure that we receive the most suitable or appropriate specimens for Laboratory analysis.

a. HOURS OF OPERATION:

Daily: 8:00 AM - 2:30 PM
Extension 2187

Complete specimen processing is available during the above hours. A technologist may be reached outside of these hours by calling extension 2181 or 2182. It is suggested that after 2:30 PM Monday through Friday and on weekends, work be limited to specimen collecting which will have an immediate influence on the care of the patient due to reduction of personnel at these times.

Cultures will be set daily until 6:00 PM. Reports on specimens arriving after that may be delayed 24 hours. Microbiology reports will generally be available in the computer before 1PM. Please check the computer before calling the Laboratory for results.

b. CRITICAL VALUES: The following will be called to the nurse/physician immediately and put into the computer:

- Positive CSF Smear/Cultures
- Positive Blood Cultures
- Positive AFB Smears/Cultures
- Positive Gram Stains of Sterile Body Fluids
- Positive Enteric Pathogens (Salmonella, Shigella, Campylobacter, etc.)
- Positive Malaria Smear
- Positive MRSA, VRE, C diff
- Diseases reportable to the Health Department

The microbiology technologist will notify the infectious disease practitioner.

c. Only gram stains and collection of blood cultures may be ordered on a true STAT basis. Microbiology cultures must be incubated at least 15-18 hours before initial reading can be done; therefore, a STAT culture has merit only in its collection.

2. TEST INFORMATION

a. IN-HOUSE TESTING SERVICES:

- Bacteriology (includes cultures from different sources):
  - Urines
  - Respiratory sources (sputum, throat, and bronchial washings)
  - Fluids (CSF, pleural, peritoneal, thoracentesis, etc.)

- Genital cultures
- Blood cultures
- Anaerobes
- N. gonorrhoeae
- Feces
- Wounds (including eye, ear, etc.)
- VRE Screens
- MRSA Screens

- Occult Blood
- Fecal Leukocytes
- Clostridium Difficile
- H. pylori AB

b. TESTS SENT TO REFERENCE LABORATORY

- Malaria
- Mycology
- KOH - scabies
- KOH - fungus
- Mycobacteriology (AFB)
- Parasitology
- Viral Studies
- Qualitative fecal fat
- Herpes culture
- Legionella DFA, cultures
- Gen-Probe – Neisseria, Chlamydia
- Influenza antigen and culture

c. REFERENCE LABORATORIES

- Laboratory Corporation of America, 6370 Wilcox Road, Dublin, OH 43016-1296
- VAMC, Fungal & Viral Serology, Lexington, KY, 40507
- Associated Clinical Laboratories, 1526 Peach Street, Erie, PA, 16501
- VAMC Pittsburgh Healthcare System, University Drive Division, University Drive C, Pittsburgh, PA 15240

d. MICROBIOLOGY TEST LIST

- See Microbiology Test List after Additional Information section

3. <u>SPECIMEN COLLECTION AND STORAGE</u>

a. REQUEST FORMS

- One of the following should accompany all specimens to the Microbiology Laboratory:
  - Microbiology Requisition
  - Ward order entry form with computer number or computer number on specimen.
  - Laboratory back-up form
  - Also acceptable – order number written directly on specimen.

- Required information on request form:
    - Patient name
    - Social security number
    - Location
    - Physician's name
    - Specimen source
    - Test requested

NOTE: Please include the date and time of specimen collection along with collector's initials.

- Gram stain can be on the same request as culture. Other tests should have separate requests or computer numbers (ex. C&S, AFB, and mycology exams - three (3) request or numbers).
- Aerobe and anaerobe cultures need separate order numbers.
- Note on request if any unusual bacteria, fungi or viruses are suspected.

b. SPECIMEN LABELING, HANDLING, & TRANSPORTATION

- All specimens should be sent to the Laboratory within two (2) hours of collection. If a delay is expected, most specimens can be refrigerated until a transport. (Exceptions: anaerobes, eye, GC, CSF, and blood cultures). Specimen received more than two (2) hours after collection will be questioned.

- Specimens for cultures should be collected prior to administration of antibiotics, if possible.

- Specimens will be accessioned in the computer upon receipt in the Laboratory.

- CSF must be transported, cultured, and gram stained ASAP.

- Cultures suspected of containing Neisseria Gonorrhoeae from eye, joint fluid, cervix, etc., should <u>not</u> be refrigerated and should be transported to Laboratory immediately.

- Anaerobe cultures must be sent to the Laboratory as soon as possible for inoculation. **DO NOT REFRIGERATE.**

4. <u>ADDITIONAL INFORMATION</u>

a. REJECTION OF MICROBIOLOGY SPECIMENS

It is the function of the Microbiology Laboratory to report as accurately and quickly as possible the presence of significant microorganisms in a clinical specimen and to provide the physician with a guide to antimicrobial therapy.

The Microbiology Laboratory has the prerogative to reject any specimen submitted for analysis if it is not properly collected or identified.

- All specimens submitted must be labeled with patient's name, social security number and source of specimen. They should also be accompanied with the properly filled out form. (See 3A. Request Forms.)

- Specimens must be received in the Laboratory within two hours of collection or be refrigerated on the floor, if available. Refrigeration will preserve the viability of most pathogens and minimize the overgrowth of commensal organisms. If the specimen has been at room temperature for more than two hours, the floor will be notified. The specimen will be recollected if possible or if not, it will be noted that the results may not be accurate. Do not refrigerate CSF, eye, GC, anaerobes or blood cultures.

- Swab specimens will be rejected if the swabs are completely dry or if the material is insufficient.

- Sputum specimens will be rejected if they are not in a sterile container, if the quantity submitted is insufficient, or if the exterior of the container is contaminated. All expectorated sputums will be evaluated by gram stain before culturing to check for oropharyngeal contamination. They may be rejected on this basis.

- Urine specimens will be rejected if they are not in a sterile container or if the quantity is insufficient or if the exterior of the container is contaminated.

- Fecal specimens will be rejected if the amount submitted is insufficient, if they are contaminated with urine, or if the exterior of the container is contaminated.

- Most duplicate specimens received on the same date should not be processed; exceptions include blood cultures, CSF, tissue, and sterile body fluids excluding urine.

- Foley catheter tips are <u>not accepted</u> for culturing. (Studies show no correlation between cultures from catheter tips and urinary tract infections). Request urine specimens.

- Anaerobe cultures must be sent to the Laboratory as soon as possible in anaerobe culturettes, otherwise they are unacceptable. They should <u>not</u> be refrigerated.

- CSF specimens should be brought to the Laboratory immediately since fastidious organisms may not survive storage or variations in temperature.

b. QUANTITATION OF ORGANISMS AND CELLS

- Growth on Agar Plates
  1+ scanty growth
  2+ few colonies
  3+ moderate growth
  4+ profuse growth

- Bacteria and Cells on Gram Stain/Oil Immersion Field

0-1	rare
1-5	1+
5-25	2+
> 25	3+

- WBC + epithelial cells in sputum are quantitated/low power field (greater than or less than 25)

c. SENSITIVITY TESTING

It is not necessary to request sensitivity testing. Sensitivities are performed routinely on most clinically significant isolates. Testing is dependent upon specimen source and type and quantity of organisms isolated. Results are reported as S (sensitive) or R (resistant), as dictated by CLSI guidelines. Some organisms have predictable sensitivity patterns and will not routinely receive sensitivity testing unless isolated from blood or CSF (Beta-hemolytic strep)

Antibiograms are available every six (6) months to all physicians and nurse practitioners and upon request to other personnel.

d. TURN-AROUND TIME

- In-house procedures:

The time until release of final results is dependent upon several factors including the number of organisms present, the nature and complexity of their identification, organism purity, and viability. Preliminary reports will be entered into the computer on aerobic cultures requiring more than 24 hours and daily thereafter until completion as more information becomes available. Final reports are available in the computer for all tests upon completion.

APPROXIMATE COMPLETION TIME	
Occult Blood	48 hours
Gram Stain	24 hours
Urine Culture	48 hours
Respiratory Culture	48 hours
Wound Culture	4 days
Feces Culture	48 hours
Anaerobic Culture	4 days
Blood Culture	5 days
Mycology Culture	6 weeks
AFB Smear	24 hours
AFB Culture	8 weeks
C. difficile	24 hours
H. pylori Ab	24 hours
MRSA Screen	4 hours – 24 hours
VRE Screen	48 hours – 4 days
Sterile Body Fluids	4 days – 7 days

- Tests Sent to Reference Laboratory:

The turnaround time of tests sent to the Reference Laboratories is dependent on several factors including the transport time, test schedule at each individual Lab, and the time for the return of the report. Because it is sometimes difficult to predict, please call the Microbiology Lab (x2187) if there are individual questions.

MICROBIOLOGY TEST LIST

Antimicrobial (Antibiotic) Susceptibility Tests
Chlamydia/Gonococcus (DNA Probe)
Clostridium Difficile Toxin
Crypotosporidium Diagnostic Procedure, Stool
Culture, Anaerobic, Routine
Culture, Blood, Routine
Culture, Body Fluid, Routine
Culture, Bone Marrow
Culture, Bronchial/Tracheal Aspirate, Routine
Culture, Catheter Tip, Routine
Culture, Cerebrospinal Fluid, Routine
Culture, Chlamydia
Culture, Ear, Routine
Culture, Eye, Routine
Culture, for Haemophilus Ducreyi (Chancroid)
Culture, Fungal, Blood
Culture, Fungal, Body Fluids
Culture, Fungal, Bone Marrow
Culture, Fungal, Cerebrospinal Fluid
Culture, Fungal, Pus
Culture, Fungal, Skin and Nails
Culture, Fungal, Sputum (Trachea Aspirates, Bronchial Washings and Brushings)
Culture, Fungal, Throat and Mouth (Oropharyngeal)
Culture, Fungal, Tissue (Biopsy)
Culture, Fungal, Urine
Culture, Genital Tract, Routine
Culture, Legionella
Culture, Mycobacterial Blood (TB Blood Culture)
Culture, Mycobacterial, Body Fluid (TB Culture, Body Fluid)
Culture, Mycobacterial, Bone Marrow (TB Culture, Bone Marrow)
Culture, Mycobacterial, (TB), (CSF)
Culture, Mycobacterial, (TB), Sputum
Culture, Mycobacterial, (TB), Tissue
Culture, Mycobacterial, (TB), Urine
Culture, Nasopharyngeal, Routine
Culture, Sputum, Routine
Culture, Stool, Routine
Culture, Throat
Culture, Urine, Routine
Culture, Wound, Routine
Culture/Direct Smear, Gonorrhea
Influenza A & B Antigen
KOH Preparation
MRSA Screen
Ova and Parasite Examination, Stool
Parasite Examination, Non-Fecal Specimen
Neisseria Gonorrhea Smear
Viral Culture
VRE Screen

MICROBIOLOGY TESTS CHART

Specimen	*Collection*	*Special Instructions*
1. ANTIMICROBIAL SUCEPTIBILITY TESTING		
This includes panels of antibiotics tested against potential aerobic pathogenic bacteria. It will be done automatically when indicated. Limitations are for organisms which fail to grow on subculture or are too fastidious to grow for susceptibility testing. For anaerobic bacteria, susceptibility tests are not done routinely. Selected isolates are held for one week in case susceptibility is indicated later. The positive blood culture isolates are held for one month. Fastidious organisms that fail to grow in susceptibility testing will be reported out with an appropriate comment "unable to perform sensitivity".		
2. CHLAMYDIA/GONOCOCCUS BY DNA PROBE		
Tests include Chlamydia trachomatis and/or Neisseria gonorrhoeae NOTE: One or both may be done from one DNA probe kit	SPECIMEN: Endocervical, urethral, or ocular swab CONTAINER: Gen-Probe collection kit (Specific for male/female) Call Microbiology, x2187, for supplies.	SPECIAL INSTRUCTIONS: GC test is valid for female endocervical and male urethral specimens only. Chlamydia test is valid for urogenital and ocular specimens.
3. CULTURE, ANAEROBIC ROUTINE		
Test includes gram stain, isolation and identification of anaerobic bacteria. No sensitivity testing is performed. a. WOUND: Specimens include pus tissue or other material properly obtained from an abscess, aspirate, exudate, lesion, or wound.	COLLECTION: Overlying and adjacent areas must be carefully disinfected to eliminate contamination with indigenous flora. Ideally, pus or other fluid obtained by needle aspiration through intact skin or mucous membrane which has been cleaned with antiseptic is optimal. Sampling of open lesions is enhanced by deep aspiration. Biopsies of base of open lesion is optimal. If irrigation is necessary, non-bacteriostatic sterile normal saline may be used.	
b. BODY FLUIDS: Specimens include aspirated pleural, pericardial, peritoneal, synovial, cerebrospinal fluid, etc.	COLLECTION: Specimens are to be aspirated from a prepared site using sterile technique. Contamination with normal flora from skin must be avoided.	
c. TISSUE: Specimens include surgical tissue and biopsy material.	COLLECTION: Specimens should be selected from a prepared site using sterile technique.	
d. URINE SUPRAPUBIC: Specimen includes suprapubic urine aspirate only. Catheterized or clean catch urines are not acceptable for anaerobic culture.	COLLECTION: Specimen should be collected from prepared site using sterile technique.	

e. UROGENITAL (FEMALE): Specimen includes scrapings or aspirates from endometrium or endocervix, cul-de-sac culture, etc.	COLLECTION: Scrapings and aspirates from endometrium or endocervix should be collected from prepared sites using sterile technique. Contamination with normal cervical or vaginal flora MUST be avoided.	
Applies to a. through e. →	CONTAINERS REQUIRED: B-D vacutainer anaerobic specimen collector (directions for collection can be found in the wrapper). STERILE CONTAINER IS ACCEPTABLE FOR TISSUE.	TRANSPORT: Specimens should be transported to the Laboratory after collection. Store the specimen at room temperature. Do NOT refrigerate.
4. CULTURE, BLOOD		
This includes isolation and identification of both anaerobic and aerobic bacteria with susceptibility testing on isolate.	In most adult infections, two separate blood culture specimens per septic episode are considered adequate in the initial 24-hour period. Any additional blood cultures may be ordered depending on the condition of the patient and these will be collected after approval by the Medical Director, Pathology & Laboratory Medicine. In critically ill patients, two separate cultures should be collected a few minutes apart before starting the antimicrobial therapy. RECOMMENDED ROUTINE COLLECTION SCHEDULE: <u>Protocol</u>: Standard blood culture protocol (For suspected endocarditis - must be specified on the request form) <u>First Draw</u>: 13-17 ml - large volume draw (Endocarditis: Same as standard blood culture except repeat at 24 hours) <u>Second Draw</u>: 13-17 ml within 1 hour first draw (Endocarditis: Same as standard blood culture except repeat at 24 hours) SPECIMEN REQUIRED: 20 ml whole blood per draw CONTAINER REQUIRED: 1 bottle Bactec Standard 10 Aerobic/F, 1 bottle Bactec Standard Anaerobic/F	
	SUPPLIES: 1. Two bottles are used routinely for all blood culture requests; one for aerobic organisms and one for anaerobic organisms. 2. Have on hand: Sterile syringe - 20 cc min. capacity Alcohol swabs Chloraprep Applicators Cotton Bactec Standard 10 Aerobic/F bottle Bactec Standard Anaerobic/F bottle (Bottles should be stored in a cool, dry place. Prior to use, examine for evidence of damage, deterioration, or contamination.) All blood cultures will be held for five (5) days. All positive results will be telephoned immediately. PROCEDURE: SITE SELECTION ●Select a different site for each culture drawn. ●Avoid drawing blood through indwelling intravascular catheters unless blood cannot be obtained by venipuncture. Blood collected from intravascular catheters should be done with the knowledge that contamination may be an issue. SITE PREPARATION ●Identify patient. ●Using a Chloraprep applicator (2% chlorhexidine gluconate), scrub the venipuncture site using repeated back and forth strokes of the applicator for approximately 30 seconds. Do not blot or wipe away. Do not re-palpate site. Let site dry before venipuncture. ●NOTE: Since the Chloraprep applicator contains alcohol; it is not necessary to use	

	an alcohol swab before the Chloraprep. Using a side-to-side friction prep has been found to be more effective than the circumferential, inside-out technique of skin preparation. DISINFECTING BLOOD CULTURE VIALS ●Remove flip-off caps from vials. ●Wipe the tops of the blood culture vials with 70% isopropyl alcohol pad and leave the pad on top of the bottle until the blood is ready to be injected. ●Do not use iodine to disinfect tops of vials. NOTE: Prior to each use, each vial should be examined for evidence of contamination such as cloudiness, bulging or depressed stopper or leakage. DO NOT USE any vial showing evidence of contamination. A contaminated vial could contain positive pressure. If a contaminated vial is used for direct draw, gas or contaminated culture media could be refluxed into the patient's vein. Prior to use, the user should examine the vials for evidence of damage or deterioration. On rare occasions, the glass bottleneck may be cracked and the neck may break during removal of the flip-off cap or in handling. Also, on rare occasions, a vial may not be sealed sufficiently. In both cases, the contents of the vials may leak or spill. If the vial has been inoculated, treat the leak or spill with caution, as pathogenic organisms/agents may be present. SPECIMEN COLLECTION AND VOLUME ●Avoid touching the site of venipuncture. ●**When using the Butterfly set, the phlebotomist MUST carefully monitor the volume collected by means of the 5 mL graduation marks on the vial label.** If the volume is not monitored, the stated maximum amount collected may be exceeded. This condition may adversely create a "false" positive result, due to high blood background. ●If using a needle and syringe, typically a 20 cc syringe is used for adults. Draw 13-17 cc for one blood culture set (aerobic and anaerobic). Aseptically inject: **8-10 mL of blood into the aerobic vial first,** then **5-7 mL of blood into the anaerobic vial.** ●For difficult draws, 1-3 mL of blood can be injected into the PEDS PLUS vial instead of the aerobic/anaerobic vials. **The volume of blood cultured is critical because the concentration of organisms in most cases of bacteremia is low, especially if the patient is on antimicrobial therapy. The use of lower or higher volumes may adversely affect recovery and/or detection times.** ●The inoculated BACTEC vials should be transported ASAP to the laboratory for incubation.	
5. CULTURE, BODY FLUIDS		
Tests include gram stain, isolation and identification of rapidly growing aerobic and facultative aerobic bacteria. Susceptibility tests done, if appropriate.	SPECIMEN: Joint fluid, pericardial, peritoneal, pleural, and ascitic fluid. VOLUME OF SPECIMEN: 10 ml. Minimum volume 0.5 ml. Container required: sterile container.	
6. CULTURE, BONE MARROW		
	Specimen collection instructions are given under headings dealing with cultures for specific organisms (e.g., "culture fungal, bone marrow", "mycobacterial cultures, bone marrow"). Consult those sections for proper procedures. The clinical diagnosis and suspected agents must be clearly stated	

	on the requisition as special culture techniques may be required.	
7. CULTURE, BRONCHIAL/ TRACHEAL ASPIRATE, ROUTINE		
Tests include isolation and identification of rapidly growing aerobic and facultative aerobic bacteria and yeasts. Susceptibility tests done, if appropriate.	SPECIMEN REQUIRED: Bronchial washings, brushings, transbronchial biopsies, bronchial sections, tracheal or tracheostomy aspirates. VOLUME OF SPECIMEN: 10-50 ml. Minimum 1 ml. CONTAINER REQUIRED: Sterile, leak proof, tightly sealed container.	SPECIAL INSTRUCTIONS: See "Sputum culture, routine". Cultures for mycobacterial and fungi must be requested separately.
8. CULTURE, CATHETER TIP, ROUTINE		
Tests include culture for rapidly growing aerobic and facultative aerobic bacteria and yeasts. Only organisms recovered in numbers indicating probable significance (see below) will be fully identified. Susceptibility tests done, if appropriate. Applies to arterial catheters, central venous pressure lines, umbilical, intravenous, Swan Ganz, Hickman catheters (not Foley catheter tip).	SPECIMEN: 1" to 2" segment of catheter COLLECTION: Aseptically prepare insertion site. Remove line without contact with adjacent skin. Send only the intra-arterial segment in a sterile, dry, screw cap container. After removal of catheter, culture any exudate from catheter site and submit to Microbiology.	
9. CULTURE, CEREBROSPINAL FLUID, ROUTINE		
Tests include gram stain and culture for rapidly growing aerobic or facultative aerobic organism type. Growth of potentially significant organisms will be reported to physician by phone immediately. Positive gram stains will be called to physician immediately.	SPECIMEN: Cerebrospinal fluid VOLUME OF SPECIMEN: 1-5 ml for bacterial culture: 10 ml when fungus or mycobacteria was suspected. Minimum volume 1 ml. Organisms may be present in low numbers; therefore the probability of detecting the organisms decreases significantly if inadequate amounts of specimen are submitted. CONTAINER: Sterile, leak proof tubes	SPECIAL INSTRUCTIONS: Include the following information on the requisition: prior antibiotic treatment (prior therapy requires that cultures be held longer), suspected etiology, presence of shunt, etc. Transport to the Laboratory ASAP. DO NOT REFRIGERATE.
10. CULTURE, CHLAMYDIA		
Tests include cell culture for detection of Chlamydia trachomatis.	SPECIMEN: Chlamydia is an intracellular pathogen. Obtain swab specimens containing epithelial cells of conjunctiva, cervix, posterior nasopharynx, throat, rectum or urethra. CONTAINER: Specific Chlamydia transport media is required for specimen collection. Call Microbiology laboratory for media (x2187) TRANSPORT: Specimen should be transported to the Laboratory immediately.	
11. CULTURE, EAR, ROUTINE		
Applies to outer ear and middle ear culture - includes gram stain culture for aerobic bacteria. Identification and Susceptibility testing of suspected pathogens.	SPECIMEN: Tympanocentesis fluid. Swab specimen from external ear canal. Aspirated pus. VOLUME OF SPECIMEN: 0.1-0.5 ml or more, if possible. OUTER EAR: Sterile culturette or container. INNER EAR: Anaerobic culturette.	SPECIAL INSTRUCTIONS: Please note on requisition clinical information, suspected organism, history of swimming, previous surgery, drainage tubes, malignant otitis externa, diabetes, etc.

12. CULTURE, EYE, ROUTINE		
Tests include gram stain, culture for rapidly growing aerobic and facultative aerobic organisms and sensitivity of suspected pathogens.	SPECIMEN REQUIRED: Conjunctival scrapings, pus fluid, corneal scrapings, exudate. VOLUME OF SPECIMEN: The amount of specimen obtainable is often limited. As much as possible should be provided. CONTAINER REQUIRED: Sterile culturette.	DO NOT REFRIGERATE.
13. CULTURE FOR HAEMOPHILUS DUCREYI (CHANCROID)		
Tests include gram stain, isolation and identification of H. ducreyi.	SPECIMEN: Clean lesion with gauze moistened with sterile saline. Collect material for gram stain and culture from the undermined edge with a culturette and send to Laboratory promptly. Alternatively, cleanse ulcer base with sterile saline. Allow exudate to collect and aspirate with syringe from undermined edge. CONTAINER: Sterile culturette.	SPECIAL INSTRUCTIONS: Note "Check for H. ducreyi" on request.
14. CULTURE, FUNGAL BLOOD		
Tests includes isolation and identification of yeasts and fungi. Growth will be telephoned to physician.	SPECIMEN: Multiple specimens accepted. Consult Microbiology Lab for correct tube and amount. Do not use Bactec bottles unless directed.	
15. CULTURE, FUNGAL, BODY FLUIDS		
Tests include isolation and identification of yeasts and other fungi. Growth will be telephoned to physician.	SPECIMEN: Synovial, pleural, pericardial, or peritoneal fluid. Multiple specimens may be necessary to exclude fungal disease. VOLUME OF SPECIMEN: As much as possible. Every effort should be made to collect at least 5-10 ml. CONTAINER: Sterile, leak proof, tightly sealed container.	SPECIAL INSTRUCTIONS: Specify species suspected.
16. CULTURE, FUNGAL, BONE MARROW		
Tests include isolation and identification of yeasts and other fungi. Any bacteria isolated will also be identified with susceptibility tests. Growth will be telephoned to physician.	SPECIMEN: Bone marrow aspirate: 0.25-0.5 ml. CONTAINER: Call Microbiology Laboratory (x2187) for media.	SPECIAL INSTRUCTIONS: Specify fungal species suspected.
17. CULTURE, FUNGAL, CEREBROSPINAL		
Tests include isolation and identification of yeast and other fungi. Any growth will be telephoned to physician.	SPECIMEN REQUIRED: Cerebrospinal fluid. Multiple specimens my be necessary to exclude fungal disease. VOLUME OF SPECIMEN: 5-10 ml. Minimum volume 1 ml. The number of organisms per ml of CSF may be very small (fewer than 1 per ml) in cryptococcal meningitis. Likelihood of detecting the organism may be significantly reduced if inadequate amounts of specimen are submitted. CONTAINER: Sterile, tightly sealed, leak	SPECIAL INSTRUCTIONS: State fungal species suspected.

	proof tube.	
18. CULTURE, FUNGAL, PUS		
Test include isolation and identification of fungi.	SPECIMEN: Aspirated exudate. Swabs should be used to collect specimens only if exudate cannot otherwise be collected. Swabs are never optimal for collecting specimens for fungi. VOLUME OF SPECIMEN: AS much as possible should be submitted. Every effort should be made to collect 3-5 ml. CONTAINER: Sterile, leak proof, tightly sealed container or capped syringe or culturette.	SPECIAL INSTRUCTIONS: State fungal species suspected.
19. CULTURE, FUNGAL, SKIN AND NAILS		
SYNONYMS: Cutaneous mycoses, dermatophytes. Identification of any fungus recovered.	SPECIMEN: Skin scrapings, nail clippings, exudate. As much material as can be collected should be submitted. The most frequent error is to collect too little specimen. CONTAINER: Sterile, leak proof, tightly sealed container.	
20. CULTURE, FUNGAL, SPUTUM (TRACHEAL ASPIRATES, BRONCHIAL WASHING AND BRUSHINGS)		
Tests include isolation and identification of yeasts and other fungi.	SPECIMEN: Expectorated sputum (first morning sputum collected prior to eating is preferred); induced sputum (use saline only for induction, do not sure propylene glycol or ethylene glycol, as these are toxic to mycobacteria and some pathogenic fungi). VOLUME OF SPECIMEN: 15-20 ml is optimal. Minimum volume 5 ml (undiluted). CONTAINER: Sterile, tightly sealed, leak proof container.	
21. CULTURE, FUNGAL, THROAT AND MOUTH (OROPHARYNGEAL)		
Tests include isolation and identification of yeasts and fungi.	SPECIMEN: Lesion scrapings or exudate. CONTAINER: Culturette. INTERPRETATION: Yeasts may be isolated from the oropharynx in 20-40% of the healthy population; therefore, the isolation of a small amount of Candida from the mouth or throat is not particularly meaningful. These results should be interpreted by correlating with the clinical history.	
22. CULTURE, FUNGAL, TISSUE (BIOPSY)		
Tests include isolation and identification of yeasts and other fungi.	SPECIMEN: Surgical specimen. As much tissue as possible should be collected and sent to the Lab. Every effort should be made to obtain at least 1 gram. CONTAINER: Sterile, leak proof, tightly-	

	sealed container containing 5.0 ml of sterile, distilled water or non-bacteriostatic saline to prevent drying.	
23. CULTURE, FUNGAL, URINE		
Tests include culture for fungi, yeast.	SPECIMEN: Single, clear, voided midstream urine. Specimen may be obtained by catheterization or by suprapubic aspiration, if indicated. VOLUME OF SPECIMEN: 20 ml. Minimum volume 5 ml. Large amounts will increase likelihood of detecting fungi. Multiple specimens may be necessary to exclude fungal infection. CONTAINER: Sterile, tightly sealed, leak proof container.	SPECIAL INSTRUCTIONS: Yeasts are isolated and identified in routine urine cultures when present in significant amounts. Fungal cultures of urine should be ordered specifically only when systemic fungal infection is suspected or detection and identification of small numbers of yeast is clinically relevant.
24. GENITAL TRACT, ROUTINE		
SYNONYMS: Vaginal, uterine, prostate. Tests include screening for N. gonorrhea and isolation with identification of aerobic bacteria and yeasts. Gram stain included.	SPECIMEN: Swab from cervix, endocervix and endometrium, vagina, urethral exudate, urethral swab, biopsy specimen. VOLUME OF SPECIMEN: 2-10 ml fluid; 1 swab from affected site. CONTAINER: Culturette sterile.	SPECIAL INSTRUCTIONS: Specimens should be collected by procedures that avoid mucosal contamination. DO NOT REFRIGERATE.
25. CULTURE, LEGIONELLA		
SYNONYMS: Legionella pneumophilia Tests include isolation and identification of Legionella species.	SPECIMEN: Pleural fluid, lung biopsy, transtracheal aspirate, bronchial washings, spleen, liver, other tissues are recommended. Sputum is acceptable but is subject to bacterial overgrowth and is not as desirable a specimen as transtracheal aspirates, pleural fluid and biopsy material. VOLUME OF SPECIMEN: 1-10 ml fluid. As much tissue as possible. CONTAINER: Sterile, leak proof containers or tube. NOTE: Direct fluorescent antibody (DFA) may also be requested as a separate test.	
26. CULTURE, MYCOBACTERIAL, BLOOD (TB BLOOD CULTURE)		
Tests include isolation and identification of all mycobacteria and other organisms. Susceptibility tests when appropriate. Positive cultures will be telephoned to physician.	SPECIMEN: Call Micro Lab (x2187).	
27. CULTURE, MYCOBACTERIAL, BODY FLUID (TB CULTURE, BODY FLUID)		
Tests include acid-fast stain, AFB culture, and susceptibility testing. Positive cultures will be telephoned to physician.	SPECIMEN: Joint, pleural, peritoneal, pericardial fluids, 0.5-5.0 ml yield will be higher if larger volumes of specimen are submitted. CONTAINER: Sterile, tightly sealed, leak proof container.	SPECIAL INSTRUCTIONS: See separate sections dealing with mycobacterial cultures on various specimen sources.

28. CULTURE, MYCOBACTERIAL, BONE MARROW (TB CULTURE, BONE MARROW)		
Tests include isolation and identification of mycobacteria and other organisms. Susceptibility tests when appropriate. Positive cultures will be telephoned to physician.	SPECIMEN: Bone marrow aspirate or biopsy. 2 ml, if possible. Chance of recovery will be decreased if smaller amounts are submitted. CONTAINER: Sterile, tightly sealed, leak proof tube or capped syringe. Call Micro lab in advance (x2187).	SPECIAL INSTRUCTIONS: Requisition must clearly request isolation of mycobacteria.
29. CULTURE, MYCOBACTERIAL (TB), CEREBROSPINAL FLUID (CSF)		
Tests include acid-fast stain and AFB culture and susceptibility testing. Positive smears or cultures will be telephoned to physician. No other organism will be isolated or identified.	SPECIMEN: Cerebrospinal fluid, 10 ml optimum. Minimum volume 1 ml. Concentration of mycobacteria in CSF is usually very low. Optimum recovery requires an adequate volume of material. Submit as much as possible. CONTAINER: Sterile, tightly sealed, heatproof container.	
30. CULTURE, MYCOBACTERIAL (TB), SPUTUM		
Tests include acid-fast stain, AFB culture and susceptibility testing. Positive smear/culture telephoned to physician. No other organism will be isolated or identified.	SPECIMEN: Expectorated sputum, 5-10 ml, three (3) early morning specimens collected on successive days should be submitted. CONTAINER: AFB sputum collection kit.	Direct smear result available in 24 hours, followed by concentrated smear results a few days later.
31. CULTURE, MYCOBACTERIAL (TB), TISSUE		
Tests include acid-fast stain and AFB culture and susceptibility testing. Positive smear/culture will be telephoned to physician. No other organism will be isolated or identified.	VOLUME OF SPECIMEN: Optimal isolation of mycobacterial from tissue is accomplished by processing as much tissue as possible. Every effort should be made to remove 1 gram.	SPECIAL INSTRUCTIONS: Tissue source must be explicitly indicated. Specimens for skin and underlying tissues use special procedures for isolation of M. marinum, M. ulcerans, and M. haemophilum.
32. CULTURE, MYCOBACTERIAL (TB), URINE		
Tests include acid-fast stain and AFB culture and susceptibility testing. All mycobacteria isolated will be identified and susceptibility tests performed. Positive cultures will be telephoned to physician. No other organisms will be isolated or identified.	SPECIMEN: First morning voided urine. Three specimens, collected on successive days, should be submitted for maximum yield. Entire clean-voided specimen (that portion after the first 20-25 ml) should be submitted. Do not submit 24-hour collection of urine. CONTAINER: Sterile, tightly sealed, container.	
33. CULTURE, NASOPHARYNGEAL ROUTINE		
Tests include isolation and identification of rapidly growing aerobic/facultative bacteria, susceptibility tests.	SPECIMEN: Nasopharyngeal swab CONTAINER: Nasopharyngeal swab. Call x2187 for media.	SPECIAL INSTRUCTIONS: Consult with Microbiology Lab prior to collection of specimens for diphtheria, pertussis, and other unusual infections.

34. CULTURE, SPUTUM, ROUTINE		
Tests include gram stain, isolation of rapidly growing aerobic and facultative bacteria and yeasts. Only predominant organisms will be completely identified. Susceptibility tests will be performed, if appropriate. Presence/absence of normal upper respiratory flora will be noted.	SPECIMEN: 1-2 ml sputum (not saliva) CONTAINER: Clean, sterile, leak proof container.	SPECIAL INSTRUCTIONS: Single, early morning specimens are recommended. Pooled specimens or 24-hour collections are frequently overgrown with contaminating organisms and will not be accepted. NOTE: Smears are done on all specimens to assess specimen quality (oropharyngeal contamination). If the specimen is saliva and not a deep cough, sputum will be rejected and repeat specimen requested from the ordering location.
35. CULTURE, STOOL, ROUTINE		
Tests include isolation of Salmonella, Shigella, Campylobacter. Predominance of Staphylococci, Pseudomonas, Candida or other organisms not usually found will be reported. Presence or absence of normal fecal flora will be noted. NOTE: Other pathogens such as Yersinia, Vibrio and E. coli 0157 must be ordered separately. These are not part of a routine stool culture.	SPECIMEN: 1 gram or 1 ml minimum, liquid fecal material. CONTAINER: Clean, wide-mouth, leak proof container. If liquid stool: Use plastic screw-cap container.	SPECIAL INSTRUCTIONS: Salmonella and Shigella are present in stool in appreciable numbers only during the acute stage (first 3 days of diarrheal disease). Specimen should be collected early in the course of disease and before antimicrobial therapy is begun. Include portions of stool containing pus, blood, or mucous. Hospitalized patients who develop diarrhea when hospitalized and more than 72 hours after admission should be tested for C. difficile.
36. CULTURE, THROAT		
SYNONYMS: Pharyngitis	SPECIMEN: Throat swab, pharyngeal exudate; 1 swab from affected area. CONTAINER: Sterile culturettes	SPECIAL INSTRUCTIONS: If any of the following are requested, notify the Microbiology Lab: Bordatella pertussis, Corynebacterium diphtheria, Neisseria gonorrhoeae
37. CULTURE, URINE		
Tests include isolation, quantitation, and susceptibility tests for rapidly growing aerobic/facultative bacteria and yeasts. Only those present in significant numbers will be completely identified. RESULTS: All potential pathogens in significant numbers will be identified to species and will have susceptibility done. The urine cultures with ≥ 3 organisms will be reported as such and a sterile repeat collection recommended. No further testing will be done on this culture.	SPECIMEN: Urine, 5-10 ml. SPECIMEN COLLECTION: The patient must be thoroughly instructed for proper collection of "clean catch" specimen. CONTAINER: Sterile container.	SPECIAL INSTRUCTIONS: Must note exact collection method when ordering. The first morning specimen is preferred because the concentration of organisms is higher after overnight incubation in the bladder. Specimens may be obtained by single urethral catheterization only when the patient is unable to void or unable to cooperate in collecting a clean-voided midstream specimen, or when catheterization must be done for diagnostic or therapeutic purposes. **Foley catheter tips are not accepted.** Indwelling Foley catheters are surrounded by an exudative sheath or urethral secretion that is invariably populated with bacteria. There is no consistent relationship between the organisms found in this exudate and urinary tract infections in patients with indwelling catheters; <u>therefore, these catheters tips are not accepted</u>. Urine for

		diagnosing urinary tract infections in these patients should be obtained from quantitative culture. Polymicrobic bacteriuria is not uncommon in patients with chronic indwelling catheters. It is very important that such specimens are sent to the Laboratory with their origin clearly indicated on the requisition form.
38. CULTURE, WOUND, ROUTINE		
Applies to culture of abscess, decubitus discharge, pus, and ulcers. Tests include gram stain, isolation and identification of rapidly growing, non-fastidious aerobic organisms. Only organisms which predominate will be completely identified. Susceptibility testing, if relevant. Anaerobic cultures must be specifically requested, properly collected, and transported.	CONTAINER: Sterile culturette. SPECIMEN: Pus or other material properly obtained aseptically from the wound site or abscess.	SPECIAL INSTRUCTIONS: Avoid contaminating with skin surface organisms.
39. CULTURE/DIRECT SMEAR FOR GONORRHEA		
Tests include isolation and identification of N. gonorrhea only. Isolates tested for production of beta lactamase.	SPECIMEN: Males: Urethral exudate, prostate secretions, rectal swab, throat swab, urine. Females: Urethral exudate, cervical swab, rectal swab, throat swab, drainage from Bartholin's glands. A separate swab should be submitted from each site sampled. CONTAINER: Sterile culturette.	SPECIAL INSTRUCTIONS: Separate specimen culturettes are required for each body site. Direct smear of exudate on glass slide may be sent for gram stain. DO NOT REFRIGERATE.
40. OVA AND PARASITE EXAMINATION, STOOL		
Testing includes an enzyme immunoassay method for the detection of antigens specific for Giardia lamblia, Entamoeba histolytica and Cryptosporidium parvum. Complete ova and parasite examination with trichrome stain will only be performed upon special request.	SPECIMEN: Fresh random stool. Three separately collected diarrheal or purged specimens should be submitted to rule out infection with intestinal parasites. Do not fill the container for liquid stool specimens. CONTAINER: Submit specimen in clean, wide-mouth, leak proof containers. A container with a tight fitting lid is suitable. (If liquid stool, use plastic screw cap container.)	SPECIAL INSTRUCTIONS: Recommended screening procedure is three random stool specimens (1 specimen per day for three days).
41. PARASITE EXAMINATION, NON-FECAL SPECIMEN		
Applies to aspirates from cyst, liver, lung and lymph nodes, muscle biopsy, rectal biopsy for Schistosomiasis, vagina, urine, etc. Tests include wet mount and stained smear (the latter on fluids or aspirate only)	SPECIMEN: Aspirate, tissue biopsy, body fluid, vaginal aspirate, rectal aspirate, urine. VOLUME: 3-4 ml of body fluids, 1-gram tissue. Sterile screw cap container. INSTRUCTIONS: Deliver specimen to Microbiology immediately. NOTE: Tissue biopsy for Schistosoma ova must be placed in sterile distilled water. Otherwise, tissue should be transported in saline to prevent drying.	

Applies to tick identification.	SPECIMEN: Tick container – plastic screw cap container	SPECIAL INSTRUCTIONS: Include clinical history such as body site, geographic location, etc.
42. CLOSTRIDIUM DIFFICILE		
Includes toxins A and B.	SPECIMEN COLLECTION: Stool, 1 gram or 1 ml minimum. Swabs are not accepted. Transport to Microbiology as soon as possible. Stool should be diarrheal. CONTAINER: Submit in a clean, wide-mouth, leak proof container. If liquid stool, use plastic screw-cap container.	
43. CRYPTOSPORIDIUM DIAGNOSTIC PROCEDURES, STOOL		
Tests include examining the stool specimen with modified acid-fast staining for the presence of cryptosporidium.	SPECIMENS AND COLLECTION: A fresh random stool in a stool container with lid and transport the specimen to Microbiology immediately. For liquid specimens, do NOT fill the container.	
44. KOH PREPARATION		
SYNONYM: Fungus smear or scabies.	SPECIMEN AND SPECIMEN COLLECTION: Call Microbiology Lab (x2187)	
45. NEISSERIA GONORRHEA SMEAR		
See Culture/Direct Smear for Gonorrhoeae.	SPECIMEN: Smear, air-dried or culturette of exudate.	
46. VIRAL CULTURE		
Based on specimen sources, viruses to be detected by cytopathic effect and/or antibody staining include adenovirus, CMV, enteroviruses, HSV, influenza, mumps, parainfluenza, RSV and U-2.	SPECIMEN AND COLLECTION: Transport media for virus culture is available in Microbiology (x2187). State specific virus requested. Blood, CSV, dermal, ocular, genital, mucosal, oral, rectal, respiratory, stool, tissue, urine, biopsy.	
47. INFLUENZA A and B ANTIGEN EIA (with reflex rapid respiratory virus culture, if antigens negative.)		
	SPECIMEN: Nasopharyngeal aspirates swab, lower nasal swab, throat swab. Nasopharyngeal aspirates have higher yields than lower nasal and throat swabs. Transport media available in Microbiology (x2187).	
48. MRSA Screen		
	SPECIMEN: Naris. Do both sides with one swab. Admission swab for DNA testing – red top culturette only. Tranfer / discharge swab for AGAR testing – regular sterile culturette.	SPECIAL INSTRUCTIONS: Test done on admission, transfer and discharge.
49. VRE Screen		
	SPECIMEN: Stool swab	SPECIAL INSTRUCTIONS: Test done on admission.

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G. URINALYSIS

G. URINALYSIS

1. GENERAL INFORMATION

Urinalysis testing is performed on an automated instrument utilizing fiber optics.

2. TEST INFORMATION

a. CHEMISTRIES TESTED BY URINALYSIS DIPSTICK:

Glucose	pH
Bilirubin	Protein
Ketone	Urobilinogen
Specific Gravity	Nitrite
(SG performed on	Leukocyte Esterase
refractometer as needed)	Blood

b. MICROSCOPIC URINE SEDIMENT EXAMINATION:

Microscopic tests on urine sediment will not be performed on urines if dipstick for all urine chemistry tests is negative and specimen is clear.

3. SPECIMEN COLLECTION AND HANDLING

During the course of a single day, the composition of urine is constantly changing. Accordingly, various types of urine specimens are used for analysis.

a. TYPE OF URINE COLLECTION:

Type of Urine Specimen	***Collection***
1. Random or spot specimen	Portion of any voided urine is collected in a clean container. Majority of urine specimens submitted for urinalysis are random specimens. Composition of random voided specimens may vary widely; however, if rules for handling the specimens are observed, the variance will be minimized.
2. Fasting Specimen	Urine is voided four or more hours following ingestion of food and discarded. The next voided specimen is collected.
3. First Morning Specimen	Patient voids before retiring and urine is discarded. On arising in the morning, the first voided specimen is collected.
4. Morning Specimen for Routine Urinalysis	First morning specimen is discarded to prevent false positive results on urine chemistry and microscopic examination from collection of constituents and formed elements retained in the bladder overnight. Second morning specimen is collected and sent to the Laboratory.

5. Midstream Specimen	With a clean collection container at hand, urination is initiated. Without interrupting the process of urination, when approximately half of voiding is completed, a portion of urine is collected in the container. The latter portion of the urine flow is discarded.
6. Clean Catch Specimen	For either males or females, the external genitalia are washed using a mild antiseptic solution. Then, midstream urine is collected in a clean sterile container.
7. Random Urine Toxicology Screen	Instruct the patient to collect urine in the collection cup and directly hand the specimen to a laboratory employee. The temperature will immediately be taken using an infra-red thermometer by aiming the thermometer at the specimen through the cup and pressing the measurement button. This temperature will be recorded on the urine collection cup. Acceptable range: 32.2 – 37.8^{o}C. The physician will be notified by the laboratory if temperature is outside this range.

b. URINE COLLECTION WITH THE BD VACUTAINER COLLECTION CUP SYSTEM:

- The healthcare professional obtains a cup for the patient and cautions the patient to NOT remove the cap label to protect against a needlestick from the integrated transfer device.
- To transfer the specimen into accompanying evacuated tubes, peel back the cap label to expose the transfer device. Advance the tubes over the puncture device and fill tubes. Once filled, carefully replace the cap label over the transfer device and treat the screw cap as a contaminated sharp. Label all tubes and collection cups appropriately.

c. SPECIMEN AMOUNT: For routine urinalysis, at least 10 mL of urine should be submitted.

d. SPECIMEN STORAGE: Specimens for routine urinalysis are stable for 48 hours at room . temperature. Specimens for C&S can remain at room temperature for 72 hours.

4. REFERENCE RANGES

a. URINALYSIS REFERENCE RANGES (DIPSTICK & MICROSCOPIC):

Refer to ***"Test and Reference Range Chart"*** (*Section IV)* for a list of Urinalysis reference ranges.

H. SEROLOGY

H. SEROLOGY

1. GENERAL INFORMATION

Limited Serology/Immunology testing is provided on a routine basis. Testing is available daily for routine serum and urine HCG - Qualitative Pregnancy Test. STAT testing is available also with <1 hour turnaround time. Testing is performed using a rapid chromatographic immunoassay kit.

2. TEST INFORMATION

Test	*Qualitative Testing*	*Quantitative Testing*	*Lab Follow-Up*	*Test Schedule*
HCG, Qual Pregnancy Test	Yes	No	Positive HCG present	Daily including STATs

3. SPECIMEN COLLECTION AND HANDLING

Test	*Serum (Red Top)*	*Urine*	*Plasma*	*Storage*
HCG, Qual Pregnancy Test	Yes	Yes	No	Refrigerate up to 48 hours

4. REFERENCE RANGES

Refer to *"**Test and Reference Range Chart**"(Section IV)* for a list of Serology reference ranges.

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I. ARTERIAL BLOOD GAS

I. ARTERIAL BLOOD GAS

1. GENERAL INFORMATION

The concentration of pH, pCO_2, and pO_2 in arterial blood is measured on an automated Blood Gas analyzer located in the Laboratory. The arterial blood specimen is aspirated into the analyzer and passed by a series of sensors. The unknown concentration of PCO2 is obtained by infrared spectroscopy measurement at three wavelengths. The unknown pH is obtained by an optical/color sensitive indicator measurement. A phosphorescence quenching measurement obtains the unknown concentration of PO2. All other results obtained are calculations. The analyzer then prints out these results.

2. TEST INFORMATION

Test	Test Schedule
• pH • pCO_2 • pO_2	Available STAT. Seven (7) days a week, 1st shift and 2nd shift. Coverage by 3rd shift as scheduled. Other shifts - Sent out to Hamot Medical Center for testing when coverage not available.

3. SPECIMEN COLLECTION AND STORAGE

Arterial Blood Gas specimens are drawn by certified Respiratory Technicians. During Laboratory off duty hours, the AOD draws the Arterial Blood Gas specimens. The Arterial Blood Gas specimens are drawn in lithium heparin syringes. The syringe is sealed and checked to assure no air bubbles are visible. Specimens are brought to the Lab within 30 minutes of collection. Specimens on ice must be tested within two hours of collection. Minimum specimen volume is 0.09 cc.

4. REFERENCE RANGES

Refer to *"Test and Reference Range Chart"(Section IV)* f or a list of Arterial Blood Gas reference ranges.

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J. BLOOD BANK

1. Blood/Blood Components Transfusion Policy

Transfusion Service Procedures

- ***Ordering Blood/Blood Components***
- ***Patient identification blood sample collection and labeling for compatibility testing***
- ***Pre-transfusion testing and processing***
- ***Inspection and Issuance of Blood/Blood Components***
- ***Emergency Blood Release***
- ***Transfusion Administration***
- ***Adverse Reactions***
- ***Reporting of Transfusion-Transmitted Diseases***
- ***Return of Un-Used Blood to Blood Bank***

2. Informed Consent for Transfusion of Blood form.

3. Blood Bank MCM's

- MCM 115-02 "Look-Back"/Recall Program for Blood and Blood Products
- MCM 115-07 Blood Warmers
- MCM 115-08 Therapeutic Phlebotomy
- MCM 115-11 Predeposit Autologous Donation and Transfusion
- MCM 115-12 Type, Screen and Hold Blood Orders
- MCM 115-16 Reporting of Post Transfusion Transmitted Diseases
- P&LM SOP Biological Product Deviations

4. Appropriateness Criteria

- Appropriateness Criteria for Blood and Blood Products
- Guidelines for Maximum Blood Order Schedule (MSBOS)

Medical Center Memorandum No. 115-01

H. BLOOD/BLOOD COMPONENTS TRANSFUSION & MANAGEMENT OF SUSPECTED TRANSFUSION REACTION

I. PURPOSE: To establish policies and procedures for blood/blood component therapy that is designed to ensure patient safety and minimize the risks associated with blood transfusion.

II. POLICY: The Blood Transfusion service will provide suitable blood, blood components and derivatives to meet the transfusion needs of patients being treated at this facility. Blood/blood components/ derivatives will be administered by qualified nursing personnel who will ensure positive identification of recipient following Medical Center policy, and manage any suspected adverse reactions.

All patients reporting for hospital admission or ambulatory procedures must be issued a patient identification wristband that contains the patient's full name, full Social Security number (SSN) and a bar code that displays the patients full SSN. Prior to ordering the necessary blood products for transfusion, informed consent will be obtained.

III. RESPONSIBILITY:

A. The Medical Director, Pathology & Laboratory Medicine (P&LM) is responsible for:

1. The clinical and administrative aspects of the Medical Center's blood transfusion policies and their implementation.
2. Delegation of the technical aspects of the Blood Bank to the Laboratory personnel who are competent in the blood bank procedures.
3. Seeking consultation from a recognized authority in the field of blood banking when complications arise in the treatment of patients.
4. Provide oversight responsibility for ensuring accreditation with The Joint Commission and meet the Food & Drug Administration (FDA) and VHA requirements.

B. The Supervisor, P&LM, is responsible for:

1. Administrative and technical supervision, ensuring that all procedures in Blood Bank are kept current and adequate controls are in place to minimize the errors and personnel performing the blood bank testing are competent.

C. Blood Bank technologist is responsible for procurement of blood, ensuring the accuracy and reliability of compatibility testing results, follow up of all adverse reactions reported, preparing monthly blood bank reports and utilization statistics, and informing the Medical Director of work-up of all complex antibody and transfusion reactions.

D. The physician(s) are responsible for appropriate ordering of blood/blood components for treatment of patient's hemodynamic status and obtaining an informed consent. The physician(s) ordering the transfusion of blood components will be ultimately responsible for transfusion including the recognition and treatment of any complications incurred during or after the transfusion.

E. Authorized nursing personnel are responsible for administration of blood/blood components.

F. Biomedical Department is responsible for performing function checks of blood warmers and equipment in Blood Bank.

G. Facilities Management is responsible for the management of refrigerator systems in the Blood Bank.

H. The Blood Utilization Review group, which includes members from departments involved in blood transfusions, are responsible for evaluating and improving the processes/outcomes involved in blood/blood component ordering, distribution and handling, administering and monitoring effects on patients.

IV. PROCEDURE:

A. Blood Supplier(s): The blood/blood components will be routinely obtained from Community Blood Bank (CBB), Erie, PA. Only in emergency situations, when CBB is not able to meet the needs, the blood/blood products will be obtained from the Florida Blood Services, St. Petersburg, Florida region, under the terms and conditions contained in their agreement.

B. The Blood Bank will work closely with the medical staff in endeavoring to provide appropriate blood/blood components to help patient care needs.

C. The SOPs (Standard Operating Procedures) in the Blood Bank are comprehensive and reflect the policies and procedures for quality control, processes for complete and accurate identification and verification of the patient, pre-transfusion compatibility testing, release of blood under routine and emergency conditions, testing in the event of an adverse reaction, blood/blood components storage, inventory control and records/equipment maintenance.

D. The policies for transfusion therapy will be maintained that are in compliance with accreditation standards of American Association of Blood Banks, The Joint Commission and meet the FDA regulatory requirements.

E. The details of the procedures for blood/blood component(s) transfusion are described in the following sections:

1. Blood/Blood Components Transfusion Policy

2. Blood Bank MCMs

- MCM 111B-527-C Operative and Other Procedures Blood and Blood Components Utilization Review Committee
- MCM 115-01 Blood/Blood Components Transfusion & Management of Suspected Transfusion Reaction
- MCM 115-02 Look Back Program for Blood and Blood Products

- MCM 115-07 Blood Warmers
- MCM 115-08 Therapeutic Phlebotomy
- MCM 115-11 Predeposit Autologous Donation and Transfusion
- MCM 115-12 Type, Screen and Hold Blood Orders
- MCM 115-16 Reporting of Post Transfusion Transmitted Diseases

3. Appropriateness Criteria:
   - Appropriateness Criteria for Ordering Blood/Blood Products
   - Maximum Surgical Blood Ordering Schedule

V. REFERENCES:

A. Department of Veterans Affairs VHA Handbook 1106.1, "Immunohematology Blood Transfusions and Transfusion Medicine," June 4, 2003.
B. VHA Directive 2005-029, "Transfusion Verification and Identification Requirements for All Sites," July 1, 2005.
C. "Technical Manual, American Association of Blood Banks (AABB)," current edition.
D. "Standards for Blood Bank & Transfusion Services," American Association of Blood Banks (AABB), current edition.
E. The Joint Commission Hospital Accreditation Standards, current edition.

VI. RESCISSION: None

MICHAEL D ADELMAN, MD
Director

Attachment: APPENDICES TO BLOOD/BLOOD COMPONENTS TRANSFUSION POLICY

APPENDICES TO BLOOD/BLOOD COMPONENTS TRANSFUSION POLICY

ORDERING BLOOD/BLOOD COMPONENTS

The authorized physician(s) are responsible for accurately prescribing blood/blood components (i.e., to give the authority to administer).

- ***Consent for Transfusion***

  Informed consent for transfusion means a dialogue has occurred between the patient and his/her physician discussing the specific risks, benefits and alternatives to the components to be transfused. The documented consent for transfusion must be obtained before ordering any blood component from the Blood Bank. For inpatients, the consent is valid for the current hospitalization. The consent for outpatients is valid up to one year as long as the patient is being treated for the same condition. (Attachment 1A)

- ***Physician(s) orders***

  The physicians will order the blood/blood components electronically with clear instructions to include, if applicable:

  √ Type and Screen
  √ Blood/Blood Component
  √ Number of units
  √ Priority of need and date/time of blood/blood components required
  √ Specify indication of transfusion (diagnosis and/or operative procedure)
  √ Specify rate of transfusion
  √ Special patient instructions/requirements (e.g., sickle cell disease, allo-antibodies, CMV negative, etc.)

- ***Transmitting request for Blood/Blood Components to Blood Bank***

  Inpatients - The nursing staff on the Unit/Operating Room will notify the Laboratory Blood Bank by phone that a type and screen or a type and crossmatch have been ordered.

  Outpatients – Oncology/Hematology patients may receive their transfusion in the Oncology Nurse Clinic. Appointments will be made at least one day prior to transfusion to allow for notification of the Blood Bank to ensure blood/blood component availability.

  Operating Room – Blood is normally pre-ordered on patients prior to an operative procedure if a transfusion is planned. For unplanned events, the operative team will notify the Laboratory of a transfusion request.

  The Physician will order a Type and Screen. If blood is required the OR will contact the Blood Bank and the Blood Bank Technologist will order the requested number of units in CPRS. The technologist will notify the OR when the blood is ready to be picked up.

  ◊**NOTE**: When either the plans for transfusion or the surgical procedure are cancelled, the nursing staff must notify the Blood Bank **immediately** of the cancellation to minimize wastage of blood/blood components.

◊When multiple units of red blood cells are transfused over a period of two days or more, a new blood specimen from the patient is required every 72 hours for typing, antibody screening and cross matching

INFORMED CONSENT FOR TRANSFUSION OF BLOOD/BLOOD PRODUCTS

A. EXPLANATION OF PROCEDURE

1. INDICATIONS: I understand that blood and blood product transfusions are given to replace parts of the blood that are missing, either because my body is not able to make enough or because I have lost those parts because of bleeding from surgery or other causes. The benefit of the transfusion is to improve my condition.

2. RISKS/COMPLICATIONS: It has been fully explained to me that blood transfusion(s) are not always successful in producing desirable results, and that there is a possibility of ill effects. I understand that just as there may be risks and hazards in continuing my present condition without transfusions, there are also risks related to the transfusion of blood and blood products.

Occasional complications are an elevation in temperature (fever), chills and allergic reactions such as itching and hives. Additional complications may include my receiving too much fluid or my developing chemical imbalances and hemolysis (destruction of transfused red blood cells). Rarely do any of these complications lead to bleeding, clotting problems, kidney failure or death. Blood transfusions can cause infections from bacteria, parasites and viruses such as those that cause hepatitis and AIDS (Acquired Immune Deficiency Syndrome). However, the risk of these infections is very small since all blood is tested for infectious disease.

NAT (Nucleic Acid Testing): The blood product you are about to receive has been obtained from an FDA (Food & Drug Administration) licensed blood bank and has passed the current standard tests, which are very effective at finding infections. However, it has been additionally tested by an experimental method called Nucleic Acid Testing (NAT), which may detect levels of infection that the current standard tests cannot detect. The blood supply is as safe as it has ever been. I understand that because the tests currently used to detect infection are so effective, the risk of receiving infected blood is very low. However, NAT is being used to see if it can be made even safer. It may not be possible to receive the results of NAT before receiving the transfusion. If NAT detects infection in this blood product, the blood supplier must immediately notify the VA. The VA will notify me and provide appropriate care. I will not be notified if the additional testing is negative.

3. ALTERNATIVES: When bleeding or severe anemia (which cannot be treated with diet or medication) becomes life threatening, there is no effective substitute for blood transfusion. I further understand that alternatives to blood or blood product transfusions, such as auto-donation (using my own previously donated blood), directed donation (blood donated by people whom I have asked to donate), may be available if my health, time and surgical procedure permit. I also understand that there are risks and consequences of refusing the blood or blood product transfusion therapy that has been recommended to me. These may include severe anemia or bleeding due to deficiency of blood components, or death due to one of these complications.

B. SIGNATURES

1. COUNSELING PHYSICIAN/DENTIST: I have counseled this patient as to the nature of the transfusion of blood and blood products, attendant risks involved, alternatives and expected results, as described above. The patient is alert, oriented and able to understand the information provided.

_____ _____

Signature of Counseling Physician/Dentist *Date & Time*

2. PATIENT: The blood transfusion procedure has been fully explained to me and I have had a chance to have all my questions answered. If I am an inpatient, I understand that whatever decision I make about receiving blood will remain valid for the length of my current hospitalization. If I am being treated as an outpatient, my decision will remain valid up to one year as long as I am being transfused to treat the same condition. However, I can change my mind about the transfusion decision at any time simply by telling my doctor.

I accept □ I do not accept □

_____ _____ _____ _____

Signature of Witness, excluding member of care team **Date & Time** **Signature of Patient** **Date & Time**

3. SPONSOR OR GUARDIAN: (When patient is unable to give consent). I, _____, sponsor/guardian of _____, understand the nature of the proposed transfusion(s), attendant risks involved and expected results, as described above, and hereby request such transfusion(s) be performed.

_____ _____ _____ _____

Signature of Witness, excluding member of care team **Date & Time** **Signature of Patient** **Date & Time**

ADDRESSOGRAPH STAMP (Patient name-last, first, middle; SSN and DOB)

VA 10-24-95 **(revised November 2001)**

Blood Transfusion Record Form

Division, City and State:	**Transfusion Requirements**
Patient Name:	**Blood Component Information**
Patient ID: / Patient Blood Type:	Blood Component:
Unit/Pool ID: / Unit Blood Type:	Component Expiration Date/Time:
Compatibility Interpretation:	Number of units/pool:
Assigned Date/Time: / Technologist initials:	**Additional Patient Information**
	Specimen UID:
	Location:

Remarks

Pretransfusion Data

Inspected and issued by:

Issued to: | Issued to location:

I have verified and compared, AT THE BEDSIDE, the transfusion recipient's identity (i.e., wristband), the unit ID tag, the blood component container label, and this form. I verify that all information matches and is consistent ITEM for ITEM. I verify that the intended recipient is the same person named on this form and on the unit ID tag. Furthermore, I verify that there is a current, valid INFORMED CONSENT, and a PHYSICIAN'S ORDER for this transfusion.

☐ Verified informed consent for transfusion | First identifier (signature): | Second identifier (signature):

Transfusion Data

	Date/Time	Temperature	Pulse	Blood Pressure	Respiration
Start					
15 minutes					
Mid (optional)					
Stop					

Amount given (mL): _____ ☐ Completed ☐ Interrupted ☐ No reaction ☐ Reaction suspected (Complete Transfusion Reaction Data section)

Other difficulties (equipment, clots, etc.): ☐ No ☐ Yes (specify) | Transfusion Data section completed by (signature):

Transfusion Reaction Data

Patient identity match with unit compatibility tag and this form reverified by (initials):

Description of reaction: ☐ Urticaria ☐ Chill ☐ Pain ☐ Fever ☐ Dyspnea ☐ Other (specify)

Transfusion Reaction Data section completed by (signature):

Suspected Transfusion Reaction: Immediate Response

If a reaction is suspected, IMMEDIATELY:
1. Interrupt the transfusion. Give emergency treatment. Keep the intravenous line open.
2. Reverify patient and blood product identification.
3. Notify physician and Transfusion Service.
4. Follow transfusion reaction procedures.
5. Do NOT discard the component. Return the blood component bag, filter set, and attached solutions to Transfusion Service. Collect patient specimens as required.
6. Order a Transfusion Reaction Workup.

Patient name: _____ Patient ID: _____ Date of birth: _____ Blood Transfusion Record Form, Version 1.0

TRANSFUSION VERIFICATION AND IDENTIFICATION REQUIREMENTS, BLOOD SAMPLE COLLECTION AND LABELING FOR COMPATIBILITY TESTING

1. **Patient Identification** (for all sites)

   ►*Proper accurate identification of the intended patient, blood sample and blood component(s) are critical to ensure transfusion safety regardless of patient location.*

   ►*For those sites that have an effective operational bar code scanning available, such as in the operating rooms, the added electronic process should be used as an identification verifier prior to administration of all blood/blood products.*

Identification Procedure:

• Require two (2) approved patient identifiers (neither to be the patient's room number) • ***Patient(s) who can communicate adequately***. Active participation with patient stating two of the verbal identifiers (full name and SSN, DOB [optional]). The other identifiers are VA Identification Card, Driver's License or their Patient Identification Band as necessary. • ***Patient(s) who cannot communicate***. Identifiers would include: VA Identification Card, Driver's License or Patient Identification Band. The healthcare worker, family member or attendant could participate in the identification process. • ***Patient(s) in Emergency Room who are unresponsive***. The attendant, family member or healthcare worker could participate in the identification process: NOTE: In case a temporary name and medical record number are assigned, these identifiers could be used to identify the patient and match against specimen labels. **These responses must be checked by staff against the completed consent form and patient's identification band as applicable.**	Approved Patient Identifiers: • Patient's Full Name • Patient's entire Social Security Number • Patient's Date of Birth • Patient's VA Identification Card or Driver's License • Patient's Identification Band

2. **Specimen Collection**
   - **Venipuncture:**
     - For Blood Bank specimens, phlebotomy will be performed only on **ONE** patient at a time to minimize the risk of error. The collected specimen should be brought to the Blood Bank before proceeding with the next patient.
     - The blood sample will be collected by the phlebotomists or other authorized personnel. It is the responsibility of the person collecting the blood specimen to accurately identify the patient and blood tube for compatibility testing.
   - **Sample Requirements**: One full 6 ml pink top or 10 ml red top tube is required for compatibility testing.

3. **Specimen Labeling**: The blood sample tube must be labeled at patient's bedside <u>immediately</u> after blood sample is drawn. Do NOT pre-label tubes as this might cause patient specimen mix-up.

- The sample tube must be labeled with the minimum patient information of:
  √ Patient's Full Name
  √ Patient's Full Social Security Number
  √ Date/time of collection
  √ Signature or initials of the person drawing the sample
  √ Signature of the healthcare provider witnessing the blood sample collection on form SF 518.
  NOTE: A signature of the healthcare provider witnessing the sample collection is only required on the VBECS order form. Healthcare providers include nursing staff, CRNA, Nurse Practitioners, Physicians and second Laboratory medical technologist.

PRE-TRANSFUSION TESTING AND PROCESSING

Pretransfusion testing is designed to ensure optimal survival of transfused red cells in recipients and prevent a hemolytic transfusion reaction from occurring. The primary purpose is to detect an **ABO incompatibility** between patient and donor and ensuring that a recipient does not get transfused with donor blood positive for an antigen to which the patient has the corresponding antibody.

- ***Specimen and request verification***

  Upon receipt of blood specimen and Blood Bank order, Laboratory personnel will check for clerical discrepancies. If any exist, the Blood Bank will request further proof of patient identification prior to acceptance. If this identification is still questionable, a re-drawn blood specimen with assured patient identification may be necessary. Physician orders will be verified by the Medical Technologist. Physician orders will be printed and a copy saved in Blood Bank. Physician orders must be clarified if not understood.

- ***Blood Bank patient records check:***

  √ When a Transfusion Request is accessioned into VistA, any historical ABO/Rh/Antibody data will be displayed. Other records to check include VBECS Patient History Report, Antibody File and Patient Antibody Reports (if VistA is down).
  √ Any discrepancies must be resolved before blood or blood components are issued.
  √ Historical records are used in:
  ◊Preventing patient misidentification
  ◊Preventing transfusion of incompatible blood
  ◊Preventing extra work due to positive DATs
  ◊Preventing non-hemolytic febrile transfusion reactions
  ◊Tracking transfusion-associated transmissible diseases

- ***Pre-transfusion testing procedures – to ensure donor and patient are compatible***

  Type and screen:
  √ To determine the ABO and Rh type
  √ To detect red cell antibodies in addition to anti-A or anti-B that could hemolyze transfused red cells.
  Crossmatch:
  √ To determine the ABO and Rh D type
  √ To detect red cell antibodies that could hemolyze transfused red cells
  √ To confirm compatibility with each of the units of red cells to be transfused

Cross match

√ The cross match will be performed in accordance with established policies in Blood Bank.
NOTE: Emergency need for blood may rarely preclude routine compatibility testing (cross match).

√ In the absence of an emergency, blood components will not be released until compatibility testing has been completed. The requesting physician will be notified by blood bank when there is any difficulty in obtaining compatible blood.

√ The Blood Transfusion Record Form (BTRF)(Attachment 1A) generated by VBECS will be properly attached to the unit before it is released from the Blood Bank. Patient information, name, full Social Security number, ABO and Rh type, assigned blood component information/donor number/ABO and Rh type, expiration date/time and cross match results will be entered into the VBECS system after all test results are completed. In addition, the sequence of ordered products to be transfused (i.e., 1 of 2, 2 of 2) will be written on the BTRF.

- ***ABO-Rh Compatibility Table***

It is ***essential*** to ensure that no ABO incompatible red cell transfusion is ever given. This accident is likely to kill or harm the patient and it is ***avoidable***. The following table indicates, for various transfusion products, the ABO and Rh types that may be administered to patients of a given blood type.

Patient Type	**Component to be Transfused and Permissible Donor Type**					
	Whole Blood	Red Blood Cells	Plasma	Single Donor Full Volume Platelets	Pooled Platelets/Reduced Volume Single Donor Platelets	Cryoprecipitate
O	O	O	Any Type	Any Type	Any Type	Irrelevant
A	A	A O	A AB	A AB	Any Type	Irrelevant
B	B	B O	B AB	B AB	Any Type	Irrelevant
AB	AB	Any Type	AB	AB	Any Type	Irrelevant
RH Considerations for Blood and Components						
Rh positive	Positive or Negative	Positive or Negative	Positive or Negative	Positive or Negative	Positive or Negative	Irrelevant
Rh Negative	Negative	Negative	Positive or Negative	Negative	Negative	Irrelevant

NOTE: Rh-positive red cells may be administered to Rh-negative patients who do not have anti-D without fear of immediate transfusion reaction. However, there is a high risk that such patients will subsequently develop Rh sensitization. Therefore, such transfusions should never be given to Rh-negative women with childbearing potential.

Platelets: ABO identical platelets are preferable, if available.

Blood Component most commonly required for transfusion, Refer to Table 1.

Blood Components Most Commonly Required for Transfusion				
Component	**Volume**	**Instructions for Use**	**Dosage Effect**	**Transfusion Criteria**
Red Blood Cells-Filtered (RCNF)	300-350 ml	Restore oxygen carrying capacity in symptomatic anemia	1 unit of RCB increases Hct~3%, Hgb~1gm	ABO/Rh compatible X-match compatible
Random Donor Platelet Pool (4 single platelets) (PLTF)	3.0×10^{11} platelets in 200-250 ml. Plasma	To correct thrombocytopenia due to increased platelet function, decreased platelet production or increased platelet consumption due to bleeding, platelet disorders, DIC, massive transfusion	Platelet count increase of ~30-60,000	ABO/Rh compatible if possible
Single Donor Apheresis Platelet (APT)	3.0×10^{11} platelets in 200-250 ml. Plasma	To correct thrombocytopenia due to increased platelet function, decreased platelet production or increased platelet consumption due to bleeding, platelet disorders, DIC, massive transfusion	Platelet count increase of ~30-60,000	ABO/Rh compatible if possible. HLA matched if patient refractory
Single Donor Apheresis Plasma (AP)	~500 mls	Replace coagulation factors, liver disease, Factor IX deficiency, Plasma Exchange, for HUS, TTP, Massive Blood Loss, DIC		ABO Compatible
Fresh Frozen Plasma (FFP)	~200 mls	Replace coagulation factors, liver disease, Factor IX deficiency, Plasma Exchange, for HUS, TTP, Massive Blood Loss, DIC		ABO Compatible
Cryoprecipi-tated Antihemo-philic Factor (CRYO)	Factor VIII: C (80 units)	Correction of Factor VIII deficiency (von Willebrand's Disease) Factor XIII deficiency Fibrinogen deficiency	Plasma Volume X % factor level needed = #units needed/80 = #cryo bags	ABO Compatible
Factor VIII Concentrate (Various Products Available)	Varies	Treatment of Factor VIII Deficiencies (Hemophilia A)	1 U Factor VIII/kg body wt should raise levels by 2%	Consult hematologist
Factor IX Concentrate	Varies	Treatment of Factor IX Deficiency	1 U Factor 1X/kg body wt should raise Factor XI Level by 1.5%	Consult hematologist

Table 1. Blood Components Most Commonly Required for Transfusion

TRANSFUSION COMPONENTS: (Available from Blood Bank unless otherwise stated.)
(*applies to allogenic blood – may not apply to autologous blood)

Component	Major Indications	Action	Not Indicated For*	Special Precautions*	Hazards*	Rate of Infusion
Whole Blood	Symptomatic anemia with large volume deficit	Restoration of oxygen-carrying capacity, restoration of blood volume	Conditions responsive to specific component	Must be ABO-identical; labile coagulation factors deteriorate within 24 hours after collection	Infectious diseases; septic/toxic, allergic, febrile reactions; circulatory overload	For massive loss, as fast as patient can tolerate
Red Blood Cells	Symptomatic anemia	Restoration of oxygen-carrying capacity	Pharmacologically treatable anemia; coagulation deficiency	Must be ABO compatible	Infectious disease; septic/toxic, allergic, febrile reactions	Generally 2 hours, as tolerated by the patient; no more than 4 hours
Red Blood Cells, Leukocytes Removed	Symptomatic anemia; febrile reactions from leukocyte antibodies	Restoration of oxygen-carrying capacity	Pharmacologically treatable anemia; coagulation deficiency	Must be ABO compatible	Infectious disease; septic/toxic, allergic reaction (unless plasma is also removed, e.g., by washing)	Generally 2 hours, as tolerated by the patient; no more than 4 hours
Red Blood Cells, Adenine-Saline Added	Symptomatic anemia with volume deficit	Restoration of oxygen-carrying capacity	Pharmacologically treatable anemia; coagulation deficiency	Must be ABO compatible	Infectious disease; septic/toxic, allergic, febrile reactions; circulatory overload	Generally 2 hours, as tolerated by the patient; no more than 4 hours
Fresh Frozen Plasma	Deficit of labile and stable plasma coagulation factors and TTP	Source of labile and nonlabile plasma factors	Conditions responsive to volume replacement	Should be ABO compatible	Infectious disease; allergic reactions; circulatory overload	Generally 2 hours (no more than 4 hours)
Cryoprecipitated AHF	Hemophilia A; von Willebrand's disease; hypo-fibrinogenemia; factor XIII deficiency	Provides factor VIII; fibrinogen; von Willebrand factor; factor XIII	Conditions not deficient in contained factors	Frequent repeat doses may be necessary	Infectious disease; allergic reactions	Generally 2 hours (no m ore than 4 hours)
Platelets, Platelets by Pheresis	Bleeding from thrombocytopenia or platelet function abnormality	Improves hemostasis	Plasma coagulation deficits and some conditions with rapid platelet destruction (e.g., ITP)	Should not use some microaggregate filters (check manufacturer's instructions)	Infectious disease; septic/toxic, allergic febrile reactions	Generally 2 hours (no more than 4 hours) (Set of platelet concentrates or one pheresis unit)
Irradiated Blood Products	Patient groups at risk for graft-vs.-host disease (GVHD)	Eliminates T lymphocytes (cause of GVHD)	Patient groups not at GVHD risk or conditions listed above	Same as non-irradiated products	Same as non-irradiated products and possible elevation of potassium level	Same as non-irradiated products
Washed Components	IgA deficiency or paroxysmal nocturnal hemoglobinuria in response to plasma components	Same as original component	Same as original component	Same as original component	Same as original component except febrile and allergic reactions will happen less frequently and there is an increased potential for microbial contamination	Same as original component

INSPECTION AND ISSUANCE OF BLOOD/BLOOD COMPONENTS

Inspection of blood and blood components is a critical element for ensuring safe transfusions to patients. Examination of components occurs several times by different professionals at:

- The Transfusion Service at different intervals and at the time of issuance.
- The bedside by a registered nurse or a doctor prior to administration.
- ***Inspection Criteria***

√ The inspection should include examination of the following for each component:

1. **Labeling** – Verify presence of:
   ◊ Expiration date
   ◊ ABO/Rh label
   ◊ Unit Number
   ◊ Component Label
   ◊ Special processes label, such as irradiated.

2. **Integrity of Unit**: Inspect for leaks, especially in port areas, by inverting and applying light pressure to the unit. Observe for missing port covers. Red Blood Cells should have at least one firmly attached segment.
3. **Appearance** – Observe for clots and color abnormalities. The color of an RBC bag should not be significantly darker than the segments. Plasma in the RBC unit should not be murky, purple, brown or red. Platelets will be clear to yellow/straw to light strawberry color. Platelets should not contain grossly visible aggregates. Thawed FFP will be clear with the color varying from yellow-straw to light green to orange. Cryoprecipitate will usually be cloudy.

   *If any abnormalities are noted, the component should **NOT** be transfused. It should be returned to the Transfusion Service.*

- ***Identification at Time of Release from the Transfusion Service***

  √ Only authorized laboratory personnel may issue blood components for the patient. A **VOLUNTEER** is NOT authorized to sign out blood from the Blood Bank.

  NOTE: No more than one unit of blood will be issued for a specific patient at any one time, unless rapid transfusions are being given. More than one unit of blood may be issued to the O.R., where it is stored in transport boxes with ice, after temperature indicating devices have been attached to each unit.

  √ The authorized person taking the unit of blood from Blood Bank must present a Blood Verification Checklist and a physician's order. This form will be completed and signed by Nursing and Laboratory staff throughout the transfusion process (Attachment 4A).

  √ Transfusion Service personnel, and qualified Nursing personnel, must verify that the following information on the BTRF, Blood Verification Checklist, and caution tag is correct: name and SSN of intended patient, ABO and Rh type of patient, blood product unit number; ABO and Rh type of unit number and, if performed, the interpretation of compatibility tests. At the time of release, the BTRF and Blood Verification Checklist must be signed by the technologist and the transproter and

documented in VBECS. Nursing will sign the Blood Verification Checklist under the area "Nursing/Lab."

- ***Transportation of Blood Products***

  √ When blood products are to be transported from the Blood Bank or from any temporary storage refrigerator to another location, the full name and full SSN of the patient who will receive the transfusion must be written or printed on a caution tag or label that is physically attached to the blood product. The BTRF, the caution tag attached to the blood product and the document identifying the patient must all be checked and the information correlated to ensure the product is the correct one for the specific patient.

  NOTE: It is imperative that blood be adequately stored (1-6ºC) at all times except during infusion. Blood should not be stored in refrigerators that are not adequately monitored by the Medical Center's Blood Bank.

BLOOD VERIFICATION CHECKLIST

This form is a vital step in preventing transfusion error and staff must be vigilant in careful checking of the details outlined below. ***If any discrepancies are found, do not release unit for transfusion or return to Blood Bank immediately.***

Patient: _____ SSN: _____

Blood Product: _____ Unit ID: _____

NURSING

Verify the following prior to collection of blood for pre-transfusion testing:

_____ Physician order for blood/blood component.
_____ Physician order for transfusion
_____ Positive patient identification by asking patient to state his/her full name and full SSN or DOB. Check this information against patient's identification wristband.

Verified by: _____

NURSING/LAB

Verify the following when picking up blood/blood component from Blood Bank:

_____ Patient's full name and SSN are identical on: this checklist, BTRF, caution tag in VistA, and on the physician's order.
_____ The component unit number and ABO/Rh is identical on: BTRF, caution tag, unit bag and in VBECS.
_____ The blood product type is written on the physician order.
_____ The expiration date and/or time has not passed.

Verified by: _____
Nursing Laboratory

Date/Time: _____ _____

NURSING

Verify the following prior to administration of blood/blood components:

_____ Signed informed consent on patient's chart.
_____ Patient identification details (full name and full SSN or DOB) must be checked and verified by two (2) nurses and found to be identical to patient's wristband, BTRF, caution tag and this checklist.
_____ The component unit number and ABO/Rh are identical to those on the BTRF, caution tag and this checklist.
_____ The unit of blood must be checked for compliance with any special requirements as indicated on the BTRF or in the provider's orders, e.g., leuko-reduced, CMV negative, irradiated or washed cells.
_____ The BTRF form must be signed by qualified persons responsible for the bedside identity check.
_____ Verify physician order and correct blood component.

Verified by: _____ 1st verifier

_____ 2nd verifier

Complete and return this form with the empty blood bag and a copy of completed BTRF to *Blood Bank*.

EMERGENCY BLOOD RELEASE

√ All requests indicating an emergency cross-match (STAT) will be given priority over the routine cross-match. The STAT crossmatch usually is completed in less than one (1) hour.

√ In rare life-threatening situations in which delay in transfusion may jeopardize the patient, blood may be issued prior to crossmatch completion. The ordering physician has the full responsibility for accepting the consequences of deviation from the routing testing procedure.

√ The requesting physician must sign an Emergency Blood Release Form and complete and sign the BTRF with statement of reason for deviation from usual practice.

√ The use of **"Group O" packed cells** is universally accepted. Even in these circumstances, the Blood Bank personnel will make an effort to perform ABO-Rh typing (which takes about 10 minutes) so that ABO type specific blood is issued. When the patient's Rh type is negative or unknown, Rh-negative blood will be issued.

√ In an emergency, a patient may deplete the supply of type specific blood. The Community Blood Bank will be notified and an emergency delivery of the product needed will be ordered by the Blood Bank. The following chart will be followed for substitution of blood when type specific blood is not available.

PACKED RED BLOOD CELLS	
Patient Type	***Substitute (in order of priority)***
O pos	O neg
O neg	O pos*
A pos	A neg, O pos, O neg
A neg	O neg, A pos*
B pos	B neg, O pos, O neg
B neg	O neg, B pos*
AB pos	A pos, B pos, O pos, A neg, B neg, O neg
AB neg	A neg, B neg, O neg, AB pos*, A pos*, B pos*

*Rh-negative RBCs should be used for females of childbearing potential because of the concern for immunizing such individuals and possibly causing a case of hemolytic disease of the newborn. In the rare instances this would occur at this facility, obtain the Medical Director's approval under this circumstance. But, for women beyond their childbearing years or men, only the current presence of anti-D is a concern, and because this antibody is no more common than certain other blood group alloantibodies, Rh-positive RBCs can be used with similar safety.

NOTE: The patient will be switched back to the type specific blood as soon as available.

√ Antibody screening on the patient's blood specimen and cross-matches will be performed immediately after the blood has been released for emergency blood transfusion from the Blood Bank, and if any incompatibility appears, the patient's physician and the Medical Director or designee of Blood Bank will be notified immediately.

√ When a situation occurs that requires the administration of blood components before all routine pre-transfusion testing can be completed, the requesting physician must sign an Emergency Blood Release Form (see Attachment 5A) and complete and sign BTRF with statement of reason for deviation from usual practice.

VETERANS AFFAIRS MEDICAL CENTER
ERIE, PA
TRANSFUSION MEDICINE

REQUEST FOR EMERGENCY BLOOD RELEASE

I REQUEST TRANSFUSION SERVICES TO RELEASE BLOOD FOR MY PATIENT FOR THE MEDICAL EMERGENCY AS DESIGNATED BELOW:

NAME OF PATIENT _____SOCIAL SECURITY # _____

I REQUEST _____ UNIT(S) OF UNCROSSMATCHED BLOOD. UNIT(S) WILL BE **ABO/Rh SPECIFIC** (TYPE DERIVED FROM CURRENT SAMPLE), **O-NEG** OR **O-POS** (IF MALE OR NON-CHILD BEARING FEMALE).

Provide a brief description of the reason for the transfusion:

_____
_____
_____

I ASSUME COMPLETE RESPONSIBILITY FOR ANY AND ALL COMPLICATIONS RESULTING FROM THE ADMINISTRATION OF THESE UNITS OF BLOOD WHICH ARE BEING RELEASED BEFORE THE COMPLETION OF ONE OR ALL OF THE TESTS INCLUDED IN THE STANDARD CROSSMATCH PROCEDURE.

_____M.D./D.O. Date: _____
(Signature of Physician)

BELOW IS FOR BLOOD BANK USE ONLY

UNIT NUMBER(S): _____ _____

ISSUED BY: _____ DATE: _____ TIME: _____

RECEIVED BY: _____

_____ notified of test results on _____ /_____ By: _____
Physician Name Date Time Tech

_____ Date: _____
Transfusion Services Medical Director

TRANSFUSION ADMINISTRATION

A. **PRE-TRANSFUSION PROCEDURE**: This is the most important part of the blood transfusion process. It is the final step to check if the blood to be given to the patient is truly intended for him/her.

RN's Role: It is essential that qualified persons authorized by Nursing Service administer the blood.

A. Before transfusing blood:

1. Verify need for transfusion
2. Verify patient informed consent
3. Verify physician order and other special instructions.
4. Verify patient ready for transfusion – Educate patient to the signs and symptoms of a transfusion reaction.
5. Verify patient utilizing two hospital-approved patient identifiers

B. Assemble equipment

1. thermometer
2. IV pump
3. 250cc IV .9NS
4. BP cuff
5. Blood transfusion tubing
6. IV site (18-20 gauge) needle

C. Visual inspection of component

D. Identification at Bedside (See Table 2. Blood Verification Checklist)

1. Before any blood component is transfused, two (2) qualified individuals must perform a bedside check of component and patient identification. The individuals qualified to make this verification are physicians and/or RNs. Other nursing personnel may be trained, qualified and competencied for this task provided one of the verifying persons is a physician or RN.

2. The following should be verified:
   - The patient identifiers on patient wristband (Ident-A-Band) are identical to the unique identifiers on the BTRF that accompanies the blood products.
   - **The unique identity of the blood components on unit bag and ABO/Rh type agree with that on the BTRF, caution tag and in VistA.**
   - Once this active identification is performed, the staff member who has performed the identification must stay with the patient until blood administration begins.
   - Both identifying personnel will sign the Blood Verification Checklist and BTRF to ensure that the information has been checked and found to be correct. The caution tag attached to the blood product must remain attached until the transfusion has been terminated.
   - Verify physician order – Is blood product correct and is it what physician ordered?

E. Bar Code Scanning of Blood and Blood Products in Operating Rooms

The two-person verification occurs in the Operating Room after the bar code scanning of the blood product. ***NOTE:*** *Bar code scanning of the blood product, when done, is never a substitute for the manual two-person verification.*

When using bar coding as a component part of blood transfusion administration in the Operating Room, the following steps must be followed to ensure accurate and complete identification of patients:

1. When the patient arrives at the Operating Room for a procedure, the patient needs to be accessed into the Surgery Package in VistA.
2. Enter into the Surgery Package "Operations" menu and go to the "Select Patient" prompt.
3. Visually check the identification wristband of the patient to ensure that the patient is scheduled for the room and the procedure. Then scan the SSN bar code on the patient's wristband. This brings up a list of procedure(s) for which the patient is scheduled.
4. Verify that the correct patient has been accessed to the Surgery Package.
5. Select the correct procedure.
6. Bring the blood product to the scanner and open the "Blood Product Identification" menu on VistA.
7. Scan the ABO blood type bar code. Ensure that what is displayed on the screen is the same ABO blood type as the label on the blood product.
8. Scan the blood product identification number.
9. Verify that the VistA message says, "No discrepancies found." If a "No discrepancies found" message is not obtained, the blood product cannot be transfused until two qualified individuals confirm that they have correctly identified the patient and the blood product.
10. Perform the two-person verification of matched blood product to patient identification. This process matches the BTRF form to the unique identifiers of the patient and blood product. The BTRF form must be completed and signed at the time of the transfusion.
11. Initiate the transfusion after the preceding steps have been completed.
12. If the blood product is found not to be the correct product for the patient, it must be returned to the Blood Bank. If new blood products are subsequently issued for the patient, the entire process is repeated for the new products.

NOTE: If the bar code scanner malfunctions and the patient immediately needs transfusion, follow the manual verification process to assure patient safety.

NOTE: If there is any question regarding the patient's identify or compatibility, **DO NOT TRANSFUSE until the patient identity question is resolved. Inform the Blood Bank immediately if any discrepancies in identification exist.**

B. TRANSFUSION ADMINISTRATION PROCEDURE: Blood will be transfused one unit at a time unless indicated otherwise during an emergency.

NOTE: Multiple units of blood products issued to the Operating Room will be transported by the Blood Bank in a cooler.

A. ***Starting the Transfusion***

1. Record date and time of beginning blood transfusion.
2. Patient's record should be checked once again to verify correct identification.
3. Record patient's vital parameters prior to initiation of blood and then every 15 minutes, as changes in vital parameters are the first change to occur in case of a transfusion reaction.
4. Consider time constraints: To minimize the likelihood of bacterial growth at room temperature, refrigerated components such as red cells should be transfused as soon as possible after being issued. Specifically, the time that blood is removed from the refrigerator to the time that the transfusion is started should be no longer then **30 minutes**. Once a red cell transfusion has begun, it must be completed with **4 hours**, preferably sooner.

B. ***Care During the Transfusion***-The first ½ hour is crucial. The risk of a catastrophic event like an ABO hemolytic and/or anaphylactic reaction is greatest during this ½ hour time interval. The risk declines sharply thereafter.

- Record vital signs every 15 minutes.
- Increase rate of infusion to required rate.
- Observe patient throughout transfusion.

Drugs, medications and IV solutions must not be added to blood/tubing except for 0.9% sodium chloride utilized for administration.

C. ***Infusion Procedures/Considerations***

1. Blood components must not be allowed to stand longer than 30 minutes at room temperature before the infusion. If blood transfusion cannot be started within 30 minutes from release from Blood Bank, return the unit to blood Bank for proper storage.
2. Drugs, medications and IV solutions must not be added to blood except for 0.9% sodium chloride injection, USP that may be added to facilitate administration.
3. Blood and Blood Components (whole blood, packed red blood cells, fresh frozen plasma, platelets and cryoprecipitate) must be administered through a straight type blood recipient set with a large capacity filter. An administration set with a filter must be used for every transfusion. Drip chamber of the administration set should be squeezed gently to avoid formation of air bubbles in the chamber. All air must be expelled from the tubing and attached needle before performing venipuncture.
4. The date and time the infusion is started must be recorded on the BTRF. **At all times, the transfusion record (compatibility label/transfusion tag) must remain attached to each unit of blood until completion of transfusion.**
5. After the infusion is started, the RN will closely observe the patient until the transfusion is completed. Bedside observation, recording and documenting of vital signs is required after the first 15 minutes of transfusion. If the patient is stable, vital signs are then taken and recorded every 30 minutes thereafter until infusion is completed. Documentation of vital signs will be completed on the Blood/Blood Products progress note (Attachment 6A).
6. Micro aggregate (pall) filters may, if indicated, be connected to regular IV tubing for administration of blood. Well-accepted indication for use of this filter is the production of leukocyte-poor red blood cells in order to prevent febrile non-hemolytic transfusion reactions.

7. Rate of Infusion:
    - Whole blood/packed cells may be infused rapidly to a patient who is in hypovolemic shock/emergency situation.
    - For non-emergency transfusion(s), Leukopoor red cells may be infused within two (2) hours with a maximum infusion time of four (4) hours. Blood should be administered at a rate of approximately 10-24 drops/minutes for the first 15 minutes. Flow rate may be increased to approximately 60 drops/minute after 15 minutes unless the physician indicates another rate. This technique will assist in detection of any transfusion reaction before a significant amount of blood is given.
    - When rapid infusion (multiple units given back-to-back in a short time period) is needed, each unit can be infused within 30 minutes. Under these circumstances, no more than two units will be given simultaneously.

Washed Red Blood Cells	These vary in volume and are marked on the unit. Infuse over 2-4 hours. Requires at least three hours to prepare and must be used within 24 hours after preparation.
Fresh frozen plasma (FFP)	One (1) unit bag of FFP contains approximately 230cc of anticoagulated plasma. Thawed FFP must be infused immediately. The unit is given over 1-2 hours unless otherwise specified by the provider. NOTE: Thawing requires 30 minutes after order is received by Blood Bank.
Platelets	A unit of platelets is a concentrate of platelets suspended in 40-70 ml of plasma. One (1) platelet dose is equal to 6-8 units. The platelets are routinely transfused over 10-30 minutes.
Cryoprecipitates	This is routinely transfused over 10-30 minutes. NOTE: Thawing requires 30 minutes after order is received by Blood Bank.
Irradiated Blood Products	These are indicated in post-transfusion graft vs. host disease (GVHD), which is a serious risk for some severely immuno-compromised or immuno-deficient patients. NOTE: This product requires advance notice to Blood Bank for availability. Irradiated units are not radioactive and require no special handling.

8. During the transfusion **if adverse reaction occurs**:
    - Stop the flow of blood by clamping the tubing below the blood unit. (Do not remove needle from vein and keep NSS I.V. running).
    - Notify the physician and Blood Bank immediately.
    - Follow the procedure on adverse reactions (Section 7)
9. Blood Warmers: When blood warmers are indicated, it should be used as specified in MCM 115-07 "Blood Warmers."

D. *Discontinuing the Blood Transfusion*

a. Record time, volume and type of component given.
b. Check patient's condition and vital signs (temperature, BP and pulse) and document in the Blood/Blood Products progress note.
c. Return transfusion form to transfusion service, i.e., Blood Bank.
d. Observe patient for one hour.

C. POST-TRANSFUSION PROCEDURE

1. Following the transfusion, the time completed, the temperature, blood pressure and pulse must be taken and recorded in the "Post-Transfusion Data" section of the BTRF. The amount of blood component transfused must also be documented on the BTRF. The "Post-Transfusion Data" section, after completion, must be signed by the qualified personnel (RN or physician).

2. A post-transfusion sample, **where appropriate**, should be collected within 24 hours as follows:
    1. Post packed cells transfused; check hemoglobin and hematocrit.
    2. Post platelet transfusion; check platelet count.
    3. Post FFP transfusion; check PT/PTT.
    4. Post FFP and/or cryoprecipitate; check fibrinogen.

3. The original copy of completed BTRF is placed in the patient's chart and a Xerox copy is returned to the Blood Bank with the empty or partially empty blood bag and completed Blood Verification Checklist. The blood bag must be placed in a secondary biohazard bag before returning to the Blood Bank. The Transfusion Record Form must be attached to the outside of the secondary bag. The Transfusion Record form being returned from the floor will remain in Blood Bank as the permanent record of the transfusion. The empty blood component bag is discarded in accordance with the standard institutional protocol for infectious waste disposal.

4. When the infusion is stopped because a transfusion reaction is suspected, a physician must complete the "Transfusion Reaction Data" part of the BTRF.

5. When the infusion is stopped because of complications or reasons other than a transfusion reaction, the person discontinuing the infusion (either RN or physician) is required to indicate the "reason" and sign the BTRF .

BLOOD/BLOOD PRODUCTS PROGRESS NOTE

_____
Date/Time

The patient was instructed that vital signs will be taken in 15 minutes, then 30 minutes thereafter, while blood is running and at completion of transfusion. Also instructed in signs and symptoms of transfusion reaction and to report if they occur (Urticaria, Chill, Fever, Pain).
Yes ☐ No ☐ _____

Blood Warmer Utilized Yes ☐ No ☐ _____

Patient Identifiers used: ☐ Full Name Stated ☐ Full Social Security Number Stated ☐ Full Birth Date Stated
☐ Patient ID Card/Driver's License ☐ Patient's Wrist Band

Patient indicated understanding of instructions. Yes ☐ No ☐ _____
Consent Signed: Yes ☐ No ☐ _____
Special Premedication: Yes ☐ No ☐ _____

RN Signature _____

TIME:												
BLOOD PRESSURE												
PULSE												
RESPIRATION												
TEMPERATURE												
URTICARIA												
INITIALS:												

IV FLUID	TIME STARTED	TIME AND AMOUNT OF INFUSION	IV SITE CARE*	SITE AND TYPE OF VENIPUNCTURE	IV HUNG BY	COMPLETED INTERUPTED	UNIT

DOCUMENTATION CODE – IV Site Care*: A = Absence of symptoms P = Pain S = Swelling R = Redness

POST TRANSFUSION NOTE BY RN

INITIALS	SIGNATURE	INITIALS	SIGNATURE
ADDRESSOGRAPH		BLOOD/BLOOD PRODUCTS PROGRESS NOTE 10-11 (562) TO BE USED IN LIEU OF VAF 10-0096	

ADVERSE REACTIONS

The transfusion reactions are a diverse group of adverse symptoms or physical signs that occur during or shortly after transfusion. PROMPT CLINICAL EVALUATION of the patient is the most important aspect in the management of these reactions.

NOTE: The Seriousness of Clinical Transfusion Reactions May Vary Greatly Within A Given Type As Classified Below. Severity And Appropriate Action Should Be Assessed By Responsible Medical Personnel.

URTICARIA (ALLERGIC) ONLY	**FEBRILE NON-HEMOLYTIC**	**HEMOLYTIC**
Symptoms Pruritis, urticaria, erythema and cutaneous flushing or rash.	***Symptoms*** Usually occurs during transfusion or may be delayed up to one hour after procedure. • Fever >1.8ºF (1ºC) with or without chills and rigors. • Secondary symptoms include headache, nausea, vomiting. NOTE: These alone do not constitute a febrile reaction without temperature rise.	***Symptoms*** Present within 24 hours of transfusion: • Chills/Fever >1.8ºF (1ºC) • Chest pain • Severe lower back pain • Hypotension (20% drop in BP) • Nausea, vomiting • Headache • Hematuria • Cyanosis • Dyspnea, tachycardia • Urticaria • Hypertension (20% increase) • Arrhythmia
Nursing Instructions: 1. Discontinue transfusion; keep IV open with normal saline. 2. Notify attending physician and give IM or IV antihistamines as ordered. 3. Wait 15 minutes; if therapy effective, resume transfusion at normal rate. 4. Notify Blood Bank. Complete and send the Transfusion Reaction form to Blood Bank. NOTE: For minor allergic reactions, blood specimens do <u>NOT</u> need to be collected.	***Nursing Instructions:*** 1. Discontinue transfusion; keep IV open with normal saline. 2. Notify attending physician Antipyretics and sedatives may be given when ordered by physician. 3. Notify Laboratory Blood Bank; order transfusion reaction investigation including blood culture. Mark blood culture slip “Post transfusion.” 4. Send first voided or catheterized urine to Laboratory. 5. Send unit(s) & IV tubing (w/o needle) to Laboratory Blood Bank. 6. Complete Transfusion Reaction Form & send to Laboratory Blood Bank. **If laboratory reports positive tests for intravascular hemolysis or patient exhibits symptoms, treat hemolytic reaction. NOTE: • DO <u>NOT</u> RESTART the same unit if there is a febrile reaction. Use leukoreduced product if additional transfusion is needed. • Premedicate only if there is a prior febrile reaction.	***Nursing Instructions:*** 1. Discontinue transfusion & keep IV open with normal saline. 2. Maintain blood pressure with IV fluids. 3. Notify attending physician. IV diuretics, antipyretics and sedatives, etc., may be given when ordered by physician depending upon clinical condition of the patient. 4. Notify Laboratory Blood Bank IMMEDIATELY and order transfusion reaction investigation including blood culture. Mark blood culture slip “post transfusion.” 5. Send first voided or catheterized urine to Laboratory STAT. 6. Send unit(s) & IV tubing (w/o needle) to Laboratory Blood Bank STAT. 7. Complete Transfusion Reaction Form & send to Laboratory Blood Bank.

Investigation of Suspected Hemolytic or Febrile Reactions

I. *IMMEDIATE STEPS TAKEN WHEN REACTION DISCOVERED*:

A. A clerical check of all labels, forms and patient identification must be made to determine if the patient has received the correct ABO compatible blood.

B. The Blood Bank must be notified immediately so that a similar clerical check can be made at the Blood Bank.

C. Two blood samples: (a red or pink top tube and a purple top tube), drawn carefully to avoid induced hemolysis, must be sent to the Blood Bank together with the discontinued bag of blood, the administration set, a report of transfusion reaction (see Attachment 7A) and the properly completed copy of Transfusion Record. An order for A Transfusion Reaction Workup should be entered in CPRS by the physician.

D. An immediate post-transfusion urine specimen and subsequent urine samples if available, with the time/date of collection noted, must be sent to the Blood Bank, when clinically indicated.

II. *THE BLOOD BANK TECHNOLOGIST RECEIVING THE REPORT OF SUSPECTED HEMOLYTIC TRANSFUSION REACTION SHOULD TAKE THE FOLLOWING STEPS IMMEDIATELY:*

A. No further blood will be issued until work up is completed and discussed with the Medical Director of the Blood Bank.

B. Check all available donor and recipient identification data and records, especially the ABO group.

C. Centrifuge both the purple top tube and red or pink top tube blood samples and examine for visible hemolysis.

D. Perform a direct antiglobulin test on the pre- and post-transfusion blood specimens of the patient.

E. Even when the findings are negative, the Blood Bank technical personnel should report the results of the investigation to the physician or RN responsible for the patient and to the pathologist as soon as possible.

F. If any of the steps are positive, continue the following work up immediately.

1. Perform ABO on unit of blood, pre- and post-transfusion samples.

2. Repeat compatibility tests with pre-transfusion sample and also with post-transfusion sample.

3. If the post-transfusion DAT is positive (and pre-transfusion sample was negative) perform eluate and test against screening cells, A cells and B cells.

4. When bacterial contamination of the unit is suspected, blood cultures from the patient and blood cultures from the discontinued unit may be requested by the physician/pathologist.

III. *POST-REACTION WORK-UP*

A. A second blood sample collected about 5-7 hours after reaction must be sent to the laboratory for Total Bilirubin analysis.

Table 3. Transfusion Reactions at a Glance

REACTION	*Timing*	*Signs and Symptoms*	*Treatment*	*Prevention*
Acute hemolytic	Usually within the first 5-15 minutes, but can happen anytime during transfusion	Fever, chills, hypotension, dyspnea, nausea, vomiting, dark urine, DIC, pain-IV site, back, flank, chest, abdomen, head	Maintain renal output with fluid replacement and diuretics (furosemide), vasopressors (dopamine), treat for DIC as needed	Proper identification of patient/sample/ unit
Febrile nonhemolytic	During transfusion; usually toward the end of transfusion	Fever, chills	Antipyretics, Demerol for shaking chills	Leukocyte-reduced blood components
Mild allergic (urticaria)	During transfusion; up to 2-4 hours after start of the unit	Hives, itching	Antihistamines, steroids	Premedication with antihistamines. Occurrence despite antihistamines warrants washed RBCs
Bacterial contamination	Usually during transfusion; can be immediate or up to 3 hours after start of the unit; less severe reactions may manifest up to 15 days after transfusion	Severe chilling, high fever, dry flushing, nausea, vomiting, hemoglobinemia, bleeding, sudden severe hypotension	Supportive treatment, broad spectrum antibiotics	Careful inspection of the unit for abnormalities before transfusion. Proper storage and handling of unit infuse for $\leq$ 4 hours
Anaphylactic	During transfusion; within 1-45 minutes of start of the unit	Fever absent, stridor, bronchospasm, dyspnea, hypotension, abdominal cramps, flushing, hives, "lump in my throat," chest tightness	Epinephrine (0.4 ml of 1:1000 solution SQ), steroids, O2	Washed RBCs for subsequent transfusion. Medic alert bracelet.
Transfusion-related acute lung injury	Usually within 1-2 hours of transfusion; occasionally up to 6 hours after transfusion	Acute respiratory distress, dyspnea, cyanosis, hypotension, tachycardia, fever, ABG's-decreased PO2, X-ray-pulmonary infiltrates	Oxygen, intubation, mechanical ventilation if necessary, vasopressors, steroids	Prompt intervention at first sign of respiratory distress will mitigate reaction
Circulatory overload	Within several hours of transfusion	Headache, elevated blood pressure and pulse, nonproductive cough, neck vein distension, cyanosis, restlessness, dyspnea, rales	Diuretics, oxygen, morphine, therapeutic phlebotomy if severe	Lung assessment pretransfusion and during transfusion in high-risk patients. Careful assessment of flow rate 1 ml/kg/hour for at risk patients

Table 3. In: Popvsky MA, ed. Transfusion Reactions, 2nd Edition. Bethesda, MD: AABB Press, 2001.

Date

REPORT OF TRANSFUSION REACTION
VA Medical Center, Erie, PA

ATTENTION: Nursing Staff

1. Stop blood transfusion immediately, but leave needle in site with saline drip.
2. Summon an available physician immediately to attend the patient.
3. Check for agreement of all identifying names, numbers and letters on transfusion unit and patient wrist tag.
4. Obtain and properly label immediate post-transfusion clotted and anti-coagulated blood specimens (red & lavender top vacutainer tubes.
5. Obtain an immediate post-transfusion urine specimen and a second post-transfusion urine specimen 5 hours later. Properly label specimens and send to the Blood Bank marked "Transfusion Reaction".
6. Record pre- and post-transfusion information below.
7. Request the attending physician to complete the section below marked "Clinical Signs and Symptoms" with signature and date.
8. Notify the Blood Bank and send the entire blood transfusion unit, post-transfusion clotted and oxalated blood specimens and urine specimens with this completed form to the Blood Bank.

……

To be completed by **ATTENDING NURSE**:

Diagnosis: _____
Has patient received a transfusion before? _____
When? _____
History of previous transfusion reaction & type (if known): _____
_____
Patient's temperature at start of transfusion _____
At end of transfusion _____
Patient's blood pressure at start of transfusion _____
At end of transfusion _____
Patient's pulse rate at start of transfusion _____
At end of transfusion _____
Time transfusion was started? _____ Stopped? _____
Amount given _____
Was anything else given with the blood? _____
What? _____
Was the blood warmed? YES _____ NO _____
At the time of reaction, did the patient name, ID number and blood type check against information on the blood pack and request? YES _____ NO _____

SIGNATURE _____ R.N.
DATE _____ TIME _____

VA Medical Center (562) **Ward #** _____
Patient's Full Name: _____
Last 4 Numbers of SS#: _____
Date of Birth: _____

Donor Unit #: _____
Donor Unit Segment #: _____

MEDICAL RECORD	PROGRESS NOTES

Date

To be completed by **ATTENDING PHYSICIAN**:

Delayed Transfusion reactions may manifest 24 hours and up to 15 days post transfusion.

Check those experienced:

Clinical Signs and Symptoms:	
Chills/Fever >1.8°F (1°C) increase	_____
Chest pain	_____
Severe lower back pain	_____
Hypotension (20% drop in BP)	_____
Nausea, vomiting	_____
Headache	_____
Hematuria	_____
Cyanosis	_____
Dyspnea, tachycardia	_____
Urticaria	_____
Hypertension (20% increase)	_____
Arrhythmia	_____
Other _____	

ADDITIONAL INFORMATION:

_____

_____

_____

SIGNATURE:

_____

DATE: _____

Date: _____

Donor Unit Number: _____

Doctor: _____

~~~~~~

MEDICAL RECORD	PROGRESS NOTES

INVESTIGATION OF TRANSFUSION REACTION
~~~~~~

Date

VA Medical Center, Erie, PA

Pathology & Laboratory Medicine

Patient Name: _____ Unit _____
Identification Number: _____
Donor Unit #: _____
Donor U.Segmt. #: _____
Time of Notification (date & hour) _____
Date and time of post reaction specimen collection_____

IMMEDIATE Clerical Comparisons & Serological Testing:

Clerical Check: Donor blood container #s, ABO group, Rh should be compared to patient's pre-crossmatch records. These items are also compared to pertinent items on post-reaction labels.
Agree _____ Disagree _____

Comments:
_____
_____

Serological Check:

	RSLT	INTERP		RSLT	INTERP		RSLT	INTERP	
*Post – DAT			IgG			Comp			*If POS., compare to pre-reaction
Pre - DAT									

Evidence of Hemolysis? YES _____ NO _____

Urine Hemoglobin results (if sent) *Pos _____ Neg _____
*Centrifuge and re-examine Pos _____ Neg_____

Comments:
_____
_____

VA Medical Center (562) **Ward #** _____
Patient's Full Name: _____
Last 4 Numbers of SS#: _____
Date of Birth: _____

Donor Unit #: _____
Donor Unit Segment #: _____

Date

ADDITIONAL TESTS:

Blood Grouping Tests:

	KNOWN ANTISERA					KNOWN CELLS			ADDITIONAL ANTISERA						
	A	B	A,B	D	DC	A	B	INTERP							
Pre-Sample															
Post-Sample															
Donor Unit: Segmt./Bag															

Compatibility Testing:

	22˚	37˚	AHG	Interpretation
Pre-Sample/major				
Indirect Coombs				
Post-Sample/major				
Indirect Coombs				

Microbiology Report: _____
_____
_____
_____
_____

Chemistry/Coagulation Studies (if applicable)
Bilirubin (5-7 hrs post) _____
Haptoglobin _____
Urine output studies:
_____
Coagulation Findings:
_____

CONCLUSIONS: _____
_____
_____
_____

Laboratory Supervisor _____ Date _____
Medical Director _____ M.D. Date _____

Original: Patient's Chart
Copy: Blood Bank File
Copy: Chief of Staff

……
……

REPORTING OF TRANSFUSION TRANSMITTED DISEASES

The report of Transfusion Transmitted Diseases is performed as specified in the following MCM's:

- MCM 115-16 Reporting of Post-Transfusion Transmitted Diseases
- MCM 115-02 "Look Back" Program for Blood and Blood Products

RETURN OF UN-USED BLOOD TO BLOOD BANK

- It is imperative that all blood components issued (but not used) be returned to the Blood Bank, together with the corresponding Transfusion Record/Records in less than 30 minutes. The blood stored in the O.R. transport box will be returned to the Blood Bank upon completion of the surgery.

- **Blood components that have been out of the Blood Bank refrigerator longer than 30 minutes cannot be released for re-use.**

- If the unit to be transfused is rejected, it should be returned to Blood Bank and the Transfusion Record should state the written reason for rejection.

SPECIAL PROCEDURES

A. PRE-DEPOSIT AUTOLOGOUS DONATION AND TRANSFUSION (REFER TO MCM 115-11)

B. TYPE, SCREEN AND HOLD BLOOD ORDERS (REFER TO MCM 115-12)

C. THERAPEUTIC PHLEBOTOMY (REFER TO MCM 115-08)

D. BIOLOGICAL PRODUCT DEVIATIONS

MONITORING & EVALUATION

- To ensure continual process improvement, the facility's transfusion practices are monitored and evaluated as a part of Performance Improvement Plan. The assessment includes the following clinical aspects of blood transfusion processes:

  √ Blood transfusion documentation
  √ Audit of blood transfusion practices
  √ Reporting of adverse reactions

- ***Deviations*** (Refer to Table 4) Identification of deviations and associated risks related to patient identification, patient monitoring and record documentation are listed in Table 4.

REFERENCES

1. JCAHO Publication, "How to Meet the Most Frequently Cited Laboratory Standards," 2001.
2. VHA Pathology & Laboratory Medicine Service Handbook, 1106.1, June 2003, "Immunohematology, Blood Transfusions & Transfusion Medicine."
3. *American Association of Blood Banks Technical Manual*, current edition.
4. VHA Directive 2005-029, "Tranfusion and Identification Requirements for All Sites," July 1, 2005.

Table 4. **Risks Associated with Deviations of Transfusion Processes**

Process	Deviation	Outcomes*
Product Order	• Failure to order correct product type • Failure to order correct quantity of product • Failure to obtain informed consent	• Inadequate/inappropriate treatment • Delay in treatment • Serious injury to patient • Death of patient
Recipient Sample Collection	• Failure to identify the correct patient • Failure to compare patient identification to request form • Failure to collect the appropriate specimen • Failure to label the specimen correctly • Failure to transport specimen to laboratory for processing	** Based on deviation from or failure to follow established procedures, possible outcomes will be the same for each process.*
Pre-Transfusion Testing	• Failure to use the correct sample • Failure to perform required historical check(s) • Failure to select appropriate unit for patient • Failure to perform required testing, i.e., ABO, Rh, compatibility	Same as above.
Issue	• Failure to perform required visual inspection • Failure to select appropriate unit for patient • Failure to properly sign out the unit (correct unit for patient)	Same as above.
Administration of Transfusion	• Failure to perform required bedside verification procedures *(See Table 2. Bedside Verification Checklist)*. • Failure to recognize the signs and symptoms of an adverse patient reaction. *(See Table 3. Transfusion Reactions at a Glance).*	Same as above.
Monitor & Evaluate	• Failure to have a clear policy on acceptable transfusion practices • Failure to assess education program for all levels of hospital staff involved in the transfusion process. • Failure to perform audit for blood transfusion practices • Failure to monitor and evaluate deviations related to patient identification, patient monitoring and record documentation.	Same as above.

Table 4. Risks Associated with Deviations of Transfusion Procedures

GUIDELINES FOR MAXIMUM SURGICAL BLOOD ORDER SCHEDULE (MSBOS)

The Maximum Surgical Blood Order Schedule (MSBOS) has been established for effective management of blood bank inventory, means of cost containment, better blood use (CT ratios), improved availability, and thus improving patient outcomes. The criteria have been reviewed and approved by Medical Director, Surgery, with input from staff surgeons.

The units recommended for crossmatching reflects the needs of a majority of patients for that particular procedure, although the surgeon or anesthetists may individualize specific requests to accommodate special needs.

The following schedule is the guideline for recommended use at the VAMC, Erie, PA:

SURGICAL PROCEDURE	RECOMMENDED MSBOS
General Surgery	
Cholecystectomy	T & S
Gastrectomy	1 unit
Esophagogastrectomy, thoraco-abdominal approach	5 units
Vagotomy and drainage	T & S
Exploratory laparotomy	T & S
Thyroidectomy	T & S
Parathyroidectomy	T & S
Bowel Resection	
- small bowel resection	T & S
- abdomino-perineal resection	3 units
- anterior resection	2 units
- hemicolectomy	1 unit
Hiatal hernia	T & S
Thoracotomy and biopsy	T & S
Orthopedic	
Simple total hip arthroplasty	T & S/2 units (2 units autologous donation)
Complex total hip revision	T & S/2 units (2 units autologous donation)
Total knee surgery	T & S/1 unit
Hip Fracture	2 units
Urological	
Transurethral prostatectomy	T & S
Radical prostatectomy	2 units
Radical cysto-prostatectomy	2-3 units
Radical nephrectomy	2 units
Nephrolithotomy	T & S
Vascular	
Femoral popliteal bypass graft	1 units
Aorto-femoral bypass graft	4 units
Abdominal aneurysmectomy	4 units

REFERENCE: AABB Technical Manual

Approved:
Original signed 6/4/08 by
WILLIAM A. SCHUCHARDT, JR, MD, FACS
Medical Director, Surgical Care

INFORMED CONSENT FOR TRANSFUSION OF BLOOD/BLOOD PRODUCTS

C. EXPLANATION OF PROCEDURE

1. INDICATIONS: I understand that blood and blood product transfusions are given to replace parts of the blood that are missing, either because my body is not able to make enough or because I have lost those parts because of bleeding from surgery or other causes. The benefit of the transfusion is to improve my condition.

2. RISKS/COMPLICATIONS: It has been fully explained to me that blood transfusion(s) are not always successful in producing desirable results, and that there is a possibility of ill effects. I understand that just as there may be risks and hazards in continuing my present condition without transfusions, there are also risks related to the transfusion of blood and blood products.

Occasional complications are an elevation in temperature (fever), chills and allergic reactions such as itching and hives. Additional complications may include my receiving too much fluid or my developing chemical imbalances and hemolysis (destruction of transfused red blood cells). Rarely do any of these complications lead to bleeding, clotting problems, kidney failure or death. Blood transfusions can cause infections from bacteria, parasites and viruses such as those that cause hepatitis and AIDS (Acquired Immune Deficiency Syndrome). However, the risk of these infections is very small since all blood is tested for infectious disease.

NAT (Nucleic Acid Testing): The blood product you are about to receive has been obtained from an FDA (Food & Drug Administration) licensed blood bank and has passed the current standard tests, which are very effective at finding infections. However, it has been additionally tested by an experimental method called Nucleic Acid Testing (NAT), which may detect levels of infection that the current standard tests cannot detect. The blood supply is as safe as it has ever been. I understand that because the tests currently used to detect infection are so effective, the risk of receiving infected blood is very low. However, NAT is being used to see if it can be made even safer. It may not be possible to receive the results of NAT before receiving the transfusion. If NAT detects infection in this blood product, the blood supplier must immediately notify the VA. The VA will notify me and provide appropriate care. I will not be notified if the additional testing is negative.

3. ALTERNATIVES: When bleeding or severe anemia (which cannot be treated with diet or medication) becomes life threatening, there is no effective substitute for blood transfusion. I further understand that alternatives to blood or blood product transfusions, such as auto-donation (using my own previously donated blood), directed donation (blood donated by people whom I have asked to donate), may be available if my health, time and surgical procedure permit. I also understand that there are risks and consequences of refusing the blood or blood product transfusion therapy that has been recommended to me. These may include severe anemia or bleeding due to deficiency of blood components, or death due to one of these complications.

D. SIGNATURES

1. COUNSELING PHYSICIAN/DENTIST: I have counseled this patient as to the nature of the transfusion of blood and blood products, attendant risks involved, alternatives and expected results, as described above. The patient is alert, oriented and able to understand the information provided.

_____ _____

Signature of Counseling Physician/Dentist *Date & Time*

2. PATIENT: The blood transfusion procedure has been fully explained to me and I have had a chance to have all my questions answered. If I am an inpatient, I understand that whatever decision I make about receiving blood will remain valid for the length of my current hospitalization. If I am being treated as an outpatient, my decision will remain valid up to one year as long as I am being transfused to treat the same condition. However, I can change my mind about the transfusion decision at any time simply by telling my doctor.

I accept □ I do not accept □

_____ _____ _____ _____

Signature of Witness, excluding member of care team **Date & Time** **Signature of Patient** **Date & Time**

3. SPONSOR OR GUARDIAN: (When patient is unable to give consent). I, _____, sponsor/guardian of _____, understand the nature of the proposed transfusion(s), attendant risks involved and expected results, as described above, and hereby request such transfusion(s) be performed.

_____ _____ _____ _____

Signature of Witness, excluding member of care team **Date & Time** **Signature of Patient** **Date & Time**

ADDRESSOGRAPH STAMP (Patient name-last, first, middle; SSN and DOB)

VA 10-24-95

(revised November 2001)

Criteria

Appropriateness Criteria
For Blood & Blood Products

Blood Usage Review Team
Revised July 2008

VA Medical Center, Erie, Pa

VAMC, Erie, Pennsylvania

Pathology & Laboratory Medicine

BLOOD/BLOOD COMPONENTS UTILIZATION CRITERIA

- These blood utilization criteria are objective guidelines for monitoring the use and effectiveness of transfusion. They are NOT intended to serve or be interpreted as medical indications for transfusion. Rather

they list clinical circumstances in which transfusion might be considered reasonable without additional justification.

- Transfusions that fall outside of the guidelines represent situations where the effort of a review would be more likely to yield practice improvement. These transfusions may be clinically indicated but are subject to review and may require additional documentation of their necessity in patient's record.

BLOOD/BLOOD COMPONENTS UTILIZATION CRITERIA

BLOOD/BLOOD COMPONENT	TRANSFUSION CRITERIA
PACKED RED BLOOD CELLS	1. *Hypovolemia due to acute blood loss*. Acute blood loss of 15% of estimated blood volume with evidence of inadequate oxygen carrying capacity. 2. *Symptomatic Chronic Anemia* with hemoglobin <8 gms/dL or hematocrit <24%. ●Anemia with bone marrow hypoplasia chemotherapy ●Anemia with other comorbidities (e.g., AZT treatment, documented infections or CRF with chemotherapy.) ●Anemia with hypoxia or cyanosis (e.g., coronary artery disease, chronic pulmonary, cerebral ischemic disease) *FOLLOW UP CRITERIA*: Hgb/Hct within 24 hours post transfusion
PLATELETS **(1 platelet dose is equal to 6-8 units)**	1. Platelet count <5,000-10,000/uL in a non-bleeding patient with failure of platelet production. 2. Platelet count <50,000/uL in a patient with: • Impending surgery or invasive procedure • Active bleeding or sepsis. 3. Bleeding in a patient with qualitative platelet defect, regardless of platelet count. NOTE: Platelet transfusions at higher platelet counts may be required for patients with: ●Sepsis ●Platelet dysfunction related to medication or disease ●Platelets should not be given to patients with ITP even if platelet count is <10,000 unless actively bleeding *FOLLOW UP CRITERIA*: Platelet counts before, within one hour and 24 hours post transfusion.

****FRESH FROZEN PLASMA****	1. PT or PTT >1.5 times the mean of reference range in a non-bleeding patient scheduled for or undergoing surgery or an invasive procedure. 2. Coagulopathy (acquired or congenital). Documented mujltiple coagulation factor deficiency/liver disease with PT/PTT >1.5 x normal <u>OR</u> coagulation factor assay of <25% activity. 3. Emergency reversal of Coumadion anticoagulation with PT > 1.5 normal in patients actively bleeding or requiring emergency surgery/invasive procedure within 12 hours. 4. Massive Transfusion with documented coagulopathy. 5. Correction of known coagulation factor deficiencies for which specific concentrates are unavailable. 6. Antithrombin III deficiency (when a concentrate is not available). **DOSE**: FFP should be given in doses calculated to achieve a maximum of 30% of plasma factor concentration, usually achieved with administration of **10-15 ml/kg of FFP** for an adult. ***<u>EXCEPT</u>*** for urgent reversal of Warfarin anticoagulation for which **5-8 ml/kg of FFP** usually is sufficient. NOTE: One (1) unit (bag) of FFP contains approximately 230 ml. **Follow-Up Criteria:** PT/PTT prior to and within 4 hours after FFP transfusion.

****ALBUMIN****	1. Shock/hypotension/burns 2. Postoperative retroperitoneal surgery 3. Pancreatitis/Hemodialysis 4. Post paracentesis 5. Treatment of refractory edema 6. Not responding to other treatment
****CRYOPRECIPITATE**** (Usual dose 1 concentrate per 7-10kg/ body weight)	1. Hypofibrinogemia with fibrinogen level <100 mg/dL. 2. Diffuse microvascular bleeding and fibrinogen level <100 mg/dL. 3. Von Willebrand's disease or hemophilia (documented deficiency of Factor VIII). 4. Uremic bleeding. 5. Factor XIII deficiency.
****SPECIAL COMPONENTS – LEUKOCYTE REDUCED RED CELLS****	1. Hematology and oncology patients requiring long term transfusion support 2. Patients who have documented recurrent febrile non-hemolytic transfusion reactions. 3. Prevention of HLA alloantibody formation in select patients. 4. Prevention of CMV transmission in select patients. 5. Outpatient transfusions.
****SPECIAL COMPONENTS – CMV NEGATIVE BLOOD PRODUCTS**	1. CMV-seronegative recipient of solid organ transplant from seronegative donor. 2. CMV-seronegative recipients of peripheral stem cell transplants. 3. CMV-seronegative patients undergoing chemotherapy that results in severe neutropenia.
****SPECIAL COMPONENTS – IRRIDATED BLOOD PRODUCTS****	1. Patient groups who are at risk for graft-vs-host disease (GVHD) 2. Patients with congenital immunodeficiency syndromes 3. Bone marrow transplant patients 4. Patients supported with HLA-matched cellular components. 5. Patients receiving directed donations from all blood relatives.
****SPECIAL COMPONENTS – WASHED BLOOD COMPONENTS**	1. Rare recipients experiencing anaphylactoid reaction to blood components. 2. IgA deficiency with documented IgA antibodies.

REFERENCES:

1. Guidelines for Blood Utilization Review, American Association of Blood Banks, current edition.
2. Transfusion Alert, National Institute of Health, 1993.
3. Transfusion Therapy, Clinical Principles and Practice, Paul D. Mintz, American Association of Blood Banks, 1998.

The Maximum Surgical Blood Order Schedule (MSBOS) has been established for effective management of blood bank inventory, means of cost containment, better blood use (CT ratios), improved availability, and thus improving patient outcomes. The criteria have been reviewed and approved by Medical Director, Surgery, with input from staff surgeons.

The units recommended for crossmatching reflects the needs of a majority of patients for that particular procedure, although the surgeon or anesthetists may individualize specific requests to accommodate special needs.

The following schedule is the guideline for recommended use at the VAMC, Erie, PA:

SURGICAL PROCEDURE	RECOMMENDED MSBOS
General Surgery	
Cholecystectomy	T & S
Gastrectomy	1 unit
Esophagogastrectomy, thoraco-abdominal approach	5 units
Vagotomy and drainage	T & S
Exploratory laparotomy	T & S
Thyroidectomy	T & S
Parathyroidectomy	T & S
Bowel Resection	
- small bowel resection	T & S
- abdomino-perineal resection	3 units
- anterior resection	2 units
- hemicolectomy	1 unit
Hiatal hernia	T & S
Thoracotomy and biopsy	T & S
Orthopedic	
Simple total hip arthroplasty	T & S/2 units (2 units autologous donation)
Complex total hip revision	T & S/2 units (2 units autologous donation)
Total knee surgery	T & S/1 unit
Hip Fracture	2 units
Urological	
Transurethral prostatectomy	T & S
Radical prostatectomy	2 units
Radical cysto-prostatectomy	2-3 units
Radical nephrectomy	2 units
Nephrolithotomy	T & S
Vascular	
Femoral popliteal bypass graft	1 units
Aorto-femoral bypass graft	4 units
Abdominal aneurysmectomy	4 units

REFERENCE: AABB Technical Manual

Approved:

Original signed 6-4-08 by

WILLIAM A. SCHUCHARDT, JR., MD, FACS

Medical Director, Surgical Care

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K. ANCILLARY TESTING (POINT OF CARE TESTING – WAIVED TESTING)

ANCILLARY TESTING

(POINT OF CARE TESTING – WAIVED TESTING)

1. GENERAL INFORMATION

- The Ancillary Testing (Point of Care Testing, Waived Testing) refers to laboratory testing or services provided within the medical center or its outreach functions (clinics, etc.) but outside the physical facilities of the main clinical laboratory.

- The important criteria for Ancillary Testing is that no permanent space is dedicated to the tests performed. The kits and instruments used are hand-carried or transported to the site of testing.

2. APPROVED ANCILLARY TESTS

All Ancillary Testing will be performed in compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards and Department of Veterans Affairs guidelines. Pathology & Laboratory Medicine (P&LM) has the overall responsibility and oversight of the program.

The following tests are being performed at VAMC Erie as Ancillary Testing:

ANCILLARY TESTS/SITES/INSTRUMENT USED
REFERENCE RANGES/CRITICAL VALUES

Ancillary Test	Classifi-cation	Extent of Use	Testing Sites	Instrument Used	Reference Ranges	Critical Values
Definitive Tests						
Bedside Capillary Blood Glucose Testing	Waived	Diagnostic	*GP-ICU *Unit 6 *Unit 5 *Unit 4 *Amb.Surg *ER *Outpatient Clinic-Erie	(Roche) Accu-Chek Inform Meter	70-100 mg/dl non-diabetic adults	Low <50 mg/dl High >400 mg/dl
Helicobacter Pylori Testing	Waived	Diagnostic	Operating Room	Pyloritek Test Kit	Positive/ Negative	

NOTE: For diagnostic tests, the results could be used for patient treatment at the discretion of the provider. The provider may order laboratory testing to confirm the ancillary test results.

Ancillary Test	Classifi-cation	Extent of Use	Testing Sites	Instrument Used	Reference Ranges	Critical Values
Screening Tests						
Fecal Occult Blood Testing	Waived Testing	Screening	*VAMC	Occult Blood Slides	Positive/ Negative	

3. HOME TESTING

The blood glucose meters are issued to diabetic patients for home testing through the VA Medical Center when prescribed by the health care provider.

4. PATIENT SELF TESTING:

When patients are VA inpatients or are in the ambulatory care setting, they may **not** perform self testing for diagnostic purposes. The self-testing may be performed during patient education training or accuracy check of glucometers for home testing.

_____ _____

Cynthia Spaniol, MT (ASCP) DATE
Ancillary Testing Coordinator

Bernadette Hall, MT (ASCP) DATE
Acting Supervisor, Path. & Lab Medicine

_____

Ritu Khera, MD DATE
Medical Director, Path & Lab Medicine

ANCILLARY TESTING (POINT OF CARE TESTING – WAIVED TESTING) POLICIES (MCM's)

ANCILLARY TESTING MCM'S

1. MCM 115-10 Ancillary Blood Glucose Bedside Testing

2. MCM 115-03 Fecal Occult Blood Testing

IV. TESTS AND REFERENCE RANGES

TESTS AND REFERENCE RANGES

- ***In House Testing:*** The attached list of Laboratory tests and reference ranges will be updated as necessary throughout the year.

- ***Reference Testing:*** The reference ranges for Laboratory tests sent to the Reference Laboratory will be provided with each test.

REFERENCE RANGES
October 2005

CHEMISTRY	
TEST	EXPECTED VALUES
Acetone	Negative
Albumin	3.5 – 4.8 g/dl
Alkaline Phosphatase	32 - 91 International Units/liter
ALT	17 – 63 International Units/liter (male) 14 – 54 International Units/liter (female)
Amylase	36 – 128 Units/liter
Anion Gap	10 – 20 mmol/liter
AST	15 - 41 International Units/liter
Carbon Dioxide (CO_2)	22 - 32 mmol/liter
Bilirubin, direct	0.1 – 0.5 mg/dl
Bilirubin, total	0.3 – 1.2 mg/dl
BUN	8 – 20 mg/dl
Calcium	8.9 - 10.3 mg/dl
Chloride	101 – 111 mmol/liter
Cholesterol	Low risk: < 200 mg/dl Borderline risk: 201 - 239 mg/dl High risk: ≥ 240 mg/dl
CPK	Male: 38 - 174 International Units/liter Female: 26 - 140 International Units/liter
Creatinine	0.7 – 1.2 mg/dl (male) 0.4 – 1.0 mg/dl (female)
gamma-GT (GGT)	7 – 50 International Units/liter
Glucose	74 - 100 mg/dl
Glucose, postprandial	ADA Guidelines for Fasting Specimen: 70 – 100 normal 101 – 125 prediabetes > 126 diagnostic for diabetes
Glucose tolerance	Fasting: 70 - 110 mg/dl 30 min: 110 - 170 mg/dl 60 min: 120 - 170 mg/dl 90 min: 100 - 140 mg/dl 120 min: 70 - 120 mg/dl
HDL cholesterol	Low cardiovascular risk ≥ 60 High cardiovascular risk < 40
Iron	Male: 45 – 182 micrograms/dl Female: 28 – 170 micrograms/dl
LDH	98 - 192 International Units/liter
LDL Cholesterol (calculated)	0 - 129 mg/dl (desirable) 130-159 mg/dl (moderate risk) ≥ 160 mg/dl (high risk)
LDL Cholesterol (direct)	Optimal: Less than 100 mg/dl Near or Above Optimal: 100 – 129 mg/dl Borderline High: 130-159 mg/dl High: 160-189 mg/dl Very High: ≥ 190 mg/dl

Lipase	22 – 51 Units/liter
CHEMISTRY (cont'd)	
Magnesium	1.8 - 2.5 mg/dl
Osmolality (calculated)	275 – 300 mOsm/kg H_2O
Phosphorus	2.4 - 4.7 mg/dl
Potassium (serum)	3.6 - 5.1 mmol/liter
Potassium (plasma0	3.4 – 4.5 mmol/liter
Sodium	136 - 144 mmol/liter
TIBC (calculated)	Male: 252 – 461 ug/dl Female: 269 – 535 ug/dl
Total protein	6.1 – 7.9 g/dl
Alcohol	Legal intoxication: 80 mg/dl or greater Flushing, slow reflexes, impaired visual activity: 50-100 mg/dl Depression of CNS: > 100 mg/dl Fatalities reported: > 400 mg/dl
Transferrin	Male: 180 – 329 mg/dl Female: 192 – 382 mg/dl
Triglycerides	Normal: < 150 mg/dl Borderline high: 150 – 199 mg/dl High: 200 – 500 mg/dl Very high: > 500 mg/dl
Uric acid	4.8 – 8.7 mg/dl (male) 2.6 – 8.0 mg/dl (female)

URINE CHEMISTRY	
TEST	EXPECTED VALUES
Amylase	1 - 17 Units/h
Calcium	100 - 300 mg/24 hrs
Chloride	110 - 250 mmol/24 hrs
Creatinine	0.6 - 1.8 g/24 hrs (female) 0.8 – 2.0 g/24 hrs (male)
Creatinine clearance	**Age (Years) Males Females** 20-30 88-146 81-134 30-40 82-140 75-128 40-50 75-133 69-122 50-60 68-126 64-116 60-70 61-120 58-110 70-80 55-113 51-105
Glucose	Random: 1 - 15 mg/dl 24 hr urine: < 0.5 g/24 hr
Microalbumin	> 1.9 mg/dl
Microalbumin/creatinine ratio	> 30 micrograms/mg creatinine
Potassium	25 - 125 mmol/24 hr
Protein (quantitative)	Random urine: < 10 mg/dl 24 hr urine: 50 - 100 mg/24 hrs
Sodium	40 - 220 mmol/24 hr

SPECIAL CHEMISTRY	
TEST	EXPECTED VALUES
B12	Normal: 180-914 pg/ml Indeterminate: 145-180 pg/ml Deficient: <145 pg/ml
CPK-MB	0.6 – 6.3 ng/ml
Ferritin	Male: 23.9-336.2 ng/ml Female: 11-306.8 ng/ml
PSA	<4.0 ng/ml
TSH	0.34-5.6 micro-International units/ml
Folate	Normal: >3.0 ng/ml Indeterminate: 2.5-3 ng/ml Deficient: <2.5 ng/ml
Free PSA	> 25%
Free T4	0.58 – 1.64 ng/ml
Troponin I	Negative: <0.03 ng/ml Myocardial Injury: 0.03-0.5 ng/ml Indicative of MI: >0.5 ng/ml
Hemoglobin A1c	4.2-5.8%

HEMATOLOGY	
TEST	EXPECTED VALUES
WBC	3.8-10.6 thou/microliters
RBC	Males: 4.4-5.9 mil/microliters Females: 3.8-5.2 mil/microliters
HGB	Males: 14-18 g/dl Females: 12-16 g/dl
HCT	Males: 40-52% Females: 35-47%
PLT	130-400 thou/microliters
MCV	Males: 80-100 fl Females: 80-100 fl
MCH	26-34 pg
MCHC	32-36 g/dl
RDW	11.5-14.5%
MPV	7.4-10.1 fl
ESR (Sedimentation Rate)	Males Under 50 years: < 15 mm/h 50-85 years: < 20 mm/h Over 85 years: < 30 mm/h Females Under 50 years: < 20 mm/h 50-85 years: < 30 mm/h Over 85 years: < 42 mm/h
Reticulocyte Count	0.76 – 2.77%
Eosinophil Count	50 – 350 mm^3

MANUAL DIFFERENTIAL	
Neutrophils	40-75%
Lymphocytes	20-44%
Monocytes	2-10%
Eosinophils	0-6%
Basophils	0-2%
Bands	2-6%
Atypical lymphocytes	0
Metamyelocytes	0
Myelocytes	0
Promyelocytes	0
Blasts	0
NRBCs/100 WBCs	0

COAGULATION	
TEST	EXPECTED VALUES
PT	12.0 – 14.5 sec
INR	0.86 – 1.15
INR – oral therapy	2-3.5
PTT	23.6 – 35.7 sec
Heparin Therapeutic Range (PTT)	67 – 107 sec

THERAPEUTIC DRUG MONITORING (TDM)			
TEST	THERAPEUTIC RANGE	TOXIC RANGE	DRAW TIME
Theophylline	8-20 micrograms/ml	> 20 micrograms/ml	½ - 1 hr before dose
Phenytoin	10-20 micrograms/ml	> 20 micrograms/ml	½ - 1 hr before dose
Phenobarbital	15-40 micrograms/ml	> 40 micrograms/ml	½ - 1 hr before dose
Vancomycin (trough)	5-15 micrograms/ml	> 15 micrograms/ml	½ - 1 hr before dose
Vancomycin (peak) (IV)	25-40 micrograms/ml	> 40 micrograms/ml	1 hr after dose infused
Gentamicin (trough)	0.5-2.0 micrograms/ml	>2.0 micrograms/ml	½ - 1 hr before dose
Gentamicin (peak) (IV)	4-10 micrograms/ml	> 10 micrograms/ml	½ hr after dose infused
Tobramycin (trough)	0.5-2.0 micrograms/ml	>2.0 micrograms/ml	½-1 hr before dose
Tobramycin (peak)	4-10 micrograms/ml	>10 micrograms/ml	½ hr after dose infused
Carbamazepine	4-12 micrograms/ml	> 15 micrograms/ml	½ - 1 hr before dose
Digoxin	0.8-1.5 ng/ml (congestive heart failure) 1.5-2.0 ng/ml (arrhythmias)	> 2.5 ng/ml	½ - 1 hr before dose
Valproic Acid	50-100 micrograms/ml	>150 micrograms/ml	

URINALYSIS	
Color	Colorless or yellow
Appearance	Clear or hazy
Sp. Gravity	1.010 - 1.025
pH	5 – 8.5
Protein	Negative - Trace
Glucose	Negative
Ketone	Negative
Bilirubin	Negative
Blood	Negative
Nitrite	Negative
Urobilinogen	Negative
Leuk Esterase	Negative
Microscopic	
WBC	0 - 5/HPF
RBC	0 - 3/HPF
Epithelial	Squamous only
Mucous	1+
Bacteria	Trace or <1+
Yeast	None
Casts	0 – 5 hyaline/LPF
Crystals	Few oxalates Few amorphous urates or phosphates

SEROLOGY	
HCG-B Qualitative	Negative

ARTERIAL BLOOD GAS	
PH	7.350 - 7.450
PCO2	35.0 - 45.0 mmHg
PO2	80.0 - 100 mmHg
HCO3a	20.0 - 26.0 mmol/liter
BE	-3.0 - 3.0mmol/l
SO2	95.0 - 100.0 %
TEMP	98.6^{o}F

GLUCOSE TOLERANCE TEST (GTT)

Normal values:

For a 75-gram oral glucose tolerance test used to check for type 2 diabetes, normal (nondiabetic) blood values are:

- Fasting: 60 to 110 mg/dl
- 1 hour: less than 200 mg/dl
- 2 hours: less than 140 mg/dl. Between 140-200 mg/dl is considered impaired glucose tolerance or prediabetes. This group is at increased risk for developing diabetes. Greater than 200 mg/dl is diagnostic of diabetes mellitus.

For a 50-gram oral glucose tolerance test used to screen for gestational diabetes, normal blood values at 1 hour are less than 140 mg/dl.

For a 100-gram oral glucose tolerance test used to screen for gestational diabetes, normal blood values are:

- Fasting: less than 95 mg/dl
- 1 hour: less than 180 mg/dl
- 2 hours: less than 155 mg/dl
- 3 hours: less than 140 mg/dl

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V. General Information ANATOMIC PATHOLOGY

ANATOMIC PATHOLOGY

Ritu Khera, MD	**Pathologist**	**Ext. 2177**
Gail Patterson **Lisa Miller** **Erin Skelly**	**Histotechnologist/** **Cytotechnologist**	**Ext. 2189**
Geri Myers	**Program Assistant**	**Ext. 2176**
Anatomic Pathology Reports		**Ext. 2176**

GENERAL INFORMATION

1. The Anatomic Pathology Service includes the following sections:

SURGICAL PATHOLOGY
CYTOPATHOLOGY
AUTOPSY PATHOLOGY

2. The hours of operation are **8:00 AM to 4:30 PM Monday through Friday**. The Histotechnologist is available from 11PM to 7AM. During duty hours, back-up technologists provide histotechnology coverage. The Pathologist is available 6:00AM to 10:00AM.

VI. SURGICAL PATHOLOGY

- **Specimen Submission and Handling**
- **Specimen Procurement and Transport**
- **Criteria for Acceptance/Rejection of Tissue Specimens**
- **Instructions for Specimen Procurement:**
    - ♦Routine Specimens
    - ♦Specimens Requiring Special Handling
        - Breast Tissue for Estrogen and Progesterone Receptor Assay
        - Muscle Biopsy
        - Open Lung Biopsy Procedure
        - Lymph Node Biopsy
        - Testicular Biopsy for Infertility
        - Bone Marrow Aspiration and Biopsy
        - Cytogenetic Studies for Bone Marrow or Peripheral Blood
        - Immunophenotyping/Flow Cytometry
- **Intraoperative Consultations (Frozen Sections)**
- **MCM's**
    - ♦MCM 115-23 Guidelines for Surgical Specimen Submission
    - ♦MCM 115-15 Returning Surgical Pathology Material to Patients

Link to Cytology Index

INSTRUCTIONS FOR SPECIMEN PROCUREMENT AND FIXATION

This includes instructions for:

I. ROUTINE SPECIMENS

II. SPECIMENS REQUIRING SPECIAL HANDLING

I. ROUTINE SPECIMENS

1. The routine small surgical specimens should be submitted in Safe-Fix preservative. The specimens should contain at least 20 times the volume of specimens.

2. The large specimens should be placed in adequate 10% neutral buffered formalin.

NOTE: DO NOT PLACE VERY SMALL OR LARGE SPECIMENS IN SALINE as it may distort the histology of the specimen. Also, undue manipulation of the specimen may cause tissue damage and hinder interpretation of the pathologic changes.

SPECIMEN	INSTRUCTIONS
Small specimens, e.g., teeth, biopsies, appendix, hernial sacs, TUR, etc.	Submit in Safe-Fix preservative 20 times the volume of specimen.
Large specimens, e.g., colon resection, mastectomy, radical prostatectomy, lung resection, etc.	Submit in 10% Neutral Buffered Formalin

II. SPECIMENS REQUIRING SPECIAL HANDLING

The following specimens require special handling:

1. Breast tissue for Estrogen and progesterone assay
2. Muscle biopsy
3. Open lung biopsy
4. Lymph node biopsy
5. Testicular biopsy for infertility
6. Cytogenetics studies
7. Flow Cytometry

Notify the pathologist and/or histotechnologist prior to any of the above named surgical procedures.

SURGICAL PATHOLOGY

SPECIMEN SUBMISSION AND HANDLING

ALL tissue specimens and foreign objects removed from patients must be promptly submitted to Anatomic Pathology section of Pathology & Laboratory Medicine (P&LM) for identification and gross/microscopic examination when indicated. The medicolegal significance of properly documenting the nature of the specimen, in addition to the surgeon's operative findings, in the patient's record cannot be over-emphasized.

The MCM 115-23, "Guidelines for Surgical Specimen Submission" outlines the guidelines for specimen submission and categories of surgical specimens that usually require a gross description and diagnosis and are exempted from mandatory microscopic description.

SPECIMEN PROCUREMENT AND TRANSPORT

The specimen procurement encompasses all activities from surgical removal of the specimen to its acceptance by the Histology section of the Laboratory. It involves close cooperation among the surgeon, operating room nursing staff, clerical/technical staff o the Histology Laboratory and the pathologist.

The initial responsibility for specimen handling including preservation and labeling, lies with the submitting physician and the assistant.

The procurement of a specimen for histological evaluation consists of the following elements:

A. Correct identification and integrity of identification.
B. A complete surgical pathology requisition.
C. Fixation or special handling appropriate to the specimen.
D. Prompt delivery of the specimen to the Laboratory.

1. **CORRECT IDENTIFICATION OF SUBMITTED SPECIMENS**: The correct identification and integrity of identification from specimen removal to accessioning within the Laboratory are essential and each part of the specimen must be properly identified at the time of the procedure. The proper identification MUST be on the container and should include:

   - Patient's name and social security number.
   - Date obtained
   - Organ/tissue site.

   This identifying information on the container must match the information on the specimen requisition form. In general, the identification should be placed on the body of the container holding the specimen, rather than on the lid, as the latter may be inadvertently transferred. Standard safety precautions should be followed in handling all specimens; however, if a specimen presents a known or suspected biohazard, the container should be so marked.

2. **COMPLETED SURGICAL PATHOLOGY REQUISITION**: A properly completed specimen requisition form must accompany all specimens and all identifying information on the requisition form must

match that on the specimen container. If the specimen presents a known or suspected biohazard, this information should be included on the requisition form. The patient identification data should be correct and legible and compared to patient's wristband, prior to submission to the Laboratory. The requisition form should include the following information:

- Full identification of the patient (including name, sex, date of birth and social security number).
- Name of submitting physician.
- Type and source of specimen (organ/tissue).
- Date/time when the specimen was obtained.
- Pertinent clinical information
- Pre- and postoperative diagnosis filled in by the submitting physician or designee.

Adequate history is essential for the most accurate pathologic diagnosis and its absence may inconvenience a number of people by necessitating telephone calls in addition to delaying the pathology report.

3. **FIXATION OR SPECIAL HANDLING APPROPRIATE TO THE SPECIMEN**: For routine specimens appropriate fixative is required for each specimen and will be available to the submitting physicians. The exceptions to routine fixation, e.g. frozen sections, cases with suspected infection or lymphoma or specimens requiring special procedures/handling should be communicated by the operating room to the laboratory staff in advance for specific specimen submission requirements. Refer to "Instructions for Specimen Procurement and Fixation" section for specific information.

4. **PROMPT DELIVERY OF THE SPECIMEN TO THE LABORATORY**

   A. After the specimens are removed from the patient, they should be placed in a clean, leak-proof container with secure closure. Before being transported to the laboratory, the primary container should be placed into a sealable secondary container, i.e., plastic zip-lock specimen transport bags, which are labeled with the biohazard symbol. Specimens too large to be contained in the zip-lock bag will be placed in a red bag with a biohazard label attached. The following precautions should be taken during specimen handling and transportation:

      - The outside of the primary container and zip-lock specimen transport bag must not be visibly contaminated.
      - Laboratory requisition slips should be protected from visibly contaminated material and, if necessary, separated from the primary container.
      - Personnel who transport specimens should be trained in safe handling practices and decontamination procedures in case of spill.
      - Laboratory personnel should examine all specimens for visible contamination before opening the specimen containers. The outside of the contaminated containers should be cleaned with hospital approved disinfectant solution before sending to the work areas for testing. Laboratory requisitions, visibly contaminated, should be discarded and replaced.
      - Laboratory personnel will initial laboratory requisition and record the number of specimens brought to the Lab.

   B. All specimens should be properly labeled in the operating room or any other location where the procedure is performed. The specimens should preferably be delivered to the laboratory as soon as qualified personnel obtain them. The late, weekend and emergency surgical specimens should remain in the surgical suite (operating room) and be delivered to the laboratory the next working day after

8:00AM. The histotechnologist will check specimens received against those expected by reviewing the daily surgery schedule. When anticipated specimens are not received, prompt inquiry will be initiated to avoid lost or misplaced specimens.

CULTURES

If there is indication that microorganisms may be responsible for the pathologic changes, appropriate material for smears and cultures of these specimens should be obtained. Such material is best obtained in the Operating Room under sterile conditions rather than in the Laboratory.

Specimens for micro-organism/cultures should not be included with the Surgical Pathology specimens, or included on the Surgical Pathology Requisition form. Specimens for Microbiology MUST be submitted to the Laboratory separately accompanied by a Microbiology Requisition form (SF 10-2129).

TISSUE IMPRINTS

In certain instances, particularly in suspected lymphomas, make touch imprints of the lymph node or tumors to better determine cell type. If imprints from any tissue are desired, please notify the pathologist and/or histotechnologist. These imprints must be properly made, quickly air-dried, labeled, and submitted to the Laboratory for further processing along with the specimen.

SPECIAL STAINS ON HISTOLOGIC SLIDES

The decision whether special stains or other procedures might be helpful in arriving at a definitive diagnosis rests with the pathologist. In cases where examination of tissues for specimen substances (i.e., amyloid) or specimen disease conditions is desired, contact the pathologist or so indicate on the specimen form. Special stains are time consuming, expensive, and should not be ordered indiscriminately.

CALCULUS

Calculi are sent for analysis to a reference laboratory.

OTHER SPECIAL PROCEDURES

- The histochemical procedures, immunofluorescent and immunoperoxidase techniques are also available. These should be limited to selected cases where they are required for definitive diagnosis. It takes approximately 1 to 3 weeks to receive the report.
- The special procedures in certain instances require special handling when removed from the patients. In all such instances, the pathologist and/or histotechnologist should be informed well ahead of the planning procedure.

CRITERIA FOR ACCEPTANCE/REJECTION OF TISSUE SPECIMENS

The specimen procurement and transport require systems of positive identification of specimens, integrity of identification throughout the procurement process, provision of demographic and clinical information, appropriate fixation, and prompt delivery of specimens to the Laboratory.

The criteria of acceptance/rejection of tissue specimens is as follows:

I. INCORRECT, IMPROPER, INCOMPLETE IDENTIFICATION OR LABELING

The technician who accessions tissue specimens will not accept specimens that are inappropriately or incompletely labeled or without a proper accompanying specimen requisition in accordance with requirements listed for specimen submission.

When a specimen has incorrect/improper/incomplete identification, the originating site will be notified. The person correcting the labeling error will need to accept responsibility and complete the "Mislabeled Specimen Responsibility" form. For specimens submitted without requisition forms, the originating site will be notified. A timely follow up will be done by Histology Section to assure proper re-submission.

NOTE: Due to uniqueness of most surgical pathology specimens, these will NOT be rejected until an exhaustive attempt has been made to correct the deficiency.

II. INADEQUATE OR IMPROPER PRESERVATION (FIXATION)

Refer to section on "Instructions for Special Procurement". Specimens submitted in improper, inadequate, or without fixative will be documented and the Operating Room/Outpatient Clinic notified.

III. LEAKING CONTAINER AND/OR SOILED REQUISITIONS

The Operating Room/Outpatient Department will be notified. If the requisition form is soiled, the Operating Room/Outpatient Clinic will be requested to provide a replacement. The rejected requisition will be disposed of with biohazard waste.

NOTE: The specimens will **not** be processed unless any identified deficiencies are corrected.

Histology/Cytology Problem Responsibility Sheet

VA MEDICAL CENTER, ERIE, PENNSYLVANIA

Mislabeled Specimen Responsibility

Specimen Accession Number: _____

Specimen sent to lab with the following error:

_____ Wrong Patient's Name

_____ No Name

_____ Misspelled Name

_____ Wrong Social Security Number

_____ Wrong Patient's Pathology Form

_____ Specimen Type & Location Missing From Label

_____ Other, Please Specify:

Person Notified: _____ Date & Time: _____

Correct Labeling should be*: (to be filled out by identifier)*

Patient's Name: _____

Social Security #: _____

Specimen Type & Location: _____

I Accept the Responsibility for Relabeling the Specimen:

Identifier's Name: _____

Signature: _____

Unit Location: _____

Date: _____ Time: _____

BREAST TISSUE FOR ESTROGEN AND PROGESTERONE RECEPTOR ASSAY

SPECIMEN REQUIREMENTS AND HANDLING

1. The pathologist or the histotechnologist should be notified at least 24 hours in advance so that arrangements can be made for handling the specimen (ext. 2176 or 2189).

2. If the breast tissue is determined to be malignant at the time of the frozen section, the specimen should be fixed in 10% neutral-buffered formalin within 20 minutes of collection. Optimum fixation time is 12-24 hours, not to exceed 48 hours.

3. After fixation, appropriate sections of the tumor will be submitted for paraffin embedding.

4. The formalin-fixed, paraffin-embedded tumor tissue (1 paraffin block) will be sent to the Reference Laboratory for estrogen/progesterone receptors immunohistochemical assay.

METHODOLOGY

The ER/PR immunohistochemical staining is a semi quantitative measurement that detects ER/PR positive tumor nuclei within sections from formalin-fixed, paraffin-embedded tissues. Because of the recent advances in the production of monoclonal antibodies and in antigen-retrieval methods, the paraffin materials methodology demonstrate good concordance with biochemical and immunocytochemical assays in frozen tissues. The immunohistochemical detection of ER/PR offers advantages over cytosolic methods.

- Less tumor tissue is required for ER/PR evaluation.
- Exact location of ER/PR positive cells can be determined (i.e., tumor cells versus normal breast tissue).

The presence or absence of positive internal control staining will be indicated on all negative reports to rule out false negative results.

CLINICAL SIGNIFICANCE

The clinical significance for the measurement of ER/PR receptors is patient prognosis and response to adjuvant endocrine therapy. Studies have shown that >50% of patients with receptor positive tumors will respond to some type of hormonal treatment whereas <10% of patients with receptor-negative tumors will have a response.

REFERENCES:

1. Battifora H, et al: Estrogen receptor immunohistochemical assay in paraffin-embedded tissue: A better gold standard. *Appl. Immunohistochem* 1:39-45, 1993.
2. Aasmundsted TA, et al: Oestrogen receptor analysis: correlation between enzyme immunoassay and immunohistochemical methods. *J. Clin Pathol* 45:125-129, 1992.
3. DeNegri F. et al: Comparison of monoclonal immunocytochemical and immunoenzymatic methods for steroid receptor evaluation in breast cancer. *Am J. Clin Pathol* 96:53-58, 1991.

MUSCLE BIOPSY

The histological study of skeletal muscle requires great care in obtaining and preparation of the specimen to assure maximum diagnostic information.

The pathologist of the Histology section of the Laboratory should be informed at least 24 hours in advance so that arrangements can be made for handling the specimens.

INDICATIONS
1. Diagnosis and classification of muscle disease.
2. Distinguish myopathic and neuropathic disorders.
3. Diagnosis of certain systemic diseases.
4. Monitor therapy in some myopathies.
5. Aid in genetic counseling.

BIOPSY SITE
A muscle believed to be actively involved but not to a severe degree is preferred. In recent myopathy, select the most impaired muscle. In chronic myopathy, select the less impaired muscle. The biceps and vastus lateralis are most often used.

AVOID SAMPLING
1. Muscles used for EMG or intramuscular injections.
2. Muscles subjected to regular trauma (deltoid, abdominal, gluteus, gastrocnemius).
3. Site of origin and insertion of the muscle.

SPECIMEN
Two (2) fresh muscle biopsy specimens at least 2 cm long in the direction of muscle fibers and 1 cm in diameter is adequate. Do **NOT** moisten the specimen with saline. Place the specimen in a **STERILE** container and deliver it to the Histology Section of the Laboratory immediately.

CLINICAL INFORMATION
The specimen must be accompanied by a completely filled out Surgical Pathology request form. The information must be detailed and should include:
1. Anatomic site of muscle biopsy.
2. Clinical history or differential diagnosis.
    - Age, sex and family history
    - Onset and rate of progression
    - Distribution of weakness
    - Other systemic disease
3. Serum enzymes – total CPK value.
4. Electromyography and nerve conduction studies.

SPECIMEN HANDLING
The histotechnologist will place the sterile container with unfrozen specimen in a second container with ice (**NOT DRY ICE**).

The specimen containers with clinical information will be shipped FedEx to Muscle Histochemistry and Electron Microscopy Laboratory, VAMC Little Rock, Arkansas.

OPEN LUNG BIOPSY PROCEDURE

An open lung biopsy is useful in selective cases. The following guidelines should be followed for properly obtaining and handling the specimen:?

1. Notify the Laboratory in advance so that preparation may be made to process the material with appropriate studies. The biopsy should preferably be done early in the day to assure prompt performance of the necessary procedures.

2. Individual Laboratory tags should be made out beforehand for any of the following studies that may be considered appropriate:

a. Surgical Pathology
b. Gram stain (routine and for Legionnaire's disease, if indicated)
c. Acid fast stain and culture.
d. Routine aerobic and anaerobic culture
e. Culture for Legionnaire's disease.
f. Tissue imprints for direct fluorescent antibody test for Legionella and other organisms (specify)

3. The biopsy specimen should be of sufficient size (4 x 3 x 3 cm is recommended).

4. The entire excised specimen must be placed in a DRY STERILE wide-capped container and immediately delivered to the Laboratory.

5. Appropriate examination will be made by the pathologist.

LYMPH NODE BIOPSY

In suspected lymphomas, the lymph node biopsies require special handling. The pathologist or the Histology section of the Laboratory should be notified at least 24 hours in advance so arrangements can be made for handling the specimen.

SPECIMEN:

The lymph node biopsy specimen should be wrapped in wet saline gauze and delivered IMMEDIATELY to the Histology Section of the Laboratory. The specimen must be accompanied by a completely filled out surgical pathology request form including pertinent clinical history and any other information.

PROCESSING

1. Make 10 imprints from unfixed, freshly cut section.
2. Place a portion of the lymph node in 10% zinc formalin.
3. Section the rest of the lymph node 3 to 5 mm in thickness and place in 10% zinc formalin fixative.

TESTICULAR BIOPSY FOR INFERTILITY

The testicular biopsy for clinical evaluation of male infertility requires special handling.

SPECIMEN:

1. Notify the histotechnologist in advance so that arrangements can be made for handling the specimen.

2. Place the specimen in Bouin's fixative and deliver to the Histology section of the Laboratory. The specimen must be accompanied by a completely filled out Surgical Pathology requisition form including pertinent clinical history and any other information.

BONE MARROW ASPIRATION AND BIOPSY

AVAILABILITY: The histotechnologist/medical technologist will assist the physician during the bone marrow procedure(s). The routine procedures should be scheduled with the Histology Section of the Laboratory, preferably between 8AM to 12Noon, Monday through Friday. The indications for cultures, special orders and any additional studies should be indicated at that time so appropriate arrangements can be made. The request form must be completed including pertinent clinical findings and accompany the specimen.

SPECIMEN - Aspirate smears
- Core biopsy and/or marrow clot
- Touch preparations are made if no aspirate
- Material for special studies (cultures, etc.) if indicated

The smeared slides are prepared at the bedside of where the procedure is being done. The biopsy and clot is placed in a fixative.

STAINING: The aspirate smears are stained with Wright's stain. The H&E stain is done on the marrow clot and core biopsy. The other special stains are performed if indicated.

IRON STAIN: The iron stain is performed on bone marrow smeared slides and aspirate.

Note: The bone marrow biopsy is not a preferred specimen for iron stain because when a bone biopsy specimen is decalcified, "leaching" of iron may occur so that the bone biopsy may be negative for iron while aspirate smear is positive. The iron stain is not done if no marrow is obtained (dry tap) or if there are no marrow particles on smears.

Interpretation: The iron stain is a semiquantitation of bone marrow iron stores. It is a sensitive test for evaluation of iron reserve and aids in diagnosis of iron deficiency and sideroblastic anemia.

BONE MARROW EXAMINATION AND INTERPRETATION: The bone marrow examination is useful in interpreting the bone marrow morphology, hematopoiesis, myeloid/erythroid ratio, megakaryocytes, myelopoiesis, cellularity and marrow iron stores. Marrow histology is helpful in staging malignancies, i.e., lymphoid malignancies and metastatic tumor. The bone marrow examination REPORT includes the description of marrow as follows:

1. **Peripheral Blood Smear and Blood Count Results Report:**

   This should include the following:
   - Morphologic assessment of red cell series including a statement about measure indices (if known).
   - Quantitative and morphologic assessment of white cells
   - Quantitative and morphologic assessment of platelets
   - Other features (rouleaux, parasites, etc.)

2. **Clot Section and/or Core Biopsy Report:**
   - Adequacy of specimen
   - Number of core biopsies examined
   - Overall cellularity and variations

- Description of process involving marrow
- Assessment of bony trabeculae

3. **Aspirate Smear Report:**

This report should include the following:

- Adequacy of specimen
- Morphologic assessment of all lines (maturation abnormalities, leukemic cell features, etc.)
- Differential count (if necessary)
- M:E ratio

4. **Iron Stores:**

Assessment of storage iron in sections/smears should include localization and semiquantitation of iron stores and percentage of ringed sideroblasts (if present).

5. **Comment/Clinicopathologic Correlations:**

The following elements should be included in the comment/clinicopathologic correlation:

- Which other surgical pathology accessions (if any) were performed in conjunction with the examination.
- Comparison with previous bone marrow biopsy (if any)
- Integration of pertinent Laboratory data (iron studies, folate, vitamin B12, etc.)
- Interpretation of cytochemical stains or other special studies.

CYTOGENETICS STUDIES

Availability:

The specimen(s) for bone marrow/peripheral blood cytogenetics studies should be preferably collected Monday through Friday and sent to LabCorp Reference Laboratory. If cytogenetics studies are needed on a tissue biopsy, the Histology Section of the P&LM must be contacted in advance so arrangements could be made with LabCorp for supply of Lymph Node Transport Kit.

Specimen Collection/Storage

Cytogenetics	***Specimen Requirements***	***Specimen Storage Instructions***
Chromosome Analysis Lymphoma/Leukemia. Hematological disorders such as myelodysplasia, acute and chronic leukemia, lymphoma or myeloproliferative disease.	• Bone marrow aspirate – 2 ml • Peripheral blood – 3 ml • Tissue biopsy – 0.5-1 cm (to be submitted in Lymph Node Transport Kit) NOTE: If bone marrow aspirate is successful, it is <u>not</u> necessary to send the peripheral blood. Blood for a hematological study should be sent only as a substitute for poor or unobtainable bone marrow aspirate.	Maintain specimen at room temperature.
CML Profile (Chromosomes and DNA)	Bone marrow aspirate – 2 ml OR Peripheral blood – 3 ml	Maintain specimen at room temperature.
Chromosome analysis (karyotyping) For suspected constitutional abnormality, sex chromosome determination, etc.	Peripheral blood – 5-10 ml	Maintain specimen at room temperature. Specimens may be refrigerated if delay in transport. **Do NOT freeze.**
Chromosome analysis For solid tumor or tissue biopsies.	Tissue biopsy/solid tumor – 0.4-1.0 cm specimen (to be submitted in Lymph Node Transport Kit)	Maintain specimen at room temperature.

Special Instructions

Include medical findings, tentative diagnosis and treatment on the request form as appropriate.

Transport of Specimens to Reference Laboratory

The specimens will be picked up by the LabCorp courier and transported to reference laboratory.

Clinical Significance

Cytogenetic analysis can identify numerical and structural chromosomal abnormalities, which are diagnostic and/or prognostic of some types of leukemias/lymphomas/other tumors, and evaluate other suspected chromosomal disorders.

IMMUNOPHENOTYPING/FLOW CYTOMETRY

Availability

The specimen for immunophenotyping/flow cytometry should be preferably collected Monday through Friday and sent to LabCorp reference laboratory.

Specimen Collection:

Immunophenotyping/ Flow Cytometry	Specimen Requirements	Storage Instructions
Acute Leukemia Profile (myeloid process). Test profile includes the following markers: CD2, CD3, CD7, CD10, CD11b, CD13, CD14, CD15, CD19, CD20, CD33, CD34, CD45, CD71, CD117, HLA-DR. Supplemental markers may be added as determined by pathologist (CD1a, CD4, CD5, CD8, CD61, lycophorin A, TdT).	• Fresh bone marrow aspirate – 2 ml collected in sodium heparin tube (green top). • Peripheral blood – 3 ml collected in EDTA tube (lavender top). • CBC	Maintain specimen at room temperature and submit using bone marrow specimen transport kit.
Chronic Lymphocytic Leukemia/Lymphoma Profile (lymphoid process) Test profile includes the following markers: CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD19, CD20, CD22, CD23, CD25, CD33, CD38, CD45, CD56, FMC-7, kappa and lambda immunoglobulin light chains. Additional markers may be added as determined by pathologist (CD71, CD138, TCR alpha/beta, TCR gamma/delta).	• Fresh bone marrow aspirate – 2 ml collected in sodium heparin tube (green top). • Peripheral blood – 3 ml collected in EDTA tube (lavender tube). • CBC	Maintain specimen at room temperature and submit using bone marrow specimen transport kit.

Transport of Specimens to Reference Laboratory

The specimens will be picked up by LabCorp courier and transported to reference laboratory.

Clinical Significance

The immunophenotyping/flow cytometry is useful in diagnosis and in determining prognosis of hematologic malignancies as well as in evaluating residual/relapse disease in conjunction with cytomorphology and histologic features of each case.

- Acute leukemia profile is useful in lineage assessment in acute leukemia for selecting appropriate therapy and assessing prognosis. It is also useful in distinguishing lymphoid from myeloid disorders.
- Chronic lymphocytic leukemia/lymphoma profile is useful to identify and characterize the following:

    - Reactive lymphocytosis vs. chronic lymphocytic leukemia (CLL)
    - Prolymphocytic leukemia vs. lymphoblastic leukemia: large granular lymphocyte proliferations, T-gamma lymphoproliferative disease, natural killer cell proliferations, T-cell CLL, T-cell gamma/delta proliferations.
    - Sezary syndrome
    - Non-Hodgkin’s lymphoma
    - Adult T-cell leukemia/lymphoma

INTRAOPERATIVE CONSULTATIONS

(Frozen Sections)

AVAILABILITY:

The facility for rapid frozen section is located in the Laboratory. The pathologist is available for consultation 6:00AM through 10:00AM, Monday through Friday. At other hours, the pathologist should be made aware of the need for consultation by contacting, at least one day prior to surgery. In cases where the need for frozen section is anticipated, it should be indicated on the SCHEDULE OF OPERATIONS.

INDICATIONS:

The frozen sections have limitations and the technique does not supplant with the standard paraffin method. The indications for frozen section are:

1. To establish the nature of a lesion and to assist in planning an IMMEDIATE surgical course of action.

2. To establish the limits of extent of a lesion in order to evaluate the completeness of a surgical procedure.

3. To establish if diagnostic material has been obtained at biopsy.

4. To decide whether or not to continue with the procedure.

PROCEDURE:

1. Identification: The specimen/specimens for frozen section should be properly identified. The specimen container should be labeled with the following:

- Patient's name
- Social security number (ID number)
- Specimen source
- Surgeon's name
- Other appropriate information (e.g., previous surgical procedures)

2. The specimen should be wrapped in sterile gauze moistened with normal saline and placed in a properly labeled container. A completed tissue consultation form, including the source of specimen and brief sufficient clinical information should accompany the specimen to allow competent examination of the specimen. The identifying information on the consultation form should match that on the container.

3. The pathologist or Histology section of the Laboratory should be notified a few minutes before removal of the specimen so arrangements could be made and there is no delay in processing the specimen.

4. The specimen should be transported IMMEDIATELY to the Histology section of the Laboratory by a qualified person.

GROSS EXAMINATION:

The specimen submitted for frozen section is appropriately measured, the description of tissue made, and recorded before sections are taken. The clinical information regarding the specimen should be available. The number of sections prepared will vary for different specimens.

If special studies, e.g. special stains, estrogen-progesterone receptor status, immunohistochemical studies are required, the tissues will be preserved for these studies.

LABELING:

The frozen section slides are labeled with a glass marking pencil. The labels should be clearly written and should include patient's name and/or accession number.

CUTTING AND STAINING:

Sufficient "facing" of the block is done to reveal the lesion under study. The pathologist will judge whether the prepared slide is adequate for the circumstances.

The slides are rapidly stained. The quality of staining is related to the freshness of the stains.

NOTE: The slides for examination are generally ready within 15 minutes of the time that the specimen is received.

INTERPRETATION:

The slides are interpreted by the pathologist in full context of all available clinical and pathological material. When previous material has been examined, the reports and/or slides are also reviewed. When significant diagnostic uncertainty exists, either further sections are prepared or diagnosis deferred.

REPORTING THE DIAGNOSIS:

The diagnosis is reported directly to the surgeon as soon as it is available. As the diagnosis is reported on the telephone, the pathologist should identify himself/herself and state the patient's name and tissue examined followed by the diagnosis. The surgeon should acknowledge the diagnosis by repeating the diagnosis.

A written copy of the frozen section diagnosis will also be sent to the Operating Room. The final report of the surgical specimen includes frozen section diagnosis.

RETENTION OF SLIDES AND BLOCKS:

The frozen section slide is labeled and retained with the remainder of the case. A permanent block and section is made from the material that was frozen.

VII. CYTOPATHOLOGY

VII. CYTOPATHOLOGY

- General Information
- Specimen Procurement Policy
- Specimen Collection and Preservation - General Information
- Instructions for Collection/Preparation of Specimens
- Instructions for Collection/Preparation of Specimens from Various Body Sites
  Gynecologic Specimens (Female Genital Tract)
  Non-Gynecologic Specimens
  Respiratory Tract
  Gastrointestinal Tract
  Urinary Tract
  Body Fluids
  Cerebrospinal Fluid
  Cytology Scrapings
  Nipple Discharge Cytology
  Cyst Fluid Cytology
  Other Special Studies
  Aspiration Cytology Specimens
- Criteria for Unacceptable/Unsatisfactory Cytology Specimens

CYTOPATHOLOGY

Ritu Khera, MD	**Pathologist**	**Ext. 2177**
Gail Patterson **Bernadette Hall**	**Histotechnologist**	**Ext. 2189**
Cytology Reports	**Program Assistant**	**Ext. 2176**

GENERAL INFORMATION

The hours of operation for the Cytology section of the Laboratory are **6:00 AM to 4:30 PM Monday through Friday**

VA Medical Center, Erie, Pennsylvania – Pathology & Laboratory Medicine/Cytology

SPECIMEN PROCUREMENT POLICY

GENERAL INFORMATION:

All Cytology specimens obtained (both outpatient and inpatient) must be sent to Pathology and Laboratory Medicine for evaluation and diagnosis by a qualified pathologist.

All specimens must be properly identified and accompanied by a requisition form. The requisitions must be prepared and specimens labeled at the location where the specimen is obtained.

The specimens should be submitted in clean appropriately labeled containers. The outer surface of the container must be clean and a firmly fitting lid must be in place to avoid biohazards. The identifying information on the container should match that on the specimen requisition form.

SPECIMEN PROCUREMENT

The specimen procurement encompasses all activities from obtaining the specimen to its acceptance by the Histology section of the Laboratory. It involves close cooperation among the physicians, nursing staff, clerical/technical staff of the Histology Laboratory, and the pathologist.

The procurement of a specimen for cytology evaluation consists of the following elements:

1. **Correct identification and integrity of identification.**

2. **A complete cytology pathology requisition.**

3. **Proper specimen collection and preservation.**

4. **Prompt delivery of the specimen to the Laboratory.**

1. CORRECT IDENTIFICATION OF SUBMITTED SPECIMENS

The correct identification and integrity of identification from specimen collection to accessioning within the Laboratory are essential. Each part of the specimen(s) must be accurately identified at the location collected. The specimen label patient identification information on the specimen container(s) MUST include:

- Patient's Full Name
- Patient's Full Social Security Number
- Date obtained
- Specimen source identification

This identifying information on the container must match the information on the specimen requisition form. In general, the identification should be placed on the body of the container holding the specimen, rather than on the lid, as the latter may be inadvertently transferred. Standard safety precautions should be followed in handling all specimens; however, if a specimen presents a known or suspected biohazard, the container should be so marked.

2. COMPLETED CYTOLOGY PATHOLOGY REQUISITION

A properly completed specimen requisition form must accompany all specimens and identifying information on the requisition form must match that on the specimen container. If the specimen presents a known or suspected biohazard, this information should be included on the requisition form. The patient identification data should be correct and legible and compared to patient's wristband, prior to submission to the Laboratory. The requisition form should include the following identification:

- Full identification of the patient (including patient's full name, full social security number and date of birth)
- Name of submitting physician
- Type and source of cytologic material
- Date/time when the specimen was collected
- Ordering location
- Pertinent clinical history such as previous conditions and treatment and prior cytology and/or history (if known). For routine gynecological specimens, information such as date of the last menstrual period, contraceptive history, hormones and obstetric history should also be provided.

3. PROPER SPECIMEN COLLECTION AND PRESERVATION

The specimens should be collected in a clean, leak-proof container with a secure closure. For further information on specimen collection and preservation, refer to "Instructions for Specimen Collection and Preservation" section.

4. PROMPT DELIVERY OF THE SPECIMEN TO THE LABORATORY

- Before being transported to the Laboratory, the primary container should be placed into a sealable secondary container, i.e., plastic zip lock specimen transport bags, which are labeled with the biohazard symbol. Specimens too large to be container in the zip lock bag will be placed in red bag with a biohazard label attached. The following precautions should be taken during specimen handling and transportation:
    - The outside of the primary container and zip lock specimen transport bag must not be visibly contaminated.
    - Laboratory requisition slips should be protected from visibly contaminated material and, if necessary, separated from the primary container.
    - Personnel who transport specimens should be trained in safe handling practices and decontamination procedures in case of spill.
    - Laboratory personnel should examine all specimens for visible contamination before opening the specimen containers. The outside of the contaminated containers should be cleaned with hospital-approved disinfectant solution before sending to the work areas for testing. Laboratory requisitions, visibly contaminated, should be discarded and replaced.
- The specimens should preferably be delivered to the Laboratory as soon as they are obtained by qualified personnel. During non-duty hours, the specimens should be obtained only if necessary. All specimens collected after regular duty hours MUST be refrigerated and deliver the next day after 6:00AM.

5. REFERENCES:

1. Quality Management in Anatomic Pathology, College of American Pathologists, 2005.
2. JCAHO Comprehensive Accreditation Manual for Pathology and Clinical Laboratory Services, current edition.

SPECIMEN COLLECTION AND PRESERVATION

Proper collection techniques and specimen preservation are essential for accurate cytologic interpretation. The addition of alcohol or use of refrigeration to retard or stop cell degeneration and bacterial growth are essential for fluid specimens that cannot be processed immediately. The immediate fixation of smears made outside the Laboratory is essential to prevent the air-drying of slides. Cell degeneration and air-drying could compromise the cytologic diagnosis.

GENERAL INFORMATION:

The material for cytologic examination generally is submitted as follows:

1. **Prepared Smears**
2. **Fluid Specimens**
3. **Fine Needle Aspirates (FNA)**
4. **Gynecological specimens**

1. **PREPARED SMEARS:** include Pap smears, brushings, imprints, and scrapes. Rapid fixation of smears is necessary to preserve cytologic detail of cells spread on a glass slide. If smears are allowed to air dry prior to fixation, marked distortion of cells occurs.

2. **FLUID SPECIMENS:** Fluid specimens from different body sites such as respiratory tract, gastrointestinal tract, urinary tract, and effusions must be submitted in a clean, leak-proof container, which is capped tightly and properly labeled. Preservation of cellular morphology until the sample can be processed is essential to accurate cytologic preparation.

   FRESH MATERIAL

   The "fresh sample" is one to which no fixative or preservative has been added. **The prompt delivery of the fresh, unfixed material is critical.** Leaving the specimen at room temperature will result in rapid deterioration of the cellular material. Such specimens are unsatisfactory for cytopathological evaluation. The length of time between collection and preparation of sample before cellular damages occur depend on pH, protein content, enzymatic activity, and the presence or absence of bacteria. It is not possible to predict these variables even in specimens from the same anatomic site. However, the following guidelines will usually yield acceptable results:

   - Specimens with a high mucus content, such as sputums, bronchial aspirates, or mucocele fluid may be preserved for 12 to 24 hours if refrigerated. Refrigeration slows the bacterial growth that causes cellular damage and the breakdown of mucus. Mucus apparently coats the cells, protecting them against rapid degeneration. The cells in specimens without thick mucus or specimens diluted with saliva are not as well protected and may deteriorate more rapidly.

   - Specimens with a high protein content, such as pleural, peritoneal, or pericardial fluids may be preserved for 24 to 48 hours with refrigeration. The protein rich fluid in which the cells are bathed acts as a tissue culture medium in preserving cellular morphology.

•Specimens with low mucus or protein content, such as urine or cerebrospinal fluid will endure only a 1 to 2 hour delay even if refrigerated. The fluid medium in which these cells are bathed contain enzymatic agents capable of causing cell destruction. Refrigeration may inhibit bacterial growth, but does not protect the cells.

•Specimens with low pH, such as gastric material must be collected on ice and be prepared within minutes of collection to prevent cellular destruction by hydrochloric acid.

3. **FINE NEEDLE ASPIRATE (FNA) SPECIMENS:** The specimen(s) are collected directly into 30 ml of Cytolyte solution.

4. **GYNECOLOGICAL SPECIMENS:** The specimens are collect in Sure Path vial.

GENERAL DIRECTIONS FOR SPECIMEN COLLECTION/PRESERVATION (SUMMARY)	
Specimen	**Instructions**
Prepared Smears • Brushings • Scrapings • Nipple discharge • Gynecological smears	Fixative should be held 6 inches from slide and sprayed evenly once across and once back across slide, making sure entire slide is covered by fixative.
Fluids • Cyst fluid • Gastrointestinal • Bronchial aspirate and washings • Tracheal aspirate • Sputum • Urine • Serous fluids (pleural, peritoneal, pericardial, ascetic, synovial and CSF)	Prompt delivery of specimens to the Laboratory. Specimens will be fixed then refrigerated IMMEDIATELY upon arrival in the Laboratory.
Fine Needle Aspirate (FNA) – breast, lung, thyroid, pancreas, lymph node, liver, neck or mediastinal mass, etc.	Collect specimen(s) directly into 30 ml of Cytolyte Solution and mix. The specimen(s) will be sent to VAMC Pittsburgh for processing and interpretation using ThinPrep technology.
Gynecological specimens	Collected in Sure Path vial and sent to Laboratory. The specimen(s) will be sent to VAMC Philadelphia for processing and interpretation using ThinPrep technology.

INSTRUCTIONS FOR COLLECTION/PREPARATION OF SPECIMENS

GENERAL INSTRUCTIONS

The instructions for collection/preparation of cytology specimens, including prepared smears and fluid specimens are as follows:

PREPARED SMEARS

These include the following:

- **Pap Smear**
- **Cytology Brushings**

MATERIALS NEEDED:

Prior to preparation of smears, it is important to secure the necessary materials and lay them out on a suitable conveniently located surface within the reach of the operator.

- Instrument(s) used to obtain smears
- Clean microscopic glass slides with frosted ends
- Lead pencil
- Paper clips for separation of slides from each other if liquid fixative is used
- Fixative
- Cardboard containers
- Cytology Requisition Form

IDENTIFICATION OF SLIDES

Label the frosted end of the glass slide(s) with the patient's last name and last four (4) digits of the social security number using a lead pencil.

PREPARATION OF SMEARS

For most diagnostic purposes, well-prepared and well-fixed smears are required. Every effort should be made to place as much as possible of the material on the slide and to prepare a thin uniform smear. Thick smears with overlapping cell layers are difficult or impossible to interpret.

FIXATION

Immediate fixation is ABSOLUTELY ESSENTIAL for cytological smears that are stained by Papanicolaou method. Even the slightest delay in fixation will cause air drying, resulting in poor cellular detail.

CHOICE OF FIXATIVE

- The choice of fixative is spray fixative, which is available in the Histology section of the Laboratory. As soon as the smear is prepared, spray fix the smear within 2-3 seconds. Hold the can at least 12 inches from the slide. Spraying any closer will freeze the cells with aerosol propellant distorting cellular detail. Once the fixative on the smear is dry, place the slide in a cardboard slide folder. Transport the specimen to the Histology section of the Laboratory.

- The fluid fixative 95% ethyl alcohol may also be used for brushings. The Coplin jar with the fixative must carry a label with identification of the patient. If more than one glass slide is placed in the same fixative, it is essential that each slide be correctly identified. A paper clip placed on the frosted or marked end of every other slide will prevent adherence of slides to each other. It is preferable to use one Coplin jar for each patient to prevent errors of identification and occurrence of "floaters".

FLUID SPECIMENS

The fluid specimens should be submitted fresh as outlined in the "Specimen Collection and Preservation - General Information" section.

VA Medical Center, Erie, Pennsylvania – Pathology & Laboratory Medicine/Cytology

INSTRUCTIONS FOR COLLECTION/PREPARATION OF SPECIMENS FROM VARIOUS BODY SITES

These instructions are categorized as follows:

- **Gynecologic Specimens**

- **Non-Gynecologic Specimens, which** include:
  - Respiratory tract
  - Gastrointestinal tract
  - Urinary tract
  - Body fluids
  - Cerebrospinal fluid
  - Cytology scrapings
  - Nipple discharge
  - Cyst fluid cytology

- **Aspiration Cytology Specimens**

GYNECOLOGIC SPECIMENS
(FEMALE GENITAL TRACT)

Types of gynecologic specimens:

- Uterine Cervix/Vaginal routine cytology evaluation
- Vaginal smear for Hormonal studies
- Miscellaneous gynecological specimens including endocervical scrapings and brushings and vaginal cuff cytology.

CYTOLOGY REQUISITION FOR GYNECOLOGIC SPECIMENS:

The cytology requisition is submitted electronically through the CPRS hospital computer system. The following data MUST be completed:

- COMPLETE NAME AND SOCIAL SECURITY NUMBER
- AGE/DATE OF BIRTH
- MENSTRUAL HISTORY
- DATE OF LMP
- OBSTETRIC HISTORY
- PREVIOUS CYTOLOGY/HISTOLOGY
- IUD OR EXOGENOUS HORMONES INCLUDING BIRTH CONTROL PILLS

PROCEDURE:

1. **Thin-Prep Cytology:** Write the patient's full name and full Social Security number on the Sure Path vial.
   - The speculum must be introduced with no lubricant jelly.
   - Insert the Rover's Cervex-Brush into the endocervical canal.
   - Apply gentle pressure until the bristles form against the cervix.
   - Maintaining gentle pressure, hold the stem between the thumb and forefinger and rotate the brush five times in a clockwise direction.
   - Remove the Rover's Cervex-Brush from the patient.
   - Placing your thumb against the back of the brush, disconnect the entire brush from the stem, dropping it into the Sure Path preservative vial.
   - Place the cap on the vial and tighten.
   - Place the capped vial into a specimen bag and sent to lab.

   NOTE: For vaginal smear for hormonal studies, the lateral wall of the vagina should be sampled some distance from the cervix.

2. **Smears**: Write the patient's full name and full Social Security number with a lead pencil on the FROSTED END OF A GLASS SLIDE. The smear recommended for routine cancer detection combines a vaginal pool smear and a cervical smear on one slide. The speculum must be introduced with no lubricant jelly. Obtain mucus from the posterior vaginal pool with a spatula and place on the slide as a thick drop but DO NOT SMEAR. Use the cervical end of the spatula to scrape high up in the endocervical canal, rotating 360˚ around. Mix all this pancervical scraping with the lower portion of the vaginal pool mucus drop. Then smear on the slide and mix the specimen in the liquid and spread the material in a small area. Spray with cytology fixative immediately.

NON-GYNECOLOGIC SPECIMEN

GENERAL DESCRIPTION

1. Cytology Washings

This applies to bronchial washings, tracheal washings, esophageal washings, urethral washings, etc. The test includes the routine cytological examination of the smears and cellblock (when applicable).

PROCEDURE:

The washings or aspirations should be collected in a clean, properly labeled container and delivered to the Laboratory immediately.

2. Cytology Brushings

This applies to bronchial brushings, tracheal brushings, esophageal brushings, colonic brushings, urethral or renal pelvis brushings.

PROCEDURE:

The physician prepares the direct smears from the brushings of the lesion. Label the frosted end of the slides with the patient's last name and last four (4) digits of the social security number. To prevent air-drying, place a small drop of saline on the frosted end of the slide. Using a circular motion, roll the brush in the saline drop and smear on the slides. Fix the smears immediately with spray fixative or 95% alcohol. Allow spray fixed smears to air-dry for 5-10 minutes. Place the slides in the cardboard slide holder and seal the folder. After the smears are made, place the brush in a test tube containing saline and deliver to the Laboratory immediately.

NOTE: Excessive crushing of material must be avoided. The cytological sampling must be performed prior to the biopsy.

3. Lavage

The lavage is limited to the esophagus and stomach. A syringe with 50-100 ml of saline solution is attached to the plastic tube and a jet of fluid directed at a lesion or an area chosen by the endoscopist. The fluid is collected in a container by a second intubation after withdrawal of the endoscope. The specimen must be delivered to the Laboratory immediately.

CYTOLOGIC SAMPLING OF ORGANS

1. RESPIRATORY TRACT

a. Sputum

It is necessary to obtain a "deep cough" specimen, bringing up material from small bronchi and alveoli. If the patient cannot bring up a "deep cough" specimen, the sputum may be obtained by stimulating the cough reflex artificially.

COLLECTION:

The patient is instructed to expectorate sputum. Morning specimens resulting from overnight accumulation of secreta yield the best diagnostic results. Upon awakening in the morning, the patient rinses the mouth with water and discards the rinse. The patient then coughs deeply and expectorates into a sterile collection cup. Seal the container tightly, label appropriately and send to the Laboratory immediately.

Three (3) specimens on three (3) successive days are usually required to ensure a maximum of diagnostic accuracy.

NOTE: The patient must be carefully instructed not to spit without a deep cough since saliva is of no diagnostic value. If pulmonary macrophages are not identified, the specimen will be reported as unsatisfactory for adequate evaluation.

b. Bronchial Aspirates and Washings

Bronchial aspirates are obtained by suction during bronchoscopic procedures. During the procedure, approximately 10 ml of normal saline is instilled in small portions of 2 to 3 ml at a time. The material is aspirated and submitted to the Laboratory in a clean container.

c. Bronchial Brushings

The fiberoptic bronchial brushing specimen is obtained and smears are prepared as outlined in "Cytology Brushings."

d. Tracheal Aspirate

The aspirate is obtained by instilling 20 ml of saline solution in 2-ml portions and re-aspirating with a catheter in various positions. The specimen is collected in a clean container and sent to the Laboratory immediately.

2. GASTROINTESTINAL TRACT

a. Esophagus

Esophageal washings are best obtained using direct endoscopy. The washings should be obtained prior to biopsy. The specimen is collected in an appropriate container and sent directly to the Laboratory immediately.

Esophageal brushings obtained during the endoscopic procedure are smeared and fixed as outlined in "Cytology Brushings".

b. Stomach

Lavage - The specimen should be collected in a clean, leak proof container. The container should be kept in ice and delivered directly to the Laboratory.

Brushings - Gastric brushings obtained during the endoscopic procedure are smeared and fixed as outlined under "Cytology Brushings".

c. Colon

Lavage - The lavage specimen should be collected in an appropriate container and sent directly to the Laboratory.

Brushings - Brushings of colonic mucosal abnormalities at the time of fiberoptic examination of the colon are smeared and fixed as outlined in "Cytology Brushings". This is usually done in high-risk patients such as patients with multiple polyps, ulcerative colitis of long duration, and past history of colonic carcinoma.

3. URINARY TRACT

a. Urine

The specimen should be a freshly voided, clean catch urine. Twenty-four (24) hour specimens are NOT acceptable; catheterized urine is acceptable. The voided urine is preferred over a catheterized sample due to atypical cell changes caused by trauma during catheterization. The history of instrumentation, if any, must be given. The specimen must be sent to the Laboratory immediately.

b. Bladder Irrigation (Washings)

Washings of the bladder with saline solution obtained at the time of cytoscopy may be collected and sent, preferably in a fixative. This has a limited use confined to symptomatic patients.

c. Renal Pelvis and Ureters

The specimens obtained by retrograde catheterization or direct brushing for suspected lesions of renal pelvis or ureters must be sent to the Laboratory immediately. Specimens must be labeled as to type (voided or catheterized). For urethral specimens, designate origin (left or right).

4. BODY FLUIDS

Body fluids include pleural, peritoneal, pericardial, ascitic, and synovial fluids. Specimens may be collected in sterile evacuation bottles, tubes, or syringes.

COLLECTION: The fresh body fluid should be collected as described above. The minimum volume should be at least 5 ml of fluid as less than that will not yield enough cells for accurate cytological evaluation. NO FIXATIVE, PRESERVATIVE, OR ANTICOAGULANT SHOULD BE ADDED TO THE SPECIMEN. The specimen should be sent immediately to the Laboratory for processing.

NOTE: If the specimen is collected on a weekend or if there is a delay in delivery of specimen, it should be refrigerated IMMEDIATELY and delivered the next working day.

5. CEREBROSPINAL FLUID

The minimum volume of cerebrospinal fluid required is 1 ml. The specimen should be sent fresh in a sterile tube from the lumbar puncture tray or a sterile disposable container. DO NOT ADD ANY FIXATIVE, PRESERVATIVE, OR ANTICOAGULANT. Deliver the specimen to the Laboratory immediately.

6. CYTOLOGY SCRAPINGS

Cytology scrapings include skin scrapes, oral scrapes, mucus membrane scrapes, and Herpes cytology.

SPECIMEN COLLECTION: A direct smear of the lesion, vesicle, or blister is prepared.

a. If the lesion is soft, moist, and clean, swab the lesion with a pre-moistened, non-absorbent, cotton-tipped applicator. Place a small drop of saline on the slide. Spread the material from the applicator onto the pre-moistened slide. Fix with spray fixative immediately. Allow the slides to dry before placing in the slide folder.

b. If the lesion is dry or has a necrotic, inflammatory surface, gently moisten and remove the necrotic debris with non-absorbent cotton, which has been moistened in saline. Discard the swab and debris. Using a second non-absorbent cotton swab moistened in saline, gently rub the growing margins of the lesion. Place a small drop of saline on a clean slide. Quickly roll the second swab onto the pre-moistened slide. Fix with spray fixative immediately. Allow the slides to dry before placing them in the slide holder.

7. NIPPLE DISCHARGE CYTOLOGY

SPECIMEN: Soak the nipple with warm saline with cotton or gauze for 10-15 minutes. Place a small drop of saline on the slide. Then place pre-moistened slide on the nipple secretion and slide across quickly. Do not make thick smears. Make as many smears as the amount of the specimen allows. If smears are prepared from both breasts, label slides as "left" and "right". Deliver slides to the Laboratory.

8. CYST FLUID CYTOLOGY

Cyst fluid applies to renal cyst fluid, breast cyst fluid, pancreatic cyst fluid, hydrocele cyst fluid, liver cyst fluid, thyroid cyst fluid, bile duct fluid, and T-tube fluid.

SPECIMEN: Fresh fluid should be submitted to the Laboratory in a clean, leak-proof container. DO NOT ADD FIXATIVE, PRESERVATIVE, OR ANTICOAGULANT. Deliver to the Laboratory immediately. After regular Laboratory hours, specimens should be refrigerated until the next working day.

9. OTHER SPECIAL STUDIES

If any special studies are required, contact the Histology/Cytology section of the Laboratory in advance so that proper arrangements can be made.

FINE NEEDLE ASPIRATE CYTOLOGY SPECIMENS (FNA)

This includes fine needle aspirations of breast, lung, thyroid, pancreas, lymph node, liver, neck, or mediastinal mass, etc.

The test includes examination of fine needle aspirate specimen(s) using ThinPrep technology. Clinical information is necessary for the pathologist to render a diagnosis. The specific site, clinical diagnosis, whether the lesion is solid or cystic and the gross appearance of the aspirate (if applicable) should be indicated on the request form.

SUBMISSION OF SPECIMEN(S)

- Collect all fine needle aspirate (FNA) specimen(s) directly into 30 ml of Cytolyte Solution and mix. Label the Cytolyte container with patient's full name/full social security number and send to the Histology section of the Laboratory.

- The FNA specimen(s) will be sent to Cytology Department of VAMC Pittsburgh for processing and interpretation.

VA Medical Center, Erie, Pennsylvania – Pathology & Laboratory Medicine/Cytology

CRITERIA FOR UNACCEPTABLE/UNSATISFACTORY CYTOLOGY SPECIMENS

SPECIMEN ADEQUACY

The general criteria for adequacy of cytology specimens include:

- Positive identification and labeling of specimens.
- Proper fixation
- Provision of demographic and relevant clinical information

The specific criteria for adequacy of non-gynecological and gynecological specimens are as follows:

- *Non-gynecological Specimen Adequacy*:

  For most non-gynecological specimens, certain cell types should be present in sufficient numbers to be considered adequate for evaluation. For example, sputum specimens should contain alveolar macrophages. Washings and lavage of certain body sites (bladder, bronchoalveolar) should contain at least minimal numbers of cells representative of those sites. In contrast, normal cerebrospinal fluids have very few cells, so scantly cellular spinal fluid should not be labeled as unsatisfactory. For fine needle aspiration biopsy (FNA) specimens, it is critical not to label unsatisfactory or non-diagnostic specimens as “negative”. A distinction should be made between specimens rejected prior to processing and those that are rejected after processing and review (unsatisfactory or inadequate for evaluation).

- *Gynecological Specimen Adequacy:*

  ♦The smears should contain adequate number of well-preserved and visualized squamous cells.
  ♦In females with cervix at least ten (10) well preserved endocervical or squamous metaplastic cells should be observed to report that a transformation zone component is present. When there is partial or complete atrophy, it may be difficult to determine the presence of a transformation zone component. Parabasal cells should not be counted as transformation zone components, and it should be mentioned in the comments regarding the difficulty in identifying a transformation zone component.

CYTOLOGY SPECIMEN UNACCEPTABLE/UNSATISFACTORY CRITERIA/HANDLING

- The cytology specimens will <u>not</u> be processed by Histology Section of the Laboratory unless any identified problems are corrected. The Histology Section of the Laboratory may process suboptimal test requests/specimens after appropriate corrective action has been taken and documented.

- The technologist is responsible for identifying all incidents of unsatisfactory/unacceptable test requests/specimens, taking appropriate corrective action before processing and documenting on “Specimen Rejection Log” worksheet. The Supervisor, P&LM/Pathologist will review incidents of problems identified and appropriateness of corrective action on a monthly basis.

VIII. AUTOPSY

- Autopsy Service
- Request Form/Autopsy Permit
- Performance of Autopsy Examination
- Post-Mortem Reports
  Provisional Anatomic Diagnosis for Post-Mortem Examination
  Final Post-Mortem Examination Report
  Turnaround Time of Post-Mortem Reports
- Autopsy Quality Assurance: MCM 115-06
  Correlation of Pre-Mortem and Post-Mortem Diagnoses

AUTOPSY SERVICE

A. **LOCATION:** MORGUE (E1-14), first floor, behind Clinical Laboratory.

B. REQUEST FORMS:

1. Standard Form 523
2. Autopsy History Form 1-20 (5243)

C. AUTOPSY PERMIT

1. The Member Services/Processing Team aids in the administrative and clinical aspects of the autopsy permission.

2. A legal autopsy permit, Standard Form 523, can be given by the following individuals:

   a. By written authorization signed by the deceased during lifetime.
   b. By written authorization of any party whom the deceased during lifetime designated by written instruction to take charge of his body for burial and the written consent of decedent's surviving spouse, if any, after death.
   c. By written authorization of the decedent's surviving spouse.
   d. If the surviving spouse is incompetent, unavailable or does not claim the body for burial, of if there is no surviving spouse, by written authorization of the following in order of precedence if the claimant agrees to provide burial (I) adult children, (II) adult grandchildren, (III) parents, (IV) brothers or sisters, (V) nephews or nieces, (VI) grandparents, (VII) uncles or aunts, (VIII) cousins, (IX) stepchildren, (X) relatives or next of kin of previously deceased spouse.
   e. If none of the above persons are available to claim the body, by written authorization of any other relative or friend who assumes custody of the body for burial.
   f. If there is no known living kin, or no one falling within the established order or precedence for claiming the body, the Director is authorized to sign for an autopsy.
   g. Autopsy may be performed on (1) patients who die outside of a VA facility while in a follow-up status after hospitalization, (2) outpatients who had been assigned solely for research purpose or who made visits solely for research purpose.

3. Authorization may be given by telegram or by telephone if the telegram or telephone authorization is certified by two persons present when it was received. When telephone consent is grant to perform an "autopsy", this is to be interpreted as permission for a "complete autopsy", including removal of the brain, permission should be considered "limited" only when expressly stated.

4. In cases where the legality of the permission is in doubt, the Medical Director, Pathology & Laboratory Medicine, will assist the clinician and Member Services in determining the legality of a permission.

D. INCLUSIVENESS OF PERMIT

1. Permission includes examination of the brain and spinal cord. Specific permission is needed for examination of unusual areas, as dismembering a limb. For exclusion of areas such as the brain, a notation of the limitation must appear on the consent form.

E. PROCEDURE

1. If the next-of-kin is available, the authorization is signed and witnessed on the unit. If not, Member Services will aid in securing a telephonic or telegraphic permission. The Laboratory will not perform an autopsy with a telephonic permission unless the words "autopsy" or "postmortem" are used in the request for the necropsy.

2. When the autopsy permission has been secured, please call:
   a. The Laboratory (8AM-3:30PM, Monday through Friday).
   b. The telephone operator (on Saturday, Sunday and legal holidays).

3. Please send the chart, autopsy permission and completed clinical history form to the Laboratory (8AM-4:30PM, Monday through Friday). At other times, please send these documents to the telephone operator's area (1st floor).

4. Please consult with the Pathology Department before giving the family an estimate as to when the body can be released to the undertaker.

5. In cases when the patient's record and a valid permit reach the Laboratory after 3:30PM and before 8:00AM, the autopsy will be delayed until 10:00AM. Special arrangements can be made with the Medical Director, Pathology & Laboratory Medicine, to have autopsy done at other times.

6. The body will be deposited in the refrigerator of the morgue until its release and the relevant date will be entered in the workbook of the morgue.

7. The release of the body, after performing the autopsy, for the funeral arrangement occurs through Member Services, filling out Form 523A.

F. CORONER'S CASE

1. In Pennsylvania, the Coroner's Office shall investigate deaths in cases of (a) sudden, violent, or suspicious death – including those in which alcohol, drugs or other toxic substances may have had a direct bearing on the outcome, and (b) any death wherein no cause of death is properly certified.

2. In Coroner's cases, the attending physician will call the Coroner's office. The Laboratory is available to render service.

3. Keep in mind that the Coroner's office does not automatically assume jurisdiction. Reportable cases are one category, and those in which jurisdiction is assumed are a second category. In some cases, the Coroner's office may grant permission for the hospital to perform the autopsy, assuming (a) the hospital will perform, and (b) the family permits the autopsy.
4. UNDER NO CIRCUMSTANCE SHOULD AN AUTOPSY PERMISSION BE REQUESTED BY A FAMILY IN A CORONER'S CASE. This is to prevent undue and possibly damaging criticism directed toward the hospital and Coroner's office in the event that the family refused permission and the Coroner's office subsequently finds it necessary to take the body to perform an autopsy. In such a circumstance, a charge could be leveled that the hospital and Coroner's office are functioning in an illicit manner in order to have autopsies performed against the wishes of the family. The Laboratory will attempt, whenever feasible, to have the autopsy performed in this hospital.

5. OFFICE REPORT TO CORONER, Erie County. Please remember that the "Report of Contact", VAF 119, must be completed by the appropriate Program or Member Services.
   a. All sudden deaths not caused by readily recognizable disease; or wherein the cause of death cannot be properly certified by a physician on the basis of prior (recent) medical attendance.
   b. All deaths occurring under suspicious circumstances, including those where alcohol, drugs or other toxic substances may have had a direct bearing on the outcome.
   c. All deaths occurring as a result of violence or trauma, whether apparently homicidal, suicidal or accidental (including those due to mechanical, thermal, chemical, electrical or radiation injury, drowning, cave-ins and subsidences); and regardless of the time elapsing between the time of injury and time of death.
   d. Any fatal death, stillbirth or death of any baby within 24 hours after its birth, where the mother has not been under the care of a physician.
   e. All therapeutic and criminal abortions, regardless of the length of the pregnancy and spontaneous abortions beyond 16 weeks gestation.
   f. All operative and perioperative deaths in which the death is not readily explainable on the basis of prior disease.
   g. Any death wherein the body is unidentified or unclaimed.
   h. Any death where there is uncertainty as to whether or not it should be reported to the Coroner's office.

   The fact that a death occurs within 24 hours following admission to a hospital is not, of itself, reason for its being considered a reportable death unless, in addition, it falls into one of the specific categories herewith defined.

PERFORMANCE OF AUTOPSY EXAMINATIONS

A. <u>GENERAL DIRECTIONS</u>:

1. Before proceeding with the autopsy, the following items should be checked:

   a. Autopsy permit to determine the limitations of the autopsy, proper signing of the permit, Medical Examiner's case or clearance by that office. When there is a question regarding the legality of autopsy authorization, contact MAA.

   b. A complete clinical record and a listing of clinical questions or concerns related to possible autopsy findings should be furnished to the Pathologist prior to the beginning of the autopsy. The Pathologist will review the clinical record carefully for positive radiological and clinical findings, which should be verified by gross and histological examination. The chart will be carefully searched for a record of administration of radioactive materials for therapeutic purposes. Patients who have received radioactive isotopes should be handled under the supervision of the Safety Specialist or person designated by him/her. The clinical information is discussed with the attending physician before conducting the autopsy.

B. <u>AUTOPSY EXAMINATION</u>: The objective of autopsy examination is full exposition of the patient's disease processes, the limits thereof and the patient's response to therapy.

1. There will be positive identification of the deceased by the Pathologist before the procedure is actually begun. Such identification will consist of checking the name and other identifying data attached to the deceased and comparing these with information recorded on SF 523, "Authorization for Autopsy." If there is uncertainty regarding identification, a physician or nurse who knew the deceased during life will make the necessary identification.

2. There will be strict adherence to the family's wishes as recorded on the SF523, "Authorization for Autopsy."

3. The Pathologist will notify the attending physician as soon as possible, as to the time of autopsy and will arrange to demonstrate the gross findings.

4. Embalming prior to autopsy, whether by arterial injection or by intracavitary trocar injection, is prohibited because of the risk of these procedures causing anatomic alterations, making it impossible to determine if these changes preceded embalming. Care must be exercised that there is no undue delay in performing the autopsy, which would inconvenience the family of the decedent.

5. Autopsy examination normally encompasses both gross and microscopic studies and sufficiently detailed protocol. Photographic documentation is an essential component of the autopsy examination and facilities are readily available.

6. Unless the autopsy is a limited one, the brain, all pelvic organs (including testes) and the abdominal organs should be removed and examined. Representative tissue samples not greater than 1 cm in thickness are taken for the stock bottles even though no gross abnormality is seen. Portions of normal and pathologic skeletal muscle, peripheral nerve and bone should also be included in the stock bottle. The latter should include portions of iliac crests, rib and vertebral bodies. The spinal cord and tongue should only be removed when there are specific indications.

7. Non-restricted autopsies should not, as a rule, have incisions other than the routine "Y" and scalp incisions unless special permission is indicated on the autopsy permit. The areas accessible through the routine incisions (parotid, tongue, nasopharynx, etc.) may be examined without special permission and portions of tissues removed providing there is no mutilation of the body.

8. Special examinations should be coordinated with the appropriate funeral directors and VA authorities as indicated. The authorization of removal of organ or tissue for donation will require completion of SF523B, “Authorization for Tissue Donation.”

9. Imprints should be made in known or suspected blood dyscrasias, Hodgkin’s disease, lymphomas and unusual tumors.

10. Cultures (bacteriological, viral and mycotic) should be taken with sterile technique when indicated. Blood cultures from the heart should be taken in all proven and suspected cases of septicemia and bacteremia. Specimens for viral cultures should be kept in the freezer.

11. Cases suspected of having toxicological problems should have adequate material saved. Store the specimen in the freezer.

12. The body will be left in the best possible condition after the autopsy is completed.

POST-MORTEM (AUTOPSY) REPORTS

A. PROVISIONAL ANATOMIC DIAGNOSIS FOR POST-MORTEM EXAMINATION

1. The diagnosis is telephoned to the patient's attending physician promptly after completion of post-mortem examination.

2. A written provisional anatomic diagnosis will be placed in the patient's medical record within 2 working days and a copy will be forwarded to the attending physician.

B. FINAL POST-MORTEM EXAMINATION REPORT

1. Only a qualified licensed Pathologist, board certified in anatomic pathology, will provided a final written diagnosis for gross and microscopic autopsy findings.

2. The following format is used for the post-mortem protocol:

a. Complete Demographic Data:

The demographic data on the face sheet should include the following:

- Name of the institution where autopsy was performed
- Patient's identification (including name, social security number, date of birth, and sex)
- Date and time of death
- Extent of autopsy
- Final autopsy completion date

b. Clinical Diagnosis:

This includes in a list form all important clinical states, process, diagnosis, and treatments.

c. Gross and Microscopic Findings:

- The gross findings are recorded as soon as possible after the post-mortem examination is completed.

- The extent of description of microscopic description varies with each autopsy. The findings generally include a record of the organs and tissues examined histologically. A record of the source of slides in relation to lesions or abnormalities as described grossly is important.

- Special Studies: The results of any special slides such as microbiologic, toxicologic, or other analysis are included in the protocol.

d. Clinical Summary and Clinico-pathologic Correlation:

•A brief clinical history generally includes patient's established medical conditions and diagnosis, risk factors, pertinent to the disease process identified, hospitalizations, surgical operations, medications, and pertinent Laboratory data.

•The Clinic-pathological summary correlates the clinical findings with gross and microscopic findings to describe and elucidate the sequence of events leading to death. The underlying cause or causes and immediate cause of death is discussed. The summary is intended to address clinical problems and questions faced by the attending physicians and to clarify quality improvement matters.

e. Final Post-Mortem Diagnosis (including neuropathologic findings if brain was removed):

•The final diagnosis should include findings in chronological order and importance with respect to the main disease process. Miscellaneous findings need not be given in special order. If chemotherapy or radiation therapy has been given, it should be indicated. In malignant tumors, the distribution of disease should be included. The reports of cultures on other studies should also be included.

•Final post-mortem examination diagnoses must be coded by employing a recognized system of coding, e.g. Systematized Nomenclature of Medicine (SNOMED) or Systematized Nomenclature of Pathology (SNOP) for retrieving diagnostic information as needed.

f. Letter to Next of Kin: Draft of lay letter to next of kin by Medical Administration if copy of autopsy is requested by family.

C. TURNAROUND TIME OF POST-MORTEM (AUTOPSY) REPORTS

1. The post-mortem examination (autopsy) reports will be made a part of the patient's medical record within 30 working days for routine cases. The cases requiring special studies will have a longer turnaround time.

2. A copy of the report will be retained in the Pathology & Laboratory Medicine.

D. AUTOPSIES WITH POSSIBILITY OF A CLAIM

1. The Medical Director, Pathology & Laboratory Medicine will provide the Chief of Staff with a copy of the post-mortem examination report in any case in which the post-mortem examination findings raise the possibility of a claim against the VA.

2. Post-mortem examination findings may be disclosed in accordance with the limited disclosure provisions of 38 U.S.C. Section 5705. In any case where there is the slightest indication of potential claim, no action will be taken to release information without first consulting with District Counsel. NOTE: Disclosure is limited by confidentiality statutes.

E. CONFIDENTIAL TREATMENT OF POST-MORTEM EXAMINATION RECORDS

1. If tissues or records are to be sent from VA for examination in non-VA laboratories or be investigators, such persons can be given access to such items only within the restrictions imposed by laws governing the disclosure of information, e.g., the Privacy Act of 1974, 38 U.S.C., Sections 5701, 5705, and 7332.

2. Some of these statutes address the disclosure of information about patients in an individual identifiable format. If the examiner requires that the slides and records contain veterans' name or other confidential information, there must be a prior written agreement that the:

3. Recipient of the slides and records will not re-disclose any information in an identifiable form without prior specific VA authorization;

4. Information will be safeguarded from disclosure. NOTE: VHA Records Control Schedule (RCS) 10-1, provides disposition instructions for agency records. Conversion of temporary paper records to laser disc storage and disposal of the paper record do not require the National Archives and Records Administration's approval; and

5. The slides and records will be returned to the VA when there is no longer a need for the recipient to retain them in order to accomplish the purpose for which they were originally supplied.

6. To the extent that any of the records discussed in this chapter are medical quality assurance records subject to 38 U.S.C. 5705 and 38 CFR Sections 17.500 through 17.540, they may be disclosed only in accordance with the statute.

7. When it is necessary to release records or slides in a manner other than that defined, the District Counsel should be consulted prior to the release.