D.23 LABORATORY POLICY AND PROCEDURES

I. PURPOSE:

To establish policies, procedures and requirements for ordering patient tests, collecting specimens, performing tests, and reporting results in accordance with regulatory agencies.

II. RESPONSIBILITY:

The Lead Pathologist, Pathology & Laboratory Medicine, or designee is responsible for the implementation of these policies and procedures.

III. PROCEDURES

A. Test Requests

1. Laboratory tests may be ordered by appropriately credentialed physicians and healthcare providers.

2. All test requests should be made electronically using the Computerized Patient Record System (CPRS). A pathologist or designee reviews requests for send-out tests (i.e. those not performed on site) for appropriateness and selection of a reference laboratory. Send-out tests may require special forms available in the chemistry section of the laboratory.

3. If a test cannot be ordered electronically (e.g. CPRS is not accessible) a written request form is used. A separate form is used for each test and must contain the following information:
   - Patient name
   - Social security number
   - Date and time specimen was obtained (*not* the time requested)
   - Ward or location of the patient
   - Name of requesting physician
   - Type and source of the specimen
   - Legible test request (not abbreviated)
   - If applicable, pertinent history, physician findings, and medication information.

4. Add-on Tests

   a. Additional tests may be added to specimens already in the laboratory.

   b. The physician or designee must call the appropriate laboratory section to determine if an acceptable specimen is available.

   c. If an acceptable specimen is available, the laboratory will instruct the ward/clinic to place a new laboratory order via CPRS. Testing will proceed on the original sample using the original date/time of collection.

   d. If there is not a suitable sample available for the add-on tests, a new specimen must be obtained with the appropriate order(s) entered via CPRS.

5. Tests may be ordered as routine or stat.

6. Critical tests at the Stratton VAMC facility have been defined as frozen sections.

7. Stat Testing

   a. Stat test availability and turnaround times are defined (STAT Test List and Turnaround Time).

   b. Stat requests must be designated as such when ordered.

   c. Changing the stat designation after the specimen is sent to the laboratory requires the physician or his designee to call the appropriate laboratory section to expedite these results.

   d. Ordering a test not on the approved list as stat requires a sound medical reason. The physician or his designee must contact the laboratory department supervisor during regular working hours, or the pathologist on call during evenings and weekends for approval.

8. Medical Emergency

   a. This designation should be limited to those medical situations where a life threatening condition exists.

   b. A “Medical Emergency” sticker (black characters on a yellow background) is available at all nursing stations for accurate specimen identification. Specimens bearing this sticker must be immediately hand delivered to the appropriate laboratory section and presented to a staff person. These specimens will be processed immediately.

   c. To expedite the turnaround time to ≤ 30 minutes, specimens for a comprehensive metabolic panel (CMP) or potassium (K^+) must be submitted in a heparinized green top tube

   d. The blood bank medical emergency protocol is specified in Memorandum DT-113-01.

9. Routine testing:
   a. A laboratory test is an examination, diagnostic, or monitoring procedure on a human specimen removed from the body to determine specific information for diagnosis, treatment, or prevention of disease, and to detect the impairment of health status, or to assess the health of human beings.

   b. It is VHA policy that all test results must be communicated by the diagnostic provider to the ordering provider, or designee, within a time-frame that allows for prompt atten tion and appropriate action to be taken. All test results requiring action must be communicated by the ordering provider, or designee, to patients no later than 7 calendar days from the date on which the results are available. For test results that require no action, results must be communicated by the ordering provider, or designee, to patients no later than 14 calendar days from the date on which the results are available. Depending on the clinical context, certain test results may require review

and communication in shorter time-frames (see definitions paragraph related to abnormal and normal results). All VA medical facilities are expected to put into place appropriate systems and processes to ensure timeliness of appropriate communication and follow-up of test results.

c. Most routine testing is performed within 60 minutes of receiving into the laboratory service. Most in-house testing not batched are performed within 24 hours of receiving. Other non routine testing may be batched once a week and send out testing can take up to 14 days for resulting.
Laboratory Service Manual

d. Delays in reporting will be documented as such and followed up as needed; following our downtime protocol.

Specimen Collection

1. Patient Identification
   a. In-patients:

      All in-patients are identified by a wristband. In-patient specimens will not be obtained from a patient without appropriate identification. The name and social security number on the order and wristband must agree. The phlebotomist may ask a competent patient to state his/her name and social security number for identification purposes and check it against the test order.

   b. Out-patients:

      All outpatients must present a VA ID card. The phlebotomist must ask the patient to state his/her name and social security number for identification purposes and check it against the test order.

2. Specimen Identification

   a. Except for blood bank orders, all specimens must be labeled *at the bedside* with an electronically generated label containing the following information:
      - Patient name
      - Social security number
      - Type and source of specimen (if applicable)
      - Location
      - Test name
      - Date and time collected
      - Order number

   b. All blood bank specimens (e.g. crossmatch, type and screen) must be hand labeled with patient's full name, complete social security number, date and time of draw, and full signature of the phlebotomist. An electronic order label is ***not*** acceptable.

3. Phlebotomy Service and Personnel Qualifications

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a. Phlebotomy is under the supervision of the MVAC care line.

b. Allied health personnel, registered nurses (RNs) and practical nurses (LPNs) that have been appropriately trained and credentialed in proper techniques are qualified to draw blood specimens. Phlebotomy services through the nursing phlebotomy team are available as follows:

1) In-Patients: Routine rounds at 6:00 a.m., 10:00 a.m. and 1:00 p.m., Mon.-Sat. For requests outside of routine rounds, call x66566.

2) Out-Patients: 7:00 a.m. to 4:30 p.m., Mon. - Fri.
The draw station is located on the 5th floor, core section.

c. Only physicians, RNs, and phlebotomists who are trained in proper collection procedures and have a documented signature in the blood bank can draw blood bank specimens.

4. Tube Selection and Specimen Handling:

a. This information is available on-line in the test description file, as well as in the test description section of the laboratory manual.

b. Types of tubes commonly used:

Stopper Color	Additive	Usage	Directions
Red	None (for serum collection)	Therapeutic drugs & specialized tests requiring Serum	*Do not mix*. Allow specimen to clot for 10 minutes at room temperature before centrifuging.
Lavender (purple) 3.0 mL/7.0 mL	K_3 EDTA 5.5 mg K_3 EDTA 12.15 mg	CBC Fluids for cell counts	Mix gently by inverting 5 times immediately after draw.
Green 10 mL	Na Heparin (143 usp unit)	Specialized tests	Mix gently by inverting 5 times immediately after draw.
Blue 2.7 mL/4.5 mL	Sodium citrate (3.2% 0.5ml)	Most coagulation tests	Mix gently by inverting 5 times immediately after draw.
Gray	Potassium oxalate and sodium fluoride	Some glucose determinations	Mix gently by inverting 5 times immediately after draw.
Red/Gray Gold	Clot activator and inert barrier material	Most tests in clinical chemistry; serology tests	Mix gently by inverting 5 times immediately after draw. Allow blood to clot for 30 minutes before centrifuging.
Yellow	1.5 ml of ACD	HLA, flow cytometry	Mix gently by inverting 5

	(adenine, dextrose, citrate, phosphate)	(improves cell survival)	times immediately after draw.
White	EDTA and inert barrier material	Molecular tests, i.e. HCV & HIV viral load; HCV genotyping	Mix gently by inverting 5 times immediately after draw
Pink	EDTA	Blood Bank	Hand labeled

c. All specimens are handled following hospital safety guidelines.

d. The individual collecting a specimen is responsible to ensure it is delivered to the laboratory in a safe and timely fashion.

B. Specimen Submission

1. Specimens are delivered to the laboratory as soon as possible. If there is a delay, specimens must be stored appropriately (refer to instructions under test information in the computer).

2. During normal working hours (8 a.m. to 6 p.m., Mon.-Fri.) specimens are delivered to the central accession area in the laboratory (2nd Floor B wing). On weekends, holidays, and off hours (6 p.m. to 8 a.m.) specimens are delivered personally to the technologist on duty in the laboratory.

3. When applicable, appropriate clinical history should be included in the submission.

4. Submission of fluid specimens (other than blood)

a. Hematology Fluids:

1) CSF: Collect in a red top tube or a black screw cap tube.

2) Fluids other than CSF: Use purple or green top tubes (to prevent clotting).

b. Crystal Analysis (synovial fluid): Use a red or green top tube.

c. Cytology Fluids:

1) Do ***not*** add fixative

2) May require a green top tube (heparinized) to prevent clotting

3) If unable to immediately bring specimen to cytology, refrigerate specimen.

d. Chemistry Fluids:

1) Glucose, protein, magnesium: Use a red top tube or a black screw cap tube.

2) pH: Collect anaerobically in a syringe, needle removed, properly capped, and labeled. Send syringe on ice to the chemistry lab, room 201-B1. If the specimen is not collected as described, the specimen may be rejected.

e. Microbiology; sterile fluids for:

1) Gram stain, C&S, anaerobic, AFB, fungus: Submit in an appropriately labeled sterile container (sterile specimen cup or red top vacutainer tube).

2) Cryptococcal antigen on CSF must be specifically requested.

3) Bone marrow for bacteria or fungi: Hematology must be notified of these special requests before the bone marrow sample is obtained. Directly inoculate into a Bactec Aerobic bottle (blue cap) for routine culture or Bactec Myco/Flytic bottle (red cap) for AFB and fungus. A smear should also be prepared and sent to microbiology.

C. Specimen Acceptability and Rejection Criteria

The laboratory determines the acceptability of any specimen upon receipt.

1. Unlabeled, mislabeled or inadequately labeled specimens:

   a. These are unacceptable.

   b. Requested test(s) will generally not be performed.

   c. For difficult to obtain specimens (e.g., spinal fluid, sterile body fluids, tissue, etc.) the person who obtained the specimen will be required to come to the laboratory to label the specimen and sign a release form (Laboratory Release Form for Unlabeled Specimens or Laboratory Release Form for Irreplaceable Specimens).

2. Specimens lacking properly completed request forms or electronic order numbers will not be tested until the proper request is received.

3. A specimen may be considered unsuitable for the following reasons:
   - It is not transported within an appropriate time frame.
   - Quantity is insufficient for the requested tests.
   - The ratio of blood to anticoagulant in the tube is incorrect.
   - An anticoagulated specimen is clotted (e.g. CBC, PT).
   - It has leaked, thereby altering the sterility, volume, or concentration.
   - Hemolysis.
   - It has been submitted in a syringe *with an attached needle*.
   - Sputum contaminated with oral secretions.
   - Not transported on ice (e.g. viral cultures, ammonia)
   - Anaerobe cultures not transported in anaerobe transport media.

4. If testing is required on a questionable specimen (e.g. by MD request), a notation will accompany the report stating that results may be unreliable.

5. The laboratory notifies the originating ward/clinic of unacceptable specimen(s) with the reason(s) for rejection, and requests re-collection. This information is documented electronically, to include the date, time and individual notified.

6. Mislabeled specimens will be reported to the Quality Assurance coordinator for further investigation and error tracking. Appropriate laboratory sections will be notified (Notice of CQI Issue form)

D. Results Reporting

1. Laboratory reports include the patient name, complete social security number, and time of specimen collection.

2. All in-house test results, including STAT requests, are entered and verified electronically upon completion by a qualified laboratorian before release.

3. All reference laboratory test results are entered in the computer when they are received. The lab performing the test and its reference ranges are entered in the comment section.

4. All abnormal numeric results are automatically forwarded to the provider through VistA/CPRS with “View Alerts”

5. Critical results and significant non-numeric results are handled as specified in section F below.

6. All critical tests are phoned to the ordering physician, regardless of result. Critical tests are defined in section 3.A.6.

7. Cumulative reports for in-patients are available electronically and are printed as needed.

E. Results Reporting for Critical Values and Significant Non-Numeric Results

Critical values are defined by the Medical Director in consultation with providers (Critical Values). Critical results and significant non-numeric results (e.g. microbiology) are called to the appropriate clinical personnel. A read-back of all phoned critical results is required. Documentation is entered electronically in VistA and includes the time, date, test, location, caller, and person who received the call. Once resulted into CPRS, critical results will generate a “View Alert” for the provider. All critical result calls are reviewed daily by laboratory supervisors. Evidence of notification of critical results is maintained by the laboratory staff and monitored for process improvement.

Specific reporting procedures are specified in the laboratory Critical Results Procedure

F. Turnaround Time & Notification

1. Turnaround times of STAT tests are defined in STAT Test List and Turnaround Time.

2. Routine testing is performed daily.

3. Certain chemistry and serology tests are batched. Testing days are specified in the laboratory manual and in the computer.

4. Tests sent to reference laboratories generally have a 1-2 week turnaround time.

5. If a significant delay is anticipated due to instrument or personnel problems:

    a. The providers awaiting test results will be notified.

    b. Wards that will be immediately impacted will be notified.

    c. In instances where the computer system is down, STAT results and critical values will be called to the wards and clinics.

IV. REFERENCES:

- CAP Commission on Laboratory Accreditation Inspection Checklist: Laboratory General.
- The Joint Commission Comprehensive Accreditation Manual for Pathology and Clinical Laboratory Series
- VHA Handbook, 1106.1