VA PUGET SOUND HEALTH CARE SYSTEM Pathology & Laboratory Medicine Service Seattle & American Lake Divisions	Document ID: PC00005
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	SECTION: POC

TITLE: URINALYSIS USING ROCHE CHEMSTRIP 5OB REAGENT STRIPS

PRINCIPLE:

1. **Clinical Relevance**
   a. Chemstrip urine test strips are multi-parameter test strips which measure certain constituents in the urine. These measurements are useful in the evaluation of renal, urinary, and metabolic disorders.
2. **Test Methodology**
   a. Chemstrip 5 OB Urine Test Strips are inert plastic strips to which are attached different reagent pads for determining pH, indication of leukocytes, nitrite, protein, glucose, and blood and hemoglobin in urine. A brief discussion of each test principle follows:
   - Appearance (Color and Clarity): Urine is generally yellow due to the pigment urochrome, small amounts of uroerythrin, and urobilin. The variety of color is due to wide variation in urinary concentration.
   - Leukocytes: Granulocytic leukocytes contain esterases that catalyze the hydrolysis of an indoxylcarbonic acid ester to indoxyl. The indoxyl formed reacts with a diazonium salt to produce a purple color.
   - Nitrite: Nitrite, if present, reacts with an aromatic amine to give a diazonium salt, which couples with sulfanilamide to yield a red-violet azo dye.
   - Protein: The detection of protein is based on the so-called “protein error of indicators.” The indicator used in this test is 3’,3’’,5’,5’’-tetrachlorophenol-3,4,5,6-tetrabromosulfo-phthalein. A positive reaction is indicated by a color change from yellow to light green/green.
   - Glucose: Glucose detection is based on the enzymatic glucose oxidase/peroxidase (GOD/POD) method. The reaction utilizes the enzyme glucose oxidase to catalyze the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. In turn, a second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with the chromogen tetramethylbenzidine to form a green dye complex. A positive reaction is indicated by a color change from yellow to green.
   - Blood/Hemoglobin: The chemical detection of blood is based on the strong pseudoperoxidase action of erythrocytes and hemoglobin. Hemoglobin and myoglobin, if present, catalyze the oxidation of the indicator by the organic peroxide contained in the test pad. Intact erythrocytes hemolyze on the test pad, and the liberated hemoglobin produces a green dot. Since the test pad absorbs several µL of urine, more erythrocytes become visible than would correspond to 1 µL. Separate sets of color blocks are given for erythrocyte and hemoglobin. Scattered or compacted green dots on the yellow test pad are indicative of intact erythrocytes. A uniform green coloration of the test is indicative of free hemoglobin, myoglobin, or hemolyzed erythrocytes in the urine
3. **Policy**
   a. Only individuals with proper training and certification are permitted to perform this procedure.
   b. The Ancillary Testing / Point-of-Care Program will perform initial training.
   c. Once staff are approved in this urinalysis procedure, all staff will be re-evaluated within 6 months and annually thereafter to assure their competency and technique.
   d. Staff assessments will be conducted when there is a change in procedure or when a problem is noted.
   e. The procedures described herein are mandatory for all personnel performing Point of Care urinalysig testing for patient treatment.

f. Quality Control must be documented onto manual log sheets (Appendix A) or into the Accuchek Inform Meter (Appendix C.) Patient results must be documented in the patient's record.

SPECIMEN COLLECTION:

1. Specimen Requirements:

a. Acceptable specimen:
   i. Chemstrip urine test strips may be used on any freshly voided urine specimen or on urines collected under special conditions, such as first-morning specimens and post-prandial urine
   ii. A fresh, clean voided midstream or catheterized specimen is required.
   iii. The urine must be collected in a clean container and should be tested within one hour after collection (do not centrifuge or use preservatives.)
   iv. The specimen container must be labeled if testing is performed at a site removed from the patient bedside (i.e. unit Soiled Utility Room.)
   v. The specimen must be labeled with the patient's full first and last name, AND
   vi. the patient's full Social Security Number.
   vii. Additional useful information includes the date and time of collection, initials of the collector, and the type of specimen (i.e. midstream or catheterized urine.)
   viii. Mix urine thoroughly before testing
   ix. If cleanly voided urine is not collected, a positive test result for leukocytes or blood may be due to a source of leukocytes or blood external to the renal-urinary system.
   x. Specimens not meeting these requirements are not to be processed, and a new specimen should be obtained.
   xi. Volume requirements:
      1. Urine should be aliquotted into a test tube which allows complete immersion of the reagent pads on the test strip. A minimum volume of 10 mL is preferred.

b. Patient Preparation:
   i. Patient testing can proceed ONLY if all quality control has been completed and results are within acceptable limits.
   ii. First morning specimens are usually more concentrated, with an acid pH, and are the specimens of choice for routine examination on bedridden patients.
   iii. Specimens collected two hours after a meal are more likely to contain protein.

c. Specimen Collection:
   i. Instruct the patient in proper collection procedures.
   ii. Provide written instructions and pre-labeled collection cup, etc. if needed. Written instructions must also be posted in the restroom.
   iii. Accurate testing depends upon collecting the specimen in a manner that avoids contaminating the specimen with foreign substance
   iv. For chemical analysis the urine should be examined within one hour after collection (do not centrifuge or use preservatives.) Specimens should be refrigerated if more than a 15 minute delay is unavoidable.
   v. First morning specimens are usually more concentrated, with an acid pH and are the specimens of choice for routine examination on bedridden patients. Specimens collected two hours after a meal are more likely to contain protein or reducing substances but they also tend to be alkaline pH.
   vi. Clean-voided, midstream specimens from the male patient usually present no problems and are obtained after thoroughly cleaning the glans penis and collecting a representative sample after the first portion of urine has been discarded.
   vii. For female patients, cleansing of the external genitalia involves spreading of the labia, cleaning the urethral area with a mild antiseptic, and thoroughly rinsing with

distilled water. The patient should void over a bedpan or toilet bowl. After the initial portion of urine is discarded, the stream is intercepted with a clean wide-mouth container and a specimen is collected.

viii. Urine volume should allow for complete immersion of the reagent pads on the test strip.If cleanly voided urine is not collected, a positive test result for leukocytes or blood may be due to a source of leukocytes or blood external to the renal-urinary system.

d. Causes for Specimen Rejection:

i. Acceptable specimens must meet requirements for collection, storage, and labeling.

REAGENTS:

1. **Bio-Rad qUAntify® Control Levels 1 and 2** (See references for contact information.)
   a. Unopened product is stable up to the expiration date printed on the label when kept at 2º to 8ºC and used as directed.
   b. Do not freeze.
   c. After opening and initial use, the product is stable for 31 days when stored at room temperature, 18º to 30ºC.
   d. Discard if turbid or any evidence of microbial contamination is present.
   e. Handle as potentially infectious.
2. **Chemstrip OB 5 urine test strips:**
   a. The urine test strips are sensitive to humidity and should be stored in the original container at room temperature (under 30ºC.) Do not freeze.
   b. Stable in the original capped vial until the listed expiration date.
   c. The vial must be closed immediately after removal of a strip, using the original stopper
   d. A visual comparison color scale for reading test results is printed on the vial label.
3. **Supplies:**
   a. Collection container:
      i. Collect the urine specimen in a commercially prepared, sterile urine container.
      ii. Other ***clean*** containers are acceptable for urine dipstick testing only, not for urine culture specimens.
   b. Timer
   c. Gauze (absorbent material).
   d. Lamp (magnifying).
   e. Personal Protective Equipment (PPE) – gloves, gowns, etc. as needed.
      i. All operators MUST comply with the OSHA Standard on occupational exposure to blood borne pathogens and the VA Puget Sound's exposure control plan. All health care workers must routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with blood or body fluid is anticipated.

EQUIPMENT:

1. **Accu-Chek Inform II Glucose Meter**
   a. For lab entry into patients electronic medical record
   b. See "Other Lab Entry" Procedure for details
2. **Maintenance**
   a. Preventative maintenance of the Accu-chek Inform meter is performed on a schedule which is based on the manufacturer's recommendations, regulatory requirements, accreditation standards, and internal requirements.
   b. Exterior: Maintenance will be performed as needed and consists of cleaning the exterior surface of the Accu-chek Inform meter with an Super Sani-Cloth wipe.
   c. Ensure that no cleaning solution gets into or on the connector located at the base of the meter. Ensure that no bleach solution gets into any other electronic port of the meter.

d. Documentation: Document cleaning of the meter by entering the comment "CLEANED THE METER." See Appendix C for instructions.

CALIBRATION: N/A

QUALITY CONTROL:

1. **Quality Control (QC)**
    a. Storage and Preparation of Quality Control Materials
        - Aqueous Controls:
            1. Bio-Rad qUAntify, Levels 1 and 2 Assayed Liquid QC Material:
                a. Used to monitor the performance of Chemstrip 5 OB urine test strips.
                    i. After opening and intial use, the product is stable for 31 days when stored tightly capped at room temperature, 2º - 25ºC
                    ii. Use before the expiration date on the label.
                    iii. Date opened, date expired, and initials must be legibly indicated on the bottle using indelible ink.
                    iv. Protect from temperature greater than 30ºC. Do not freeze.
                    v. If the product has been refrigerated, warm one vial of each level of control to room temperature (18º to 25ºC) for 15 to 30 minutes.
            2. Bio-Rad qUAntify®, levels 1 and 2 assayed liquid QC Material:
                a. Used to monitor the performance of Chemstrip 5 OB urine test strips.
                    i. After opening and initial use, the product is stable for 31 days when stored tightly capped at room temperature, 2º - 25ºC.
                    ii. Use before the expiration date on the label.
                    iii. Date opened, date expired, and initials must be legibly indicated on the bottle using indelible ink.
                    iv. Protect from temperature greater than 30ºC. Do not freeze.
                    v. If the product has been refrigerated, warm one vial of each level of control to room temperature (18º to 25ºC) for 15 to 30 minutes.

2. **Quality Assurance (QA)**
    a. The Quality Assurance log must be initialed each day of patient testing
    b. The Quality Assurance log must be marked with a "slash" (/) each day that testing is **not** performed.
3. **Proficiency Testing**:
    a. Proficiency Testing is available from the College of American Pathologists and will be:
        i. performed *three (3)* times per year and
        ii. rotated among all operators.
4. **QC Frequency**
    a. Daily Liquid Quality Control:
        i. Quality Control (QC) must be performed, and results must be acceptable each day of patient testing.
        ii. Quality Control results must be entered into the Accuchek Inform meter (instructions in Appendix C) and downloaded promptly or entered into the manual log (blank form in Appendix A.)

iii. A minimum of two levels of the **Bio-Rad qUAntify** (Levels 1 and 2) will be tested each day of patient testing to evaluate the quality of day-to-day test performance.

1. QC is also performed when a new vial and/or number of dipsticks is opened.

5. **QC Procedure**
   - **a.** Ensure that controls are at room temperature. DATE AND INITIAL WHEN OPENING A NEW BOTTLE. INDICATE DATE OPENED AND DATE EXPIRED.
   - **b.** To mix, invert and gently swirl each bottle before removing cap
   - **c.** Inoculate all reagent pads of the urine test strip. Do not touch tip of control bottle to strip.
   - **d.** Turn the test strip on its side and drain excess control onto absorbent material.
   - **e.** Read all test pads at one minute. Hold the strip close to color blocks and match carefully, ensuring that the strip is properly oriented to the color chart on the vial label. If the leukocytes pad indicates a trace result, it should be read again at 2 minutes.
   - **f.** Color changes that occur after 2 minutes are not of clinical value. Color changes that occur only along the edge of the test pad should be ignored. Careful removal of excess urine (step d.) should eliminate this effect.
   - **g.** Record the results into the Accuchek Inform Other Test Entry Urine database (instructions in Appendix C) or on the QC Log Sheet (blank form in Appendix A.)
   - **h.** Initial the test performed on the QC Log Sheet or enter operator ID into Accuchek Inform database.
   - **i.** Expected values are printed and POSTED at each site for all controls.
   - **j.** Repeat for next QC level.
   - **k.** Patient testing cannot be performed unless acceptable control performance is observed and documented.Indicate with a slash mark (/) on the Quality Control Log Sheet each day that patient testing is not performed, and thus that no QC was performed.
6. **Corrective Action:**
   - **a.** If expected results are not obtained and repetition of the assay excludes errors in technique, the following steps should be taken:
     - **i.** Check the expiration date stamped on the controls and test strips
     - **ii.** Repeat, using a new vial of Chemstrip® 5 OB.
     - **iii.** If control is still out, repeat, using a new vial of Bio-Rad qUAntify Control.
     - **iv.** If control is still out, consult Supervisor and/or Point of Care Coordinators
     - **v.** For further information, contact Roche Diagnostics Technical Service Center, 1.800.428.4674.
   - **b. Do not perform any patient testing until all QC is within control. Send specimens for testing in the Main Clinical Laboratory until all QC is within control at the POC site**
     - **i.** Document in PROBLEM / ACTION LOG.

PROCEDURE:

1. **Procedure**
   - a. Patient testing can only be done if quality control is completed and the results are documented and within acceptable limits.
   - b. Routine Urinalysis:
     - i. Patient testing can only be done if quality control is completed and the results are documented and within acceptable limits.
2. **Routine Urinalysis:**
   - a. Turn on the Accu-chek Inform meter and confirm that that QC was successfully performed and documented for the day.
   - b. Cross check the patient's full name and social security number (SSN) on urine container with name and SSN on provider orders.
   - c. Enter the patient's SSN into the Accu-Chek Inform meter under "Other Patient Tests" option in the meter.
   - d. Mix urine thoroughly before testing.

e. Urine should be collected in a container which allows complete immersion of the reagent pads on the test strip. If cleanly voided urine is not collected, a positive test result for leukocytes of blood may be due to a source of blood or leukocytes external to the renal-urinary system. A fresh, clean voided midstream or catheterized specimen is required.
f. Note and record on the Point of Care Urinalysis slip (Appendix B,) or into the "Other Test' entry option in the Accuchek Inform meter (instructions in Appendix C):
    i. color (light yellow to amber, or other color you observe,) (Appendix D,)and
    ii. clarity (clear, hazy, slightly cloudy, cloudy, turbid.) (Appendix D.
g. Assay urine dipstick:
    i. Decant specimen into a test tube for dipping, this the original container remains contaminant-free.
    ii. Briefly (no longer than 1 second) dip test strip into the urine. Ensure that the chemically impregnated pads on the test strip are totally immersed.
    iii. Draw the edge of the strip alone the rim of the specimen container to remove excess urine.
    iv. Turn the test strip on its side and press against a piece of absorbent paper to remove any remaining urine and to prevent the possible mixing of chemicals.
    v. Hold the strip horizontally close to the color blocks on the strip vial and match carefully, ensuring that the strip is properly oriented to the color chart. Results are obtained by direct visual comparison with the color scale printed on the vial label.
    vi. All test pads should be read at 1 minute. If the Leukocytes pad indicates a trace result, it should be read again at 2 minutes. Color changes that occur after 2 minutes from immersion are not of clinical value. Color changes that occur only along the edge of the test pad should be ignored. Careful removal of excess urine (steps b. and c.) should eliminate this effect.
    vii. Note: Poorly mixed samples may cause inaccurate results.

METHOD RANGE(S):

3. **Result Reporting**
    a. All results must be recorded:
        - In the Accu-Chek Inform II meter under "Other Test Entry" or
        - On a Point of Care Urinalysis result reporting form (see Appendix B) with documentation of date, time and initials of person performing the test. Note: Urinalysis normal ranges are listed on the result reporting form.
        - VISTA/CPRS electronic medical record. Note: Urinalysis normal ranges are included in the electronic medical record
    b. Patient records and results storage must meet VHA privacy rules.
    c. Critical Values: Due to the nature of bedside testing, the results are reported directly to the caregiver. Normally the lab would establish guidelines for critical values and results that fall outside the guidelines would be called to the caregiver and so noted in the computer. The caregiver would in turn notify the clinician. The lab results in Point of Care testing are first examined by the caregiver/clinician so the caregiver/clinician can make the determination as to the results' validity, repeat the tests and/or act on it if necessary.

PROCEDURE NOTE(S):

4. **Procedure Notes**
    a. Urine dipstick testing is intended for use by persons trained in health care delivery and should be used only by authorized personnel.

b. Operator should be trained, tested, and found to be fully competent on the information in this procedure before using the test for diagnostic purposes.
c. Operator should take appropriate precautions when handling potentially infectious urine samples.

4. **Limitations**
   a. Definitive diagnostic or therapeutic decisions should not be based on any single result or results obtained by any individual method. When unexpected or unusual results are obtained, the patient care team may need to further investigate the findings through repeat testing, testing for the same analyte in the main clinical laboratory, using other techniques of patient monitoring, correlation with other clinical findings, or by other means available.
   b. Substances that cause abnormal urine color, such as drugs containing azo dyes, nitrofurantoin, and riboflavin, may affect the readability of the reagent areas of the reagent dipsticks. The color development may be masked, or a color reaction may be produced that could be interpreted visually as a false positive. It is recommended that highly pigmented urine specimens be sent to the main clinical laboratory for testing.
5. **Sources of Error**
   a. Not keeping sample well mixed
   b. Urine specimens that stand for more than 2 hours may have changes in red cell or white cell morphology. Casts also disintegrate on standing. If urea-splitting organisms are present, alkaline urine often results. Glucose is also lost in the presence of microorganisms
   c. Specimens should not be collected in containers that have been cleaned with strong oxidizing agents or when residues of disinfectants containing quaternary ammonium groups or chlorhexidine are present in the urine container.
6. **Competency Testing**
   a. Competency will be assessed:
      - Initially, to include color blindness testing and a written quiz
      - After 6-months (the first year)
      - Annually thereafter
      - As needed for troubleshooting purposes
7. **Division of Responsibility Regarding Oversight**
   a. **The Site Supervisor**
      - Technique is in accordance with standard operating procedure
      - All results are recorded in the patient medical chart via the Accu-Chek Inform II Glucose Meter (results must be retained for a minimum of 2 years)
      - Quality Assurance is performed and documented in accordance with this procedure (Section VI,) and the results are evaluated and acted upon.
      - Corrective action is taken as appropriate
      - Ensures that no tests are performed when QC fails. Send patient tests to the main lab for testing until QC problems are resolved at the POC site.
      - Maintenance is performed in accordance with the procedure
      - Results are reported in accordance with the procedure
      - All testing personnel receive competency assessment and retraining in accordance with the procedure
      - Sevice works effectively with Laboratory Point of Care Program
   b. **The Point of Care Coordinator**
      - The Point of Care Coordiantor is responsible for oversight of the program, reviewing policy, and assuring quality testing
      - Original records are maintained by Site Supervisor where testing is performed. Additional records will be kept with the Point of Care Program.
8. **Employee Identification Number**

a. Each operator of the Accu-Chek Inform II glucose meter must have a unique hospital identification number (DUZ#) which is required to operate the meter and to perform quality control or patient testing.

REFERENCES:

1. Package insert, Chemstrip OB 5, Roche Corporation; 9115 Hague Road, Indianapolis, IN 46256; 2005.

2. Urinalysis Screening Procedure, Point-of-Care / Ancillary Testing Program, VAPSHCS.

3. Package insert, Bio-Rad qUAntify® Control Levels 1 and 2; Bio-Rad Laboratories, Clinical Diagnostics Group, 9500 Jeronimo Road, Irvine, CA 92618; 2006.

4. Modern Urine Chemistry, Miles Inc., Diagnostics Division, Elkhart, IN 46515, 1991.

APPENDICES:

1. Appendix A: Urine Quality Control System Back-Up Temporary Data Log
2. Appendix B: Urinalysis Result Card
3. Appedix C: Other Test Entry Instructions
4. Appendix D: Color and Clarity Chart

Review/Revision History

Date of		Revision Description	Signature (With Printed Name)
Review	Revision		

Appendix A: Urine Quality Control System Back-Up Temporary Data Log

URINE QUALITY CONTROL SYSTEM
BACK-UP TEMPORARY DATA LOG
Chemstrip 5

DATE																												

WRITE IN RESULT VALUES

LEVEL I NORMAL

Glucose																												
Leukocytes																												
Nitrite																												
Protein																												
Bl/Hemo																												

LEVEL 2 ABNORMAL

Glucose																												
Leukocytes																												
Nitrite																												
Protein																												
Bl/Hemo																												
Initials																												

Appendix B: Urinalysis Result Card

UA RESULTS using CHEMSTRIP 5	
Patient Full Name: **Full SS#:**	
Glucose =	**Protein =**
Leukocytes =	**Blood/Hgb =**
Nitrite =	**Test performed by:**
UA Normal Ranges: Glucose: normal Leukocytes: negative Nitrite: negative Protein: Negative Blood/ Hgb: negative	

Appendix C: Other Test Entry Instructions

"Other Test Entry" Instructions

1. Turn Accuchek Inform meter on.
2. Scan Operator Identification using the Scan icon.
3. Press ▶ key.
4. Press Control Test or Patient Test icon.
5. Press Other Control Tests or Other Patient Tests.
6. Press UA.

   Respond to prompts displayed on the meter screen:

   a. Choose Normal UA, Abnormal UA, or Scan to scan Patient Identification.

   b. Enter date, press ▶ key.

   c. Enter time, press ▶ key.

   d. Confirm or enter strip lot number.

   e. Confirm or enter control lot number (for patient testing, omit this step and advance to step "f.")

   f. Select results from pop-up lists on meter screen.

7.. Enter comments:

   a. Press flashing Comments icon.

   b. Select comment(s) from lists.

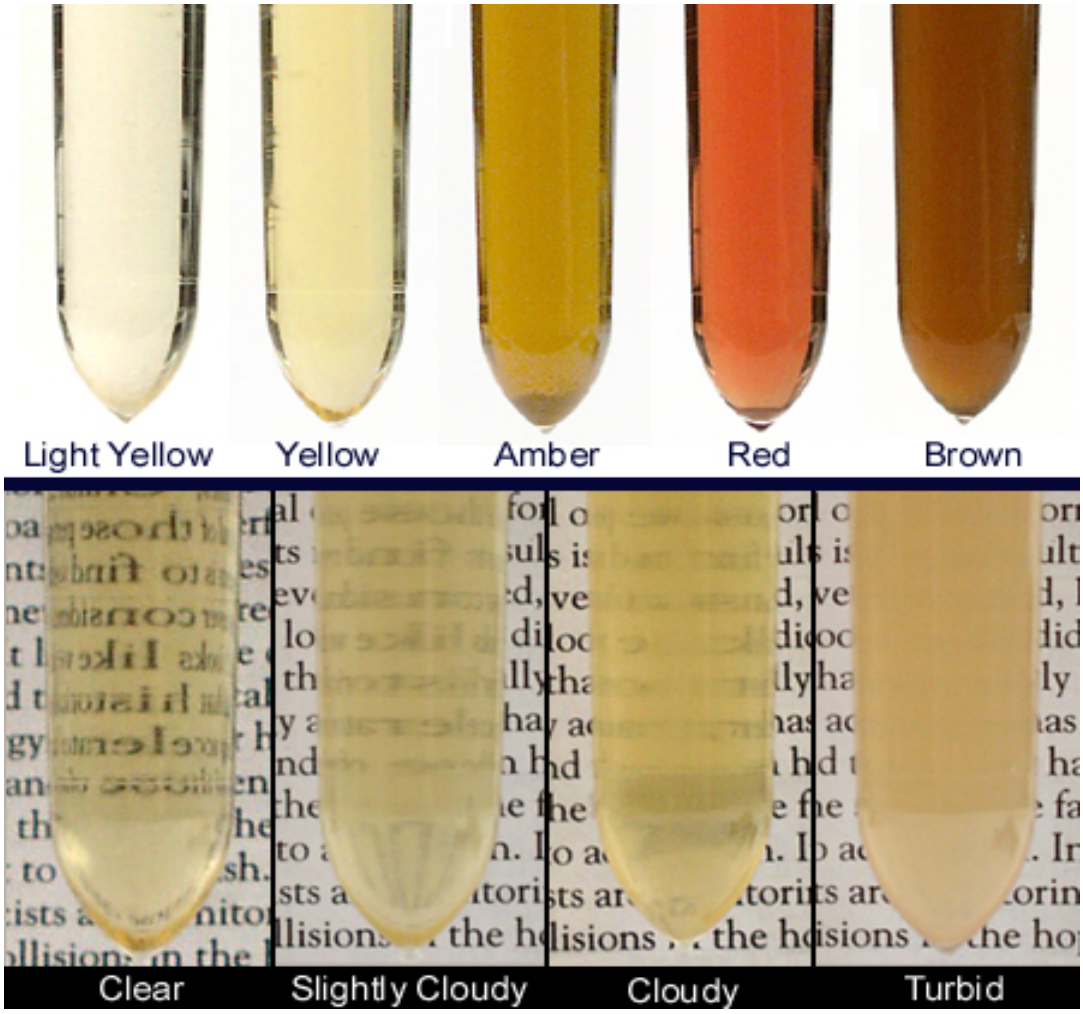
   c. Press ▶ key.

   d. Verify displayed results.

   e. Press ▶ when finished.

8. Place the meter in the base unit.

Appendix D: Color and Clarity Chart.



PLEASE DOCUMENT THE URINE COLOR AND CLARITY:

(when reporting the urine dipstick results)

COLOR:	CAUSE:
Pale/Colorless	Dilute Urine
Amber/Dark Yellow	Concentrated urine, dehydration, fever, Bilirubin, urobilin, pyridium, foodstuffs, carrots, vitamins
Pink/Red	Hematuria, Hemoglobinuria, myoglobinuria, porphyrins, beets, food dyes and drugs
Brown/Yellow-Brown	Bilirubin or Biliverdin
Black	Melanin, homogentistic acid, phenol poisoning, alcaptonuria
Green, Blue, Orange	Drugs, Foodstuffs, indicans, Pseudomonas Infections

Approvals:

Written by: Christina Webster, MT(ASCP) Christina M. Webster
Sharon Norman, MT (ASCP) Sharon Norman
Ancillary / Point-of-Care Coordinators
Date: 2-17-09

Approved by: Roberto F. Nicosia M.D., Ph. D Roberto F Nicosia
Chief Pathology & Laboratory Medicine
Date: 2/17/09

Accepted by: 2/17/09.
Donna Mackenzie 2/19/09

Reviews & Revisions:

Name	Action	Date
Sharon Norman	Reviewed	03/08/2010
Sharon Norman	upgraded & Reviewed ✓	06/22/2010
Sharon Norman (designee)	reviewed ✓	02/22/2011
Sharon Norman	reviewed	02/10/2012
Sharon Norman	Reviewed	2/15/2013

✓ **Note: Annual review dates & signatures of current Laboratory Director or designee will be found in the Point-of-Care program Master copy of the policy and procedure manual (hard copy or electronic) kept on file within the Ancillary Testing Coordinator**