POC-S8102 VISUAL DIPSTICK URINALYSIS AT CBOC

Purpose

In vitro measurement of certain chemical and cellular constituents in the urine are assessed using a dipstick method.

Principle

The Siemens Multistix 10SG urine strip is a multi-parameter test strip that measures bilirubin, urobilinogen, ketones, glucose, protein, blood, pH, nitrites, leukocyte esterase and specific gravity. These measurements are useful in the evaluation or renal, urinary and metabolic disorders.

Bilirubin: The detection of bilirubin is based on the coupling reaction of a diazonium salt with bilirubin in an acid medium. A pinkish-tan color proportional to the bilirubin concentration is produced

Urobilinogen: Urobilinogen is coupled with a stable diazonium salt in a buffer. A pink to red color proportional to urobilinogen is produced.

Ketones: This test is based on the coupling of methylketone with glycine and sodium nitroprusside in alkaline buffer. A violet color proportional to ketone concentration is produced.

Ascorbic Acid: The test is based on the decolonization of Tillman's reagent. The presence of ascorbic acid causes the color of the test pad to change from gray-blue to orange.

Glucose: Glucose detection is based on the enzymatic reaction of glucose with glucose oxidase, peroxidase and a chromogen. The intensity of the green or blue color formed in the reaction is proportional to the concentration of glucose present. Other sugars are not detected.

Protein: The test is based on the "protein error" of the pH indicator on the green color formed in the presence of protein. The reaction is particularly strong for albumin.

Blood: This buffered test contains organic peroxide and a chromogen. The peroxide activity of hemoglobin and myoglobin results in a green color.

pH: This contains a mixed indicator of methyl red and bromthymol blue, which assures a marked change of color between pH 5 and pH 9 (orange *to* yellowish *to* turquoise). The indicators are unaffected by protein.

Nitrite: This test directly detects the presence of nitrite-forming bacteria in urine. The buffered test pad for nitrite is impregnated with amine and a coupler. Nitrites present in the urine diazotized the amine. The subsequent coupling reaction produces a pink color.

Leukocytes: This test is based on the enzymatic reaction of granulocyte esterases with an indoxyl ester in the presence of diazonium salt. Granulocyte esterase's split the ester, and as a result the free indoxyl can react with the diazonium salt to produce violet color.

Specific Gravity: This test contains a detergent and Bromthymol blue that indicates the presence of ionic constituents in the urine by changing from green

	to yellow. The test pad for specific gravity is impregnated with a reddish dye so that the color produced is yellow-brown tan.
Policies	1. Clinic must have CLIA Certificate for Waived testing 2. Clinic must enroll in a VA approved formal proficiency testing program. 3. Tests performed must be ordered by a physician or nurse practitioner. 4. Initial training and yearly competencies must be done by the site trainer. or the Ancillary Testing Coordinator. 5. Site trainer must be trained by the Ancillary Testing Coordinator or designee. 6. Original training must be submitted to the Ancillary Testing Coordinator In a timely manner. 7. Testing must be performed by trained and competent personnel. 8. Results must be communicated to the ordering provider. 9. Results must be interpreted by providers. 10 Results must be entered in the patient medical record through the Accuchek Inform II and/or on CPRS on the Point of Care template. 11. Access codes must not be shared with anyone. 12. All Quality Control and patient logs must be reviewed and signed off by the CLIA site director at the end of each month. 13. Quality Control Records and patient records are retained for a minimum of Two (2) years.
Definitions	CBOC – Community Based Outpatient Clinic POC – Point of Care QC- Quality Control CPRS – Computerized Patient Record System
Responsi-bilities	A. Clinic personnel from Community Based Outpatient Clinics (Victorville, Murrieta, Palm Desert, Corona and Rancho Cucamonga) ***Including:*** • Physicians • Registered Nurses • License Vocational Nurse and • Certified nursing assistant • Medical Assistant ***are responsible for***: 1. Running 2 levels of Quality Control once a week. 2. Documenting Quality Control results on the quality control log. 3. Monitoring and documenting temperature including room temperature where reagents are stored. 4. Entering results at the electronic patient log through Accuchek Inform II. 5. Entering results in CPRS under Point of Care template for Urinalysis. 6. Maintaining original documents on site for 2 years. 7. Getting the monthly Quality Control logs reviewed and signed off by the site CLIA director. B. Ancillary Testing Coordinator from Pathology and Laboratory Medical Service is responsible for:

1. Performing Lot to Lot testing of new reagents before use at the clinic.
2. Daily review of electronic patient log in RALS/ALERE.
3. Quarterly site visit to do Point of Care audit, including QC logs.
4. Review, update and implement Policy and Procedure as needed, and communicate these updates to the sites at the monthly CBOC meeting.

Special Safety Precautions

Precaution – All human body fluid should be handled with precautions and considered as infectious.

Observe Universal Precautions during processing of specimens and control materials:

- Use Universal Protective Equipment, including gloves.
- Wear Goggles or eye protection during procedures that could generate splashes.
- Wash hands after removal of gloves.

Sample and Sample Preparation

Urine specimen should be:

- Freshly voided.
- Collected in a properly labeled clean container.
- Tested as soon as possible after collection.

Note: ***Volume of urine must be sufficient for clinic testing and for any other follow testing that are done at the main Laboratory.***

- Kept at refrigerator temperature if testing is delayed for more than 1 hour.
- Refrigerated at all times if the urine will be sent to the clinical lab for testing.
- Urine that is kept refrigerated is stable for 4 hours.

Urine that was refrigerated should be at room temperature for testing.

Materials And supplies

A. Urine Chemstrip
   1. Store at room temperature. Stable until expiration date On label.
   2. Strips should be protected against light and moisture.
   3. Do not remove desiccants from bottle.
   4. Date and initial the vial when opened.
   5. DO NOT use after the expiration date.
   6. Must pass Quality Control weekly.

B. Urine specimen container.
C. Clean wipes

Note: Run 2 levels of Quality Control on every new lot of reagents/strips Before use.

Quality Control

Control testing must be done:

- **Once a week**
- **When opening a new bottle of UA strips**

Quality Control Testing:

1. ***Once a week***;
   a. Bring Liquid controls to room temperature
   b. Remove a strip from the bottle and recap container.
   c. Briefly (no more than 1 second) dip the test strip into the urine.
   d. Ensure that the chemically impregnated patches on the test strip are totally covered.
   e. Squeeze Control Level 1 in to the strip and tap gently on a piece of paper towel or gauze to remove any remaining solution, and to prevent the possible mixing of the chemicals.
   f. Hold strip close to color blocks and match carefully, ensuring that the strip is properly aligned to the color chart vial.
   g. Quality Control must be read as follows:

Glucose	Negative, 1+, 2+, 3+	30 seconds
Bilirubin	Negative, 1+, 2+, 3+	30 seconds
Ketones	Negative, 1+, 2+, 3+	40 seconds
Specific Gravity	1.000 - 1.035	45 seconds
Blood	Negative, 1+, 2+, 3+	60 seconds
pH	5 - 9	60 seconds
Protein	Negative ,1+, 2+, 3+	60 seconds
Urobilinogen	0.2, 1, 2, 4, 8	60 seconds
Nitrite	Negative, Positive	60 seconds
Leukocytes	Negative, 1+, 2+, 3+	60 seconds

   h. Document results on the Quality Control Log
   i. Repeat step *a* to *h* using Liquid Control Level 2

NOTE

- **Quality Control Logs must be reviewed and signed off by the site Director at the end of each month.**
- **Original Quality Control logs will be reviewed and signed off by the Ancillary Testing Coordinator during the quarterly site visits.**
- ***Original documents are retained at the sites for 2 years***.

2. **When opening NEW bottle of strips**;
   a. ***Refer and follow*** step by step procedure on how to run Liquid Control once a week.
      - Run Liquid Quality Control levels 1 and 2 on ***the new lot of strips.***
      - Record results on the Lot to Lot Quality Control Log

NOTE

- ***Original documents are retained at the sites for 2 years.***

Procedure:

Logging and Labeling

1. Fill urine results log accordingly including the patient's full name, full SS#, date, time, physician's name and the name of the testing personnel. Using a printed label is recommended.
2. Label testing tube with patient's name and full SS#. Using a printed label is recommended.
3. Pour urine to the properly labeled testing tube, up to at least ¾ full.
4. ***Verify that the label on the test tube matches the label on the original specimen before and after the transfer.***

Do not test an unlabeled or partially labeled specimen.

Examining Physical Characteristics

5. Observe urine for physical characteristics such as color and clarity. Record color and clarity on the log sheet.

A. COLOR:
- a) Straw
- b) Yellow
- c) Amber
- d) Orange
- e) Red
- f) Brown

B. CLARITY:
- a) Clear
- b) Hazy
- c) Slightly Cloudy
- d) Cloudy

Patient Testing

1. Remove a strip from the bottle and recap container.
2. Briefly (no more than 1 second) dip the test strip into the urine.
3. Ensure that the chemically impregnated patches on the test strip are totally immersed.
4. Draw the edge of the strip along the side and tap gently on a piece of paper towel or gauze to remove any remaining urine, and to prevent the possible mixing of the chemicals.
5. Hold strip close to color blocks and match carefully, ensuring that the strip is properly aligned to the color chart.

Read as follows:

Glucose	*Negative, 1+, 2+, 3+*	*30 seconds*
Bilirubin	*Negative, 1+, 2+, 3+*	*30 seconds*
Ketones	*Negative, 1+, 2+, 3+*	*40 seconds*
Specific Gravity	*1.000 - 1.035*	*45 seconds*
Blood	*Negative, 1+, 2+, 3+*	*60 seconds*
pH	*5 - 9*	*60 seconds*
Protein	*Negative ,1+, 2+, 3+*	*60 seconds*
Urobilinogen	*0.2, 1, 2, 4, 8*	*60 seconds*
Nitrite	*Negative, Positive*	*60 seconds*
Leukocytes	*Negative, 1+, 2+, 3+*	*60 seconds*

Patient Results

6. Record all results on the CBOC electronic Urinalysis Dipstick Result Log
7. ***Enter results in the Accuchek Inform II***
   - *Turn Accuchek Inform II on*
   - *Scan access code accordingly*
   - *Select "Patient Testing" from the main menu*
   - *Select "Other Test"*
   - *Select "Visual UA (MS)s"*
   - *Enter Patient's FULL SOCIAL NUMBER*
   - *Confirm "Date Tested" is correct*
   - *Confirm "Time Tested" is correct*
   - *Scan "Urine Strip Lot #"*
   - *Enter Expiration Date*
   - *Confirm "Patient ID" before entering results*
     a. *Select a color*
     b. *Select a clarity/apprearance result*
     c. *Select a glucose result*
     d. *Select a bilirubin result*
     e. *Select a ketone result*
     f. *Select a specific gravity*
     g. *Select a blood result*
     h. *Select a pH result*
     i. *Select a protein result*
     j. *Select a urobilinogen result*
     k. *Select nitrite result*
     l. *Select a leukocyte result*
   - *Confirm that all results are correct before accepting.*
   - *Return Accuchek Meter to the docking station*
8. ***Or document results in POC CPRS pregnancy template if Accuchek Inform II is not available.***
   - *Log in to CPRS*
   - *Under "File" select your patient*
   - *Type the FULL SOCIAL NUMBER of the patient*
   - *Click "OK"*
   - *Click "New Template" then OK*
   - *Click on the box for "Point of Care/Ancillary Testing".*
   - *Look for "Pregnancy Testing" then click box.*
   - *Fill in template, then sign*
8. Notify ordering physician of the results.

Note: All results that needs to be corrected must be reported to the Ancillary Testing Coordinator (909-503-2865) immediately.

Confirmatory Testing

9. ***Refrigerate all specimens that will be sent to the VA main clinical***

laboratory for chemical tests and or submitted for culture.

10. Site director or designee must review the patient result log once a week to make sure that all results were entered correctly into patient's medical record.
11. Reviewed patient logs must be kept for two years and readily available for review by the Ancillary Testing Coordinator or during inspection.

Method Limitations

Note: *Diagnostic or therapeutic decision should not be based on any single result or method.*

Bilirubin: Some urine constituents (medicine, urinary indicators) may produce a yellowish or reddish discoloration of the test pad that may interfere during result interpretation. Elevated concentration of ascorbic acid and nitrite may have an inhibitory effect on the reaction. Bilirubin is light sensitive and prolonged exposure of urine to light may result in diminished or false negative values. Elevated urobilinogen concentrations may slight intensify the response of the bilirubin test.

Urobilinogen: This test Is inhibited by elevated concentrations of formaldehyde. Excreted pigments and medications that have a red intrinsic coloration in acidic medium may produce false positive results phenazopyridine, red beets, azo dyes, p-aminobenzoic acid.

Ketones: Raised concentrations of phenyl pyruvic acid interference with the reaction and may produce a variety of colors. Phthalein's and anthraquinone derivatives exhibit a red color in alkaline medium and this may mask the response.

Ascorbic Acid: No interference is known.

Glucose: Ascorbic acid is the main interference. If the ascorbic acid is positive, glucose should be repeated 10 hours after discontinuing vitamin C administration or photometric test that is not affected by ascorbic acid should use.

Protein: False positive results may occur in highly alkaline urines (pH>9) with high specific gravity as well as disinfectants. Therapeutic dyes (methylene blue, pyridium) or red pigment may mask the color.

Blood: Non-specific oxygen acceptors such as uric acid, glutathione, gentistic acid and ascorbic acid may interfere by reducing the sensitivity of the test. Formalin, hypochlorite or peroxide containing cleaning agents can cause false positive reactions. Very high levels of nitrite or high specific gravity can delay the response.

pH: No interferences are known.

Nitrite: A negative response with the presence of bacteria can be caused by non-nitrite producing microorganism's antibiotic therapy, low-nitrate diets, strong dieresis, and high levels of ascorbic acid, high specific gravity or insufficient urinary retention time in the bladder. False positive responses can be caused by dyes excreted in the urine (e.g. pyridium, red beets)

Leukocytes: False positive reactions may be caused by formaldehyde (preservative). Protein concentration $\geq$ 300 mg/dL, cephalexin, gentamicin very high concentrations of glucose or a high specific gravity may diminish the color response. Leukocyte Esterase results may be positive in the absence of observable cells if the granulocytes have lysed.

	Specific Gravity: ph<5 yield slightly elevated results whereas pH>8 yield diminished results.

References

1. Multistix 10 SG Urine Chemistry Strips package insert, Siemens Healthcare Diagnostics, Inc. Tarrytown. NY 10591-5097 USA, Rev. 06/10 USA, TN30516A
2. Liquichek Urine Chemistry Control package insert, Bio-Rad Laboratories, 9500 Jeronimo Road, Irvine, Ca. 92618,
3. CLSI, GP16-A2, Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guidelines-Second Edition.

Related Documents

8-102-ATT1 Quality Control Log

Review and Approval of Site Clinic Director

Name & Title (Role)	Date	Signature
Reviewed By:		
Reviewed By:		