



Urinalysis

CHAPTER 5: URINALYSIS DIPSTICK - BAYER MULTISTIX

Procedure: Urinalysis Dipstick - Bayer Multistix

Urine Multistix: Tests for Glucose, Bilirubin, Ketones (acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrites and Leukocytes in Urine.

PURPOSE

The purpose of this procedure is to provide optimal Urinalysis Dipstick Point Of Care Testing services to Outpatients and to provide consultations directed to the medical staff. It is essential that the quality of results and timeliness of their availability are assured. The following guidelines for Urinalysis Dipsticks are a necessary step for achieving these goals and for complying with the laboratory accrediting requirements of the Department of Health and Human Services, the New Jersey Department of Health and Senior Services, and the College of American Pathologists.

POLICY

Properly trained and certified physicians, nurses or qualified technical personnel may perform Urinalysis Dipstick testing outside the laboratory, under the authority and licensure of the bioanalytical laboratory director.

PRINCIPLE

The Diagnostic Strips for Urinalysis are firm plastic strips to which are affixed several separate reagent areas. These tests may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection.

Glucose - This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.

Bilirubin - This test is based on the coupling of bilirubin with diazotized dichloraniline in a strongly acid medium. The color ranges through various shades of tan.

Ketone - This test is based on the development of colors ranging from buff-pink, for a negative reading, to purple when acetoacetic acid reacts with nitroprusside.

Specific Gravity - This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentrations.

Blood - This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetra methylbenzidine. The resulting color ranges from orange through green; very high levels of blood may cause the color development to continue to blue.

pH - The test is based on the double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.

Protein - This test is based on the protein-error-of-indicators principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.

Urobilinogen - This test is based on a modified Ehrlich reaction, in which p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.

Nitrite - This test depends upon the conversion of nitrate (derived from the diet) to nitrite by the action of Gram negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h)quinolin-3-ol to produce a pink color.

Leukocytes - Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product.

SPECIMEN COLLECTION AND HANDLING

- Clearly label a clean collection container with the patient's name and date.
- Collect 10 - 15 mL of urine in a clean container and test it as soon as possible.
- Do not centrifuge. The use of urine preservatives is not recommended.
- If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.
- Nitrite results are optimized by using a first morning specimen or one that has incubated in the bladder for four hours or more.
- Prolonged exposure to room temperature may result in microbial proliferation with the resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose. Bacterial growth from contaminating organisms may cause false positive blood reactions from the peroxidases produced. In random urine specimens from females, a positive result for leukocytes may be due to a source external to the urinary tract.

REAGENTS, CONTROLS, EQUIPMENT

1. Clear Dry Urine Collection Container
2. Label Pen
3. Multistix 10 SG
4. Quantimetrix Level 1 and Level 2 Urinalysis Dipstick Controls
5. Timer or Watch with a Second Hand
6. Disposable medical gloves.

Reagents and controls must be labeled with: Date Received, Date Opened, Expiration Date as well as the signature of the person putting them into circulation!

Reagent Storage and Stability

- Store at room temperature between 15-30 °C (59 - 86F).
- Do not use product after expiration date.
- Do not store the bottle in direct sunlight.
- All unused strips must remain in the original bottle.
- Do not remove desiccant from bottle.
- Do not mix lot numbers.
- Do not touch reagent areas of the reagent strips.

The reagent tests areas are ready to use upon removal from the bottle and the entire reagent strip is disposable. The strips are to be read visually. **Accurate timing is essential to provide optimal results. The reagent strips must be kept in the bottle with the cap tightly closed to maintain reagent activity.** To obtain optimal results, it is necessary to use FRESH, well-mixed, uncentrifuged urine.

New lots of reagent will be compared against old lots by the POCT Central Administration before new lots are placed into use.

Control Storage and Stability

- Store at 2-8 °C before initial use. Do not freeze. When stored at 2-8 °C, the controls are stable until the expiration date stated on the label.
- On initial use remove the controls from the refrigerator and allow to come to room temperature (25 - 25 °C), about 15 to 30 minutes.
- After the initial use, the opened Control Bottles are to be stored at **room temperature**. Do not store above 30 °C. (86 °F).
- When stored at room temperature (20-25 °C) the controls are stable for one month. Room temperature expiration date must be noted on the control bottle label when the bottle is opened.

Discard the controls and open a fresh vial if they are turbid or there is any evidence of microbial contamination (discoloration, unusual odor) is present.

QUALITY CONTROL

For optimum performance, accuracy of reagent strips must be confirmed and documented by testing known negative and positive controls **once per day** if patients are tested, and when a new bottle of reagent strips is first opened. Quantimetrix Level 1 and Level 2 controls are used for this daily validation.

1. Remove cap and invert bottle. While holding dipstick, gently squeeze the sides of the dropper bottle, and touch the drop of fluid to the dipstick. Draw across the reagent pads, thoroughly saturating each pad. Do not aspirate excess control back into the bottle. Turn dipstick on its side and drain excess control onto absorbent material.
2. Wipe off dropper tips and recap controls.
3. Read the urine dipsticks by comparing reagent blocks to the Color Chart on the label, at the proper time interval, in accordance to the Reagent Procedure.
4. All control results must be documented on the testing log. Be sure control and reagent lot numbers are recorded on the log sheet.
5. If controls are successful, indicate so on the Testing Log. If not, determine the cause and rectify. Document everything. Notify your POCT site supervisor or the POCT testing coordinator for technical assistance if needed.

PATIENT TESTING

1. Testing should be performed with adequate lighting. Inadequate light can lead to incorrect color comparisons. Testing should not be done by those with limited color discrimination, or those who have not yet been tested for color discrimination.
2. Collect FRESH urine specimen in a clean, dry container. Label specimen container with patient's name (preferably before giving it to the patient). Wear disposable medical gloves.
3. Mix urine well immediately before testing.
4. Remove one strip from bottle and replace cap.
5. Completely immerse reagent areas of the strip in FRESH urine and remove immediately to avoid dissolving out reagents.
6. While removing, run the edge of the strip against the rim of the urine container to remove excess urine.
7. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent area and / or contamination.
8. Visually compare reagent area to corresponding Color Chart on the bottle label at the time specified. **HOLD STRIP CLOSE TO COLOR BLOCKS AND MATCH CAREFULLY.** Avoid laying the strip directly on the Color Chart, as this will result in the urine soiling the chart.
9. Proper read time is critical for optimal results:
 - Glucose and bilirubin at 30 seconds after dipping
 - Ketone test at 40 seconds
 - Specific gravity at 45 seconds
 - pH, protein, urobilinogen, blood and nitrite at 60 seconds
 - Leukocytes at 2 minutes.

RESULTS AND INTERPRETATION

Results with the Diagnostics Reagent Strips are obtained in clinically meaningful units directly from the Color Chart comparison. All expected reference ranges are indicated on the Patient Result Form.

A routine urinalysis includes reporting of

1. Appearance: Clear, Hazy, Cloudy, Turbid
2. Color: Colorless, Straw, Yellow, Amber, Etc.
3. Specific Gravity: Note Result
4. Leukocyte Esterase: Negative, Trace, 1 +, 2 +, 3 +
5. Nitrite: Positive or Negative
6. pH: 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0

7. Protein: Negative, Trace, 1 +, 2 +, 3 +, 4 +
8. Glucose: Negative, Trace, 1 +, 2 +, 3 +, 4 +
9. Ketones: Negative, Trace, Small, Moderate, Large
10. Blood: Negative, Trace, 1 +, 2 +, 3 +, 4 +
11. Bilirubin: Negative, Small, Moderate or Large.
12. Urobilinogen: 0.2, 1.0, 2.0, 4.0, 8.0

Documentation:

1. All patient results are to be recorded on the Result Log and in the patient's record.
2. All reference ranges are noted on the Reference Range sheet that should be in each patient's chart.

LIMITATIONS

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.

All positive results should be confirmed and/or followed-up by repeat testing at the laboratory.

REFERENCES

Bayer Multistix Package Insert, Revised 9/95; Bayer Corporation, Diagnostics Division; Elkhart, IN 46515 USA

Quantimetrix Dropper Plus Urine Dipstick Control Package Insert, Quantimetrix Corporation, Redondo Beach, CA 90278-1205

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