



Urinalysis

CHAPTER 5A: AUTOMATED URINALYSIS - BAYER CLINITEK 50

Procedure: Bayer Clinitek 50 Urine Chemistry Analyzer running Multistix 10 SG

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 optimize Urinalysis Dipstick Point Of Care Testing services by use of an automated dipstick reader designed for use with Bayer reagents strips including Bayer MULTISTIX® 10SG. 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. Disposable medical gloves.
6. The Clinitek 50 instrument.

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

Reagent Storage and Stability

- Store at room temperature between 15-30° C (59° – 86° F).
- 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

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

- Store controls 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.

Equipment

The Clinitek 50 is an automated urine dipstick reader which consists of an optical system employing an incandescent lamp and photodiode pack containing four filters: blue (400-510 nm), green (510-586 nm), red (586-660 nm), and infrared (825-855 nm).

The lamp illuminates a fixed "read area" that reflects light back into the photodiode pack. These signals are converted electronically by the instruments microprocessor and converted into clinically meaningful results.

When the instrument is first turned on, it performs a series of electronic, signal and memory checks. Each time a reagent strip is read, the instrument positions the table electronically and checks the electronics and signals. A series of reference readings are taken based off of a white plastic bar on the test strip table. These readings are taken at all four wavelengths and are then used to calculate the sample readings.

Equipment Maintenance

1. Tray cleaning

The tray should be cleaned daily or more often if buildup is seen. The instrument is set to remind you to clean the table after every 50 strips. Press CONT to return to the Ready for Test screen:

- a. Remove table by simply pulling it out
- b. Clean strip area using a cotton-tipped applicator wetted with distilled water. Rinse both sides of table.
- c. Disinfect the table. Several solutions are safe to use on this table including: Cidex®, Theracide®, AmphyI®, 5% household bleach and Isopropyl alcohol (70-80%).
- d. Dry thoroughly
- e. **Do not touch the white bar.**
- f. Periodically, check the white bar to insure that it is free of dust, scratches or other marks. **If it is scratched** or has other marks on it, contact UDL administration for a replacement!

2. Changing the paper roll

- a. Pull out the remainder of the paper from the existing roll
- b. Open cover and remove the paper core.
- c. Insert new paper roll so that **paper unrolls from underneath**
- d. Trim insert end to resemble a large "V" shape.
- e. Insert paper under printer roller until the paper comes through other side of roller. Pull paper towards the back. **Do not pull paper up** or to the front as it may damage the printer.
- f. Feed paper through printer cover and snap cover into position.

Instrument Troubleshooting:

1) If DISPLAY IS BLANK

- a) Printer cover is not latched
- b) Power cord is not plugged in
- c) The instrument is broken – Contact UDL administration.

2) ERROR MESSAGES:

- a) Strip Problem-Retest
 - i) A test strip is not present, is dry or is not properly positioned (not at the end, not flat, not in the middle). Discard the strip, press CONT and retest using a new strip and the correct table.
- b) Table Problem-Retest
 - i) The test table is not in the correct position. The instrument or table may have been moved or bumped during the testing, or the bottom of the table may be dirty. Remove and clean the table, then reinsert. Press CONT and retest with a new strip.
- c) Instrument Error 3
 - i) The table is not present or is not pushed in far enough to allow movement. Push the table in about halfway.
- d) All other errors:
 - i) Discard the strip
 - ii) Turn the instrument *off*
 - iii) Wait several seconds
 - iv) Turn the instrument back *on*.
 - v) If error reoccurs contact UDL administration.

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.
2. **Press START button** on Clinitek 50 as soon as control is applied to strip. See below for detailed instructions on using the Clinitek 50.
3. Turn dipstick on its side and drain excess control onto absorbent material (eg paper towel).
4. Place dipstick in central trough of the analyzer table
5. Wipe off dropper tips and recap controls
6. Read the urine dipsticks
7. All control results must be documented on the testing log. Be sure control and reagent lot numbers are recorded on the log sheet. It is permissible to tape a copy of the instrument printout into the log as a record of having performed the procedure. Since tape will cause print to fade, do not put tape over any printed data.
8. Record controls on the Testing Log. If QC is out of its expected range, determine the cause and rectify. Document everything. Notify your POCT site supervisor or the POCT testing coordinator for technical assistance if needed.
9. If the Clinitek 50 is not working, or if QC is out of range, use manual Urinalysis Dipstick procedure, including running manual quality control.

PATIENT TESTING USING THE CLINITEK 50

- 1) The Clinitek 50 reader should be placed on a level work surface. The room temperature should be between 22° C and 26° C (72° F to 79° F).
- 2) The power switch is on the back of the instrument. It should be ON.
 - a) Analyzer OPTIONS – These will be preset before you are provided the unit
 - b) Output –
 - i) *Number of Copies* – The number of copies can be set by pressing the key under the word OUTPUT. You need to print two copies: one for the doctor and chart, and the second for the result log.
 - ii) *Device* – If you press the key under the word PRINTER you can select more than one copy. Press the key under your choice.
- 3) Check test strip table; clean if needed.
- 4) Note the following:
 - a) The instrument display
 - b) START keys (GREEN) on either side of the control keys
 - c) Option keys – each dark gray key corresponds to one of four words that may be shown on the bottom line of the display. Pressing the key beneath the word will select that choice.
- 5) Testing can be started only from READY FOR TEST screen. Be sure Reagent Strip Name agrees with the strip being used.
- 6) 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.
- 7) Mix urine well immediately before testing.
- 8) Remove one strip from bottle and **replace cap tightly**.
- 9) Completely immerse reagent areas of the strip in FRESH urine and remove immediately to avoid dissolving out reagents.
- 10) **Immediately press** either green Start key **as you remove strip from urine!** You will have 10 seconds to run the **edge** of the strip along the container rim or on an absorbent paper towel to remove excess urine; and then to place the reagent strip in the center plastic trough of the strip analyzer table.
- 11) Slide the strip to the end of the analyzer trough. **Do not pull or push table**, the analyzer table is automatically drawn into the analyzer. Results are obtained in one minute.
- 12) When the test is finished, discard strip into biohazardous waste.
- 13) The analyzer will generate two (2) copies of the report; one copy should be placed on the patient testing log, the other should be handed to the physician and placed in the patient record.

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. One copy of the instrument printout must be taped into the result log. Since tape will cause the thermal printing to fade quickly, tape should only be placed on blank areas of the printout.
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.

REFERENCES

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

Bayer Clinitek 50 User's Guide, Revised 3/02; 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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