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Clinitek Status+ Analyzer

Principle

The Clinitek Status+ Analyzer urine dipstick requires a freshly voided urine specimen. The Clinitek Status+ uses the Siemens Healthcare Diagnostic Reagent Strips Multistix 10 SG which semi-quantitatively detects glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes. These tests also provide information regarding the status of carbohydrate metabolism, kidney function, liver function, acid- base balance, and urinary tract infection. The Clinitek Status+ utilize the light reflected from specific wavelengths to detect the color changes that occur on the pads of the MultiStix 10 SG test strips.

Principles of Chemical Reactions

This is a short summary of the chemical reactions. For further details, refer to the product's package insert.

A. **Glucose** - Based on a double sequential enzyme reaction. The two enzymes, glucose oxidase and peroxidase, work as catalysts in two reactions to oxidize chromogen.

B. **Bilirubin** - Based on the coupling of bilirubin with diazotized dichloroaniline in a strong acid medium.

C. **Ketone** - Based on the development of colors ranging from buff- pink for a negative reading and to maroon when acetoacetic acid reacts with nitroprusside.

D. **Specific Gravity** - Based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration.

E. **Blood** - Based on the peroxidase-like activity of hemoglobin which works as a catalyst in the reaction.

F. **pH** - Based on the double indicator principle that gives a range of colors covering the entire urinary pH range.

G. **Protein** - Based on the protein error-of-indicators principle.

H. **Urobilinogen** - Based on the Ehrlich reaction in which a color enhancer reacts with urobilinogen in a strong acid medium.

I. **Nitrite** - Based upon the conversion of nitrate (derived from the diet) to nitrite by the action of Gram-negative bacteria in the urine.

J. **Leukocytes** - Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester.

Specimen Collection

A. Patient Preparation
   - Follow department policy for patient preparation for urine collection.

B. Specimen Type
   1. The preferred specimen is a fresh clean catch urine specimen. Random, supra-pubic, catheterized, and midstream specimens are also acceptable for testing.
   2. Urine must be collected in a clean screw cap container.
   3. If the specimen cannot be tested within two hours after collection, it can be refrigerated (2-8°C) for up to 24 hours after collection. All urine specimens should return to room temperature (15-30°C) before testing.
      - Write the date and time of collection and initials of who collected on the urine container.
      - Do not perform testing and reject patient samples on specimens that have been sitting more than one hour at room temperature.
   4. Urine specimens should not be centrifuged and should not contain preservatives.
   5. Substances that cause abnormal urine color may affect the readability of test pads on urinalysis reagent strips. These substances include visible levels of blood or bilirubin and drugs containing azo dyes, nitrofurantoin and riboflavin. This could cause results to be read as a false positive.
   6. Drug interference(s) for each test pad.
      a. Glucose test pad:
         - Moderately high ketone levels may cause false negative for specimens containing small amounts of glucose.

b. Bilirubin test pad:
    - Indican (indoxyl sulfate) can produce a yellow-orange to red color that may interfere with the interpretation of a negative or positive reading.
    - Metabolites of Lodine may cause a false positive bilirubin result or atypical results.
    - Atypical color reaction of the test pad may cause false positive and may mask the true bilirubin reaction.

c. Ketone test pad:
    - False trace results may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites.
    - Compounds containing sulfhydryl groups may cause false positive reactions or an atypical color reaction.

d. Protein test pad:
    - A visibly bloody urine may cause falsely elevated results.

e. Urobilinogen test pad:
    - May react with ρ-aminosalicylic acid, sulfonamides and ρ-aminobenzoic acid to cause atypical color reactions.
    - The presence of formalin may cause a false negative.

f. Nitrite test pad:
    - Pink spots or pink edges should not be interpreted as a positive result.
    - False negative results may occur with shortened bladder incubation of urine, absence of dietary nitrate or the presence of nonreductive pathological microbes.

g. Leukocytes test pad:
    - Elevated glucose concentrations (>/= 3 g/dL) may cause decreased test results.
    - The presence of cephalexin, cephalothin, oxalic acid, and tetracycline may cause a decreased reactivity.
    - Positive results may occasionally be due to contamination of the specimen by vaginal discharge.

Reagents

Materials

1. Multistix 10 SG Reagent Pads **(The reagent strips have been determined to be non-hazardous**

under the guidelines issued by OSHA).

a. Glucose: 2.2% w/w glucose oxidase, 1.0% w/w peroxidase, 8.1% w/w potassium iodide, 69.8% w/w buffer, and 18.9% w/w nonreactive ingredients.

b. Bilirubin: 0.4% w/w 2, 4-dichloroaniline diazonium salt, 37.3% w/w buffer, 62.3% w/w nonreactive ingredients.

c. Ketones: 7.1% w/w sodium nitroprusside, 92.9% w/w buffer.

d. Spec. Grav: 2.8% w/w bromthymol blue, 68.8% w/w poly (methyl vinyl ether/maleic anhydride), 28.4% w/w sodium hydroxide.

e. Blood: 6.8% w/w diisopropylbenzene dihydroperoxide, 4.0% w/w 3,3',5,5' tetramethylbenzidine, 48.0% w/buffer, 41.2% nonreactive ingredients.

f. pH: 0.2% w/w methyl red; 2.8% w/w bromthymol blue; 97% w/w nonreactive ingredients.

g. Protein: 0.3% w/w tetrabromphenol blue; 97.3% w/w buffer; 2.4% w/w nonreactive ingredients.

h. Urobilinogen: 0.2% w/w p-diethylaminobenzadehyde; 99.8% w/w nonreactive ingredients.

i. Nitrate: 1.4% w/w p- arsanilic acid; 1.3% w/w 1,2,3,4-tetrahydrobenzo (h) - quinolin-3-ol; 10.8% w/buffer; 86.5% w/w nonreactive ingredients.

j. Leukocytes: 0.4% w/w derivatized pyrrole amino acid ester; 0.2% w/w diazonium salt; 40.9% w/w buffer; 58.5% w/w nonreactive ingredients.

2. Quantimetrix Dropper Dipstick Controls

    1. Contains human urine, human blood cells and human chorionic gonadotropin. Preservatives have been added to inhibit microbial growth.
    2. Since there is no known test method that can assure that a product derived from human material does not contain the hepatitis or the HIV virus, it is recommended that such samples be handled using the Standard Precautions. QC materials should be used and disposed of in accordance with laboratory and accreditation requirements.

Storage Requirements

1. Reagent Strips

    a. The reagent strips must be kept in the bottle with the cap tightly closed to maintain reagent reactivity.

    b. Store at room temperature between 15- 30°C.

    c. The strips are stable until the expiration date on the bottle.

    d. Do not store in direct sunlight.

    e. Do not remove desiccant from the bottle.

2. Quantimetrix

1. The urinalysis dipstick control kit should be stored at 2-8ºC when not in use.
2. When stored at 2-8ºC the controls are stable until the expiration date stated on the label.
3. Dropper Plus: After the initial use, the opened controls can be stored at room temperature (18-25ºC). The control are stable for one month.
    - Room temperature 30-day expiration date must be noted on the bottles.
4. Discard the controls if turbid or any evidence of microbial contamination is present.

Quality Control

Quality Control materials - Quantimetrix Dropper (Plus) Urine Dipstick Control Level 1 and Level 2.

Preparation and Handling - The control materials are ready to use and should be handled using Standard Precautions.

Procedure:

1. Remove the controls from the refrigerator and allow to come to room temperature (18-25ºC), at least 15 minutes, depending on remaining volume.
2. Mix gently by inversion to assure homogeneity of the contents.
3. Gently squeeze the sides of the dropper bottle, touch the tip of the bottle to the dipstick and thoroughly saturate each pad. Do not aspirate excess control back into the bottle.
4. Turn dipstick on its side and drain excess control onto a paper towel.
5. Select "Enter New Patient". In the "Enter Patient ID", enter the Lot Number of the control.
6. Insert into Clinitek Status+ Analyzer.

Frequency:

1. Both levels of controls should be performed each day of patient testing.
2. Each time a new vial of strips are opened.
3. At least 30 days (even if patient testing has not occurred within 30 days).
4. When troubleshooting analyzer.
5. When results of strips are questioned.
6. After every maintenance procedure, aside from weekly maintenance.

Acceptance limits:

- Acceptance limits are established by using the information on the package insert for each level of control solution.
- Compare QC results to the Quantimetrix Quality Control Results Package Insert.

Corrective Action:

If the quality control results fall outside the values, try the following corrective action:

1. Use a fresh strip out of a bottle and repeat the QC.
2. Use a fresh bottle of strips to repeat the QC.
3. Use a fresh quality control solution and repeat QC.
4. Troubleshoot with the Point of Care Coordinator.
5. Corrective Action - Corrective action should be documented. If quality control does not pass, do not report patient results.

Quality Control Data:

- Document on the Quality Control log if QC was ok by circling Yes or No.
- Attach all QC printouts to the back of the Quality Control Log and ensure to document QC is acceptable prior to patient testing.
- At the end of each month, review and send to the Point of Care (POC) Coordinator/Quality Assurance (QA) or designee for review and storage.
- If testing was not performed on a day, mark (X) to indicate "No patient tested."

Testing Procedure

1. Collect fresh urine in a clean, dry container.
2. **Touch** the **Strip Test** menu on the LCD screen of the CliniTek Status+.
3. **Operator Name** will appear. Touch the "**Enter New Operator Name**" box and enter your initials.
4. **Patient Information** will appear and touch the "**Enter New Patient**" box.
    - Enter Patient ID will appear and enter patient's medical record number.
5. **Strip Lot** will appear and touch "Enter new lot and expiration date" or "Use last lot" (if it is the same lot number in use).
6. **Prepare Test** will appear and touch **Start.**
    - After you select **START**, you have 8 seconds to dip the reagent strip in the urine sample and place the strip in the test table channel.
7. Use Standard Precautions when performing the test.
8. Remove one strip from the bottle and replace the cap.
9. Completely immerse the reagent strip in the urine.
10. Run the edge of the strip against the rim of the urine container.
11. Blot by touching the edge of the test strip to the paper towel to remove excess urine.
12. Place the test strip in the channel of the table with the test pads facing up. Slide or push the strip to the end of the channel. Do not touch thee pads of the strip.

- After the 8-second countdown ends, the analyzer pulls in the test table and strip and then calibrates.

13. **Select Appearance**, select the urine sample color and clarity:
    - If the urine sample is yellow and clear, select **Yellow and Clear**.
    - If the urine sample is not yellow and clear, select **Other**, and select a color.
14. A timer counts down the time remaining in the strip analysis process. The analyzer displays the first page of the test results on the **Results** screen.
15. Remove printout and report patient results in EHR.
16. Attach patient label on the backside of patient printout. Initial the patient printout. Save all patient printouts.

Reference Range

Analyte	Normal Range
Color	Yellow-Straw
Clarity	Clear
Glucose	Negative
Bilirubin	Negative
Ketones	Negative
Specific Gravity	<1.005 - ≥1.030
Blood	Negative
pH	5.0-8.5
Protein	Negative
Urobilinogen	0.2-1 E.U./dL
Nitrate	Negative
Leukocytes	Negative

Result Reporting

A. Results must be entered into EHR using the POC Lab Entry button. See the "Electronic Health Record POC Lab Entry Button for Entering Point of Care Test Results Procedure" for detailed instructions.

B. **Send patient specimen to the laboratory to confirm abnormal results when results are positive for nitrite or leukocyte esterase.**

C. In the event testing is not available due to unforeseeable circumstances, send patient specimens to laboratory for testing.

D. The Clinitek is not interfaced to the Electronic Health Record. Per laboratory accreditation, analyzer patient test results printouts are to be retained for two (2) years.

- Printouts are to be saved and sent to the POC Coordinator for review and storage.

Maintenance

When patient testing is not performed or on weekends, mark (X) on the maintenance log to indicate "No Patient Testing".

Weekly

Clean test table and test table insert.

1. Remove the test table by pulling it slowly out of the analyzer. Lift the table insert to remove it from the test table.
2. Drain the drip tray, if necessary.
3. Rinse both sides of the table insert and test table under running water.
4. Dry thoroughly and replace test table.
    - CAUTION: Do not touch the calibration bar. Your fingerprints or line on the bar could cause unreliable test results.
5. Clean outside of analyzer. Always keep the outside of the analyzer clean and free of dust.
6. Check printer paper.

As Needed

Cleaning the White Calibration Bar

- Inspect white calibration bar. Clean if dirty or discolored. Do not scratch, use soft cloth or lint free tissue. Wet a new cotton tipped swab or lint-free cloth with distilled water and gently wipe and clean the calibration bar. Do not use solvents of any kind ot clean the calibration bar.

Disinfecting the test table and insert

1. Prepare a solution of 70% isopropyl alcohol (full strength) in a tall, narrow container (empty MultiStix bottle) to a depth of about 4 inches.
2. Place the test table insert and the test table into the solution. Make sure the white calibration bar on the test table remains above the liquid level.
3. Soak the table and insert for a minimum of 2 minutes. Do NOT soak longer that 10 minutes.
4. Rinse the test table and insert thoroughly with water.
5. Dry thoroughly with a soft cloth or lint free tissue. Do NOT touch the white calibration bar.
6. Reinsert the test table into the analyzer by holding the table at the end opposite the white calibration bar (the calibration bar should be facing upward). Push the test table

just over halfway into the analyzer.

7. Replace the test table insert.

Calibration

- The analyzer calibrates automatically before each measurement by reading the white calibration bar at the appropriate wavelength to ensure accurate test results. Take care to not scratch or discolor the bar.

Troubleshooting

1. Contact the POC Coordinator when experiencing error messages or other problems with the analyzer(s). If analyzer's performance is in question, do not use.
2. If the analyzer is out of service, patient specimens are to be sent to laboratory temporarily for analysis until the analyzer is repaired.

Procedure Notes

A. Use fresh, well mixed, uncentrifuged urine for each dipstick test on the Status.

B. Remove one test strip from bottle and replace cap (never leave bottle open).

C. Dip the reagent test strip completely, but briefly, to avoid dissolving the reagents on the test pads.

D. There is a time limit in placing the strip on the reading table of the CliniTek Status+ analyzer.

E. Do not let water, moist cloth or other solvents come in contact with the white calibration bar. Do not scratch the white calibration bar.

Limitations of Procedure

A. The color development on the reagent pad may be masked or a color reaction may be produced on the pad that could be interpreted visually as a false positive.

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

C. Care should be taken to avoid liquid from entering the printer compartment.

D. Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.

E. Glucose - Reactivity may be influenced by urine specific gravity and temperature. The reportable limit on the low end is 40 mg/dl.

F. Bilirubin - The test is less sensitive than the ictotest.

G. Ketone - Clinical judgment is needed to determine the significance of reactions up to and including trace.

H. Specific Gravity - The reportable range is from 1.000- 1.030. For increased accuracy, 0.005 may be added to urine with ph equal to or greater than 6.5 (the CliniTek Status+ and CliniTek

Status makes adjustments automatically).

I. Blood - The sensitivity of this test may be reduced in urine with high specific gravity.

J. pH - The pH test measures pH values generally to within 1 unit in the range of 4.6-8.0 instrumentally (CliniTek Status+ and CliniTek Status).

K. Protein - A negative result does not rule out the presence of other proteins.

L. Urobilinogen - The test will detect urobilinogen in concentrations as low as 0.2 mg/dl. The absence of urobilinogen in the specimen tested cannot be determined.

References

1. CliniTek Status+ Analyzer, Operator's Guide, Siemens Healthcare Diagnostics Inc., Tarrytown, NY 10591-5097 USA, 10490853 Rev. D, 2020-08.
2. Siemens Healthcare Diagnostics Inc. (July 2017). *Multistix 10 SG Reagent Strips: Package Insert*. Tarrytown, NY. 11306391 Rev. A.
3. Quantimetrix Corporation. Quantimetrix Dropper Urinalysis Dipstick Control Level 1 & 2. Redondo Beach, CA. M044343B-03/23.
4. Recent The Joint Commission Accreditation,The Joint Commission Resources. Waived Testing (WT). *Laboratory Accreditation Requirements. E-dition.*

Attachments

07-2017 11306391_Mulltistix_10_USA_IFU_-_English_-_Rev_A_DXDCM_09008b838086fec3-1556673394888.pdf

Approval Signatures

Step Description	Approver	Date
Medical Officer Pathologist	Noelle Blue Arm: Medical Officer Pathologist	07/2024
Chief Nurse Executive	Rachel Hamblin: Chief Nurse Executive	07/2024
Lab Supervisor	Kendrick Fritz: Supervisory Medical Technologist	06/2024
Director of Quality Management	Jose Burgos: Public Health Nurse Director	05/2024

Medical Technologist	Jeanna Begay	05/2024
	Jeanna Begay	05/2024

Applicability

Hopi Health Center

References

WT.01.01.01, WT.02.01.01, WT.03.01.01, WT.04.01.01, WT.05.01.01