

PROCEDURE: URINALYSIS ON THE CLINITEK STATUS+

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PRINCIPLE:

The Siemens Clinitek Status Analyzer is a portable instrument powered by batteries or by an electrical outlet for bench top use. It is for in vitro diagnostic use in the semi-quantitative or qualitative detection of protein, blood, leukocytes, nitrite, glucose, ketone, pH, specific gravity, bilirubin, and urobilinogen in urine samples. The system utilizes the reflection from 6 LED's to quantify urine constituents. The light is converted into electrical impulses, which are processed by the instrument's microprocessor and converted into clinically meaningful results. Siemens Multistix reagent strips are intended for use to assist diagnosis in kidney function, urinary tract infections, carbohydrate metabolism (e.g. diabetes mellitus), and liver function. The strips also measure physical characteristics, including acid-base balance and urine specific gravity. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic evaluation is needed. Multistix reagent strips are ready to use upon removal from the bottle and the entire reagent strip is disposable. The reagent strips are for in vitro diagnostic use. They have been determined to be nonhazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).

EQUIPMENT/SUPPLIES

1. Seimens 10SG MultiStix
2. Clinitek Status +
3. Quantrimetrix Urine Quality Control Dropper Plus Level 1 and 2.

Chemical Principles of the Reagent Strips

Test Name	Chemical Principle
Glucose	Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Peroxidase catalyzes the reaction of hydrogen peroxide That couples 4-aminoantipyrine and 4-methylcatechol to create an orange to dark red color reaction.
Bilirubin	Bilirubin couples with diazotized dichloroaniline in a strongly acid medium. Colors range through various shades of tan.
Protein	At a constant pH, the development of any green color is due to the presence of protein (Protein error-of-indicators principle). Colors range from yellow for negative through yellow-green and green to green-blue for positive reactions.
pH	The double indicator principle gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.
Blood	Hemoglobin catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. Colors range from orange through green; very high levels of blood may cause the color development to continue to blue.
Ketone	Acetoacetic acid reacts with nitroprusside. Colors range from pink, for a negative reading, to maroon for a positive reading.

Urobilinogen	In a modified Ehrlich reaction, p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.
Nitrite	Nitrate (derived from the diet) is converted 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. This diazonium compound couples with 1,2,3,4-tetrahydrobenzo(h)quinolin-3-ol to produce a pink color.
Leukocyte	Esterases in granulocytic leukocytes 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.
Specific Gravity	pKa changes occur for 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 concentration

STORAGE:

Store **Multistix 10 reagent strips** at room temperature (15-30°C) and out of direct sunlight. All unused strips must remain in the original bottle. Transferring to any other container may cause reagent strips to deteriorate and become nonreactive. Do not use the strips after their expiration date. Do not remove the desiccant from the bottle. Protection against exposure to light, heat, and ambient moisture is mandatory to guard against altered reagent activity. Avoid touching the test areas of the reagent strip. Discoloration or darkening of the reagent areas may indicate deterioration, discard the deteriorated strips.

Quantrimetrix Urine Quality Control is stored in EU Department at room temperature and is stable for 30 days. New Quality control vials are supplied by the Point of Care testing area in the Core lab. These are stored refrigerated in 2N54 and need to be brought to room temperature to run quality control.

SPECIMEN

10 mL (optimal) freshly voided, well mixed urine. **Do Not** centrifuge urine. Minimum volume = 1mL. Specimen must be labeled with patient identification. Collect the urine in a clean, dry, covered container. If the urinalysis can not be performed within 30 minutes, the urine should be refrigerated. Refrigerated specimens must be analyzed within 8 hours. Refrigerated urines must be brought to room temperature before analysis.

UNACCEPTABLE SPECIMENS:

1. Any specimen left at room temperature more than 2 hours.
2. Any refrigerated specimen greater than 8 hours old.
3. Grossly bloody specimens should be sent to the core laboratory for analysis.
4. Specimens with urine preservatives.

If an unacceptable specimen is received, note the reason for rejection and the physician notified in Wellsoft and request a new, acceptable specimen from the patient.

PROCEDURE - QUALITY CONTROL

1. At the main Select screen, touch QC Test/Due “QC”. QC Due will appear when 24 hours have passed since the last Quality Control analysis.
2. Next screen select: QC Strip Test (Required). “Required” will be on the screen when 24 hours have passed since the last Quality Control analysis.
3. Screen then prompts for Operator ID. Use the scanner(Yellow Button) and scan your SLCH ID barcode. Press Enter. Users when competency has been completed will be scanned in as users. This will not allow anyone that has not been trained to enter the system.
4. Screen prompt then requires the operator to enter their name. Use the alpha keyboard and enter your name. Press Enter.
5. Control 1 Level 1 appears on the Screen. Press Enter Lot Number and Expiration date.
6. Enter Level 1 (White Cap) Lot Number using the alpha key pad. The current lot number is posted by the Clinitek Status.
Press Enter.
7. Enter Control Level 1 Expiration Date. Found on vial under Lot number. The current lot/expiration date is posted by the Clinitek Status. Press Enter.
8. Press Enter new Lot and Expiration date of MultiStix.
9. Enter Lot number on Siemens MultiStix 10SG. Lot number is found on the vial and is posted by the Clinitek Status. Press Enter.
10. Strip expiration screen appears. Using the arrow key enter the year and month. Expiration date is on the vial of MultiStix 10SG and is posted by the Clinitek Status. Press enter.
11. START button will appear. BEFORE you press start, take one MultiStix out of the vial and have the Level 1 QC ready to dose the strip. Once you press START you have 8 seconds to apply Quality Control 1 drop to each pad, starting at the bottom of the strip. This is the Glucose pad (aqua) color. Remove excess urine. Blot strip by turning on edge against a paper towel. Place strip on the strip guide on the Clinitek Status reader table.
12. At the end of the 8 Second countdown, the test table and strip will automatically be pulled into the instrument. WARNING: Do not push or pull the test table.
13. The analyzer will perform an automatic calibration and finish analyzing the sample.
14. Once the analysis is complete the Results screen will be displayed. The instrument will “PASS” or “FAIL” the quality control. QC “ Pass” select the PRINT button and results will be printed. Place in the envelope marked ‘Quality Control’ next to the instrument. Results will be entered manually in the Cerner Lab system. You do not have to manually record the results from the quality control. The instrument knows the status of pass/fail and will not allow patient testing until successful quality control has been analyzed.

15. Select Done. The Clinitek then prompts you for Control 2.. Select Enter Lot and expiration date. Press Enter.
16. Enter Control lot number for Control 2 (Blue Cap) and expiration date. This is posted by the Clinitek. Same screens as for Control 1.
17. Strip Lot: Select: Use last lot is this is the same lot number of MultiStix used for running Control 1. Press Enter.
18. START. Press only when you are ready to apply Control 2 to MultiStix. Same procedure as in #11 above.
19. The results will appear once the analysis is completed. The instrument will "PASS" or "FAIL" the quality control. QC "PASS" select PRINT button and results will be printed. Place in the envelope marked "Quality Control" next to the instrument. See #14 above.
20. Select "Done". You will now be able to perform patient testing when both levels of Quality Control have passed.
21. When one or both levels of the Quality Control fail the instrument will prompt you to repeat the failed QC test. Repeat and follow the instrument screens.

Remember to check to make certain that you are running Level 1 when prompted by the instrument, if you mix up the Quality Control it will not pass.

Quality Control fails contact the Core Lab/Point of Care and send specimens to the Core Lab until Quality Control can be resolved.

When Instrument failures occur specimens must be sent to the Core Lab for testing.

You must put the strip on the test table in the correct position or it will not assay the strip. When this happens it pulls the strip in and it is not analyzed but is returned to the original position. You must get a new strip and repeat the assay.

PROCEDURE – PATIENTS

1. At the main screen, touch Strip Test. The Operator ID screen will appear.
2. Scan operator ID badge, press Enter.
3. Select Enter New Patient.
4. On the Alpha Key Board type in the Patient's name. Press Enter.
5. Patient ID screen will appear, Scan the patient's MRN bar code. Press Enter.
6. Press START Button. Once you touch the START button you have 8 seconds to dip the test strip into urine specimen and place it on the test table.

7. Dip test strip in urine specimen. Remove excess. Blot strip by turning on edge against absorbent orange wipe or paper towel.
8. Place the strip on the instrument test table. **DO NOT PUSH OR PULL THE TEST TABLE.**
9. At the end of the 8 second countdown, the test table and strip will automatically be pulled into the instrument.
10. The analyzer will perform an automatic calibration and finish analyzing the sample.
11. When analysis is complete, the **RESULTS** screen will be displayed. Results will automatically print. Record results in WELLSOFT. Result tapes should be placed in the shred for HIPPA.
12. Remove the test strip and dispose of it in biohazard container.
13. Touch done to complete the test and return to the main Select screen.

CALIBRATION

The Clinitek Status Analyzer performs a “self test” and calibration each time it is turned on. In addition, the analyzer performs an automatic calibration each time a test is run. The while calibration bar (on the test Table) provides NIST traceable calibration.

SYSTEM START UP AND MAINTENANCE

The system is turned on by pressing the on/off button located at the front of the instrument. The analyzer automatically runs a system diagnostic check during which it performs a series of electronic, signal and memory checks, as well as ensures there is sufficient battery voltage to operate when necessary.

Daily Maintenance (Performed by the EU staff or Point of Care Staff)

- A. Wipe off instrument.
- B. Clean feed table.
Remove the feed table insert by grasping the front end of the insert on each side with a thumb and finger. Clean the insert with a gauze or kimwipe wet using distilled water.

Weekly Maintenance (Performed by the EU staff or Point of Care Staff)

- A. Wipe the feed table with a kimwipe dampened with distilled water. Replace the feed table insert the same way as when removing it.

Periodic Maintenance (Performed by the EU staff or Point of Care Staff)

- A. Change the paper. See “Operator’s Manual” for instructions.
- B. Extensive cleaning of feed table insert when excessively dirty. Remove the feed table insert as described under the daily maintenance procedure.

NOTE: Do not use any material that will scratch the calibration chip. Do not use solvents of any kind to clean the feed table, insert, or chip. If the calibration chip becomes damaged, the feed table insert must be replaced.

LIMITATIONS:

1. Substances that cause abnormal urine color may affect integrity of reagent areas on strip. The color development may be masked or a color produced that could be interpreted as a false positive. Results should include a notation of urine color and a comment about the possible false positive results.
2. Protein: visibly bloody urine may cause elevated results.
3. Blood: Capoten (captopril) may reduce the sensitivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.
4. Leukocytes: Elevated glucose concentrations (≥ 3 g/dL) may cause decreased test results. The presence of some cephalosporin antibiotics or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. Positive results may occasionally be due to contamination of the specimen by vaginal discharge.
5. Nitrites: Pink spots or pink edges should not be interpreted as a positive result. A negative result does not rule out significant bacteriuria. False negative results may occur with shortened bladder incubation of the urine, absence of dietary nitrate, or the presence of nonreductive pathological microbes.
6. Glucose: Ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dL) may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dL), but the combination of such ketone levels and low glucose levels is metabolically improbable in screening.
7. Ketone: False trace results may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as mesna (2-mercaptoethane sulfonic acid) that contain sulfhydryl groups may cause false positive results or an atypical color reaction.
8. Bilirubin: Indican (indoxyl sulfate) can produce a yellow-orange to red color response that may interfere with the interpretation of a negative or positive reading. Metabolites of Iodine may cause false positive or atypical results. Atypical colors (colors that are unlike the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine sample and may be masking the bilirubin reaction.
9. Urobilinogen: The test pad may react with interfering substances such as p-aminosalicylic acid and sulfonamides. Atypical color reactions may be obtained if formalin is present. Strip reactivity increases with temperature; the optimum temperature is 22-26°C. The test is not a reliable method for the detection of porphobilinogen.
10. Bilirubin and urobilinogen are very unstable when exposed light.
11. Contamination of the urine specimen with skin cleaners containing chlorhexidine may affect protein,

bilirubin and specific gravity test results.

Results that do not match the patients clinical picture, a specimen should be sent to the Core Lab for verification.

Correlations with the Atlas and Siemens Manual Dipstick are performed quarterly.

Status instrument is down specimens should be sent to the Core lab.

REFERENCE RANGE:

Specific gravity values normally range between 1.008 and 1.022 depending on fluid intake

<u>Analyte</u>	<u>Normal</u>
pH	5 – 8
Protein	<i>Negative</i>
Glucose Qual.	<i>Negative</i>
Ketones Qual.	<i>Negative</i>
Bilirubin Qual.	<i>Negative</i>
Urobilinogen	<i>0.2-1.0 Ehrlich units/dL</i>
Nitrites	<i>Negative</i>
Leukocyte Esterase	<i>Negative</i>

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4. Henry, John, *Clinical Diagnosis and Management by Laboratory Methods*, W.B. Saunders Co., 16th ed., 1979.
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6. Siemens Medical Solutions Diagnostics Clinitek Status Analyzer Operator's Manual 13287. rev. T, 2008-05.



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Location of hard copy location(s): Core Lab Office
See Test Methods / Test Locations (POC.1.0002.0)

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