

Title: Point of Care - Clinitek Status Procedure - Urine Dipstick		
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TITLE: Urinalysis – Clinitek Status[®] *Macroscopic Examination of Urine*

PRINCIPLE: The Clinitek Status[®] urine analyzer is used for the semi-quantitative detection of bilirubin, blood (occult), glucose, ketone, leukocytes, nitrites, pH, protein, specific gravity, and urobilinogen. The Multistix[®] 10 SG reagent strips used with this analyzer are read through an optical system.

The optical system consists of six light emitting diodes, a light guide, a mirror, a lens, and a detector. Light from the LEDs travels along the light guide and is reflected off the calibration bar or test strip onto the mirror. It is then directed through an aperture on the lens, from where it is focused onto the detector. The light intensity detected is then converted into electrical impulses, which are processed by the instrument's microprocessor and converted into clinically meaningful results.

Each time a test strip is read, the instrument positions the table correctly and checks the electronics and signals. It then takes reference readings off the white calibration bar on the test table. The readings are taken at all six wavelengths and are then used to calculate the sample readings.

SPECIMEN:

- *Patient Preparation:*
None.
- *Specimen Collection and Preparation:*
Fresh, well mixed, uncentrifuged, random urine collected in a clean, screw capped urine container. Specimen must be properly labeled.
- *Minimum Requirement:*
10 ml of urine.
- *Storage:*
Two hours at room temperature. Twelve hours refrigerated. Refrigerated specimens must come to room temperature before testing.



All body fluids should be handled as if capable of transmitting infectious diseases. Use standard precautions when in contact with such materials. Refer to Laboratory Infection Control Policy.

EQUIPMENT AND MATERIALS:

- Clinitek Status[®] urine analyzer or Clinitek Status + urine analyzer
- Multistix[®] 10 SG reagent strips – all unused strips must remain in the original bottle. Strips are stable at room temperature until manufacturer's expiration date. Immediately recap bottle after use to block out light and heat and to maintain the effectiveness of the drying agent in the canister. Do not touch test areas of reagent strips. *Label canister with open date.*
 - Siemens Reagent Strips have been determined to be nonhazardous under guidelines issued by OSHA in 29 CFR 1910.1200(d).
- Printer paper.

CALIBRATION:

- The analyzer will run an automatic system diagnostic test and calibration each time it is turned on. Each time a test is run, the instrument calibrates again using the white plastic bar located on the end of the test strip table.

QUALITY CONTROL:

When a Clinitek Status + analyzer is used, The Auto-check ID band on the MultiStix 10 SG test strip is read to include automatic strip identification and quality checks.

- Urine controls, Level 1 and Level 2. Use within manufacturer's expiration. Write date when opened on bottles.
- When stored refrigerated, QC is good until expiration date. When opened for use, reassign a 30day expiration date and continue to store refrigerated.
- Frequency – both levels run each day of patient testing.
- Tolerance limits – refer to assay sheet for current lot in use. If QC results are not acceptable, repeat with new test strip. If needed, open new bottles of test strips and/or controls. If still unacceptable, do not perform any patient testing and notify the Point of Care Specialist.
- When completed, document acceptability on the QC log sheets.

PROCEDURE FOR QUALITY CONTROL

- Press the on/off button located on the front of the instrument.
- The first main screen is the **SELECT** screen. All screens are touch screens. Touch **STRIP TEST** to conduct a urinalysis strip test.
- From the **OPERATOR ID** screen, touch the **ENTER NEW OPERATOR ID** button.
- Enter your operator ID number. Touch **ENTER**.
Touch **ENTER NEW PATIENT**. The **ENTER PATIENT ID** screen appears.
Enter the lot number on the bottle of liquid QC
- The **ENTER NAME** screen appears. Select ABC and **ENTER QC**.
Touch **ENTER**.
- At the **PREPARE TEST** screen, touch **START**
- You have 8 seconds to complete the following four steps:
 1. Dip reagent strip into urine QC tube, wetting all pads and immediately removing strip from QC tube.
 2. Blot strip by touching the edge to a paper towel to remove the excess urine. Do not lay pads on the paper towel or cover the pads by the paper towel.
 3. Place the strip in the channel on the test table with the pads facing up. Slide the strip all the way to the end of the channel.

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- A **Clinitek Status[®] is Calibrating** screen will appear
- At the end of the 8 seconds countdown, the test table and strip will be automatically pulled into the analyzer.
- A **SELECT APPEARANCE** screen will be displayed. Choose either “**Yellow and Clear**” or “**Other**”. If **Other** is selected, select appropriate color of urine. Touch **NEXT**. Select appropriate clarity of urine. Touch **NEXT**.
- A timer will count down the time remaining in analyzing the strip results. Total testing time is 60 seconds.
- When analysis is complete, **PRINT DATA** is displayed. The test results will be printed from the analyzer as well as displayed on the screen. Touch **MORE** to view the remainder of the test information. Touch **DONE** to return to the **SELECT** screen in order to perform another test.
- Remove the used strip and store in appropriate envelope.
- Clean the table by wiping it with a piece of gauze moistened with water before placing another test strip on the table. Make sure the test table is completely dry before performing another test.
- The printouts are retained for a period of two years.
- Document QC results on the log and review for acceptable performance.
- If result(s) are not acceptable, repeat testing using another test strip from the canister, test strip from a new canister, and /or new liquid QC bottles.
- If, on retest, results are still not acceptable, perform QC by visual method.
- With the QC by visual method, document results on log. If the results are within range, perform patient testing by Visual Method.
- Inform Point of Care Specialist of problem QC results using the Clinitek Status.

PROCEDURE FOR PATIENT TESTING

For CHMG Practices:

- Press the on/off button located on the front of the instrument.
- The first main screen is the **SELECT** screen. All screens are touch screens. Touch **STRIP TEST** to conduct a urinalysis strip test.
- From the **OPERATOR ID** screen, touch the **ENTER NEW OPERATOR ID** button.
- Enter your operator ID number. Touch **ENTER**.
- Touch **ENTER NEW PATIENT**. The **ENTER PATIENT ID** screen appears. Enter the patient’s Date of Birth.
- The **ENTER NAME** screen appears. Select ABC, and **enter the patient’s last name**. Touch **ENTER**.
- At the **PREPARE TEST** screen, touch **START**.
- You have 8 seconds to complete the following four steps:
 - 1 Dip reagent strip into urine sample, wetting all pads and immediately removing strip from urine.
 2. Drag the edge of the strip against the side of the sample container as you remove it.
 3. Blot strip by touching the edge to a paper towel to remove the excess urine. Do not lay pads on the paper towel or cover the pads by the paper towel.
 4. Place the strip in the channel on the test table with the pads facing up. Slide

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the strip all the way to the end of the channel.

- A **Clinitek Status® is Calibrating** screen will appear
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- A **SELECT APPEARANCE** screen will be displayed. Choose either “**Yellow and Clear**” or “**Other**”. If **Other** is selected, select appropriate color of urine. Touch **NEXT**. Select appropriate clarity of urine. Touch **NEXT**.
- A timer will count down the time remaining in analyzing the strip results. Total testing time is 60 seconds.
- When analysis is complete, **PRINT DATA** is displayed. The test results will be printed from the analyzer as well as displayed on the screen. Touch **MORE** to view the remainder of the test information. Touch **DONE** to return to the **SELECT** screen in order to perform another test.
- Remove the used strip and store in appropriate envelope.
- Clean the table by wiping it with a piece of gauze moistened with water before placing another test strip on the table. Make sure the test table is completely dry before performing another test.
- The printouts can remain as a continuous strip for a specified period of time. When they are torn off the instrument they must be kept for 2 years.
- Record patient test results in the patient record.

For In Hospital, Walk In Urgent Care Lab, Occupational Health Family Health Center:

- Enter the Soft Lab Order number as the patient ID
- Continue patient testing steps from “PREPARE TEST” above.

INTERPRETATION / REPORTING RESULTS:

- An * will appear next to all results marked as positive.
- All patient results are recorded in the patient record.
- Instrument reportable ranges: Normal system is used.
- *Upper limits of glucose, bilirubin, ketone, and protein are to be verified by visual inspection of the test strip against the colored result chart on the Multistix® 10 SG reagent bottle.*

REFERENCE RANGES:

- Glucose -----Negative
- Bilirubin -----Negative
- Ketone -----Negative
- Specific Gravity ----- 1.003 -1.030
- Blood -----Negative
- pH -----5.0 - 8.5
- Protein -----Negative
- Nitrite -----Negative
- Leukocyte Esterase --Negative

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Test Name & Abbreviation	Units	Reportable Results
Glucose (GLU)	mg/dL	Negative 100 250 500 ≥1000
Bilirubin (BIL)		Negative Small Moderate Large
Ketone (KET)	mg/dL	Negative Trace 15 40 80 ≥160
Specific Gravity (SG)		≤ 1.005 1.010 1.015 1.020 1.025 ≥1.030
Occult Blood (BLO)		Negative Trace-lysed Trace-intact Small Moderate Large
pH (pH)		5.0 5.5 6.0 6.5 7.0 7.5 8.0 ≥9.0
Protein (PRO)	mg/dL	Negative Trace 30 100 ≥300
Urobilinogen (URO)	E.U./dL	0.2 1.0 2.0 4.0 ≥8.0
Nitrite (NIT)		Negative Positive
Leukocyte Esterase (LEU)		Negative Trace Small Moderate Large

LIMITATIONS:

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- Ensure complete saturation of all test pads with specimen. The side edge of the test strip needs to be blotted so that chemical contamination between the test pads does not occur.
- ***When the color of a urine specimen is anything other than yellow, it can cause the results to look positive when in fact they are not. In these situations inform the provider the results of the urine dip tests are suspect and further follow-up testing can be done at the Concord Hospital Laboratory.***

CONFIRMATORY TESTING OF UNUSUAL OR UNEXPECTED RESULTS:

- When encountering unusual results or when there is uncertainty about a conclusion, collect a new patient sample and repeat the test.
- At the discretion of the ordering provider, the patient sample can be sent to Concord Hospital Laboratory for analysis or other follow up tests may be ordered.

PROCEDURE NOTES:

- Do not bump or move the table or instrument while in use.
- Instrument error messages will be displayed when the analyzer detects something that needs attention. A list of these codes is found in the Operator's Manual.

RECALL OF PATIENT RESULTS:

- From the **SELECT** screen, touch **RECALL RESULTS**.
- At the **SELECT TEST RESULTS** screen, all tests performed are displayed with the most recent test at the top.
- Use the ^ and v keys to scroll through the list. Locate the correct test by matching the patient's accession number and date/time performed.
- Once the correct test/patient is highlighted, touch **SELECT** to view result details. If there is more than one page of results for this test, touch **MORE** to display the additional results.
- When finished viewing, touch **DONE** to return to the **SELECT TEST RESULTS** screen.
- Touch **EXIT** to return to the main **SELECT** screen.

CLEANING AND MAINTENANCE:

- Remove test table by pulling it straight out of the analyzer.
- Remove the test table insert.
- Clean test table insert and test table with cotton tipped swab moistened with water.
- **DO NOT** clean the white calibration bar. Care should be taken not to scratch or scuff the white bar.
- Allow to air dry, or dry with a lint free cloth.
- Reinsert the insert into the test table. Reinsert the test table into the analyzer by pushing it in just over half way.
- With the analyzer turned OFF, the outside can be cleaned by wiping with a damp cloth.

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POWERING DOWN:

- Before turning the analyzer off, ensure that there are no test strips on the test table and that the test table is clean.
- Press and hold the on/off button for at least 2 seconds.
- The test table will retract into the analyzer, the door will close, and the analyzer will switch off.

REFERENCES

Clinitek Status® Operator's Manual; Siemens Healthcare Diagnostics, Inc. Tarrytown, NY 10591 USA

Multistix® 10 SG package insert; Siemens Healthcare Diagnostics, Inc. Tarrytown, NY 10591 USA

Semi-Quantitative Dipstick Liquid Urine Control package insert; Kenlor Industries, Inc. Santa Ana CA. 92705

DISTRIBUTION

Concord Hospital Medical Group (CHMG) Practices at Concord Hospital

RESPONSIBLE

DEPARTMENT/UNIT

Point of Care, Laboratory.

HISTORICAL APPROVAL

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Reviewed (date): SEC 1-14-09

Revised (date): KH 01/07/ Suzanne Chute BS MT BB(ASCP) 1/14/09

PATHOLOGY APPROVAL

Gary York, MD Date: