

**Employee Health CLINITEK STATUS +**

 **Clinic**

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| Effective Date: March 2022 | Department: Laboratory |
| Date of Review: March 2024 | Created/Maintained by: Laboratory Management |

1. Purpose:

This test is used to rapidly measure specific chemical components of urine utilizing the Clinitek Status Analyzer. Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocyte results are reported through the point of care lab entry tab. This test is to be performed on the Inchokma mobile unit only. This procedure is approved by the Clinical Laboratory Improvement Amendments (CLIA) director/or delegate at least every three years and at any time the procedure is revised. The procedure follows manufactures recommendations and is readily available to all testing personnel through the CNDH portal.

1. Mission:

The mission of the Chickasaw Nation is to enhance the overall quality of life of the Chickasaw people. The Chickasaw Nation Department of Health (CNDH) meets this mission by providing exceptional customer experience that focuses on health promotion and disease prevention.

1. Standard Operating Procedures (SOP):

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1. Specimen Criteria:

1. Acceptable Specimen:

a. A fresh, clean catch, midstream or catheterized specimen is preferred.

1. 10-12 milliliters of random urine is optimum. One milliliter is the minimum required.
2. Specimens are collected using a sterile collection container with lid.
3. Specimens are labeled with the patient’s name, date of birth, chart number and date and time of collection on the urine cup. Label the specimen in the presence of the patient to prevent mislabeling.
4. The specimen should be tested within one hour of collection. If unable to test within one hour, store immediately at 2-8 °C (35.6-46.4°F).
5. If refrigerated, return to room temperature and mix thoroughly before testing.

 2. Unacceptable Specimens:

a. Specimens more than 24 hours old.

1. Specimens which have not been refrigerated within one hour of collection.
2. Improperly labeled specimens.
3. Aliquots of 24 hour urine collections. (Except for protein screening tests.)
4. Specimens containing feces or preservatives.
5. Equipment and Reagent Materials:
6. Clinitek Status
7. 12 mL Urintek tubes
8. Sterile urine containers
9. Siemens Multistix 10 SG Reagent Strips
10. Urine quality control- (2 levels)
11. Distilled water
12. Storage and Handling of Reagents and Quality Control Material:
13. Store at room temperature (15-30°C) (59-86°F).
14. Do not use after expiration date stated on bottle.
15. Do not store bottle in direct sunlight.
16. Protection from ambient moisture, light and heat is essential to guard against altered reagent activity.
17. All unused strips must remain in the original bottle.
18. Do not remove desiccant from the bottle.
19. Do not remove strip from the bottle until immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip.
20. Do not touch test areas of the reagent strip.
21. Work areas must be free of detergents and other contaminates.
22. Dip reagent strips briefly to prevent the dissolution of reagents.
23. Quality Control and Calibration:

1. Calibration:

The instrument performs a system test each time it is turned on. Then, each time a test is run, the instrument automatically calibrates. The white calibration bar (on the test table) provides a National Institute of Standards and Technology (NIST) traceable calibration.

2. Quality Control (QC) Testing:

Quality control is performed each day of testing and when a new bottle of reagent strips is opened. Records of the strip lot number, Chek-Stix lot numbers and dipstick results are kept in the daily patient/QC folder within the Inchokma Mobile Unit.

Urine quality control strips are firm plastic strips on which 7 separate analyte areas are affixed. These strips each contain 1 or more natural or synthetic ingredients that, when dissolved out of the analyte areas in a measured quantity of distilled or deionized water produce a Positive or Negative Control solution.

* + 1. Reconstitution procedure:
1. Place 12 mL of distilled or deionized water in an appropriately labeled specimen tube. Do not use tap water.
2. Remove a Clinitek Atlas Control Strip from the bottle and replace the cap immediately and tightly.
3. Place the strip into the tube. Cap tightly.
4. Repeat steps 1-3 if using a second control.
5. Gently invert the tube(s) back and forth for 2 minutes.
6. Allow the tube(s) to stand for 30 minutes at room temperature.
7. Invert one more time, then remove and discard the strip(s).
8. Test control material following the patient testing procedure.
9. The solution is stable for 3 hours.

**Quality controls should be within acceptable ranges before any patient testing is performed. If quality control deems unacceptable, follow the reconstitution procedure with new Chek-Stix reagent sticks. Please be sure to adhere to time frames indicated. If Quality control continues to fail, notify the point of care coordinator, remove from service and refrain from using the analyzer for patient testing.**

1. Procedure:
2. Pour 10-12 mL of well mixed urine into a 12 mL Urintek tube and record the color and clarity. If urine specimen quantity is less than 10 mLs use as much as you can.
3. On the main screen of the Clinitek Status, press **Strip Test**.
4. Press **Enter New Patient**- enter/scan the patient chart number and press enter.
5. Dip the reagent strip into the urine, then blot off the excess, and place the dipstick on the dipstick test table.
6. Press **Start**.
7. Enter color and clarity one of two ways:
	1. **Default** –yellow and clear
	2. **Other**- determine what the color is and touch that color or touch other and press next, then determine what the clarity is and touch that corresponding button and press next.

G. Reporting Results:

Results are reported out in Electronic Health Record (EHR) thru the POC Lab Entry tab. Results should be reviewed by approved operators before being reported in the patient chart.

Glucose, Bilirubin, Ketone, Blood, Protein, and Leukocyte Esterase results are reported as semi-quantitative (e.g., negative, trace, 1+,2+,3+ etc.). Specific Gravity, pH and Urobilinogen results are reported as the stated value. Nitrite results are reported as Positive (Pos) or Negative (Neg).

Grossly bloody or intensely colored urines can give erroneous results due to the color interference. In this instance, a urine specimen may need to be collected at a later date.

H**.** Cleaning and Maintenance:

The test table insert and the test table should be kept clean if the analyzer is to operate properly.

 Routine Cleaning of the Test Table Insert – Day of use

1. Remove insert and thoroughly clean.
2. Rinse both sides of the table insert under running water.
3. Dry and replace insert.

 Periodic Cleaning of Test Table when required-As needed.

1. Remove the test table by pulling slowly out of the analyzer. Lift the test table insert from the test table; drain the drip tray if necessary.
2. Wet a cotton-tipped stick with water and carefully clean test table (except for white calibration bar).
3. Dry the test table thoroughly (except for the white calibration bar) with a soft cloth or lint-free tissue. **NOTE: Care should be taken not to scratch the white calibration bar. Instructions for cleaning the white calibration bar are given later in this section.**
4. Reinsert the test table into the analyzer by holding the table at the end opposite the white calibration bar facing upwards. Push the test table firmly but slowly, just over halfway into the analyzer. Replace the test table insert.

 Disinfecting the Test Table and Insert-Monthly

1. Prepare a cleaning solution, consisting of Isopropyl Alcohol(70% to 85%) in a tall, narrow container (e.g., empty Multistix bottle) to a depth of about 4 inches (10 cm):
2. Place the insert and/ or test table into the solution, making sure the white calibration bar on the test table remains above the liquid level.

**NOTE: Be sure the solution does not come in contact with the white calibration bar. Do not cover the container while the test table is soaking.**

1. Soak the table and insert for a minimum of 2 minutes and maximum of 10 minutes. Do not soak longer than 10 minutes.
2. Rinse the test table and insert thoroughly with water.
3. Dry with a soft cloth and replace test table and table insert in the analyzer (as described above).

 Cleaning the White Calibration Bar- Monthly

1. Remove the insert from the test table.
2. Remove the test table by pulling it slowly out of the analyzer.
3. Check the white calibration bar on the test table for dirt or discoloration.
4. If the white calibration bar is clean and unmarked, replace the table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over half way into the analyzer. Replace the test table insert.
5. If the white calibration bar is dirty or discolored, gently wipe and clean it with a new cotton-tipped stick or lint-free cloth wet with distilled water.

**NOTE: Care should be taken not to scratch the white calibration bar. Solvents of any kind must not be used to clean the bar.**

1. Allow the calibration bar to air dry and then inspect the surface for dust, foreign material, scratches or scuffs. If the calibration bar cannot be cleaned or is still marked, obtain a new test table.
2. Reinsert the test table as described earlier in step 4.

I. Limitations:

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

1. Substances that cause abnormal urine color, such as drugs containing Azo dyes (Pyridium, Azo, Gastrisin, Azo Gantan), Nitrofurantoin (Macrodantin, Furadantin), and riboflavin may affect the readability of the reagent areas on urinalysis reagent strips. 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 and/or instrumentally as a false positive.
2. Glucose: Ascorbic acid concentrations of 50 mg/dL or greater may cause false negatives for specimens containing small amounts of glucose. Ketone bodies reduce the sensitivity and may cause false negatives. The reactivity of the test decreases as the specific gravity of the urine increases. Reactivity may also be affected by temperature.
3. Bilirubin: Indican (indoxyl sulfate) may produce a yellow-orange to red color response that may interfere with the interpretation of a negative or a positive bilirubin reading. Iodine may cause false positive or atypical results. Ascorbic acid may cause false negatives.
4. Ketone: False positive 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 positives or an atypical reaction.
5. Specific Gravity: Highly buffered alkaline urines may cause low readings. Elevated specific gravity readings may be obtained in the presence of moderate quantities of protein.

V. Reference(s):