### HACKETTSTOWN REGIONAL MEDICAL CENTER LABORATORY POLICY MANUAL CLINITEST (USING BIO-RAD QUANTIFY)

Effective Date: April, 2009	Policy No: UA124.01
Cross Referenced:	Origin: Urinalysis
Reviewed Date: 6/2012	Authority: Laboratory Director
Revised Date:01/12	Page: 1 of 2

**PRINCIPLE**: The dipstick used in urine testing will only detect glucose. Clinitest tablets will detect other sugars such as lactose, fructose, galactose, and pentoses. These other sugars can be characteristic of certain metabolic disorders when found in urine of small children. Copper sulfate in Clinitest reacts with reducing substances in urine converting cupric sulfate to cuprous oxide. The resultant color, which varies with the amount of reducing substances present, ranges from blue through green to orange. Sodium hydroxide provides the alkaline medium necessary for the reaction to take place. Heat required is furnished by the reaction of sodium hydroxide with water and with citric acid. Sodium carbonate and citric acid help to dissolve the tablet.

### **SPECIMEN COLLECTION:**

Urine specimen should be collected according to SOP. Clinitest should be used only with fresh urine since glucose and other reducing sugars are consumed by bacteria. Refrigerate urine specimens if they cannot be tested immediately. Urine preservatives may affect test results.

### **REAGENTS AND EQUIPMENT:**

Clinitest Reagent Tablets – Protect tablets from light, heat ,and moisture. Do not refrigerate. Test tube Pipette Distilled Water

# QUALITY CONTROL

A positive and negative control is run once each day Clinitest is performed and whenever a new bottle of reagent tablets is opened. Bio-Rad qUAntify Level 1 (neg) and Level 2 (pos) is used. Enter results of testing on log sheet whenever testing is performed.

# **PROCEDURE:**

# Five Drop Method – Standard Procedure (measures up to 2% sugar)

- 1. Holding pipette in an upright position, place 5 drops of fresh urine (or control) into test tube. Rinse dropper with water and then add 10 drops of fresh water to test tube.
- 2. Remove one Clinitest tablet from the bottle and drop into test tube. Watch while complete boiling reaction takes place. Do not shake test tube during boiling or for 15 seconds once the boiling is complete.
- 3. At the end of the 15 second waiting period, shake test tube gently to mix contents. Compare color of liquid to Color Chart supplies with tablets. Ignore sediment that may have formed. Do not read any changes that occur after the 15 second waiting period.
- 4. Report results as the % whose color most closely matches the color observed in the test tube.
- 5. Document QC on log sheet with a check or "CA" for corrective action
- 6. If QC is out of tolerance limits, repeat test, if still out, examine tablet for decomposition and open a new bottle or choose a new control.
- 7. Document on log and notify supervisor if necessary

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#### Two Drop Method (measure up to 5% sugar)

- 1. Holding pipette in an upright position, place 2 drops of fresh urine (or control) into test tube. Rinse dropper with water and then add 10 drops of fresh water to test tube.
- 2. Remove one Clinitest tablet from the bottle and drop into test tube. Watch while complete boiling reaction takes place. Do not shake test tube during boiling or for 15 seconds once the boiling is complete.
- 3. At the end of the 15 second waiting period, shake test tube gently to mix contents. Compare color of liquid to Color Chart supplies with tablets. Ignore sediment that may have formed. Do not read any changes that occur after the 15 second waiting period.
- 4. Report results as the % whose color most closely matches the color observed in the test tube.
- 5. Document QC on log sheet with a check or "CA" for corrective action
- 6. If QC is out of tolerance limits, repeat test, if still out, examine tablet for decomposition and open a new bottle or choose a new control.
- 7. Document on log and notify supervisor if necessary

Note: Urine containing more the 2% sugar using the standard procedure or more than 5% sugar using 2 drop method may cause a very rapid color change during the boiling and 15 second waiting period. Observe solution closely during this time to detect any "pass through" color changes. Should these occur, color will pass rapidly through bright orange to dark brown or greenish brown. See Reporting Results section for how to report results.

### **REPORTING RESULTS**

Clinitest results are obtained in percent (equivalent to grams per deciliter) directly from comparison to appropriate color chart supplied with tablets. Color blocks for the standard procedure are designated as negative, <sup>1</sup>/<sub>4</sub>%, <sup>1</sup>/<sub>2</sub>%, <sup>3</sup>/<sub>4</sub>%, 1%, and 2%. Color block for the 2 drop procedure are designated as negative, trace, <sup>1</sup>/<sub>2</sub>%, <sup>3</sup>/<sub>4</sub>%, 1%, 2%, 3% and 5%.

If a pass through color reaction is noted, the result is recorded as "over 2% sugar" if using the standard procedure and as "over 5% sugar" if using the 2 drop method. Do not compare final color to the Color Chart.

Clinitest should give negative results with urine specimens from healthy individuals. Clinitest is not specific for glucose and will react with sufficient quantities of any reducing substance in the urine. Failure to observe reaction at all times can lead to erroneously low results if the pass through reaction is missed. Low specific gravity urines containing glucose may give slightly elevated results.

### REFERENCES

Clinitest Reagent Tablet Product Insert. Bayer Corporation, Elkhart, IN. rev. 9/95