HACKETTSTOWN REGIONAL MEDICAL CENTER LABORATORY POLICY MANUAL CLINITEK 500 OPERATION

Effective Date: August, 2008 Policy No: UA110.01 Cross Referenced: Origin: Urinalysis

Reviewed Date: 6/2012 Authority: Laboratory Director

Revised Date: 12/03, 06/08, 04/09, 07/09, 04/10, Page: 1 of 2

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PRINCIPLE: The Clinitek 500 is a semi--automated benchtop instrument designed to read multi-reagent

urinalysis strips.

REAGENTS AND EQUIPMENT:

Bayer Clinitek 500 Analyzer Multistix 10 SG Reagent Strips Bio-Rad qUAntify Levels 1 and 2

QUALITY CONTROL:

Both positive and negative controls are run daily for each screening test contained on the Multistix strip. In addition, both controls are run whenever a new bottle of reagent strips is opened. Bio-Rad qUAntify Levels 1 and 2 are used as a negative and positive control respectively. (See QC procedure).

PROCEDURE:

- 1. The Clinitek 500 autocalibrates when the Reagent strip comes into position under the two readheads.
- 2. The Clinitek 500 has a touch screen so you may touch the screen to come to the Ready/Run screen.
- 3. Touch the ID key to enter the number for the first specimen.
- 4. Scan the barcode for the sample.
- 5. Confirm that the correct barcode number is displayed.
- 6. Mix room temperature urine well immediately before testing.
- 7. Pour an aliquot of the specimen into a labeled centrifuge tube.
- 8. If the specimen is in a BD Collection tube from the ER, retain a small sample in the tube for potential add on testing. (ex preg or drug screen).
- 9. Perform visual exam for color and clarity of specimen.
- 10. Edit the clarity if it is not the default (clear) by touching the CLARITY button until the appropriate clarity is displayed.
- 11. The color will be read by the instrument.
- 12. Touch

 to enter the number into memory and repeat steps 4-8 for each additional specimen.
- 13. To review, change, or delete a loadlisted number or clarity description that has been entered, use the ↑or ↓ to display the desired number, using the loadlist order number to help you locate the proper location. Adjustments must be made in the ready mode not run. Edit the selection and then touch ↓ to store.
- 14. When all the IDs have been entered touch \uparrow to return to the Ready/Run screen to begin testing.
- 15. Completely immerse all reagent areas of a Reagent strip in urine and immediately remove the reagent strip. While removing, slowly run the edge of the entire length of the Reagent Strip against the side of the urine container to remove excess urine.
- 16. Place the Reagent Strip, with reagent areas facing up, onto the strip supports of the strip loading station, to the right of the small-embossed arrow and against the rear wall of the platform. **NOTE:** be sure the Reagent Strip is lying parallel to the push bar. The end of the strip should be against the rear wall of the platform and should not be touching the bottom of the strip loading station.

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Improper placement may cause the instrument to jam and the strip to incorrectly align under the readheads.

- 17. The presence of the Reagent Strip is detected as soon as it is placed on the leading station. The push bar will return to the sample position when it is ready to accept a new specimen.
- 18. Each strip will automatically be advanced along the strip loading station, under the readheads for reading, then into the waste contained. The results will be printed after all the reagent areas have been read. They will then be downloaded to the host computer, reviewed, and released.

REPORTING RESULTS:

Positive bilirubins require an Ictotest to confirm the presence of bilirubin. All children one year and under are required to have a Clinitest done.

REFERENCE RANGES:

Normal Ranges

pН	4.6-8.0
Specific Gravity	1.001 –1.035
Glucose	Negative
Ketone	Negative
Urobilinogen	0.2 – 1.0 EU/dl
Bilirubin	Negative
Blood	Negative
Protein	Negative
Nitrites	Negative
Leukocyte Esterase	Negative

Reference ranges are obtained from the Multistix 10G package insert; and approved by the current medical director. The Reference ranges will be re-evaluated with each Multistix 10G package insert revision.

REFERENCES:

Multistix 10SG Reagent strips package insert, Siemens Healthcare Diagnostics Inc., Tarrytown, NY Rev. 2/11

Clinitek 500 Urine Chemistry Analyzer Operating Manual, Bayer Corporation, Elkhart, IN. Revised 5/01.