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Clinitek Chemical Urinalysis

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this procedure is to provide instruction for performing urinalysis testing on the Clinitek analyzer. This is a semi-automated bench-top instrument designed to "read" Siemen's Reagent Strips for Urinalysis. The instrument system includes a program card that contains the programming necessary for the Clinitek Instrument to read these reagent strips. The system is used to automate the chemical portion of urinalysis.

II. PRINCIPLE:

The Clinitek is a reflectance spectrophotometer that analyzes the color and intensity of the light reflected from the reagent area and reports the results in clinically meaningful units. No calculations are required by the user.

III. SPECIMEN COLLECTION AND HANDLING:

A. Patient Preparation: No special preparation required for random urine sample.

B. Specimen Type: Urine

1. Acceptable Containers

a. Vacutainer Urine Collection Kit should be used for clean catch midstream urines.

b. ~~BD Vacutainer Plus UA Preservative Tubes, conical bottom, 8 milliliter (mL).~~

c. Sterile urine container.

d. A separate, preserved specimen is required for Microbiology Culture and Sensitivity.

2. Volume

a. Optimum volume for non Vacutainer specimens is 20 mL.

b. A minimum of 5 mL of urine is required for automated urinalysis.

c. A minimum of 10 mL of urine is required for a manual microscopic examination only.

d. A minimum 3 mL of urine is required for automated microscopic examination.

3. Collection

a. First morning clean catch midstream urine is preferred.

b. Random urine specimens will be accepted.

4. Storage/Stability Instructions

a. Specimen is stable for 2 hours at room temperature (20-26º C).

b. Refrigerated (2 – 8ºC) urine samples are stable for 8 hours.

c. Specimens must be brought to room temperature before analysis.

d. Refrigerated specimens greater than 2 hours old may be reported with the following smart phrase comment: "**.2HO" (Sample greater than 2 hours old - may be loss of cell casts and other formed elements. Dipstick testing may yield inaccurate results.)**

e. Specimens left at room temp for greater than 2 hours may be reported with the following smart phrase comment: "**.UA2H" (Sample >2 hours old and not refrigerated-may be loss of cell casts and other formed elements. Dipstick testing may yield inaccurate results.)**

5. Causes for rejection

a. Improperly identified specimen.

b. Insufficient quantity to perform the test (< 1 mL)

c. Specimens greater than 24 hours old.

d. Specimens that have been frozen.

e. Specimen received in container with preservatives ~~present other than the BD Vacutainer preservative~~.

6. Specimen Identification

a. All specimens should be labeled with patient's name, unique identification number, time, date of collection which is included on the Laboratory Information System (LIS) label.

7. Specimen Handling

a. Follow Universal Precautions due to the potential presence of pathogenic material. CAUTION: Gloves and a lab coat must be worn when handling open specimens.

IV. REAGENTS:

A. **Multistix 10 SG:** Protection from exposure to light, heat and ambient moisture is mandatory to guard against altered reagent activity. All unused strips must remain in the original bottle. Do not use strips past the expiration date on the bottle.

1. **pH**: This test is based on a double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.
2. **Protein**: This test is based on the protein-error-of-indicators principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for “Negative” through yellow-green and green to green-blue for “Positive” reactions.
3. **Glucose**: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.
4. **Ketone**: This test is based on the development of colors ranging from buff-pink, for a negative reading, to purple when acetoacetic acid reacts with nitroprusside.
5. **Bilirubin**: This test is based on the coupling of bilirubin with diazotized dichloroaniline in a strongly acid medium. The color ranges through various shades of tan.
6. **Blood**: This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3, 3’, 5, 5’-tetramethylbenzidine. The resulting color ranges from orange through green; very high levels of blood may cause the color development to continue to blue.
7. **Nitrite:** This test depends upon the conversion of nitrate 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 in turn couples with 1,2,3,4 – tetrahydrobenzo (h)-quinolin-3-ol to produce a pink color.
8. **Leukocytes:** Granulocytic leukocytes contain esterases that catalyze the hydrolysis of 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.
9. **Urobilinogen:** This test is based on a modified Ehrlich reaction, in which p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.
10. **Specific Gravity:** This test is based on the apparent pKa change of 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.

V. EQUIPMENT:

A. Clinitek analyzer

B. Centrifuge

C. Refractometer

VI. SUPPLIES:

A. Transfer pipettes

VII. EQUIPMENT CALIBRATION:

Calibration is performed at each read head immediately before each Reagent strip is read and stored in the memory. A report of the most recent successful calibration can be printed by touching MENU from the Ready-Run screen, then Print and Calibration confirmation will give current calibration information. Note this print function is not available on the Clinitek Status. If calibration fails no results will generate, refer to instrument troubleshooting guide.

VIII. MAINTENANCE:

See operating manual for specific instructions.

A. **Daily**:

1. Clinitek Advantus/ Clinitek 500- Empty waste bin
2. Clinitek Status- Clean test table after each sample

B. **Weekly**:

1. Clinitek Advantus/ Clinitek 500 - From the Ready/Run screen, turn off instrument. Remove push bar or strip feeder, waste bin liner, fixed platform moving table and hold down plate for cleaning with mild soap and warm water. While cleaning the platform, avoid wiping the two white calibration bars, use a cotton tip swab with plain water to clean. Air dry.
2. Clinitek Status- Remove the test table by pulling it slowly out of the analyzer. Lift the test table insert from the test table, drain the drip tray if necessary. Check the white calibration bar on the test table for dirt or discoloration. 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. Wet another cotton-tipped stick with water and carefully clean test table. Air dry and return the test table.

C. **As needed**: Clean exterior of instrument, change paper roll.

D. **Start Up and Shutdown:**

1. Use the power toggle switch to turn on the instrument.
2. The Clinitek will perform an initialization and return to the main Ready/Run screen

when the initialization is complete.

3. With the instrument at the Ready/Run screen, the instrument may be shut down by turning off the power toggle switch.

Note: If the instrument is not at the Ready/Run screen when the power is turned off, the instrument may need to be reinitialized and returned to the Ready/Run screen and then shutdown again before any parts may be removed for cleaning or replacement according to the maintenance procedures.

IX. QUALITY CONTROL (QC):

~~A. KovaTrol I and KovaTrol III are run daily.~~

~~B. Controls are prepared weekly by reconstituting with clinical laboratory reagent water (deionized water) using a graduated cylinder. See package insert for more details based on the bottle size.~~

~~C. Gently rotate the bottle until completely dissolved (approximately 15 minutes).~~

~~D. Allow refrigerated controls to come to room temperature prior to testing.~~

~~E. Results will automatically upload to BioRad Unity Realtime or documented on QC log as appropriate.~~

~~F. All Quality Control results will be reviewed for acceptability prior to reporting patient results.~~

A. KOVA Liquatrol (Dearborn):

1. KOVA Liquatrol with microscopics is a ready-to-use liquid product intended for use in the laboratory as a control for qualitative and semi-quantitative procedures used in physiochemical and chemical determinations and for microscopic sediment analyses of human urine. KOVA Liquatrol with microscopics contains measured amounts of chemicals, stabilized human red cells and organic particles to simulate leukocytes. Liquatrol serves as a control for physical, chemical and microscopic tests routinely performed in urinalysis. Liquatrol Abnormal contains 0.03% Microcide I and Liquatrol Normal contains <0.1% sodium azide.
    a. Control Usage: All QC must be performed prior to reporting patient results.
        i. KOVA Liquatrol Control Level I = Positive control
        ii. KOVA Liquatrol Control Level II = Negative control

B. KOVA-Trol (Taylor, Trenton, Wayne and Canton):

1. KOVA-Trol Human Urinalysis Controls are freeze-dried preparations of human urine combined with predetermined amouts of chemicals, stabilized human red cells and organic particles to simulate leukocytes. They are intended for use in the clinical laboratory as a urine control for qualitative and semi-quantitative procedures used in physiochemical and chemical determinations and may also be used for microscopic sediment analyses. KOVA-Trol contains 0.008% gentamicin as a preservative.
    a. Control Usage: All QC must be performed prior to reporting patient results.
        i. KOVA-Trol I High Abnormal with Urobilinogen = Positive control

ii. KOVA-Trol III Normal with hCG = Negative control

C. See individual package inserts for acceptable ranges.

D. Lyophilized controls are prepared weekly by reconstituting with clinical laboratory reagent water (deionized water) using a graduated cylinder or a micro-pipettor. See package insert for more details based on the bottle size.

1. Gently rotate the bottle until completely dissolved (approximately 15 minutes).

E. Allow refrigerated controls to come to room temperature prior to testing.

F. Results will automatically upload to BioRad Unity Realtime or documented on QC log as appropriate.

G. All Quality Control results will be reviewed for acceptability prior to reporting patient results.

X. PROCEDURE:

A. Mix specimen well.

B. Press ID icon, scan patient bar code or manually enter the Instrument Identification number (Instrument ID).

C. Note color and clarity, manually select or scan bar codes for determinations; instrument will default to yellow/clear.

D. Completely immerse all reagent areas of the reagent strip in the well mixed urine. Immediately remove the reagent strip. While removing, slowly run the edge of the entire length of the strip against the side of the urine container to remove excess urine. DO NOT BLOT. For low volume samples, use a transfer pipette to fully saturate each pad on the reagent strip.

E. Place the reagent strip, with the reagent areas facing up, onto the strip supports of the loading station, to the right of the push bar and against the rear wall of the platform. The presence of the reagent strip is detected as soon as it is placed on the loading station. For the Clinitek Status, the strip should be placed on the strip loader when prompted by the instrument.

F. Repeat steps A-F for each new sample, note that there may be a delay of up to seven seconds after the strip is placed on the loading station before the push bar moves. The instrument will move the strips across the read area until the final strip is moved to the waste bin. A new strip can be placed on the loading station at any time prior to then. For the Clinitek Status, the instrument will prompt when testing on a new sample can be performed.

G. Evaluate the results for the requirements of a microscopic exam. Any positive macroscopic result (except urobilinogen) reflexes a microscopic exam. Refer to Laboratory Examination of Urinary Sediment procedure.

H. Evaluate the results for any confirmatory testing that is needed for Specific Gravity, or possible false positive Nitrite results.

XI. EXPECTED VALUES/REPORTABLE RANGE:

Parameter	Reference range	LIS Reportable Range

Urine pH	5.0-8.0	5-8.5, >9.0
Urine Specific Gravity	1.005-1.030	≤1.005-≥1.030 SG values will be reported from the Clinitek that are ≥1.030 will be confirmed on the refractometer
Urine Glucose	Negative	Neg, 100 (trace), 250 (1+), 500 (2+), >=1000 (3+) mg/dL
Urine Ketone	Negative	Neg, 5 (trace), 15 (1+), 40 (2+), >=80 (3+) mg/dL
Urine Bilirubin	Negative	Negative or Positive
Urine Blood	Negative	Neg,Trace (intact-lysed),1+, 2+, 3+
Urine Protein	Negative	Neg, 15 (trace), 30(1+), 100 (2+), >=300 (3+) mg/dL
Urine Urobilinogen	0.2-1.0 Ehrlich units/dL	Neg, 0.2, 2.0, 4.0, >=8.0
Urine NitrItes	Negative	Negative or Positive
Urine Leukocyte	Negative	Neg, Trace, 1+, 2+, 3+
Color		Yellow, Amber, Red, Orange, Blue, Colorless, Other
Clarity	Clear	Clear, Cloudy, Turbid

XII. CRITICAL RESULTS:

Urine Ketones >=80 mg/dL

Note: Critical call notification is waived for patients in the Emergency Center (EC)

XIII. LIMITATIONS:

A. Color Interference

1. Abnormally colored or very dark urine may interfere with or obscure reagent strip test results. If such a specimen is submitted, all results (except color, clarity and Specific Gravity) should not be reported and should be resulted as COLOR INTERFERENCE in the LIS. Color and Clarity should be determined visually, and Specific Gravity testing should be performed on the refractometer and these results should be manually entered into the LIS. A microscopic exam should be performed.

B. Bloody Urine

1. Enter the smart phrase comment **".bldyua" (Bloody specimen. Urine chemistry testing was performed on the supernatant of a centrifuged specimen. Interpret results cautiously)** in the white comment box in the LIS.
2. ~~Spin the urine and process the chemistries manually on the Clinitek using the supernatant.~~Spin the urine and process the chemistries manually on the Clinitek using the supernatant.
    a. If the supernatant remains red, DO NOT perform the chemistry portion of

the urinalysis.

i. Manually result the color and clarity.

ii. Perform and report the Specific Gravity by refractometer.

iii. Report "color interference" for Glucose, Bilirubin, Ketone, Blood, pH, Urobilinogen, Nitrite, and Leukocytes.

XIV. INTERFERING SUBSTANCES:

A. Substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium, Azo Ganstrisin, Azo Gantanol), nitrofurantoin (Macrodantin, Furadantin) and riboflavin, may affect the readability of 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. In these cases, results that are affected by the color (Pyridium dye) should not be reported and resulted as COLOR INTERFERENCE (see Limitations above).

B. pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as “run-over” may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing a false lowering in the pH result.

C. Protein: False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds (e.g. from some antiseptics and detergents) or with skin cleansers containing chlorhexidine may also produce false positive results.

D. Glucose: Ascorbic acid concentrations of 50 milligrams per deciliter (mg/dL) or greater may cause false negatives for specimens containing small amounts of glucose (100 mg/dL). 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 (100 mg/dL) but the combination of such ketone levels and low glucose levels is metabolically improbable in screening. The reactivity of the glucose test decreases as the specific gravity of the urine increases. Reactivity may also vary with temperature.

E. Ketone: False positive results (trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites.

F. Bilirubin: Indican (indoxyl sulfate) can produce a yellow-orange to red color response which may interfere with the interpretation of a negative or a positive bilirubin reading. Ascorbic acid concentrations of 25 mg/dL or greater may cause false negatives.

G. Blood: Elevated specific gravity or elevated protein may reduce the reactivity of the blood test. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.

H. Nitrite: Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as positive. Color development is not proportional to the number of bacteria present. Sensitivity of the nitrite test is reduced for urines with a high specific gravity. Ascorbic acid concentrations of 25 mg/dL or greater may cause false negative results.

I. Leukocytes: Elevated glucose concentrations (> 3 mg/dL) or high specific gravity may cause decreased test results. The presence of cephalexin, cephalothin, or high concentrations of oxalic acid may cause decreased reactivity and high levels of the drug may cause a false negative reaction.

J. Urobilinogen: The test area will detect urobilinogen in concentrations as low as 0.2 mg/dL (approximately 0.2 Ehrlich Units per deciliter (EU/dL) in urine. The absence of urobilinogen in a specimens being tested cannot be determined.

K. Specific Gravity (SG): The specific gravity test permits determination of urine specific gravity between 1.000 and 1.030. In general, it correlates within 0.005 with values obtained with the refractive index method. Strips read instrumentally are automatically adjusted for pH by the instrument. The Siemens Diagnostics SG is not affected by certain nonionic urine constituents such as glucose or by the presence of radiopaque dye. ~~All Specific Gravities ≥1.030 should be verified using a refractometer.~~

    1. All Specific Gravities ≥1.030 should be verified using a refractometer. See Urine Specific Gravity by Refractometry (Taylor, Trenton, Wayne and Canton) or Manual Urinalysis Quality Control - Dearborn procedures.

XV. NOTES:

A. Verification of unusual results is accomplished by comparing reagent strip to the color chart on the Multistix bottle and/or repeating the analysis from start to finish.

B. Nitrite test results are optimized by using a first morning urine specimen or one that has incubated in the bladder for 4 hours or more.

C. Bilirubin and urobilinogen must be done on fresh urine to achieve optimal results as these substances are very unstable when exposed to room temperature and light.

D. Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with a resultant change in pH. A shift to alkaline pH may cause false positives in the protein test area.

E. Bacterial growth from contaminating organisms may cause false positive blood reactions due to production of peroxidases.

XVI. REFERENCES:

1. Multistix package insert, Siemens Healthcare Diagnostics, Tarrytown, NY 06/2010
2. CAP Standard URN.24345 Calibration

Attachments

Clinitek Maintenance for Canton, Trenton

Clinitek Microscope Bench Maintenance for Taylor

Wayne Clinitek Microscope Bench Maintenance Form

Approval Signatures

Step Description	Approver	Date
Medical Director	Jeremy Powers: Chief, Pathology	10/23/2024
Medical Director	Muhammad Arshad: Chief, Pathology	10/22/2024
Policy and Forms Steering Committee Approval (if needed)	Laura Bellon: Medical Technologist Lead	10/15/2024
	Christopher Ferguson: Dir, Lab Services	10/14/2024
	Helga Groat: Supv, Laboratory	10/11/2024
	Kristen DiCicco: Mgr, Laboratory	10/7/2024
	Katherine Persinger: Mgr, Laboratory	10/4/2024
	Ashley Beesley: Mgr, Laboratory	10/3/2024
	Laura Bellon: Medical Technologist Lead	10/3/2024

Applicability

Dearborn, Taylor, Trenton, Wayne