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Urinalysis – Clinitek Advantus Procedure	**Attachments** ☐ Yes ☒ No
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I. PURPOSE/PRINCIPLE

To provide direction for performing a urinalysis using the Clinitek Advantus.

A routine urinalysis consists of testing for pH, specific gravity, color, clarity, leukocytes, nitrite, glucose, protein, ketones, bilirubin, urobilinogen, and blood. A microscopic examination of the urinary sediment can also be performed to detect the presence of RBCs, WBCs, casts and other formed elements. Multistix 10-SG is an inert plastic strip to which is attached 10 different reagent test pads. A brief discussion of each follows:

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.

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. Substances that can interfere with the test and produce a false positive include, but are not limited to urobilinogen, Indican (Indoxyl Sulfate) and metabolities of Lodine (Etodolac).

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.

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 urine of increasing ionic concentration.

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.

pH:
This test is based on the 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.

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.

Urobilinogen:
This test is based on a modified Ehrlich reaction, in which *p*-diethlaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.

Nitrite:
This test depends upon the conversion of nitrate (derived from the diet) 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 turns couples with 1, 2, 3, 4,-tetrahydrobenzo(h)quinolin-3-ol to produce a pink color.

Leukocytes:
Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with diazonium salt to produce a purple color.

II. POLICY

Laboratory Staff will follow the approved techniques outlined in this procedure.

Specimen: Midstream Urine Specimen

1. A fresh specimen is preferred, but urine held in the refrigerator for up to 24 hours can be used. Urine must be allowed to come to room temperature before testing.
2. No preservatives should be used.
3. Specimens should be run within one hour, or be refrigerated at 2-8˚ C.
3. A specimen collected at home in a clean container is acceptable if brought to the lab within one hour, or refrigerated until delivered to the lab within 24 hours.
4. Collect a sufficient volume for analysis (approximately 50 ml preferred).

Reagents/Materials:

1.5 mL Pre-calibrated Urine Tube (Lawson #110384)

Glass Slides and Coverslips

Multistix 10-SG

- Test strips are good until the expiration date on the canister as long as the canister is closed after EVERY strip removal and the desiccant remains in the canister.

Clinitek Advantus Urine Chemistry Analyzer and handheld bar code reader

BioRad Urine Controls Level 1 and Level 2:

Store in refrigerator at 2-8º C until expiration date on the bottles. Once opened, the product is stable for 31 days when tightly capped at (2ºC to -25ºC). Document open date and revised expiration date on the bottle. Refrigerator storage is preferable. If it is at the end of the vial or close to the expiration date and there are problems with one or more parameters, try opening a new control vial.

Calibration:

Calibration is automatically performed at each read-head immediately before each reagent strip is read. The fixed platform contains 2 white calibration bars, positioned directly under each read-head. As a strip comes into position under a read-head, the analyzer reads the calibration bar and calibrates for that scanning cycle. A calibration confirmation can be printed by selecting "Calibration Confirmation" under the menu and selecting print.

Quality Control:

Multistix 10-SG strips should be checked with BioRad Urine Controls Level 1 and Level 2 of the urinalysis control each day and with each change of lot# of test strips. Positive and negative controls should be performed and compared to the package insert for acceptability. Results will be entered as Pass/Fail in Epic Beaker.

-Microscopic QC: Microscopes are cleaned daily, lab enrolls in proficiency testing, reference material (pictures) available to staff.

III. PROCEDURES

1. Preparing for a run

- **NOTE: Leave the Clinitek Advantus analyzer on at all times, except during maintenance and cleaning procedures.**

a. When the analyzer is not in use, the screen saver or **Ready/Run** screen displays.

b. Touch the screen to activate. Do not use anything hard or pointed as this will damage the screen.

c. The analyzer automatically enters the Run mode when a strip is placed on the platform. If the push bar is positioned at the left side of the loading station, the analyzer is ready to accept placement of a strip. If the bar is positioned to the right, the analyzer is not ready and ignores any strip placed on the platform.

d. Ensure that the strip loading station and push bar are clean and in the correct position. If contaminants are present, remove and clean the push arm, the platform and the moving table.

e. Change the Technician Identification

1. Select **Menu**.
2. Select **Tech ID**.
   A numeric keypad displays.
3. Enter your Tech ID number

Select **Enter** to return to the numeric keypad.

4. Select  to save the Tech ID.

2. Testing QC Samples

a. At the **Ready/Run** screen, select **ID**.

- The QC function will not be used. Run QC as a patient. Tape the QC printout onto the logsheets and record the QC values on the QC log, verifying that parameters are in range.

b. Scan the QC barcodes or manually enter lot number if scanner unavailable.

c. Gently swirl controls to assure good mixing. Apply control to reagent strip. Hold strip horizontally to assure saturation; remove excess control by tilting strip on it's edge on a paper towel. Do not blot as this will affect results.

d. Place strip onto the analyzer platform with reagent pads facing up. The Clinitek Advantus automatically detects its presence. The push bar will move the strip over the platform to the right and into the reading area.

e. Results will print once the analysis of the reagent pads is complete.

f. The strip is automatically advanced to the waste bin.

g. Repeat for additional controls.

h. Record QC results on the UA QC logsheet and compare to the values given on the appropriate lot# product insert. If any results are not within the expected range, troubleshoot and repeat the controls before patient testing.

3. Patient testing

a. At the **Ready/Run** screen, **select ID**

b. **Before immersing the Multistix 10 dipstik**, use the cycle key to move through the options

for color and clarity for the specimen.

COLOR

Pale Yellow
Yellow
Dark Yellow
Orange
Bloody
Colorless
Red
Blue: can be entered on Epic keyboard
Green: can be entered on Epic keyboard

CLARITY

Clear
Hazy
Cloudy

c. The urine cup must be labeled with a Beaker foot label with the CID barcode. Affix the Beaker foot label directly below the original specimen container label and verify last name, first name and medical record number.

d. Scan the barcode label that is affixed to the specimen container to enter the CID into the analyzer.

e. When this information is correctly entered, select ENTER.

f. Completely immerse all of the reagent pads into a fresh, well-mixed, uncentrifuged urine. Be sure all test pads are wet.

g. Immediately remove the test strip from the urine, dragging the edge of strip against the side of the container as you remove the strip. You now have 8 seconds to complete steps g, h and i.

h. Blot the reagent strip to remove excess urine by touching the edge to a paper towel or gauze. Do not drag the strip across the towel or gauze; touch the edge only.

i. Place the strip on the analyzer platform with the reagent pads facing up.

j. Place the strip to the right and parallel to the push bar. Ensure that the end of the strip is against the back wall of the platform and that it is not touching the bottom of the strip loading

station.

CAUTION: Improper placement may cause the analyzer to jam or the strip to incorrectly align under the readheads.

k. Repeat steps b. through i. for each additional specimen.

l. Testing does not need to be completed before running the next patient.

4. Managing results

a. Results are transmitted to the printer and computer as soon as all reagent areas on the strip are read.

b. A microscopic exam will be performed on all UAM orders and when UAif results show the following: trace or more leukocyte, small or more blood, positive nitrite, or trace or more protein. A microscopic analysis will also be performed when ordered by the physician.

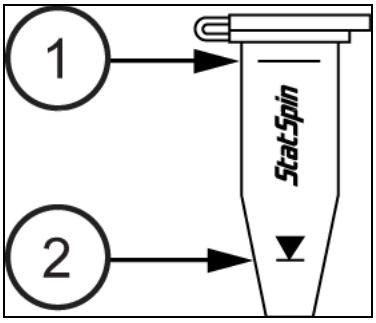
5. Microscopic exams

When a UA "if" is ordered a microscopic analysis will automatically be ordered if the test strip shows: trace or more leukocyte, small or more blood, positive nitrite, or trace or more protein. A microscopic analysis will also be performed when ordered by the physician.

Preparation of Urine Sediment for Microscopic Examination

The StatSpin MP quickly prepares urine sediment for microscopic examination. This preparation is accomplished with the pre-calibrated urine tubes.

Figure 4.1 Calibrated Urine Tube



1. Add fresh urine to a 1.5mL calibrated urine tube. Fill to the top mark (1).
2. Cap the tube using the attached stopper and place it in the StatSpin.
3. Balance the rotor either with another sample or with a water-filled tube.
4. Insert the rotor shield and push down until it is fully seated. Close cover.
5. Select the Urine setting and select Start (Green Button). (Spins for 45 sec.)
6. When the cycle is complete, the cover releases. Remove the tube from the rotor and remove the stopper.
7. Invert the tube to drain fluid to the lower mark (2). (The surface tension retains 0.1mL.)
8. Recap the tube and resuspend the sediment at the bottom of the tube by holding the tube with the index finger and thumb and flicking the tube with the opposite hand.
9. After sediment has been resuspended, apply one drop to a microscope slide, cover slip, and examine the slide.

Scanning Slide

a) Scanning a minimum of 20 fields, report as follows:

1. **RBCs:** select the result from the Epic Beaker drop down menu
2. **WBCs:** select the result from the Epic Beaker drop down menu
3. **All other results are not mandatory:** Add all other results as appropriate from the Epic Beaker drop down menu choices available.
4. Crystals:
    1) Normal Crystals in Acid Urine (pH≤ 6.5)
        a. Amorphous Urates, Uric Acid and Calcium Oxalate
    2) Normal Crystals in Alkaline Urine (pH> 7)
        a. Amorphous Phosphates, Triple Phosphate, Calcium Carbonate, Calcium Oxalate, Ammonium Biurate and Calcium Phosphate
    3) Abnormal Crystals
        a. Cystine: Cystine crystals can be easily confused with uric acid crystals. The differentiation between them is critical, as cystine crystals are indicative of a rare inherited metabolic disease. Uric acid crystals have little, if any, clinical significance. Cystine crystals normally appear as hexagonal plates. Uric acid are pleomorphic in shape and color. Among other shapes, they can appear as rhombic plates, which can be a source of confusion with cystine. For further explanation, pictures, and chemical differentiation, refer to laboratory reference books. A polarizing microscope can be used in differentiating cystine from uric acid crystals: cystine will polarize blue/white while uric acid will polarize multicolored.
        b. Tyrosine: Tyrosine crystals are very fine, highly refractile needles occuring in sheaves or clusters.
        c. Leucine: Leucine crystals are oily, highly refractile, yellow or brown spheroids with radial and concentric striations.

d. Cholesterol: Cholesterol crystals are colorless, large, flat, rectangular plates with one or more corners notched out. They are usually seen in acidic or neutral pH urine.

e. Bilirubin: Bilirubin crystals are seen as reddish-brown needles that cluster in clumps, or as spheres.

f. Hemosiderin: Hemosiderin granules are coarse, yellow-brown granules that occur as free granules in the urine, in renal epithelial cells or macrophages, or in casts

Reference Ranges:

Color:	Pale yellow, yellow
Clarity:	Varies with diet and age of specimen
S.G.:	1.005-1.030
Leukocytes:	0
Nitrite:	0
pH:	4.5-8.0 (varies with diet)
Protein:	0
Glucose:	0
Ketones:	0
Urobilinogen:	0.2-1
Bilirubin:	0
Blood:	0-Trace
RBCs:	0-3/hpf
WBCs:	0-5/hpf
Epithelials:	0-few
Casts:	0-1 hyaline/lpf:

REPORTING RESULTS: Refer to Epic Beaker resulting procedure

PROCEDURE NOTES

1. If the Clinitek fails to perform for any reason, the Multistix 10-SG strip may be read visually. Compare the color changes with those on the vial. Glucose and bilirubin are read at 30 seconds. Ketones are read at 40 seconds, Specific gravity at 45 seconds, Blood, pH, protein, urobilinogen, nitrite are read at 60 seconds. Leukocytes are read at 2 minutes. A positive nitrite is a strong indicator of the presence of bacteria.
2. Reflex criteria:

Reflex Microscopic Criteria	Reflex Urine Culture Criteria
Leukocyte Esterase Positive	Positive Nitrite and ≥ 10 WBC
Urine Protein >Trace	Positive Leukocyte Esterase and ≥10 WBC
Nitrite is Positive	Any patient that is < 5 years old
Blood is >Trace	

3. Urines with strong color due to medication (pyridium) or elevated bilirubin should not be read on the Clinitek Advantus, due to the abnormal color changes on the reaction pads of the Multistix. If, when the Multistix is dipped in the urine, the reaction pads immediately change color, and the colors are not representative of a positive reaction, select the option: Unable to report chemical reaction due to color interference. Record the color and clarity only.
4. All cellular elements (RBCs, WBCs, and casts) are extremely labile in hypotonic solutions. Low specific gravities will cause them to lyse. Centrifugation and resuspension also places stress on cellular elements. The test strip is capable of measuring the esterases from lysed granulocytes and

hemoglobin from lysed RBCs. Therefore, the microscopic analysis may not correlate with the dipstick results; the dipstick is a better indication of WBCs and RBCs.

6. When a urine sample is grossly bloody and some of the parameters are unable to be read, it can be centrifuged. You may need to centrifuge multiple StatSpin tubes in order to get enough supernatant to wet all of the Multistix pads. Dip the Multistix 10-SG into the supernatant, or use a pipette to place drops of supernatant onto each pad, and read and report all parameters except leukocytes and blood. Result the leukocyte and blood parameters with the option: Unable to report chemical reaction due to color interference.

Cleaning Procedure for the Clinitek Advantus:

1. General cleaning
    a. Keep the exterior of the analyzer free of dust at all times
    b. Clean the exterior using a damp cloth and a mild detergent as needed
        - Caution! Do not use any type of solvent, oil, grease or silicone spray on any part of the analyzer. Harsh chemicals can damage the platform components.
2. Daily Cleaning (end of day):
    a. Ensure that the run is complete and the analyzer is at the Ready/Run screen, before removing components. In this state, the moving table is in its lowest position and the fixed platform can be reinstalled when cleaning is completed.
    b. Turn the analyzer off
    c. Remove the push bar by tilting the bar slightly upwards and pulling it straight out.

    d. Remove the waste bin liner
    e. Discard the used reagent strips into an appropriate container.
    f. Remove the fixed platform by pulling the entire assembly towards you.

g. Remove the moving table by pulling the entire assembly towards you.

h. Remove the holddown plate from the fixed platform by pressing upwards on the tab at the back of the plate. Pull the other end from its retaining hole.

i. Clean the push bar, platform, holddown plate and the table with warm water and a mild detergent. When cleaning the platform, avoid wiping across the 2 white calibration bars. Use a cotton-tipped swab, wetted with plain water, to clean the bars. Cleaning solution can damage the calibration bars.

- If the holddown plate of push bar is extremely dirty, soak it in warm water and a mild detergent to loosen the dried material.

m. Rinse each piece thoroughly and dry with a paper towel or soft cloth. Use care when drying around the pins on the moving table.

n. Allow the calibration bars on the platform to air dry.

o. After cleaning, inspect the calibration bars for scratches, marks or discoloration. If the bars are damaged or cannot be cleaned, discard the platform and replace with a new platform.

p. Reinstall the moving table:
   1) Hold the table with the small rectangular tab facing to the back.
   2) Align the two grooves on the bottom of the table with the edges of the platform on which the table rests.
   3) Gently push the table in until you hear the tab latch into the hold position.
   4) Make sure the table is secure.

q. Reinstall the holddown plate:
   1) Position the holddown plate with the arrow side facing up and the arrow pointing to the back.
   2) Place the pin on the front of the holddown plate into the hole at the front of the fixed platform.
   3) Align the tab at the back of the holddown plate with the slot at the back of the platform.
   4) Snap the holddown plate into place
   5) Ensure that the white calibration strips are visible.

r. Reinstall the fixed platform:
   1) Align the 2 grooves on the bottom of the fixed platform with the arms extending forward from the analyzer. The flanges on the sides of the holddown plate align just outside the read area cover. The top edge of the platform aligns just under the cover.
   2) Gently push the platform in as far as possible. Push past the ridge to correctly position the platform. Do not force the platform. Ensure that the moving table is correctly positioned before attempting to reinstall the fixed platform.

s. Reinstall the push bar:

1) Hold the push bar at the indented end.
2) With this end slightly upward, insert the peg on the other end of the bar into the hole in the pusher mechanism.
3) Lower the push bar into place.

t. Place a new liner into the trash bin.

u. Clean the display screen with a soft, nonabrasive cloth dampened with a mild glass cleaner.

v. Turn the analyzer power on.

TROUBLESHOOTING

A. Urinalysis Control Troubleshooting:

BioRad Urine Controls Level 1 (negative) and Level 2 (positive) are used to test the Mulitstix each day of use and when a new lot#/shipment of Multistix is opened. Make sure the correct package insert is being used for control result validation. Each lot may have different control values.

1. If the Level 1 values are unacceptable, check and make sure the strips have not become discolored by exposure to air. The strips should be negative before use. Check expiration date of strips and control and rerun strips with a fresh aliquot of control.
2. If Level 2 values are unacceptable, verify expected values for the current lot number of BioRad Urine Dipstick Control with its package insert values. Make sure the Multistix control ranges have been correctly recorded. Check expiration date of strips and control and rerun strips with a fresh aliquot of control.
3. For testing of Multistix, make sure the pads have been saturated with control. Let it sit 2-3 seconds then dab the edge of the strip on a paper towel to prevent run-off/bleeding reagents from pad to pad.
4. For testing of Multistix, some possible explanations for controls that are out of range are:
   - The controls must be at room temperature. pH and Specific gravity are particularly affected if the controls are *not* at room temperature.
   - Make sure the test strip placement is correct. Place the test strip onto the supports of the strip loading station, with the reagent pads facing up. Place the strip to the right of, and parallel to, the push bar. Ensure that the end of the strip is against the back wall of the platform and that it is not touching the bottom of the strip loading station.
   - The control bottle is almost empty or close to the expiration date. Controls expire 31 days after opening when controls are refrigerated, unless the expiration date on the bottle comes first. Open a new bottle.
5. If positive control values are still unacceptable, open a new vial of strips and run the current bottle of BioRad Level 2 Urine Control.
6. If positive control values are still not in range, use a different lot number of strips.
7. For backup, cross-reference with another lot number of strips, if applicable.
8. If available, run a new lot number of controls with first vial of strips.
9. Notify your Regional Clinic Laboratory Supervisor. The manufacturer may be called for possible causes and recommendations.

Reminder: According to the Internal Quality Control Policy, if expected QC Values are not attained, patient results will not be reported until troubleshooting is complete.

B. Clinitek Advantus Troubleshooting:

If an operational of analyzer problem occurs, an error number may display on the analyze screen with an explanation of the problem. Refer to the analyzer manual for explanations and troubleshooting of the various errors and messages, along with probable causes and corrective actions. If the problem persists, record the error number being displayed and contact technical service.

1. Removing a jammed test strip:

a. Select **Stop Run** to stop the run and return to the Ready/Run screen.
b. To determine the specimen(s) to retest, record the information provided on the Results Error Report.
c. Turn the analyzer power off.
d. Remove the push bar, fixed platform and holddown plate. Refer to daily cleaning section for instructions.
e. Remove the jammed strip.
f. Replace the push bar, fixed platform and holddown plate. Refer to daily cleaning section for instructions.
g. Turn the analyzer power on and rerun specimens that were not tested.

2. Reinstalling the fixed platform:
   If the analyzer is turned off during a run, or at any screen other than the Ready/Run screen, the moving table may not be in its lowest position. If the fixed platform is removed, the moving table will be pulled out at the same time. The platform cannot be reinstalled at this position because the pins of the moving table are in the way. To resolve this problem:
   a. Turn the analyzer power on.
   b. Let the analyzer initialize.
   c. An error displays because the fixed platform is not in place, but the moving table is rotated into the correct position.
   d. Turn the analyzer power off.
   e. Install the fixed platform. Refer to daily cleaning section for instructions.
   f. Turn the analyzer power on.

REFERENCES

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Clinitek Advantus operating manual

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IV. DEFINITIONS

V. COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

VI. ATTACHMENTS

VII. OTHER RESOURCES

VIII. ENDORSEMENT

Laboratory Administration