Urinalysis – Clinitek Status Procedure	**Attachments** ☐ Yes ☒ No
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APPROVAL(S) Laboratory Medical Director	

Clinic Lab Procedure (Pages 1-5)
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I. PURPOSE/PRINCIPLE

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 dessicant remains in the canister.

Clinitek Status Urine Chemistry Analyzer

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 8ºC). Document open date and revised expiration date on the bottle. 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.

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 to lot # of the 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. Instrument Preparation for Testing

   a. Turn on Clinitek Status, if not already on, by pressing the gray button on the front of the instrument. Once the instrument is on, the test table will extend out of the instrument.
   b. On the touch screen choose the "strip test" option.
   c. Touch the "enter new operator ID" window or touch "last operator" if you are the last to use the analyzer.
   d. Enter your tech ID number. Press enter.
   e. Touch "enter new patient" window.
   f. Enter the patient's medical record number as the PT ID and press enter.
   g. **Press the "start" window. You now have 8 seconds to dip the urine test strip.**

2. Macroscopic

   a. Dip a Multistix 10-SG reagent strip into the urine. Be sure *all* the test pads are wet.
   b. Immediately remove the Multistix 10-SG 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 C, D and E.
   c. Blot the Multistix 10-SG 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.
   d. Place the Reagent Strip, with the test pads facing up, into the middle trough of the test strip table. Slide the strip along the table until it touches the end of the trough.
   e. The table is automatically pulled into the instrument for reading. While the strip is being analyzed, a "select appearance" screen will be displayed. If the urine sample is yellow and clear, touch the "yellow and clear" window. If the urine sample is not yellow and clear, touch the "other" window for more choices. If you touched the "other" window, select the appropriate color by touching the circle button that corresponds to the correct description. Press "Next" for clarity options. Select appropriate clarity. Then, touch "Next". For color and clarity options, see table listed in H-1.
   f. Results are available in one minute. Be sure not to move or bump the table. Results will print automatically. Tape this printout on the urinalysis worksheet.

      NOTE: *Thermal paper will fade with time. Do not place tape over test results printed on thermal paper.*
   g. Remove the used Multistix 10-SG reagent strip and discard it in the proper container. Wipe the test strip table with gauze to prevent urine from building up.
   h. Result each parameter from the Epic Beaker drop down menu choices.

i. For urines which have strong coloration it may be necessary to select the option "Unable to report chemical reaction due to color interference.

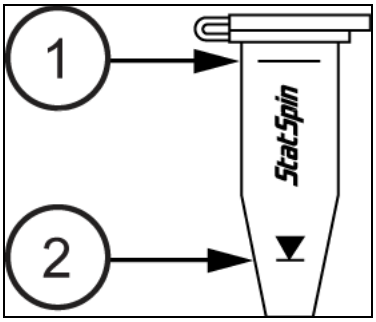
3. Microscopic

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 the 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 the Epic Beaker resulting procedure

PROCEDURE NOTES

1. If the Clinitek Status 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. 2. 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 Status, 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 only the color and clarity.
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 Status:

1. Daily Cleaning (end of day):
   a. Remove the test strip table by pulling it straight out of the instrument.
   b. Wet a cotton-tip swab with water. Thoroughly scrub the trough and surrounding areas. Do not touch the white bar. Rinse the entire table with water.
   c. Allow the table to air-dry, or dry with gauze or lint-free tissues.
2. Disinfecting the table (weekly):
   a. Start with a clean table – see Daily Cleaning.

b. Fill a tall narrow container (an empty Multistix 10-SG container) with 5% bleach. Place the table into the solution, making sure the white bar remains above the liquid.

c. Soak the table for a minimum of 2 minutes to a maximum of 10 minutes.

d. Rinse the test table and insert thoroughly with water.

e. Allow to air-dry, or dry with lint-free tissues.

TROUBLESHOOTING

A. Urinalysis Control Troubleshooting:

BioRad Urine Controls Level 1 (negative) and Level 2 (positive) are used to test the Mulitsticks each day of use and with new lots/shipments. 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. Check expiration date of strips and control, rerun strips with a fresh aliquot of control.
3. For testing of Multisticks, 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 Multisticks, 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 that the strip is correctly seated on the Clinitek Status. The strip must be placed with the top of the strip butted up against the back of the strip guide. The edge of the strip must be flat and not sticking-up even slightly.
   - 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.

B. Clinitek Troubleshooting:

1. Error messages will be displayed to help you when the Clinitek Status analyzer detects something which needs your attention.
2. See pages 7-4 through 7-7 in your Clinitek Status Manual for error code descriptions and follow-up actions.
3. If the problem is not resolved, contact a Laboratory Technical Consultant or Customer Service, phone 1-877-229-3711.

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.

REFERENCES

Bayer Multistix 10-SG Package Insert
StatSpin MP Centrifuge Model Number M901 IFU
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Graff, L.: A Handbook of Routine Urinalysis
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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