CLINTEK ADVANTUS

PURPOSE Provide instructions for performing urinalysis to evaluate and assist diagnosis in kidney function, urinary tract infections, carbohydrate metabolism, and liver function.

METHOD The Clinitek Advantus strip reader is used to read Multistix 10SG reagent strips which include test pads for protein, blood, leukocytes, nitrite, glucose, ketone, pH, specific gravity, bilirubin, and urobilinogen. The urine is centrifuged and the concentrated sediment is examined with low power microscopy for casts and high power microscopy for red blood cells, leukocytes, epithelial cells, crystals, bacteria and other miscellaneous elements.

SAFETY All specimens should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing scheduled maintenance. Refer to: Policy and Procedures Safety Manual *Infection Control and Procedures* 11-030-01

SPECIMEN A clean-catch urine specimen should be obtained. If microbiology studies are ordered the specimen must be collected in a sterile container. The urine specimen may be stored at room temperature for up to two hours prior to testing. For storage longer than two hours and up to 24 hours, the specimen must be refrigerated. Refrigerated specimens must be brought to room temperature before testing. The specimen must be labeled according to laboratory policy on the side of the container.

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CONTROLS

Controls must be performed once every 24 hours. Quality Controls must be within the acceptable range (See value assignment sheet for the lot number being run.) before processing and releasing any patient results.

Bio Rad qUAntify Advance Liquid Urine Control Level 1 and 2 are the control material for Multistix 10 SG strips
qUAntify Advance Liquid Urine Controls are prepared from a liquid base matrix with human urine and added constituents of human and animal origin, chemicals, and preservatives. The control is provided in liquid form.

- Controls are stable until the expiration date when stored unopened at 2–8 degrees C.
- Once opened the controls are stable for 31 days when stored tightly capped at 2–25 degrees C.
- Before sampling, allow the control to reach room temperature. Invert the bottle several times to ensure homogeneity.
- Compare the test results with the lot-specific assigned values recorded on the QC sheets. If the controls are not within the specified limits retest with new QC material. If the controls are still not within limits, retest with a new vial of Multistix. If QC results are still unacceptable, report situation to a supervisor. DO NOT PERFORM ANY PATIENT TESTING UNTIL QUALITY CONTROL IS ACCEPTABLE.
- Dispstick and Microscopic QC for Level 1 and Level 2 is performed.

CALIBRATION

Calibration is performed at the readhead immediately before every reagent strip is read. The calibration can be confirmed by selecting “print” from the menu screen. Then select “calibration confirmation”. The date and time of the latest successful calibration prints. Be careful not to clean the calibration bars with a harsh cleaner or scratch them. Let them air dry after rinsing with water.

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TESTING CONTROLS

Step	Action
1	At the Ready/Run screen, select **Menu**.
2	Select **QC**. The display changes to a numeric keypad.
3	Enter the Lot Identification of the controls using the handheld barcode reader or the numeric keypad on input screen.
4	When you are ready to test the control, select **Enter**.
5	Completely immerse all of the reagent pads on the reagent strip into the quality control solution.
6	Immediately remove the reagent strip.
7	While removing the strip, run the edge against the side of the container. This will remove excess liquid. **Note**: Do not blot the edge of the strip. This could affect results.
8	Place the reagent strip onto the supports of the strip loading station, with the reagent pads facing up.
9	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. **Note**: Improper placement may cause the analyzer to jam or the strip to incorrectly align under the read heads.
10	When the push bar is to the far left of the platform, you can place a new strip on the loading station until the previous strip placed enters the waste bin. When the final strip moves to the waste bin, the run ends, and the end of run reports are processed. Note: Select Stop Run if you need to stop the run before all readings are complete. Also a run may be interrupted for a stat by touching "stat" on the Run/ready menu screen.
11	Repeat steps 1 to 10 for the next control level.

PREPARING FOR A RUN

The analyzer will begin to run when the first reagent strip is placed on the platform of the Advantus. Check that the strip loading station and push bar are clean and in the correct position. The push bar should be positioned at the left side of the loading station to accept a test strip. Leave the Advantus on at all times though it may be turned off for maintenance or cleaning.

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Testing Routine Specimens using the Specimen ID

Specimen IDs may be entered immediately prior to testing each specimen. The table below describes the sample processing instructions:

Step	Action
1	At the Ready/Run screen, select **ID**.
2	Enter the specimen accession number using the handheld barcode reader or the numeric keypad on input screen.
3	When this information is correctly entered, select Enter. The display changes to allow entry of the next ID number, and the push bar moves to the left so you can place a strip on the loading station.
4	Select a reagent strip.
5	Completely immerse all of the reagent pads on the reagent strip in fresh, well-mixed, un-centrifuged urine.
6	Immediately remove the reagent strip.
7	While removing the strip, run the edge against the side of the container. This will remove excess liquid. **Note**: Do not blot the edge of the strip. This could affect results.
8	Place the reagent strip onto the supports of the strip loading station, with the reagent pads facing up.
9	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. **Note**: Improper placement may cause the analyzer to jam or the strip to incorrectly align under the read heads.
10	When the push bar is to the far left of the platform, you can place a new strip on the loading station until the previous strip placed enters the waste bin. When the final strip moves to the waste bin, the run ends, and the end of run reports are processed. Note: Select Stop Run if you need to stop the run before all readings are complete. Also a run may be interrupted for a stat by touching “stat” on the Run/ready menu screen.
11	Repeat steps 1 to 9 for each specimen.

Managing Results

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

Clinitek Downtime

Multistix may be read manually using the read times and color chart on the label. Result manually.

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REPORTING FOR MULTISTIX 10SG

Glucose: Report as negative, trace (100 g/dL), 1/4 (250 g/dL), 1/2 (500 g/dL), 1 (1000 g/dL or greater), or 2 (2000 or more g/dL).
Ketone: Report as negative, trace (5mg/dL), small (15mg/dL), moderate (40mg/dL), or large (80-160mg/dL).
Specific Gravity: Report as 1.000, 1.005, 1.010, 1.020, 1.025, or 1.030
Blood: Report as negative, non-hemolyzed trace or mod, hemolyzed trace, small (1+), mod (2+) or large (3+)..
pH: Report 5, 6, 6.5, 7, 7.5, 8, 8.5.
Protein: Report as negative, trace, 1+ (30 mg/dl), 2+ (100 mg/dl), 3+ (300 mg/dl), or 4+ (2000 or more mg/dl).
Nitrite: Report as negative or positive.
Leukocytes: Report as negative, trace, small (1+), moderate (2+), or large (3+).
Urobilinogen: Report as normal (0.2 or 1), 2EU/dL, 4 EU/dL, 8 EU/dL.
Bilirubin: Report as negative, small 1 (1+),moderate(2+),large >5(3+).

MICROSCOPIC EXAMINATION

Microscopic examination must be performed if ordered or if any of the following parameters are positive:

- Blood
- Nitrite
- Leukocyte esterase
- Greater than a trace of protein.

Step	Action
1.	Centrifuge 10-12 ml of urine for 5 minutes at 1500 RPM.
2.	Decant the supernatant completely and shake sediment into suspension.
3.	Place a drop of urine sediment on a slide and cover slip.
4.	Scan for casts with low power and subdued light before switching to high dry to read. Report as follows: WBC: choose one of the selections available from LMS list of results. Epithelial cells: numerical ranges or "full field" if too numerous to count. RBC's: choose one of the selections available from LMS list of results. Casts: number per low power field, specifying type. Bacteria: few to 4+. Mucous threads: trace to 4+. Crystals, amorphous: few to 4+. Miscellaneous: yeast, trichomonas, and all other elements present not listed above: few to 4+. Cell and parasite identification can be difficult. If you have any doubt of the correct identification, you may consult your co-worker, supervisor, or pathologist for assistance. **Note: Do not report presence of spermatozoa as it is considered an incidental finding and is not used for medical treatment.**

REAGENTS

Multistix 10 SG strips
qUAntify Advance Liquid Urine Controls Level 1 and 2

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LIMITATIONS OF PROCEDURE FOR MULTISTIX 10 SG

Analyte	Substances causing false negative results	Substances causing false positive results	Other
Glucose	Moderately high Ketone levels (40 mg/dL) with specimens containing small amounts of glucose (75-125 mg/dL)		
Protein		• Urine with large amount of hemoglobin	
Bilirubin	Indican (indoxyl sulfate) may produce a yellow orange color	• Metabolites of Iodine (etodulac)	Unstable in sunlight
Urobilinogen	Formalin	• High concentrations of p-aminosalicylic acid, paba, and sulfonamides.	Strip reactivity increases with temperature; the optimum temperature is 72-79° F.
pH			Bacterial growth by certain bugs may cause a marked alkaline shift.
Blood	Large amount of Capoten	• Oxidizing substances such as hypochlorite and chlorine • Microbial peroxidase associated with urinary tract infections	
Ketones		• Highly pigmented urine: L-Dopa, BSP, PSP, Phenylketone, Cephalosporin • Mesna Compounds (2-mercaptoethane sulfonic acid) that contain sulfydryl groups	
Nitrite	• Shortened bladder incubation of urine • Absence of dietary nitrate • Presence of nonreductive pathological microbes.	None	Urine not refrigerated within 1 hour may affect results
Leukocytes	• Glucose >/= 3 gm/dL • Tetracycline in high levels • Cephalexin, cephalothin, for high concentrations or oxalic acid	• Contamination of specimen by vaginal discharge	
Specific Gravity	• Highly buffered alkaline urines may reduce reactivity	Protein (100-750) mg/dL	

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MAINTENANCE

Daily remove table of Clinitek and clean push bar, fixed platform, moving table, and strip holddown plate with detergent and water. Do not use alcohol or other chemicals. Dry with lintless cloth. Take care not to clean calibration bars. If they get wet, let them air dry. Reassemble the parts snapping the holddown plate into place tightly on the platform. Note: Strips will not read properly, and nitrate may read positive when assembly is not tight. Push platform securely onto table.

INSTRUMENT FUNCTION CHECK

If a testing instrument does not meet function checks or performance testing requirements, this instrument MUST NOT BE USED TO REPORT PATIENT RESULTS. Corrective action must be taken to remedy the problem. Record action taken on the action logs.

If problem is not corrected, go to back up procedure as indicated in the test procedure.

REFERENCES

Clinical Diagnosis and Management, 16th Edition, pp. 566-572.
Clinitek Advantus Technical Procedure, Rev A
Multistix 10SG product insert

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Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Dir. Lab Ops reviewed/ date	Date change Implemented
Minor	Page 4 step 1 under microscopic Examination “Centrifuge 10-12 ml	Sam Ibe 05/2011			05/11/2011
Minor	Page3: Removed Ictotest. Test no longer performed due to lab	Charles Park			
Minor	1. Format Change 2. Replaced Count-10 control material with BioRad qUAntify Advance Control Level 1 and 2	Yvette Lingat 1/31/19			
Minor	1. Revised index no 2. Added control procedure 3. Added instrument function check	Yvette R Lingat 8/20/20			