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Document Contact	Colette Kessler: Mgr, Division Laboratory
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Operation Protocol for Clinitek Advantus - Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The Clinitek Advantus is a semi-automated instrument designed to “read” Siemens Multistix 10 SG Reagent Strips. The instrument 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. Each Siemens Reagent Strip contains reagent areas for testing glucose, bilirubin, ketone, specific gravity, occult blood, pH, urobilinogen, nitrite, and leukocytes. The color and clarity of the urine are manually entered for each specimen. The document describes how to test urines using the Clinitek Advantus.

II. SPECIMEN COLLECTION AND HANDLING:

A. Fresh, well-mixed, un-centrifuged urine is required. A fairly concentrated specimen e.g., the first morning void is preferred. It is recommended that testing be done within two hours after voiding. Otherwise immediately refrigerate the specimen at 2-8°C and return to room temperature before testing. Optimum specimen volume is at least 20mL. Minimum specimen volume is 1mL.

III. REAGENTS/SUPPLIES:

A. Siemens Multistix 10 SG (#2161)

B. Kova-Trol Normal and Abnormal Urine Controls

IV. CALIBRATION:

Calibration is performed at each readhead immediately before each reagent strip is read. The fixed platform contains two white calibration bars that are positioned directly under each readhead.

V. QUALITY CONTROL (QC):

A. All Clinitek Advantus QC is required at the start of each shift!

B. Document in Unity Realtime.

C. Dipstick QC is **required** whenever a new bottle of Siemens Multistix 10 SG strips is opened, with each new lot number of strips, with each new shipment of strips and whenever troubleshooting warrants it. Please DATE new bottle, verify current lot # and record QC.

D. All shifts are to **DOCUMENT** troubleshooting maintenance performed in the provided troubleshooting log.

VI. SPECIAL SAFETY PRECAUTIONS:

See Routine Urinalysis Procedure

VII. PROCEDURE:

A. Perform and record on posted checklist the daily and as scheduled maintenance. Other shifts should clean pushbar, platform, etc. as warranted.

B. Daily Maintenance:

1. Clean pushbar, platform, fixed table, and holddown plate (5.1-5.19 Clinitek Advantus Operator's Guide).
2. Empty waste bin.
3. Clean display screen (5.21 Clinitek Advantus Operator's Guide).

C. Run Kova-Trol Normal for NEGATIVE Control strip (ALL SHIFTS).
See **Urinalysis Procedure Manual** for Kova-Trol(s) reconstitution and usage precautions.

D. Run Kova-Trol Abnormal for POSITIVE Control strip (ALL SHIFTS).
See **Urinalysis Procedure Manual** for Kova-Trol(s) reconstitution and usage precautions.

E. To run specimens: Hit 'ID' key

1. <u>If building loadlist</u>:
    a. Enter specimen identification (ID) by touchscreen or barcode reader.
    b. Enter color and clarity by touchscreen.
    c. Hit enter key "↵ ".
    d. After all ID's are entered return to the main screen by hitting "↑" key in the upper right hand corner.
    e. Match specimen ID with display, dip urine (run strip along side of tube—DO NOT BLOT STRIP) and place strip on platform by arrow: Strip will be sensed and pushbar will advance strip. ID will change; continue until all specimens are tested.
2. <u>If running continuously</u>:
    a. Enter specimen ID by touchscreen or barcode reader.

b. Enter color and clarity by touchscreen.
c. Hit enter key "↵ ".
d. Dip strip – Run strip along lip of tube (DO NOT BLOT STRIP).
e. Place strip on platform by arrow—Strip will be sensed and pushbar will advance strip.
f. Enter next ID, color and clarity and hit enter key.
g. Continue until all specimens have been run.
h. Note: If running with loadlist, you cannot add specimens to your batch.

F. Review Clinitek printout for each patient to match results with Laboratory Information System (LIS) computer screen. Match order #, SG, pH, UBG, and flagged abnormals. Check printout as each patient is reported.
    1. If all results are NEGATIVE (acceptable), and only a UA was ordered the results will auto-verify. If a UAC was ordered the Clinitek results will remain in the LIS until the micro is completed.
    2. If color interference was noted:
        a. Attempt visual read and edit report to indicate interference.
        b. Perform microscopic exam.
        c. NOTE: The Clinitek appears to be sensitive to bilirubin, especially in the presence of brown colored urine.
    3. Edit SG ≤1.005 and SG ≥1.030 with refractometer result. You may free text the refractometer result.

G. Process specimens that require a microscopic exam. See procedure "Examination of Urinary Sediment by Phase Microscopy" in Urinalysis procedure manual #1. If manual microscopic exam is required, spin specimens for 5 minutes @ 1600-1700 rpm.

H. MICROSCOPIC EXAM:
    1. Enter results for the manual microscopic into the appropriate result fields in the LIS.
    2. **Check for correlation of "TOPS" with "MICROSCOPIC" report**. Repeat testing as necessary for discrepant results.
    3. **Verify** in LIS and click **Confirm Final.**

VIII. REPORTABLE RANGE:

See respective procedures for reportable ranges.

IX. REFERENCE RANGE:

Specific Gravity	1.005 - 1.030
Nitrate	Negative
pH	5.0 - 8.0

Protein	Negative
Glucose	Negative
Ketones	Negative
Urobilinogen	<2.0 EU/dL
Bilirubin	Negative
Heme	Negative
Microscopic examination of sediment WBC (white blood cell) RBC (red blood cell) Hyaline Casts	 ≤5 cells/hpf (high power field) ≤2 cells/hpf (high power field) 0-2 casts/lpf (low power field)

X. LIMITATIONS/INTERFERING SUBSTANCES:

Bloody urines should not be run on the Clinitek Advantus. See Urinalysis Procedure for Analyzing Bloody Specimens

XI. REFERENCES:

1. Clinitek Advantus Operator's Guide, Siemens Healthcare Diagnostics, Inc, Tarrytown, NY 10591-5097, 2014-2016.

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	4/17/2023
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr, Division Laboratory	4/5/2023
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	4/5/2023
Lab Chemistry Best Practice Committee	Caitlin Schein: Staff Physician	4/5/2023
Lab Chemistry Best Practice Committee	Qian Sun: Tech Dir, Clin Chemistry, Path	3/28/2023
	Colette Kessler: Mgr, Division Laboratory	3/28/2023