PROCEDURE
Corewell Health East – Sysmex UN Series (UN-9000, UN-3000, and UN-2000) Comprehensive Automated Urinalysis System Operation

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Dearborn Hospital, Corewell Health Farmington Hills Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to:	Within Corewell Health Wayne Hospital, Wayne only. Within Grosse Pointe Hospital, Grosse Pointe only.
Reference #:	33186
Version #:	2
Effective Date:	10/15/2025
Functional Area:	Clinical Operations, Laboratory
Lab Department Area:	Lab - Urinalysis

1. Purpose
A. This procedure provides guidance for laboratory personnel to perform analysis of patient urine samples utilizing the Sysmex UN Series Comprehensive Automated Urinalysis System.

2. Principle
A. The Sysmex UN-Series are integrated, automated urinalysis solutions used for the in vitro analysis of human urine. The series is designed to automate urine sediment testing by utilizing the Siemens CLINITEK Novus® Automated Urine Chemistry Analyzer, UF-5000® Automated Urine Particle Analyzer, the UD-10® Automated Urine Particle Digital Imaging Device, and Urinalysis Data Manager® (UDM).
B. The CLINITEK Novus® Automated Urine Chemistry Analyzer is a fully automated analyzer that combines proven dry-pad urine chemistry technology with an easy-to-use cassette test format to ensure standardized test results and maximum productivity in busy laboratories.
C. The CLINITEK Novus® 10 urinalysis cassette, used with the analyzer, contains test cards on which are mounted single-use dry reagent pads for measuring bilirubin, blood (occult), glucose, ketone (acetoacetic acid), leukocytes, nitrite, pH, protein, and urobilinogen. An additional pad containing no reagents is used for measuring color.
D. During analysis, an aliquot of sample is dispensed onto the individual test pads and concentration of each analyte is determined by intensity of color that subsequently develops on each pad. Light reflected from the reagent pads is captured at a specified time after addition of sample using a color digital camera. The image of the test pads is then analyzed, and the color and intensity data from each pad are converted into clinically meaningful results.
E. Specific gravity and clarity of each urine specimen are also determined by the analyzer, by measuring the transmission and scattering of light that passes through the specimens.

Test Name	Chemical Principle
Bilirubin	The coupling of bilirubin with diazotized dichloroanitine in a strong acid medium.
Blood	Peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine.
Glucose	Double sequential enzyme reaction. Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide form the oxidation of glucose. Peroxidase catalyzes the oxidative coupling of 4-amino-antipyrine and 4-methylcatechol by hydrogen peroxide.
Ketone	The reaction of nitroprusside with acetoacetic acid.
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 a diazonium salt.
Nitrite	Conversion of nitrate (derived by diet) to nitrite by the action of Gram-negative bacteria in urine.
pH	Double indicator principle that gives a broad range of colors covering the entire urinary pH range.
Protein	At a constant pH, the presence of protein causes a change in the color of the indicator.
Urobilinogen	p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strong acid medium (Ehrlich reaction).
Color	The white pad absorbs the sample to detect urine color.

F. The UF-5000® is an in vitro diagnostic analyzer for the determination of formed elements in human urine. The UF-5000® automatically mixes and aspirates human urine for the analysis of formed elements using fluorescent flow cytometry. The UF-5000® displays and enumerates populations of formed elements and provides flagging information for other pathological elements.

G. The UF-5000® executes an anti-carryover function (auto-rinse) when high concentrations of RBC, WBC, BACT or Sperm are detected.

H. **UF-5000® Parameters**

Test Code	Reportable Parameter
RBC	Red Blood Cells
WBC	White Blood Cells
EPI	Epithelial Cells
CAST	Hyaline Casts
BACT	Bacteria

Test Code	Flagged Parameters
X'TAL	Crystals
Sperm	Spermatozoa
YLC	Yeast Like Cells
MUCUS	Mucus
PATH CAST	Pathological Cast

1. Flagged parameters are not directly reportable from the analyzer. Even though the UF-5000® can flag for MUCUS, it is not reported.

I. The UD-10® is an automated reflex system for the UF-5000®. An image of the particles in the sample can be captured, and the particles in the image are displayed by size. The image results are displayed in the UD-10® LCD touch panel.

Displayed Items	Particle Image Size
Class 1	2-6 µm
Class 2	6-10 µm

Class 3	10-16 µm
Class 4	16-36 µm
Class 5	36-71 µm
Class 6	71-101 µm
Class 7	101-151µm
Class 8	151 µm or more

J. The Urinalysis Data Manager® (UDM) is an instrument status and data management software system specifically for Sysmex urine analyzers and imaging devices.
K. The UDM performs analysis order registrations and patient information management.
L. The UDM supports the technical validation of diagnostic results combined with rule-based judgments, as well as quality control management and the manual classification of human urine particle images captured by the UD-10®.
M. The software does not modify analytical data from any of the analyzers. The UDM can transmit results to a host computer and printer for result review.
N. Rules are built in the UDM to correlate microscopic sediment findings with macroscopic results.

3. Responsibility

Personnel who have completed the competency requirements will perform this testing.

4. Definitions

A. Urinalysis Data Manager® (UDM)
B. Laboratory Information System (LIS)
C. White Blood Cell (WBC)
D. Red Blood Cell (RBC)
E. Quality Control (QC)
F. Milliliter (mL)

5. Specimen Requirements

A. Acceptable specimen requirements
    1. See Laboratory Test Directory
    2. Specimen volume
        a. Sampler mode
            1) Novus requires a minimum of 2.0 mL of urine.
            2) UF-5000® requires a minimum of 2.0 mL of urine.
            3) UD-10® requires a minimum of 1.6 mL of urine.
        b. Manual/STAT mode
            1) UF-5000® requires a minimum of 0.6 mL of urine.
            2) UD-10® requires a minimum of 0.6 mL of urine.
                a) **NOTE**: Novus does not have a manual/STAT mode.
B. Unacceptable urine specimens including those listed below should not be analyzed:
    1. Turbid samples containing high number of WBC, bacteria, or crystals.
    2. Urines that are visibly bloody.
    3. Urine that is visibly mucoid or has visible large particles.
    4. Urine containing visible foam.
    5. Urines that are collected in a specimen tube with a preservative.
    6. Urines that are colored orange from suspected azo dyes.
        a. Urinalysis chemistry results are to be reported as “Color Interference”
C. Specimen Stability
    1. Urine analysis should be performed as soon as possible, preferably within one to two hours of collection or be refrigerated immediately at 2-8ºC and return to room temperature before testing. MIX THOROUGHLY before testing.
        a. Refrigerated samples are viable for 8 hours from collection. Samples that exceed the 8-hour stability time should be reported with a disclaimer.
            1) Enter the following in the “Urine Comment” field

a) “Specimen is greater than 8 hours from time of collection, interpret results with caution as some elements may be degraded.”

b. Formed elements may disintegrate at varying rates depending on pH, osmolality, and storage conditions.
c. Chemical changes can occur if samples are left at room temperature for 2 hours or more.
d. If analysis is not possible within one to two hours of collection, the urine may be refrigerated at 2-8ºC.
e. No significant interference from amorphous urates or phosphates has been demonstrated on the UF-5000®.

6. Supplies and Reagents

A. Supplies
1. Deionized water.
2. Kimwipes™, gauze, or plastic lined wipes.
3. Urine sample tubes with a diameter of 12-16 mm and a height of 95-120 mm.
4. Urine sample cup compatible with closed bottom STAT adapter.
5. 5.25 % Sodium Hypochlorite.

B. Follow the manufacturer’s instructions for the storage and expiration date for all reagents.
1. Record date received and date opened on reagent container.
2. All reagents are stable unopened at room temperature 15-25ºC until expiration date on container.
a. All reagents are azide-free and intended for in vitro diagnostic use as directed. Do not ingest.

CLINITEK Novus		
REAGENT	**OPEN STABILITY**	**STORAGE**
CLINITEK Novus 10 Urinalysis Cassette	14 days	1. Unopened, 15 to 30ºC, humidity less than or equal to 80% 2. Opened cassette should be loaded within 10 minutes 3. Protection against exposure to light, heat, and ambient moisture 4. Do not use if the foil lid or plastic tray is damaged
CLINITEK Novus Rinse Additive	2 weeks after dilution with distilled water	Room temperature, do not freeze
CLINITEK Novus Calibration Kit	Until expiration on the bottles	Store in original, tightly capped bottles 2 to 8ºC, Do not freeze
Siemens Clinitek Atlas Controls	Until expiration on the bottles	Room temperature, do not freeze
Siemens Chek-Stix Liquid QC Kit	Until expiration on the bottles	2 to 8ºC

UF-5000/ UD-10			
REAGENT	**ANALYZER(S)**	**OPEN STABILITY**	**STORAGE**
UF- CELLSHEATH	UF-5000 UD-10	60 days	1. 2 to 35ºC, out of direct sunlight 2. Do not freeze 3. Avoid creating bubbles 4. Sheath that shows signs of contamination such as turbidity or discoloration should not be used.
UF- CELLPACK SF	UF-5000	90 days	
UF- CELLPACK CR	UF-5000	90 days	
UF-Fluorocell SF	UF-5000	90 days	1. 2 to 35ºC, out of direct sunlight 2. Do not freeze 3. Avoid creating bubbles
UF-Fluorocell CR	UF-5000	90 days	
CELLCLEAN	UF-5000 UD-10	60 days	1. 1 to 30ºC, out of direct sunlight
UF CONTROL	UF-5000 UD-10	30 days	1. 2 to 8ºC, out of direct sunlight. When not in use, store in box to avoid direct sunlight 2. Do not freeze

C. Reagents
1. UF-CELLSHEATH™
a. This reagent is used to count formed elements by the flow cytometry method.
b. UF-CELLSHEATH Active ingredients:
1) Tris Buffer 0.14%
2. UF-CELLPACK SF

a. UF-CELLPACK SF is intended for use only in conjunction with UF-Fluorocell SF and is used to mark formed elements in urine for the determination of materials lacking a nucleus (RBCs, casts, etc.).
b. UF-CELLPACK SF Active ingredients
    1) Hepes: 1.2%
    2) 1,2-Benzisothiazolin-3-one:

3. UF-CELLPACK CR
    a. UF-CELLPACK CR is intended for use only in conjunction with UF-Fluorocell CR and is used to mark formed elements in urine for determination of materials containing a nucleus (WBCs, epithelial cells, bacteria etc.).
    b. UF-CELLPACK CR Active Ingredients
        1) Acetic Acid: <0.1%
4. UF-Fluorocell SF
    a. UF-Fluorocell SF is used to mark formed elements in urine for determination of materials lacking a nucleus (red blood cells, casts, etc.). The reagent is used in conjunction with UF-CELLPACK SF.
    b. UF-Fluorocell SF Active Ingredients
        1) Polymethine dye: 0.05%
        2) Ethylene glycol: 99.9%
5. UF-Fluorocell CR
    a. UF-Fluorocell CR is used to mark formed elements in urine for the determination of materials containing a nucleus (WBCs, epithelial cells, and bacteria, etc.). The reagent is used in conjunction with UF-CELLPACK CR.
    b. UF-Fluorocell CR Active Ingredients
        1) Polymethine dye: 0.02%
        2) Ethylene glycol: 99.9%
6. CELLCLEAN
    a. CELLCLEAN is a strong alkaline detergent which must be used as the rinse solution to clean the fluid system components of the UF-5000® and UD-10®.
7. CLINITEK Novus® 10 Urinalysis Cassette
    a. CLINITEK Novus® 10 Urinalysis Cassettes is intended for the measurement of albumin, bilirubin, blood (occult), glucose, ketone, leukocytes, nitrite, pH, protein, and urobilinogen. It is designed to be used only with the CLINITEK Novus® Automated Urine Chemistry Analyzer.
8. CLINITEK Novus® Calibration Kit
    a. The Calibrators are used with the CLINITEK Novus® Automated Urine Chemistry Analyzer to enable the user to obtain readings in a urine specimen for: color, clarity, glucose, bilirubin, ketone, specific gravity, occult blood, pH, protein, urobilinogen, nitrite, and leukocytes.
9. CLINITEK Novus® Rinse Additive™
    a. Shelf stable until expiration date.
    b. Do not freeze.
    c. CLINITEK Novus® Rinse Additive™
        1) 3.5% w/v hexadecyltrimethylammonium hydrogen sulfate; 3.5% w/v magnesium chloride hexahydrate; surfactant

10. UF CONTROL™ Commercial Control Material
    a. UF CONTROL is a bi-level commercial control for in vitro diagnostic use with the UF-5000® and UD-10®.
    b. UF CONTROL contains latex particles representing red blood cells, white blood cells, epithelial cells, casts, and bacteria.
        1) UF CONTROL L - Control Particles: 0.10%
        2) UF CONTROL H - Control Particles 0.40%

D. Reagent Replacement
   1. **Replacing CELLSHEATH – UF-5000® and UD-10®**
      a. If the reagent runs low during analysis:
         1) The reagent icon will turn yellow. Click on the reagent icon to reach the reagent replacement screen.
      b. If the reagent is empty or expires:
         1) The [ErrorHelp] dialog box will appear, and analysis is suspended.
         2) Touch the [Reset Alarm] button and replace the reagent immediately.
      c. A message displays as to what reagent is empty/expired. Touch [Reagent Replace].
      d. In the Reagent dialog box, touch the icon that indicates the reagent needing replacement.
      e. Place a check in the Reagent dialog box and be sure the cursor is displayed.
      f. Using the handheld reader, scan the “Reagent Code” on the new reagent container.
      g. Touch [Register] on the Reagent Dialog box.
      h. The Reagent Box will indicate ‘Received’ when the registration is complete.
      i. Open the cap on the new container. When switching reagents, be sure to avoid contamination of the tubing.
      j. Remove the cap from the expired/empty container and carefully remove the spout.
      k. Insert the spout straight into the new container.
      l. Tighten the cap on the new container and move the new container into position.
      m. If multiple reagents require changing, return to step “d”.
      n. Touch [Replace] to prime the new reagent. A “Replacing Reagent” dialog box is displayed showing a replacement timeline.
      o. When the process is complete, the “Reagent” box return. Touch [Close].
   2. **Replacing Dye Cartridges on the UF-5000®**
      a. If the dye runs low or expires during analysis, the [Error Help] dialog box will appear, and analysis is suspended.
      b. Touch the [Reset Alarm] button and replace the reagent immediately.
      c. Read the error message to determine which reagent is empty/expired and then touch [Reagent Replace].
      d. Lift up the top front cover of the analyzer.
      e. Remove the old dye cartridge from its holder by lifting the handle straight up, and discard.
         1) Install the new dye cartridge into the holder, making sure the color matches.
         2) The analyzer will beep as the information is automatically registered by the Radio Frequency Identification (RFID) chip.
         3) Close the holder door, then close the top front cover of the analyzer.
         4) Reagent replacement will begin automatically, when complete the reagent registration dialog box updates.
      f. Touch Close.
      g. **NOTE**: If the incorrect reagent is installed, an error occurs, and an alarm will sound. Check the error and install the correct reagent.
   3. **Replenish Rinse Water – UF-5000® and UD-10®**
      a. Remove the cap from the rinse water bottle.
      b. Pull the spout kit straight up.
      c. Replenish the rinse water using DI water until the bottle is full.
      d. Insert the spout kit straight into the rinse bottle.
      e. Close the cap of the rinse bottle.
      f. Touch the [Reagents Replacement] icon on the [MENU] screen.
      g. Touch [Rinse Water].
      h. Touch [Register]. The progress dialog box appears, and reagent replacement starts.
   4. **Load reagent cassettes – CLINITEK Novus®**
      a. Select [System] then [Load & Unload].
      b. Select [Yes] to confirm unloading of a cassette.
      c. Open the system cover.
      d. Turn the lock on the cassette door counterclockwise then open the door.

e. Hold the cassette by the handle and slide it backwards out of the analyzer to remove.
f. Prepare the new cassette:
    1) Use the foil tab to peel the foil seal off the tray.
    2) Remove the cassette from the tray.
    3) Pull the shipping card out of the cassette.
    4) Do not turn the cassette upside down, as the cards may fall out.
    5) Strip cartridges need to be loaded onto the analyzer within 10 minutes of breaking the foil seal.
g. Load the new cassette onto the rails and slide it into the instrument.
h. Close the door and turn the lock clockwise to lock the door.
i. Close the system cover. The system reads the lot number and expiration date from the cassette.
j. The system will prompt a calibration to be performed if necessary.
k. Run QC.

5. **Preparing Rinse Solution – CLINITEK Novus® (Applicable Sites)**
    a. The system is configured with an external rinse bottle. It must be checked visually.
    b. Locate the rinse bottle on the side of the Novus.
    c. Remove the cap and empty the remaining rinse.
    d. Fill the rinse bottle with 1000 mL. distilled or deionized water.
    e. Add 2 mL. of CLINITEK Novus® Rinse Additive. Gently swirl to mix trying to avoid excess bubbles.
    f. Replace the cap.
    g. Prime the pump.
6. **Urinalysis Data Manager® (UDM) reagent tracking**
    a. Information on reagent status can be viewed by touching the Reagent Levels box on the bottom of the UDM computer screen. The UDM history log receives the reagent information from barcoded reagents for each of the analyzers connected to the UDM. The storage capacity for reagent replacement history is 3000 entries. To view the reagent log:
    b. From the main menu – touch [History].
    c. Touch [Analyzer].
    d. Touch the [Reagent] tab.
    e. To filter the log for a specific date range, touch [Filter] >[Date]>[Select]. Enter the opening date and end date using the on-board touch screen.
    f. Select the [Output] button on the toolbar and click [CSV output].
    g. Specify a folder or create a new folder.
    h. Enter a file name.
        1) The file name will end in .csv
    i. Click [Save].
        1) The dialog box closes, and the selected log is saved in CSV format.
    j. The CSV file can be viewed on a computer using Excel.

7. Calibration

A. Initial calibration is performed during installation on the UF-5000® and UD-10® by the Sysmex Service Engineer (SE). Calibration compensates for any bias inherent to the pneumatic, hydraulic, and electrical systems that may affect the accuracy of results. Calibrators traceable to reference methods are used in the calibration of the instrument. Documentation of parameters that can be calibrated and reference methods for calibrator target value assignments are contained in the calibrator package inserts (if applicable).
B. Calibration by a Sysmex Service Engineer is also required if one or more of the following occur:
    1. Critical dilution components, analytical parts, and assemblies are replaced.
    2. Controls/calibrators are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting.
    3. When advised by a Sysmex Representative.

C. Calibration should only be completed when troubleshooting indicates that there is no major underlying problem with the analyzer, reagents, or quality control materials.
D. **UF-5000® bi-annual calibration verification**
   1. The most common processes for Precision and Calibration of the Sysmex analyzer are the utilization of Sysmex sponsored calibration/precision events defined by the analyzer service contract. Calibration verification procedures may be done by a Sysmex Service Engineer on site or remotely through the Sysmex Network Communications System (SNCS™) with the Sysmex Calibration Specialist. The following items are completed by the Sysmex representative during the calibration verification process.
      a. Documentation and review of analyzer service history.
      b. Documentation and review of QC testing results.
      c. Documentation and review of historical Sysmex QC reports.
      d. Analyzing the Sysmex calibrator according to the manufacturer's recommendations to verify precision and calibration (accuracy) of the analyzer.
      e. Documentation of calibration verification results and generation of a calibration verification certificate for laboratory records.
E. **UD-10® Calibration**
   1. Unless UD-10® control values are outside of manufacturer's stated ranges, Bi-annual calibration verification or remote calibration on the UD-10® will be performed based on the following:
      a. Manufacturers recommendations.
      b. Documentation and review of analyzer service history.
      c. Documentation and review of QC testing results.
      d. Documentation and review of historical Sysmex QC reports.
      e. Analyzing the Sysmex calibrator according to the manufacturer's recommendations to verify precision and calibration (accuracy) of the analyzer.
      f. Documentation of calibration verification results and generation of a calibration verification certificate for laboratory records.
F. **CLINITEK Novus® Calibration**
   1. Calibration Frequency
      a. When a cassette is loaded with the same lot but did not calibrate the system within the last 24 hours. The status bar displays Not Ready.
      b. When loading a new cassette lot. The status bar displays Not Ready.
      c. The system displays error messages requiring the system to be calibrated. The status bar displays Not Ready.
      d. Upgrade to the software.
      e. Replacing the pipette, SG sensor, or syringe.
      f. At least weekly if not otherwise prompted to do so.
   2. Calibration Preparation
      a. **NOTE**: Before calibrating, be sure the SG well has hydrated if the power has been off for longer than one hour.
      b. Pour at least 2 mL of a 5.25% sodium hypochlorite into a properly labeled sample tube. Reuse this tube throughout the day as needed without discarding it. However, the tube must always contain at least 2 mL.
      c. Pour at least 3 mL of each calibration solution (from the Calibration Kit) into the properly labeled sample tubes (1 tube per solution) for CAL #1, # 2, #3, and CAL #4.
      d. Allow all the solutions to equilibrate to room temperature before use.
   3. Calibration Procedure
      a. Press the start/stop switch on the CV-11. The LED status display will illuminate orange.
      b. Place the rack with the calibrator tubes on the right pool of the Novus.
      c. Select [System] from the home screen.
      d. Select [Calibration].
      e. To change or add a lot number, touch [Change], then enter the information. Touch [Next].

f. Follow the instructions on the screen to place the tubes in the rack.

Rack Position	Reagent	Volume (mL)
1	5.25% Bleach	3
2	Cal 4	5
3	Cal 1	3
4	Cal 2	3
5	Cal 3	3

g. Select [Start] and the screen will count down from 3:13 to zero.
h. The analyzer updates the progress of the run.
i. Select [Exit] to return to the system menu.
j. If calibration passes, the status bar will return to “Ready” and the system will be ready to process quality control and patient samples.
k. After the calibration, record utilizing site specific workflow.

8. Quality Control

A. See site specific workflow for how to prepare and/or process QC material.
B. Quality Control is performed to monitor an analyzer’s performance over time. Quality control should be run in accordance with licensing agency regulations. It should be noted that for troubleshooting purposes, additional control runs may be necessary.
C. **QC Frequency**
1. UF Control will be run every 8-12 hours on the UF-5000® depending on site.
2. UF Control will be run every 8-24 hours on the UD-10® depending on site.
3. Novus QC is run daily or as needed if strips are loaded.
4. Techs will review QC as it is performed to ensure QC is in control prior to running patients.
5. Supervisor or designee will review quality control monthly.

D. **QC New Lot Registration Entry on the UDM**
1. QC lot entry for the CLINITEK Novus® is REQUIRED. It is NOT required for the UF-5000® and UD-10®.
2. Click the [QC] Icon on the Main Menu Screen.
3. Select the analyzer from the drop-down menu.
4. Select an open file number and select [Register] on the tool bar. The lot information dialog box appears.
5. Enter the Material from the drop-down menu.
6. Enter the QC lot #.
7. Enter the expiration date of the control material.
8. For Novus analyzers ONLY.
   a. Siemens controls:
      1) Once the QC lot and Expiration date of the new lot is entered, click RESTORE and open the NOVUS QC Limits file.
      2) Choose the appropriate QC limit file for the control that is being added.
      3) Verify that the restored ranges match the package insert
   b. Non-Siemens controls:
      1) Enter the upper and lower target values from the package insert.
      2) Designate “Control 1” material as the positive control. Place a check mark in the “Analysis registration lot” on the bottom of the target limit set screen. This will always designate tube one as the positive control.
      3) Designate “Control 2” material as the negative control. Place a check mark in the “Analysis result registration lot” on the bottom of the target limit set up screen. This will always designate tube two as the negative control.
      4) Select [OK] to save the entry.
      5) Repeat the process with subsequent controls.

E. **Preparation of QC files – CLINITEK Novus®**
1. Select [System > Control].
2. Select the [Change] button that corresponds with the control being added.

3. Select [Add].
4. Enter the control lot #, select [Enter].
5. Enter the control lot expiration date, select [Enter].
6. Repeat for additional control.

F. **Analysis of Quality Control Material – CLINITEK Novus®**
   1. Place two tubes of control solution into a rack in the following positions:
      a. Positive Control: Position 1
      b. Negative Control: Position 2
   2. Press the stop/start button on the CV-11. The status indicator light will illuminate orange.
   3. Place the rack in the loading area on the right side of the analyzer.
      a. **NOTE**: Do not place the tubes with control solutions in incorrect rack positions. The system will process those samples, and the control results will be incorrect.
   4. Select [System > Control]. Verify control lots are correct.
      a. To change or add lots, follow instructions for Preparation of QC Files in this document.
   5. Select [Next]. The rack moves into position for testing and the system tests each control once.
   6. After the system moves the rack to the left side of the analyzer, remove the rack.
   7. Press the start/stop switch on the CV-11. The indicator light will illuminate green and is now available for patient testing.

G. **Preparation of QC files – UF-5000®**
   1. Before analyzing controls, input the lot numbers and expiration dates in the QC files to be used.
      a. Some sites may require logging in with Admin credentials.
   2. New Lot:
      a. Select Main Menu. Touch [Menu] and select [QC].
      b. Select either UF CONTROL L or UF CONTROL H tabs for the desired QC.
         1) **NOTE**: Lot number information must be entered into both the UF CONTROL L and UF CONTROL H tabs.
      c. Select [Register] from the top tool bar.
         1) If there are 3 lots already scheduled, a prompt will appear to delete the oldest lot before proceeding.
         2) **NOTE**: This process does not delete files from the UDM
      d. QC Lot information may be entered by one of the following methods:
         1) **NOTE**: Before entering in new lot information, verify that the package insert matches the intended instrument type.
         2) Handheld Barcode Reader
            a) With the handheld barcode reader, scan the QC barcode for each parameter on the UF CONTROL assay sheet that coordinates with the analyzer.
            b) When the barcode has been successfully read, the handheld barcode reader will beep.
            c) When complete touch [Register].
            d) **NOTE**: If the [Register] icon is not available, one or more of the parameters failed to scan. Review the parameters and scan again.
            e) Expiration date will default to open vial stability (30 days) or Lot expiration, whichever is earlier
            f) Touch [Register].
            g) Date bottles with updated expiration date and initials.
         3) Manual Entry
            a) Access the touch screen keyboard by touching the Lot Number, which has a prefix of [QC-].
            b) Manually enter the lot# and expiration date of control type.
            c) Touch each parameter by using the on-screen keyboard and manually enter each target/ limit provided on the control/assay sheet.

d) Touch [Register] when all items are registered.

4) **NOTE**: When connected to the UDM, newly created QC files and results for the UF-5000® will automatically transfer to the UDM.

3. Same Lot, New Bottle:
   a. MUST be updated in both the UF and the UDM (otherwise the expiration dates will not match).
   b. UF
      1) Select Main Menu. Touch [Menu] and select [QC].
      2) Select Analysis.
      3) Select either UF CONTROL L or UF CONTROL H tabs for the desired QC.
      4) Update the new bottle expiration by selecting the "Change Bottle" button. This will automatically update the expiration date to 30 days from the current date.
         a) **NOTE**: Bottle information must be changed in both the UF CONTROL L and UF CONTROL H tabs.
   c. UDM
      1) To update the new bottle expiration date, register a new vial by opening the Levy Jennings graph for each level of QC. Select the [Vial] button in the black toolbar.
   d. Date bottles with updated expiration date and initials.

H. **Analysis of Quality Control Material – UF-5000®**
1. Allow control material to come to room temperature (15-30°C) for 20-30 minutes before use.
2. From the main menu, touch [QC].
3. Select the Lot# from the radio button on the bottom of the screen.
4. Mix the control according to the package insert.
   a. Invert the bottle until there is no particle sediment remaining at the bottom.
   b. Invert vigorously an additional 20 times.
5. Immediately dispense (13-18 drops) of UF CONTROL into a new sample cup. Place the sample cup into the adapter.
6. Within 10 seconds after dispensing, touch [Analysis] > [Yes].
7. Touch UF CONTROL L or UF CONTROL H and touch [Next].
8. Push the STAT sample tube holder in and touch [ANALYSIS START]. This will initiate sampling.
9. After QC analysis is complete, results will display in the dialog box. Use left ◄ or right ► arrows to view QC results.
   a. If results are outside expected ranges, or if the control material has expired, the analyzer will alert the operator with a warning and audible sound. Touch L-J Limit Control on the analyzer screen. A pop-up box appears. Touch [ERR Recovery] to acknowledge error and exit.
10. Touch [Exit] to accept control if acceptable.
    a. **NOTE**: Do not use the “Repeat” option as it will delete the unacceptable point and will not be reported in the QC files.
11. Press the STAT button on the analyzer to retrieve the sample cup.
12. To continue QC analysis, return to step 4.
13. Exit the QC analysis program by touching [Close].

I. **Preparation for QC Files for the UD-10®**
1. New Lot:
   a. Select Main Menu. Touch [Menu] and select [QC].
   b. Select either UF CONTROL L or UF CONTROL H tabs for the desired QC.
      1) **NOTE**: Lot number information must be entered into both the UF CONTROL L and UF CONTROL H tabs.
   c. Select [Register] from the top tool bar.
      1) If there are 3 lots already scheduled, a prompt will appear to delete the oldest lot before proceeding.
   d. QC Lot information may be entered by one of the following methods.

1) Handheld Barcode Reader
   a) With the handheld barcode reader, scan the QC barcode for each parameter on the UF CONTROL assay sheet.
   b) **NOTE**: For the UD-10® the only parameter that needs to be entered is Class 2. Scan the barcode for WBC as it is equivalent to Class 2 on the analyzer. Leave all other parameters blank.
   c) When the barcode has been successfully read, the handheld barcode reader will beep.
   d) When complete touch [Register].
      1. **NOTE**: If the [Register] icon is not available, one or more of the parameters failed to scan.
   e) Review the parameters and scan again.
   f) Expiration date will default to open vial stability (30 days) or Lot expiration, whichever is earlier.
   g) Date bottles with updated expiration date and initials.
   h) Touch [Register].
2) Manual Entry
   a) Access the touch screen keyboard by touching the Lot Number, which has a prefix of [QC-].
   b) Manually enter the lot# and expiration date of control type.
   c) Touch each parameter by using the on-screen keyboard and manually enter each target/ limit provided on the control/assay sheet.
   d) Touch [Register] when all items are registered.
3) **NOTE**: When connected to the UDM, newly created QC files and results for the UD-10® will automatically transfer to the UDM.

2. Same Lot, New Bottle:
   a. Select Main Menu. Touch [Menu] and select [QC].
   b. Select Analysis.
   c. Select either UF CONTROL L or UF CONTROL H tabs for the desired QC.
      1) Update the new bottle expiration by selecting the "Change Bottle" button. This will automatically update the expiration date to 30 days from the current date.
      2) **NOTE**: Bottle information must be changed in both the UF CONTROL L and UF CONTROL H tabs
   d. Date bottles with updated expiration date and initials.
   e. Expiration dates will be updated in the UDM after QC is run.

J. **QC Analysis on the UD-10®**
1. Touch the [QC] icon on the menu screen.
2. Touch the [Analysis] button on the tool bar. A QC dialog box appears.
3. Touch [Yes].
4. Select the appropriate QC file tab: L for Low and H for High.
   a. To switch the control to a new bottle, touch [Change bottle] > [Yes] in the dialog box that appears.
5. Select the lot number, then touch [Next]. The “QC Analysis” dialog box appears, and the STAT sample tube holder lock is released.
6. Mix the control according to the package insert.
   a. Invert the bottle until there is no particle sediment remaining at the bottom.
   b. Invert vigorously an additional 20 times.
7. Immediately dispense (23-28) drops of the UF Control to the sample cup.
8. Set the control into the STAT sample holder.
9. Push in the STAT sample tube holder until it locks.
10. Touch [Analysis Start] to start QC analysis.
    a. This button becomes available once the STAT sample tube holder is correctly locked into place.

b. Once the aspiration of the control is completed, the STAT sample tube holder lock is automatically released.
c. Progress of the QC analysis is shown in a progress bar on the bottom of the dialog box. Wait until this is completed.

11. Touch [Exit] to accept control if acceptable.
    a. **NOTE**: Do not use the "Repeat" option as it will delete the unacceptable point and will not be reported in the QC files.
12. Press the release button on the sampler section. The STAT sampler tube holder slides out.
13. Remove the control from the STAT sampler holder.
14. Return to step 4 to run additional QC.
15. Check the analysis results.
16. Touch [Close].
17. **NOTE**: If a QC analysis result without analyzer lot information is received in the UDM from an analyzer, a confirmation dialog box appears after the QC is processed on the analyzers. Acknowledge the confirmation box to receive the QC results.

K. **Recalling/Reviewing Quality Control Data**

1. **Siemens CLINITEK Novus®**
    a. At the home screen, click on [Results].
    b. Select [Control].
    c. After the search criteria are entered, a list of controls will be available.
    d. Highlight the control and select [View].
    e. If a flag was generated during testing, a symbol denoting the flag is displayed adjacent to the result:

Symbol	Meaning
^	Range Adjusted
‡	Sieve
*	Out of expected range
†	Sample Quality

    f. If any results are not within the expected range, do not test patient specimens. Troubleshoot and rerun the controls. Test and report patient specimens only when control results are acceptable.
    g. If the control is out of range and needs to be repeated, repeat both control to ensure that the results will file correctly in the UDM.

2. **UF-5000® and UD-10® Quality Control Results Review Management**
    a. Radar Charts
        1) From the QC Chart Screen on the desired analyzer, select control level and lot#.
        2) Touch [Radar] from the top tool bar.
            a) **NOTE**: the Radar view shows only the last accepted QC run for the control and lot# selected.
        3) Results are displayed on the Radar Chart in BLUE. Parameters outside of acceptable limits are displayed with a BLUE X with the name of the parameter backlit in red.
        4) Return to the QC Chart (L-J Chart) by touching [QC Chart] on the top tool bar.
    b. **L-J Charts**
        1) Touch the [QC] icon on the Menu screen on the desired analyzer to display the QC Chart screen (L-J Charts).
        2) Touch Lot Selection buttons to display the lot# desired.
            a) The red line on the L-J display indicates the last analysis; the analysis date is posted on the top of the chart.
            b) Results outside of control limits are notated with a Blue X.
            c) Scroll to view additional QC parameters by using the up and down arrows to the right of the L-J graphs.
    c. **Selecting a range of results**
        1) Touch the [QC] icon on the MENU screen.

2) Select the control type and lot# desired.
3) Touch the plotted point that will be the starting point of the selection range.
4) Touch the range selection mode button.
   a) Cursor moves and the range between the sub-cursor and cursor are selected.
   b) Mean, SD, and CV will display to the right of each parameter.

d. **Managing QC results using Cursor Data Settings**
1) Touch [QC] icon on the MENU screen.
2) Select control type and lot# desired.
3) Touch [Chart Control] and touch [Cursor Data Management]. The Cursor Data Management dialog box appears.
4) Select [Manage] to include results in the QC statistical values.
5) Select [Not Manage] to exclude results from the QC statistical values.
6) Input comment from the list in the drop-down box or free text comment into the "any comment box".

3. **UDM Quality Control Results Review Management**
a. **Radar Charts**
1) Click the [QC] icon on the Main Menu Screen.
   a) Select the analyzer from the drop-down box in the analyzer selection area.
   b) Select the QC file to review.
   c) To view charts, click on the Display selection button to the right of the files.
   d) The radar chart displays the latest QC analysis result of the QC files selected from the file list.
2) If a parameter exceeds the limit value:
   a) The parameter name is displayed in white characters on a red background.
   b) The point is displayed as a Red X.
3) QC (L-J) Charts
   a) **NOTE**: Each Quality Control file menu holds 50 files. Each file can display 300 plotted points.
   b) Click the [QC] icon on the Main Menu Screen.
   c) Select the analyzer from the drop-down box in the analyzer selection area.
   d) Select the QC file to review.
   e) The cursor line will be on the most recent QC analysis. The date and time stamp will be attached to the top of the QC chart display area. Move the cursor line by using the up and down arrows to the right of the QC chart display screen. To move the cursor line to a different analysis, use the bottom left and right arrows on the bottom of the QC chart display screen.
   f) Plotted points are displayed as follows:
      1. ●- (Solid circle) – QC analysis within range.
      2. X – QC analysis outside the limit range.
      3. ○– (Open circle) – results are NOT managed.
   g) Data Information displays the value of the QC analysis result selected with the cursor. Values outside range of limit are displayed in white characters with a red background. Values that exceed the limit are displayed with an [+] or [-].
   h) Mean displays the average value calculated from all managed QC analysis results.
   i) SD displays the standard deviation calculated from all managed QC analysis results.
   j) CV displays the coefficient of variation calculated from all managed QC analysis results.
4) Selecting a range of analysis
   a) While in the QC chart of the selected analyzer, click the plotted point that will be the start point for the range selection area.
   b) Click the [Range] button on the toolbar.

c) Click the end point of the range to be selected on the QC chart. The results between the two reference lines are selected.
d) To cancel the range selection, click [Range].

5) Including or excluding data from QC
a) In the 'QC Chart' screen, Select the analysis results that you want to manage.
b) Select the [Management] button on the toolbar.
c) Configure each item.
d) Select the 'Exclusion specified' and comment.
1. [Exclusion specified] Specify whether the cursor data is included in or excluded from the overall quality control data calculations.
2. [Managed]: Include the data point in the QC calculations.
3. [Not Managed]: Exclude the data point from the QC calculations.
4. Set comments to be added to the cursor data.
5. [None]: Do not add a comment.
6. [An arbitrary comment is inputted.]: Add a free-text comment entered in [Arbitrary comment] field.
7. Fixed comments: Add a comment selected from the drop-down list.
e) Select [OK].

6) Output results
a) Select the output button on the toolbar and click the output destination.
1. Graphic printing to print L-J charts.
2. List Printing to print QC in list format.

2) Saving and restoring QC file data in CSV format
a) In the QC file menu, click the QC file to save.
b) Select the [Output] button on the toolbar and click [CSV output].
c) Specify or create a folder.
d) Enter a file name and click [Save]. The file extension is ".csv".
e) To restore a file, select a QC file that does not have a lot registered.
f) Select the [File] button on the toolbar and click [Restore].
g) Search for the QC folder that file was stored in and select the QC file.
h) Click [Open].
i) **NOTE**: A QC file that has the same lot number currently on board cannot be restored.

9. Operating Procedure

A. Sample Processing

1. Confirm all CV-11 status indicator LED lights are illuminated and green.
2. Allow samples to reach room temperature.
3. Mix each sample thoroughly.
4. Do not test samples that are visibly bloody, mucoid, or foamy. In the case of a visibly bloody specimen, refer to Urinalysis Protocol for Analyzing Bloody Specimens
5. For the most accurate results, test the samples within two hours.
6. Prepare a well-mixed urine sample into a clean sample tube labeled with the appropriate barcode.
7. Place tube(s) in rack with barcode visible within the rack opening.
8. Load the rack with the groove to the right onto the right sampler pool.
   a. In case of a rack jam, an alarm will sound on the CV-11. Status indicator LED will illuminate red and rack position indicator LED will indicate the position of the rack.
      1) Press the alarm reset switch.
      2) Reposition the rack.
      3) Press the start button. Rack will advance.

B. Rack movement behavior.

1. If there is more than one identical analyzer, the system will load balance the racks and distribute to analyzers equally.
    a. The first rack will proceed to the [identical] analyzer on the right; the second rack will proceed to the [identical] analyzer on the left.
    b. When analysis is complete and analyzers go into standby, the next rack loaded will always move to the [identical] right analyzer.
2. The racks will then move onto the second type of analyzer (reflex analyzer) and will load balance in the same fashion.
    a. All tubes will be presented to the reflex analyzer(s).
    b. The barcode will be read, and the analyzer will query for an order.
        1) If there is no order, no aspiration will occur, and the rack will proceed to the next sample.
        2) If there is an LIS or reflex order from the UDM, the sample will be analyzed.
        3) The reflex will occur for:
            a) Samples that have an abnormal result (trace or greater) for Glucose, Bilirubin, Ketone, Blood, Protein, Nitrite or Leukocyte Esterase.
            b) Samples with a clarity of anything other than clear.
            c) Samples with the color of anything other than Yellow or Dark Yellow.
            d) When the microscopic is specifically ordered.
3. When all required samples are analyzed, racks will eject to the left sampler pool of the last analyzer and will remain there until the user removes them.

C. **Analysis of an "urgent" sample during sample analysis**.
1. UF-5000® and UD-10® only. Novus does not have manual mode analysis.
2. Touch [STAT] analysis button in the control menu at the bottom of the screen. Do NOT remove racks.
3. The instrument will change to STAT analysis as soon as analysis of the current sample finishes.
4. Analyze the sample using the STAT [URI] mode.
    a. **NOTE**: See "UF-5000®" and "UD-10®" Manual Mode Analysis using STAT (URI) Mode in the following procedures of this document.
5. Once the sample has resulted, sampler analysis will resume.

D. **UF-5000® and UD-10® Manual Mode Analysis using STAT (URI) Mode**
1. Confirm the UF-5000® LED light is green and the "Sampler Ready" message is displayed on the left side of the control toolbar, or the LED light is orange and the "Sampler Int. Ready" message is illuminated.
2. Press the [STAT URI] icon on the bottom of the LCD screen to switch to STAT/Manual mode. The CV-11 will be interrupted, and the orange light will illuminate.
3. A STAT Analysis dialog box appears. Touch [YES] to "Start STAT analysis of urine sample".
4. Enter the sample ID using the on-screen keyboard or manually scan the barcode with the barcode reader. If performing multiple STAT samples, place a check next to "Start STAT when the analysis finished". This will enable tube ejection at the end of the sample analysis.
5. Mix the urine sample and insert the uncapped tube into the sample holder or transfer the well-mixed urine into a sample cup.
    a. If using a sample cup, set the sample cup in a closed bottom STAT adapter.
    b. Dispense 0.6 ml. (13-18 drops) per sample cup.
6. Push in the STAT sample tube holder.
7. Touch [START] in the STAT Analysis box.
    a. **NOTE**: The sample tube holder is locked during STAT analysis. Do NOT forcibly open the STAT sample tube holder or press the release button. It may cause a malfunction of the instrument.
8. The orange LED flashes, and the "STAT Processing" message is displayed.
9. After aspiration completes, press the [STAT] button to eject the sample.
    a. Repeat steps 1-9 and repeat analysis.

1) NOTE: Verify specimen ID number when running multiple STAT samples.

10. Once sample analysis is complete, remove the sample. CV-11 will return to ready.

10. Analysis Registration and Review of Results on the UDM:

A. Registering an analysis order (Process for Downtime): during LIS downtime, specimen ordering is performed on the UDM:

B. Click the [Order Entry] icon on the Main Menu Screen.
   1. Scan or type the specimen ID# and a second identifier (Name and Birthdate)
   2. Click [Test Selection].
   3. Select the [Chemistry] and [UF-5000®] parameters in case of a urinalysis with microscopic is ordered.
   4. Click [OK] > [Save] > [OK].

C. Run sample as stated above.

D. Searching for patient information:
   1. Click the [Patient] icon on the Main Menu screen.
   2. Click the [GO] button on the toolbar.
   3. Select the search conditions
      a. Patient ID
      b. Patient name
      c. Sex
   4. Click [OK].

E. Searching for analysis results
   1. Click the [Explorer] icon on the Main Menu screen.
   2. Click the [Search] button on the tool bar.
   3. Configure the search item
      a. Sample ID
      b. Patient ID
      c. Patient name
   4. Click [Search]. If search is successful, patient results will appear on the Explorer.
   5. After reviewing patient results and information, click [X] to return to the previous screen.

F. Checking Analysis results – Explorer
   1. From the Main Menu, click [Explorer] icon.

G. Search for patients using search conditions described previously or scan Explorer screen. View Status Symbols to indicate analysis status.

Icon	Status	Description
Cancel / Cancel	Cancel order	All parameters of the profile to be analyzed were canceled.
● / Pending	Unanalyzed	The profile has not been analyzed.
↻ / Analyzing	Initial analysis in progress	Initial analysis of the profile is in progress.
✓ / Analyzed	Analysis completed	Initial analysis of the profile is completed.
✓→| / ✓→	Waiting for the validation group	Initial analysis of the profile is completed and waiting for automatic validation.
Rerun / Rerun	Rerun	Sample awaiting rerun analysis.
Rerun / Rerun	Rerun in progress	Rerun analysis of the profile is in progress.
Rerun / Rerun	Rerun completed	The profile has 2 or more analysis results.
Reflex / Reflex	Reflex	The profile has a reflex order.
Validated / Validated	Validated	The analysis results of the profile have been validated.
✓ / Reported	Output completed	The analysis results of the profile have been output to the host computer.

   1. Review Explorer screen for analysis results and patient information.
      a. Rerun or cancel rerun on a sample.
         1) Select the analysis for which to rerun or cancel rerun.
         2) Click [Rerun] on the tool bar.
            a) Select [Profile] to retest a specific profile.

b) Select [Rerun] to rerun the same profile.
c) Select [Cancel] to cancel a rerun.
3) Click [OK].

b. Validate a sample
1) Select the analysis for which to validate.
2) Click the [Validate] button on the tool bar.
a) Select [Profile].
b) Select [Validate] [will be available if not validated].
c) Select [Unvalidate] [will be available only if validated and not sent to the LIS].
3) Click [OK].

c. Outputting analysis results
1) Select the analysis for which to output.
2) Select the [In/Output] button on the toolbar.
a) Select [Host output] to output validated parameters to a host computer.
b) Select [Report GP] to output validated parameters in report format.
c) Select [List Printing] to output validated parameters in list format.
d) Select [CSV] to output to a folder in .csv format.

d. Checking detailed information in Browser
1) From the Explorer screen, select the analysis for which to check details.
2) Click the [Browser] button on the toolbar.
a) Click [Main] for numerical data results.
b) Click [Graph] for Distributions and Scattergrams.
c) Click [Cumulative] for analysis results of patients over time.
d) Click [Rerun Results] for rerun analysis results of patient.

11. Classifying and Reporting Particle Images on the UDM for sites with the UD-10®:

A. **Viewing the particle images**.
1. Click the explorer icon on the Main Menu screen.
2. Select the sample whose particle image needs to be reviewed.
3. Click the [UD Manual] button on the tool bar to view the Overview screen.
a. Overview Tabs
1) Total display – Displays various comments on the analysis results for UF5000 analysis results and scattergrams.
2) Image – Displays the image captured on the digital imaging device.
3) Order Information – Displays patient and order information.
b. Head Particle Image tab
1) Displays the particle image of each class.
2) Click each class to magnify the images.
3) Click the right arrow to move to the next image and the left arrow for the previous image.
4) Double click an image to enlarge.
c. Patient information area
1) Displays patient information.

B. **Manually entering analysis results from the captured images.**
1. **NOTE**: Results for the UD manual are strictly confirmatory and are never numerical. Therefore, the result option of “Present” is reportable.
2. Click the [Explorer] icon on the Main Menu screen.
3. Select the sample particle image to view and classify.
4. Click the [UD Manual] button on the toolbar to review the Overview screen.
5. In the particle information area, select class 1 to begin viewing and classifying the particles.
6. In the classification results list, double click the analysis parameter to enter a result.
7. Click [PRESENT].
8. Double click [REVIEW].
a. Select [REVIEWED] to send the results out to the LIS.

b. Select [NEEDS MANUAL] to reference to a manual microscopic (if applicable)

9. Click the [Close] button on the tool bar, then choose [Save].

C. **Review Messages**

1. Review messages and symbols alert the operator to reflex an additional test or hold validation of analysis to review.
2. ERR – The analysis has been completed, but there are analysis parameters that have been affected by errors.
3. REV – The analysis has been completed, but there are analysis parameters that require confirmation.
4. [----] – Indicates that an analysis was not obtained due to an analysis error. Marks do not appear.
5. [++++] – Indicates that results exceed the display range and cannot be displayed.
6.  Low reliability mark. The reliability of the data is low. This is displayed on a red background.
7.  Outside of reference range and considered abnormal (Novus). This is displayed on a yellow background.
8.  With a RED background. The value is higher than the set value of a [review interval].
9.  With a YELLOW background. The value is higher than the set value of a [reference interval].

12. Workflow for Failure of Crosscheck Rules

A. **UD-10® Sites**

1. A Crosscheck rule is any of the following messages generated from the UF-5000®.

BLD is [>=small/1+] and UF RBC[<=cells/HPF] follow SOP, confirm results
RBC=>6 cells/HPF and BLD NEG
WBC=>11 and LEU NEG
NIT POS and BACT NEG
DEBRIS High Flag, confirm results

2. To process a urine that has failed crosscheck rules:
   a. Check the sample ID in EXPLORER.
   b. Chemistry and UF-5000® results will have a green checkmark. Results are not sent to Beaker.
   c. Centrifuge the urine.
   d. From the UDM, select the patient file, double click to open.
   e. Select ‘Validate’ from the top toolbar.
   f. Choose CHEMISTRY and then OK.
   g. Alternatively choose the [NEEDS MANUAL] option in the review tab and validate all. (If applicable)
   h. Perform the manual microscopic exam (Reference site specific workflow) and confirm the results based on the cross-check rule and record the microscopic results in Beaker.
3. For the cross-check rule "BLD is [>=small/1+] and UF RBC[<=cells/HPF]" the following comment has been approved to be added and a manual microscopic is not required.
   a. "Positive dipstick result for blood but no red blood cells detected by fluorescent flow cytometry and/or microscopic exam. The result could be seen in patients with hemoglobinuria and/or myoglobinuria. In rare cases, the result can be caused by discolored urine following ingestion of certain drugs/dyes."
   b. If the BLD result is 2+ or 3+, perform a manual microscopic review of the RBC count.
      1) If the RBC count is incorrect, manually result the microscopic results in Beaker and then validate only the Chemistry portion of the Urinalysis in the UDM.

2) If the RBC count is correct, manually add the .BLDRBC smart-phrase in the white comment box in Beaker and then manually validate both the Chemistry and UF results in the UDM.

B. **Sites without a UD-10®**

1. A Crosscheck rule is any of the following messages generated from the UF-5000®

BLD is [>=small/1+] and UF RBC[<=cells/HPF] follow SOP, confirm results
RBC=>6 cells/HPF and BLD NEG
WBC=>11 and LEU NEG
NIT POS and BACT NEG
DEBRIS High Flag, confirm results
RBC/YLC Possible Interference. Confirm results.

2. If any of these messages appear on the Rule comment section of the printout (also can be found in the comment section in EXPLORER on the UDM), the following workflow will need to be followed:
   a. Paper will print out indicating that a manual review needs to be performed.
   b. Check the sample ID in EXPLORER.
   c. Green check marks (without circle) indicate results have not been sent to Beaker.
3. If the rule BLD POS and RBC <=5 cells /HPF is flagged:
   a. Check the BLD result from the NOVUS on the printout:
4. If the BLD result is trace or 1+, then the Chemistry and UF results may be validated in the UDM (top toolbar) and the .BLDRBC smart-phrase In Beaker (Positive dipstick result for blood but no red blood cells detected by fluorescent flow cytometry. The result could be seen in patients with hemoglobinuria and/or myoglobinuria. In rare cases, the result can be caused by discolored urine following ingestion of certain drugs/dyes.) will automatically be added to the results once the results are verified in Beaker.
5. If the BLD result is 2+ or 3+, perform a manual microscopic review of the RBC count.
6. If the RBC count is incorrect, manually result the microscopic results in Beaker and then validate only the Chemistry portion of the Urinalysis in the UDM.
7. If the RBC count is correct, manually add the .BLDRBC smart-phrase in the white comment box in Beaker and then manually validate both the Chemistry and UF results in the UDM.
   a. **NOTE**: If there are other rules that require a manual microscopic review, follow the workflow below along with the BLD POS and RBC <=5cells/HPF workflow.
8. For all other crosscheck rule flags: Centrifuge specimen and perform a manual microscopic review.
   a. If the microscopic results match what is on the paperwork:
      1) Indicate results ok and initial the paperwork.
      2) Go to the EXPLORER in the UDM and manually validate both the NOVUS and UF results by checking the boxes under the “Validate” icon (top toolbar).
      3) Save paperwork in designated area.
      4) **NOTE**: If other rules requiring a manual review (X’TAL, YLC, SPERM…) are also present, or another result causing them to be held (>=80 ketone, < 1.005 SG, >1.030 SG, abnormal color) the result will not auto-release in Beaker. Flagged elements will need to be resulted when necessary and manually verified.
   b. If the microscopic results DO NOT match what is on the paperwork:
      1) Write the correct results on the paperwork and initial.
      2) Manually result all the microscopic results in Beaker, including any X’TAL, YLC, SPERM , or Path Casts if present.
      3) Go to the EXPLORER in the UDM and manually validate the NOVUS results only by checking the NOVUS box under the “Validate” icon (top toolbar). DO NOT check the UF box if the results have been determined to be incorrect.
      4) Results will auto-release in Beaker

a) **NOTE**: If a Chemistry result is causing them to be held (>=80 ketone, < 1.005 SG, >1.030 SG, abnormal color), the result will need to be manually verified in Beaker

9. Save paperwork in designated area.

13. Results Interpretation

A. Units for Reporting Results

Parameter	Report
Glucose	Negative, 100, 250, 500, >1000
Bilirubin	Negative, Positive
Protein	Negative, 15, 30, 100, 300, >=1000
pH	5.0 – 9.0 (in 0.5 increments)
Blood	Negative, 1+, 2+, 3+, Non Hemolyzed Trace (NHT)
Ketone	Negative, 5, 15, 40, >=80
Urobilinogen	0.2, 1.0, 2.0, 4.0, >=8.0
Nitrite	Negative, Positive
Leukocyte Esterase	Negative, Trace, 1+, 2+, 3+
Specific Gravity	1.000 to 1.045 in .001 increments
Color	Yellow, Dk Yellow, Orange, Red, Green, Other
Clarity	Clear, Cloudy, Turbid

B. Reference Intervals for Random Urine Specimens

Parameter	Reference Range
Glucose	Negative
Bilirubin	Negative
Protein	Negative
pH	5.0-8.0
Blood	Negative
Ketone	Negative
Urobilinogen	0.2-1.0 EU/dL
Nitrite	Negative
Leukocyte Esterase	Negative
Specific Gravity	1.005-1.030

C. Reference Range Urinalysis Microscopic

Parameter	Reference Range
RBC	0-2 cells/hpf
WBC	0-5 cells/hpf
Epithelial Cells	0-5 cells/hpf
Casts	0-2 cells/lpf
Bacteria	Negative

D. UDM General Information

a. Although patient information can be reviewed on each analyzer, overall patient results management should be performed on the UDM.

b. If Chemistry results and UF-5000® results are acceptable and no flags are triggered, the results will automatically upload to the LIS.

c. UF-5000® Reportable and Flagged Parameters

Test Codes	Reportable Parameters	Test Code	Flagged Parameters*
RBC	Red Blood Cells	X'TAL	Crystals
WBC	White Blood Cells	Sperm	Spermatozoa
EPI	Epithelial Cells	YLC	Yeast Like Cells
CAST	Hyaline Casts	MUCUS	Mucus
BACT	Bacteria	PATH CAST	Pathological Cast

d. NOTE: The UF-5000® will automatically perform an additional washing when triggered to eliminate carryover into subsequent samples for the following parameters:
   1) High WBC
   2) High RBC
   3) High Bacteria
   4) SPERM Flag

14. Limitations

A. **CLINITEK Novus®**

1. CLINITEK Novus® Optical System.
   a. There are inherent differences between the colors that are perceived by the human eye and that are detected by any instrumental optical system. The human eye is capable of detecting minute differences in shade and very small areas of color; artificial optical systems are less sensitive to such small changes. Conversely, analyzer optics are capable of detecting certain colors that are masked by or blended with other colors to the human eye. For this reason, exact agreement between visual results and analyzer results might not be obtained. However, agreement is generally within one reported level and is equal to or better than the agreement between two visual readers. Agreement of urine color is generally within one step along the chromatic scale.
2. Interfering substances
   a. For all tests, false positive results (increased values) and/or false negative results (decreased values) can occur when substances that cause abnormal urine color are present, such as:
      1) Visible levels of blood or bilirubin
      2) Drugs containing dyes
      3) Nitrofurantoin
      4) Riboflavin
   b. In cases where color interference is suspected, the following parameters are reported as such:

Parameter	Reported Result
Glucose	Color Interference
Bilirubin	Color Interference
Protein	Color Interference
pH	Color Interference
Blood	Color Interference
Ketone	Color Interference
Urobilinogen	Color Interference
Nitrite	Color Interference
Leukocyte Esterase	Color Interference
Specific Gravity	Report from Refractometer
Color	Visual Assessment
Clarity	Visual Assessment

   c. Limitations given for the reagents include specific substances and conditions that may affect the test results. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single results or method.

d. Protein: false positive results may be obtained with highly buffered or alkaline urine.
e. Blood: Captopril (Capoten) and other compounds containing sulfhydryl groups may reduce the sensitivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.
f. Leukocytes: Elevated glucose concentrations (≥3 g/dL or 160 mmol/L) may cause decreased test results. The presence of cephalexin (Keflex), cephalothin (Keflin), or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. Positive results may occasionally be due to contamination of the specimen by vaginal discharge.
g. Nitrite: A negative result does not rule out significant bacteriuria. False negative results may occur with shortened bladder incubation of the urine, absence of dietary nitrate, or the presence of nonreductive pathological microbes. The presence of color precipitates may cause a false positive result.
h. Glucose: Urine samples with a pH of 9.0 and greater will cause falsely elevated glucose results.
i. Ketone: False trace results may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds that contain sulfhydryl groups, such as mesna (2-mercaptoethane sulfonic acid) and captopril, may cause false positive results or an atypical color reaction.
j. pH: Bacterial growth by certain organisms in a specimen may cause a marked alkaline shift (pH > 8.0), usually because of urea conversion to ammonia.
k. Bilirubin: Indican (indoxyl sulfate) can produce a yellow orange to red color response that may interfere with the interpretation of a negative or positive reading. Metabolites of etodolac (Lodine) may cause false positive or atypical results. Atypical colors may indicate the presence of bile pigment abnormalities, and the urine specimen should be tested further.
l. Urobilinogen: The reagent area may react with interfering substances known to react with Ehrlick's reagent, such as ρ-aminosalicylic acid and fulfonamides. False negative results may be obtained if formalin is present. The test is not a reliable method for the detection of porphobilinogen.

3. Color: Because of the inherent differences between the perception of the human eye and the optical system of the instrument, there may be differences between the color that is perceived visually and that is reported by the instrument, especially when there are low levels of a color present

B. **UF-5000®**

1. Manufacturer's Stated Reportable Ranges

Formed Element	Reportable Range
RBC	2.0 – 10,558/µL
WBC	1.8 – 5,548/µL
Epithelial Cells	1.4 – 201.7/µL
Cast	1.41 – 21.83/µL
Bacteria	4.5 – 9,821/µL

2. Samples with the following conditions may not recover correct results:
   a. High Density samples with pyuria.
   b. Macroscopic hematuria samples.
   c. Samples that include fluorescent matter due to the inclusion of chemicals.
   d. Samples that include preservatives.
   e. Samples consisting of pooled urine.
   f. Samples incorporating bubbles.
   g. Samples that have changed due to long-term storage.
   h. Samples with high turbidity.

i. Samples with a high concentration of mucus strands.

15. Checking Log History on the UDM:

A. **Check the [HISTORY] icon on the [Main Menu]**
1. Click the [HISTORY] icon on the [Main Menu] screen.
2. Select the analyzer.
3. Click the tab of the history to be checked on the bottom of the [History] screen.
   a. Operation detail tab. Displays the history of operations.
   b. Error history tab. Displays the history of errors that have occurred.
   c. Reagent Replacement History. Displays the history of reagent replacement.
4. Maintenance history. Displays the history of performed on board maintenance.

B. **Setting filter conditions for a history**
1. Click the [History] icon on the [Main Menu] screen.
2. Select analyzer in the analyzer selection area.
3. Click the tab of the history to be checked.
4. Click the [Filter] button on the toolbar.
5. In the filter condition selection area, select the checkbox of the condition to be set and click [Select].
6. Set the filter conditions and click [OK]. The dialog box closes.

16. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

17. References

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N. National Committee for Clinical Laboratory Standards (NCCLS). Clinical Laboratory Procedure Manuals – Third Edition (GP2-A3), 1996.
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18. Procedure Development and Approval

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19. Keywords

Not Set