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Sysmex Urinalysis Series – UN9000, UN3000, UN2000 Comprehensive Automated Urinalysis System

Document Type: Procedure

I. 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 on 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

Test Name	Chemical Principle
	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. **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

*Flagged parameters are not directly reportable from the analyzer. Even though the UF5000 can flag for MUCUS, MUCUS is not reported.

H. 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

I. The Urinalysis Data Manager (UDM) is an instrument status and data management software system specifically for Sysmex urine analyzers and imaging devices.

J. The UDM performs analysis order registrations and patient information management.

K. 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.

L. 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.

II. SPECIMEN REQUIREMENTS:

A. Acceptable specimen requirements

1. Uncentrifuged urine without preservative.
2. Sampler mode
    a. Novus requires a minimum of 2.0 ml of urine.
    b. UF-5000 requires a minimum of 2.0 ml of urine.
    c. UD-10 requires a minimum of 1.6 ml of urine
3. Manual/STAT mode
    a. UF-5000 requires a minimum of 0.6 ml of urine.
    b. UD-10 requires a minimum of 0.6 ml of urine.
    NOTE: Novus does not have a manual/STAT mode
4. If analysis is not possible within one to two hours of collection, the urine may be refrigerated. No significant interference from amorphous urates or phosphates has been demonstrated on the UF-5000.

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.

C. Specimen Stability

1. Urine analysis should be performed as soon as possible, preferably within one to two hours of collection or refrigerate immediately at 2-8 C and return to room temperature before testing. MIX THOROUGHLY before testing.
    a. Formed elements may disintegrate at varying rates depending on pH, osmolality, and storage conditions.
    b. Chemical changes can occur if samples are left at room temperature for 2 hours or more.

III. SUPPLIES AND REAGENTS:

A. **Supplies**

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

B. Follow 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 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 35°C, 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 35°C, 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 30°C, out of direct sunlight
UF CONTROL	UF-5000 UD-10	30 days	1. 2 to 8°C, 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:
        i. 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
        i. Hepes: 1.2%
        ii. 1,2-Benzisothiazolin-3-one: <0.01%
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
        i. 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
        i. Polymethine dye: 0.05%
        ii. 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

i. Polymethine dye: 0.02%

ii. 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. Chek-Stix Urinalysis Liquid Quality Control

a. When used with the CLINITEK Novus and CLINITEK Novus 10 Urinalysis Cassette, the Positive and Negative controls provide defined results for: glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes.

b. Control Storage and handling

i. When stored at 2-8ºC, the control is stable until the expiration date of the product labeling.

ii. Once the QC is aliquoted for testing, it is good for 7 days at 20-25ºC.

9. 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.

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.

i. UF CONTROL L - Control Particles: 0.10%

ii. UF CONTROL H - Control Particles 0.40%

D. Reagent Replacement

1. **Replacing DILUENT/SHEATH – UF-5000**

a. If the reagent runs low during analysis or expires, the [ErrorHelp] dialog box will appear and analysis is suspended.

b. 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 time line.
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.
      i. Install the new dye cartridge into the holder, making sure the color matches.
      ii. The analyzer will beep as the information is automatically registered by the Radio Frequency Identification (RFID) chip.
      iii. Close the holder door, then close the top front cover of the analyzer.
      iv. Reagent replacement will begin automatically; when complete the reagent registration dialog box updates.
   f. Touch Close.

CAUTION:
If you install the incorrect reagent, an error occurs and an alarm sounds. Check the error and install the correct reagent.

3. **Replacing UF-CELLSHEATH on the UD-10**
    a. When UF-CELLSHEATH runs out or expires, an error message appears and analysis is suspended. Replace the reagent immediately.
    b. Touch the [Reagent Replacement] icon on the menu screen to display the [Reagent] dialog box. The [Reagent] dialog box allows the user to check the status of reagents and to replace the reagent(s).
    NOTE: The reagent dialog box can also be displayed by touching the indicator for reagent status on the control menu at the bottom of the screen.
    c. Prepare the new reagent according to package instructions.
    d. Display the [Reagent] dialog box.
    e. Enter the reagent code of the new reagent using the barcode reader.
    NOTE: if barcode reader is not available, enter the reagent code manually into the reagent code box. Select [Replace the reagent] box and touch [Register], then follow instructions.
    f. Remove the cap from the new reagent.
    g. Remove the cap from the old reagent turning the lower part of the cap in the direction of the arrow.
    h. Pull out the float switch straight up.
    i. Insert the float switch into the new reagent.
    j. Touch [Replace] in the reagent dialog box. The progress dialog box appears, and reagent replacement starts.

4. **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.

5. **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 towards you to remove.
f. Prepare the new cassette:
    i. Use the foil tab to peel the foil seal off the tray.
    ii. Remove the cassette from the tray.
    iii. Pull the shipping card out of the cassette.
    iv. Do not turn the cassette upside down, as the cards may fall out.
    v. You only have 10 minutes to replace the cartridge.
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.

6. **Fill the rinse bottle – CLINITEK Novus**
    a. The system is configured with an external rinse bottle. It must be checked visually.
    b. Locate the rinse bottle for your specific analyzer.
    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.

7. **Urinalysis Data Manager (UDM) reagent tracking (Available at some sites)**
    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. 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. To print the log, touch [Output] on the tool bar.

IV. 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 is 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 manufacturer's recommendations.

F. **CLINITEK Novus Calibration**
    1. Calibration Frequency
        a. When you load another cassette with the same lot but did not calibrate the system within the last 24 hours. The status bar displays Not Ready.
        b. When you load a new cassette lot. The status bar display Not Ready.
        c. The system displays error messages requiring you to calibrate the system. The status bar displays Not Ready.
        d. When you upgrade the software.
        e. When you replace the pipette, SG sensor, or syringe.
    2. Calibration Preparation
        a. Important: 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. You can 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 of the solutions to equilibrate to room temperature before you use them.

3. Calibration Procedure

a. Press the start/stop switch on the CV-11. The LED status display will illuminate yellow.

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 the calibration information: Date, Time, Reagent Lot #, Cal Lot # and Pass/Fail onto a log or if you have a printer connected to the Novus you can print out the calibration report.

V. QUALITY CONTROL:

A. Quality Control is performed in order to monitor an analyzer’s performance over time. Quality control should be run in accordance to licensing agency regulations. It should be noted that for troubleshooting purposes, additional control runs may be necessary.

B. **QC Frequency**

1. Refer to each lab for their QC frequency for their instruments.

2. Techs will review QC as it is performed to ensure QC is in control prior to running

patients.

3. Supervisor or designate will review quality control weekly and monthly.
4. The Lab Director or designate will review the quality control monthly.

C. **Preparation of QC files – CLINITEK Novus**

1. Select [System > Control].
2. Select the [Change] button that corresponds with the control you wish to change or add.
3. Select [Add].
4. Enter the control lot #, select [Enter].
5. Enter the control lot expiration date, select [Enter].
6. Repeat for additional control.

NOTE: Before processing QC samples on the Novus, controls must first be programmed on the UDM in order for the results to be received. See procedure *"QC new lot registration on the UDM"* in this section

D. **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. Depress 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
4. **CAUTION!** Do not place the tubes with control solutions in incorrect rack positions. If you do, the system processes those samples anyway and the control results will be incorrect.
5. Select [System > Control]. Verify control lots are correct.
    a. To change or add lots, follow instructions for Preparation of QC Files in this document.
6. Select [Next]. The rack moves into position for testing and the system tests each control once.
7. After the system moves the rack to the left side of the analyzer, remove the rack.

E. **Preparation of QC files – UF-5000**

1. Before analyzing controls, verify UF-5000 QC settings, and input the lot numbers and expiration dates in the QC files to be used.
2. From the Main Menu, touch [Settings].
3. Touch [QC].
4. Touch [QC METHOD] and select the radio button for L-J. Touch [Register].
5. Touch [Limit], and select the radio button for Value (#). Touch [Register].
6. Return to Main Menu. Touch [Menu] and select [QC].
7. Select either UF CONTROL L or UF CONTROL H tabs for the desired QC.

8. Select [Register] from the top tool bar.
    a. If there are 3 lots already scheduled, a prompt will appear to delete the least current lot before you can proceed.
9. QC Lot information may be entered by one of the following methods.
    a. Hand held Barcode Reader
        i. With the handheld barcode reader, scan the QC barcode for each parameter on the UF CONTROL assay sheet.
        ii. When the barcode has been successfully read, the handheld barcode reader will beep.
        iii. When complete touch [Register].
        iv. Note: If the [Register] icon is not available, one or more of the parameters failed to scan. Review the parameters and scan again.
        v. Expiration date will default to open vial stability (30 days) or Lot expiration, whichever is earlier.
    b. Manual Entry
        i. Access the touch screen keyboard by touching the Lot Number, which has a prefix of [QC-].
        ii. Manually enter the lot# and expiration date of control type.
        iii. Touch each parameter by using the on screen keyboard and manually enter each target/limit provided on the control/assay sheet.
        iv. Touch [Register] when all items are registered.

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

F. **Analysis of Quality Control Material – UF-5000**

1. Allow control material to come to room temperature (15-30^{O}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 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 adapter.
6. Within 10 seconds after dispensing, touch [Analysis] > [Yes].
7. Touch UF CONTROL L or UF CONTROL H and touch [Next].
    a. If open bottle stability of the bottle has expired, touch [CHANGE BOTTLE] to switch the control to a new bottle.

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. A pop-up box appears. Touch [ERR Recovery] to acknowledge error and exit.
10. Touch [Exit] to accept control if acceptable. Touch [Repeat] to discard results and reanalyze using a freshly prepared sample.
11. Press the STAT button on the analyzer to retrieve the sample cup.
12. To continue QC analysis, return to step 6.
13. Exit the QC analysis program by touching [Close].

G. **Preparation for QC Files for the UD-10**

1. New control lot registration can be uploaded by reading the barcodes on the assay sheet with the barcode reader.
2. Touch the [QC] icon on the [Menu] screen.
3. Touch the tab of the control that you want to enter lot information.
4. Touch the [Register] button on the tool bar. The [Register lot Information] dialog box appears.
    a. Note: When 3 lots are already registered for the controls a dialog box appears with the existing lots on board. Select the lot number that you want to be replaced by the new lot.
5. With the barcode reader in hand, scan the barcode on the assay sheet provided with the new control. The barcode reader will beep when the barcode is successfully read.
6. Enter the package expiration date. Opened expiration date will be automatically recorded.

H. Touch [Register].

NOTE: WBC on the UF-CONTROL assay sheet is equivalent to Class 2 on the instrument.

NOTE: *When connected to the UDM, newly created QC files and results for the UD-10 will automatically transfer to the UDM.*

I. **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 bottle until there is no particle sediment remaining at the bottom.
    b. Invert vigorously an additional 20 times.
7. Immediately dispense (18-20) 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 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. Press [Exit] to accept or [Repeat] to reanalyze.
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 5 to run additional QC.
15. Check the analysis results.
16. Touch [Close].

J. **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.
    a. For UF-5000 and UD-10, highlight the first QC run plotted and touch [vial line] on the top tool bar. This will alert the user that the QC material has expired the 30 day open expiration date.

8. Enter the upper and lower target values from the package insert.
9. For Novus analyzers ONLY.
    a. 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.
    b. 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.
10. Select [OK] to save the entry.

K. Repeat the process with subsequent controls.

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.

L. Recording/Storage of Quality Control Data

1. **Siemens CLINITEK Novus**
    a. At the home screen, click on [Results].
    b. Select [Control].
    c. After the search criteria is 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 your control is out of range and you are going to rerun your QC. Always choose the option to rerun the whole control and not just the parameter that was out of range.

2. **UF-5000 and UD-10 Quality Control Results Review Management**
    a. Radar Charts
        i. From the QC Chart Screen on the desired analyzer, select control

level and lot#.

ii. Touch [Radar] from the top tool bar.

iii. NOTE: the Radar view shows only the last accepted QC run for the control and lot# selected.

iv. 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 back lit in red.

v. Return back to the QC Chart (L-J Chart) by touching [QC Chart] on the top tool bar.

b. L-J Charts

i. Touch the [QC] icon on the Menu screen on the desired analyzer to display the QC Chart screen (L-J Charts).

ii. 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

i. Touch the [QC] icon on the MENU screen.

ii. Select the control type and lot# desired.

iii. Touch the plotted point that will be the starting point of the selection range.

iv. 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. Delete analysis results

i. Touch the [QC] icon on the MENU screen.

ii. Select control type and lot# desired.

iii. Move cursor to desired analysis results, or select a range or results.

iv. To delete, touch [DELETE] on the top tool bar.

v. Touch [Yes].

e. Managing QC results using Cursor Data Settings

i. Touch [QC] icon on the MENU screen.

ii. Select control type and lot# desired.

iii. Touch [Chart Control] and touch [Cursor Data Management]. The

Cursor Data Management dialog box appears.

iv. Select [Manage] to include results into the QC statistical values.

v. Select [Not Manage] to exclude results from the QC statistical values.

vi. 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

i. Click the [QC] icon on the Main Menu Screen.

ii. Select the analyzer from the drop down box in the analyzer selection area.

iii. Select the QC file you want to check.

iv. To view charts, click on the Display selection button to the right of the files.

v. The radar chart displays the latest QC analysis result of the QC files selected from the file list.

vi. 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.

b. QC (L-J) Charts

i. NOTE: Each Quality Control file menu holds 50 files. Each file can display 300 plotted points.

ii. Click the [QC] icon on the Main Menu Screen.

iii. Select the analyzer from the drop down box in the analyzer selection area.

iv. Select the QC file you want to review.

v. The cursor line will be on the most recent QC analysis. The date and time stamp will be attached on 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.

a. Plotted points are displayed as follows:

i.  - (Solid circle) – QC analysis within range.

ii. X – QC analysis outside the limit range.

iii. O – (Open circle) – results are NOT managed.

vi. 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 [-].

a. Mean displays the average value calculated from all managed QC analysis results.
b. SD displays the standard deviation calculated from all managed QC analysis results when more than point is ranged.
c. CV displays the coefficient of variation calculated from all managed QC analysis when more than one point is ranged.

c. Selecting a range of analysis
    i. While in the QC chart of the selected analyzer, click the plotted point that will be the start point for the range selection area.
    ii. Click the [Range] button on the tool bar.
    iii. Click the end point of the range you want to select on the QC chart. The results between the two reference lines are selected.
    iv. To cancel range selection, click [Range].

d. Deleting analysis results
    i. In the QC Chart screen, select the analysis result, or range of analysis results that you wish to delete.
    ii. Click the [Delete] button on the tool bar.
    iii. Click [OK].

e. Output results
    i. In the QC Chart screen, select the analysis results, or range of analysis results that you wish to delete.
    ii. Select the output button on the tool bar, and click the output destination.
        a. Graphic printing to print L-J charts.
        b. List Printing to print QC in list format.

f. Saving and restoring QC file data in CSV format
    i. In the QC file menu, click the QC file you want to save.
    ii. Select the [Output] button on the tool bar and click [CSV output].
    iii. Specify or create a folder.
    iv. Enter a file name and click [Save]. The file extension is ".csv".
    v. To restore a file, select a QC file that does not have a lot registered.
    vi. Select the [File] button on the tool bar, and click [Restore].
    vii. Search for the QC folder that file was stored in and select the QC file.
    viii. Click [Open].
    ix. NOTE: you cannot restore a QC file that has the same lot number

currently on board.

VI. 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. In the case of a grossly bloody specimen, refer to *Urinalysis Protocol for Analyzing Bloody Specimens.*
3. Mix each sample thoroughly.
4. Do not test samples that are visibly bloody, mucoid, or foamy.
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.
    a. Novus minimum sample requirements - 2.0 mL.
    b. UF-5000 minimum sample requirements – 2.0 mL.
    c. UD-10 minimum sample requirements – 1.6 mL.
7. Place tubes(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 of the first analyzer on the automation line.
    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.
        i. Press the alarm reset switch.
        ii. Reposition the rack.
        iii. Press the play button. Rack will advance.
9. Rack movement behavior.
    a. If there is more than one identical analyzer on the line, the system will load balance the racks and distribute to analyzers equally.
        i. The first rack will proceed to the [identical] analyzer on the right; the second rack will proceed to the [identical] analyzer on the left.
        ii. When analysis is complete and analyzers go into standby, the next rack loaded will always move to the [identical] right analyzer.
    b. The racks will then move onto the second type of analyzer (reflex analyzer) and will load balance in the same fashion.
        i. All tubes will be presented to the reflex analyzer(s).
        ii. The barcode will be read and analyzer will query for an order.
            a. If no order, no aspiration and the rack proceeds to next sample.
            b. If there is an LIS or reflex order from the UDM, the sample will be analyzed.

i. The reflex will occur:

i. Samples that have an abnormal result (trace or greater) for Glucose, Bilirubin, Ketone, Blood, Protein, Nitrite or Leukocyte Esterase

ii. Samples with a clarity of anything other than clear.

iii. Samples with the color of anything other than Yellow or Dark Yellow.

iv. When the microscopic is specifically ordered.

c. 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.

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

B. **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 tool bar, 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 adapter No.368.
    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.

> Caution: 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. If "Start STAT analysis of urine sample" was selected during the sample programming, the sample will eject automatically.
    b. Repeat steps 1-9 and repeat analysis.
10. Once sample analysis is complete, remove the sample. CV-11 will return to ready.

VII. 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:
    1. Click the [Order Entry] icon on the Main Menu Screen.
    2. Scan or type in your specimen ID# and a second identifier (Name and Birthdate)
    3. Click [Test Selection].
    4. Select the [Chemistry], instrument will reflex to the UF-5000 if needed and, (for those with a UD-10 Manual will reflex if the UF results are abnormal)
    5. Click [OK] > [Save] > [OK].
    6. Run sample as usual.

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

C. 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.

D. Checking Analysis results – Explorer

1. From the Main Menu, click [Explorer] icon.
2. Search for patient using search conditions described previously or scan Explorer screen. View Status Symbols to indicate analysis status.

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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.

3. Review Explorer screen for analysis results and patient info.
    a. Rerun or cancel rerun on a sample.
        i. Select the analysis for which to rerun or cancel rerun.
        ii. 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.
        iii. Click [OK].
    b. Validate a sample (Needed for sites without the UD-10 that fail cross-check rules or if you are running the sample on your standalone analyzer).

i. Select the analysis for which to validate.

ii. 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].

iii. Click [OK].

c. Outputting analysis results

i. Select the analysis for which to output.

ii. Select the [In/Output] button on the tool bar.

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.

E. 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 tool bar.

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.

VIII. 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 you want to review.
3. Click the [UD Manual] button on the tool bar to view the Overview screen.

a. Overview Tabs

i. Total display – Displays various comments on the analysis results for UF5000 analysis results and scattergrams.

ii. Image – Displays the image captured on the digital imaging device.

iii. Order Information – Displays patient and order information.

b. Head Particle Image tab

i. Displays the particle image of each class.

ii. Click each class to magnify the images.

iii. Click the right arrow to move to the next image and the left arrow for the previous image.

iv. Double click an image to enlarge.

c. Patient information area

i. 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 whose particle image you want to view and classify.
4. Click the [UD Manual] button on the tool bar to review the Overview screen.
5. In the particle information area, select the class in which you want to view and classify the particle.
6. In the classification results list, double click the analysis parameter in which you want to enter a result.
7. Click [PRESENT].
8. Once you have selected all the parameters that you see in the images, double click [REVIEW]
    a. Select [REVIEWED] if you want to send the results out to the LIS
    b. Select [NEEDS MANUAL] if you want to perform a manual microscopic on the urinalysis.
9. Click the [Close] button on the tool bar, then touch [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].

IX. WORK FLOW FOR FAILURE OF CROSSCHECK RULES

A. A Crosscheck rule is any of the following messages generated from the UF.

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

B. For sites with the UD-10, to verify these rules you would need to choose "Needs Manual" and send the results to Beaker. They will hold in Beaker until a manual microscopic is completed.

C. For sites without a UD-10, results will automatically print for any specimen requiring a manual microscopic review. The rule flag messages will be on the printout and can also be viewed in the COMMENT tab in the UDM explorer:
    1. Check the sample ID in EXPLORER.
    2. Chemistry and UF results will have a green check mark. Results are not sent to Beaker..
    3. Centrifuge the urine.
    4. Perform the microscopic exam and confirm the results based on the cross check rule and record the microscopic results in Beaker.
    5. Go back to the UDM, select your patient, double click to open.
    6. Select 'Validate' from the top tool bar.
    7. Choose CHEMISTRY and then OK.
    8. IF YOU VALIDATE BEFORE PERFORMING THE MANUAL MICROSCOPY YOUR RESULTS WILL AUTOVALIDATE AND YOU WILL HAVE TO CORRECT YOUR REPORT!

D. For all sites 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.
    1. "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."

X. CHECKING LOG HISTORY ON THE UDM:

A. You can check the logs of the connected Novus chemistry analyzer, urine quantitative analyzer or digital imaging device.

B. **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 you want to check 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.
    d. Maintenance history. Displays the history of performed on board maintenance.

C. **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 you want to check.
4. Click the [Filter] button on the toolbar.
5. In the filter condition selection area, select the checkbox of the condition that you want to set and click [Select].
6. Set the filter conditions and click [OK]. The dialog box closes.

XI. RESULTS/INTERPRETATION:

A. Units for Reporting Results

Test	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+, NHT*
Ketone	*Negative, 5, 15, 40, >=80*
Urobilinogen	*0.2, 1.0, 2.0, 4.0, >=8.0*
Nitrite	*Negative, Positive*
Leukocyte	*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

Test	Report
Glucose	Negative
Bilirubin	Negative
Protein	Negative
pH	5.0 - 8.0
Occult Blood	Negative
Ketone	Negative
Urobilinogen	*0.2 – 1.0 EU/dl*
Nitrite	Negative
Leukocytes	Negative
Specific Gravity	1.003 - 1.030

C. Reference Range Urinalysis

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

1. Although patient information can be reviewed on each analyzer, overall patient results management should be performed on the UDM.
2. If Chemistry results and UF-5000 results are acceptable and no flags are triggered, the results will automatically upload to the LIS.
    a. UF-5000 Reportable and Flagged Parameters

Test Codes	Reportable Parameters
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

XII. LIMITATIONS OF PROCEDURE:

A. CLINITEK Novus

1. CLINITEK Novus Optical System.
2. 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.

3. 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:
        i. Visible levels of blood or bilirubin
        ii. Drugs containing dyes
        iii. Nitrofurantoin
        iv. Riboflavin
    b. 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.
    c. Substances that cause abnormal urine color may affect the readability of reagent areas on urinalysis reagent strips. These substances include visible levels of blood or bilirubin, drugs containing dyes (for example, Pyridium, Azo Gantrisin, Azo Gantanol), Nitrofurantoin (Macrodantin, Furadantin), and riboflavin.
    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 associate 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 results 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 Ehrlich's reagent, such as ρ-aminosalicylic acid and sulfonamides. False negative results may be obtained if formalin is present. The test is not a reliable method for the detection of porphobilinogen.

m. 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/ul
WBC	1.8 – 5,548/ul
Epithelial Cell	1.4 – 201.7/ul
CAST	1.41 – 21.83/ul
BACT (Bacteria)	4.5 – 9,821/ul

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.

3. There are no reportable ranges for the UD-10
    a. Samples with the follow conditions may not recover correct results.
        i. Samples that have changed due to long-term storage.

ii. Samples that have high turbidity.
iii. High density samples with pyuria.
iv. Samples consisting of pooled urine.
v. Macroscopic hematuria samples.
vi. Samples with a high concentration of mucus strands.
vii. Samples incorporating bubbles.

XIII. REFERENCES:

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Attachments

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Approval Signatures

Step Description	Approver	Date

Jennifer Yaker: Mgr, Laboratory	Pending
Michelle Alexander: Medical Technologist Lead	10/29/2024
Kristen DiCicco: Mgr, Laboratory	10/28/2024
Katherine Persinger: Mgr, Laboratory	10/23/2024
Ashley Beesley: Mgr, Laboratory	10/17/2024
Sharon Cole: Mgr, Laboratory	10/15/2024
Kristin Russell: Mgr, Laboratory	10/15/2024
Leah Korodan: Mgr, Division Laboratory	10/15/2024
Kelly Walewski: Supv, Laboratory	10/15/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne