PROCEDURE
Corewell Health East - Sysmex UN Series (UN-9000, UN-3000, UN-2000) Maintenance

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 Corewell Health Grosse Pointe Hospital, Grosse Pointe only. Within Corewell Health Farmington Hills Hospital, Farmington Hills only.
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Functional Area:	Clinical Operations, Laboratory
Lab Department Area:	Lab - Urinalysis

1. Purpose and Objective
A. This procedure is to assist laboratory personnel in performing maintenance tasks on the Sysmex UN Series Automated Urinalysis Analyzers.

2. Responsibility
Personnel who have completed the competency requirements will perform these tasks.

3. Definitions/Abbreviations
A. Red Blood Cell (RBC)
B. White Blood Cell (WBC)
C. Epithelial Cells (EC)
D. Urinalysis Data Manager (UDM)
E. Deionized (DI)
F. TTW (Taylor, Trenton and Wayne)

4. Reagent/Equipment Needed
A. 5-5.25% Bleach
B. CELLCLEAN™
   1. Shelf stable until expiration date. Stable for 60 days once opened.
   2. Store 1-30°C, out of direct sunlight.
C. UF - CELLSHEATH™
   1. Shelf stable until expiration date. Stable for 60 days once opened.
   2. 2-35°C out of direct sunlight.
   3. Do not freeze.
   4. Avoid creating bubbles.

5. **NOTE**: CELLSHEATH that shows signs of contamination such as turbidity or discoloration should not be used.

D. DI water
E. 70% Isopropyl Alcohol
F. CLINITEK Novus Rinse Additive™
   1. Shelf stable until expiration date.
   2. Stable for 2 weeks after dilution with distilled or deionized water.
   3. Store at room temperature.
   4. Do not freeze.

5. Equipment

A. Clinitek Novus
B. UF-5000
C. UD-10 (TTW excluded)
D. CV-11

6. Supplies

A. Disposable pipettes
B. Sample cups
C. Beaker, Sterile Container, other suitable vessels to hold hot water

7. CV-11

A. Daily:
   1. Clean the Rack Handler using isopropyl alcohol or germicidal wipes.
      a. Perform during shutdown of UF-5000 and UD-10 (If applicable).
      b. Perform on Novus after placing in offline mode and prior to running daily maintenance tasks.

B. Weekly: Clean Rack Pushers using isopropyl alcohol or germicidal wipes.

8. Clinitek Novus

A. Daily:
   1. Clean the SG Well
      a. Place the CV-11 in offline analysis mode.
         1) If utilizing the CV-11, press the mode button to change the indicator light from green to orange.
      b. Perform SG well cleaning on CLINITEK Novus
         1) Select [System] from the Home screen.
         2) Select [Clean SG Well].
         3) Place a tube of 5.0% - 5.25% bleach in rack position 1.
         4) Place the rack on the rack handler.
         5) Select [Start] and the screen will count down from 3:13 to zero.
         6) When the cleaning cycle is completed, the software returns to the System menu.
         7) Select the [Home] button to return to the Home screen.
         8) The SG Well error will no longer display in the Status Log and the system will be ready to process quality control and patient samples.
         9) Remove the rack stored in the left pool.
      c. Place the CV-11 in online analysis mode
         1) If utilizing the CV-11, press the mode button to change the indicator light from orange to green.

B. Weekly:
   1. SG well cleaning
      a. Powering off the CLINITEK Novus
         1) On the Home screen, select the Off button.
         2) Select Yes. The system shuts down the software and powers off the system.

3) At the back of the system, press the power switch to the off position. The system is completely powered off.

b. Clean the SG well with hot water flush
   1) Open the System door.
   2) Fill a beaker, sterile container, or other suitable vessel with hot tap water (90° to 110°F / 32° to 43°C).
   3) Use a pipette to manually dispense the hot water into the SG well. Do not remove the SG/Clarity sensor from the instrument.
   4) Place tip of the pipette over the sensor well. Do not touch the SG sensor with the pipette.
   5) Dispense three full pipettes of hot water into the SG well.
   6) Close the system door.

c. Powering on the CLINITEK Novus
   1) At the back, lower left side of the system, press the power switch to the on position.
   2) On the right side of the system, press the On button.
   3) The system performs a self-test while the screen is blank for approximately 45 seconds.
   4) The system loads the software while displaying the product name, software version, and copyright information.
   5) The Home screen displays.
   6) The Status bar displays the Ready mode indicator.
   7) The Status bar might display the Not Ready mode indicator. Warning messages might display in the Status log. For example, the cassette is not present, the cassette has a low quantity of tests remaining, or the onboard stability of the cassette expired. Also, you might be prompted to calibrate the system.
   8) Run the Clean SG Well, following the instructions on touchscreen user interface under Cleaning the SG Well.
   9) Calibrate the system.
   10) If calibration is not successful, repeat steps 1-7 two more times.
      a) **NOTE**: If powering the system on after a power loss greater than 10 minutes, the onboard stability of the cassette may be jeopardized. Recovery of the analyzer will take approximately 1 hour to complete.

C. Monthly
   1. SG Well Cleaning
      a. Removing the old SG sensor (See site specific workflow)
         1) Remove the racks from the rack handler.
         2) Select System > Diagnostics > Replace or Adjust > Replace SG Sensor.
         3) The SG Sensor Replacement Assistant displays the first of 9 screens of instructions and select Replace.
         4) Open the cover and locate the SG well behind the right corner of the card platform, and then select Next.

5) Remove the SG sensor by holding down the sensor well lever and pulling the SG sensor out, and then select Next.
6) Unhook the SG sensor cables from the clips on the wall of the system, and then select Next.
7) Locate the 5 color-coded SG sensor connectors to the left and above the card platform.
8) Remove the connectors, starting at one end and working to the opposite end:
   a) Push the connector down.
   b) Turn the collar counterclockwise ¼-turn.
   c) Lift the connector.
9) After you remove all of the connectors, select Next.

b. Step 2: Flushing the sensor
   1) Rinse or submerge the SG/Clarity sensor under warm 32 to 38°C (90 to 100°F) tap water for 3 to 5 minutes. This will flush any debris out of the sensor. Hold the sensor so that the main stream of the water from the faucet is flowing into the sensor, as shown in picture below.

   2) Dry the sensor with a paper towel, making sure that the connector ends are free of water.

c. Re-installing the sensor. (See site specific workflow)
   1) Install the SG sensor by sliding the SG sensor (facing up) into the sensor well, until you hear a click.
   2) Select Next.
   3) Hook the SG sensor cables by holding the sensor connectors in one hand, while hooking each sensor cable to the clips, and then select Next.
   4) Attach the connectors, starting at one end and working to the opposite end:
      a) Holding the connector collar, align the tab to the slot in its matching color socket.
      b) Push the collar down and turn it clockwise ¼-turn.
      c) To ensure the connector is locked, gently try to lift the connector.
   5) Select Done and close the cover.
   6) After complete hydration, calibrate the system.

D. As Needed:
   1. 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 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 (See below).
   2. Prime the pump

a. This primes the syringe pump with a rinse solution and should be performed:
   1) When refilling the rinse bottle.
   2) If air bubbles appear in the rinse solution line.
   3) If the analyzer has been powered off for greater than 1 hour.
   4) When an error message indicates that pump should be primed.
b. Select [System] from the home screen.
c. Select [prime pump].
   1) Prime the pump 1-5 times to ensure there is consistent flow of rinse solution and no air bubbles in the lines.

3. Empty the Card Waste Drawer:
   a. The system detects when the card waste drawer is full or empty.
      1) Remove the racks from the rack handler.
      2) To release the latch, press the latch and pull the card waste drawer back out of the analyzer. Slide the drawer all the way out of the slot.
      3) Dispose the used test cards according to laboratory and biohazard guidelines.
      4) Remove the internal liner.
      5) Press the ridges of the liner on the bottom of the drawer.
      6) Lift up the liner and slide it out of the drawer.
      7) Clean the liner with 70% isopropyl alcohol.
      8) Replace the internal liner into the card waster drawer.
      9) Slide the drawer into the slit until the drawer is fully closed and latched.
4. For the following Periodic Maintenance Tasks, refer to the CLINITEK Novus Automated Urine Chemistry Analyzer Operator's Guide.
   a. Cleaning the card platform.
   b. Cleaning the moisture gate.
   c. Cleaning the card grippers.
   d. Cleaning the pad sensor.

E. Start up and Emergency Shutdown:
1. Start up:
   a. Make sure the main power switch located at the back of the analyzer is in the "ON" position. Press the power button located on the right side of the analyzer and allow the system to perform its self-test.
      1) **NOTE**: The Novus SG well continually needs to be hydrated. If the system has been powered off for more than 1 hour, prime the pump. Leave the system powered on for at least 1 hour to rehydrate the SG well before resuming operations.
   b. If the System displays "Not Ready", review the messages in the status Log. Complete the necessary troubleshooting to bring the system to "Ready" Status.
   c. Check the status of the reagent cards. If necessary, load a new reagent cassette.
   d. Check the external supply of rinse.
   e. Press the CV-11 power switch.
   f. The conveyor will turn on. The green status light will illuminate when ready.
2. Emergency Shutdown:
   a. In case of an emergency, the power to the analyzer can be disrupted by switching the main power switch located at the back of the analyzer.

9. UF-5000

A. Daily
1. Shutdown:
   a. Make sure the UF-5000 is in the green "Sampler Ready state".
   b. On the Main Menu screen, touch the [Shutdown] icon.
   c. When the "Shutdown" dialog box appears, touch [YES].
   d. Another "shutting down" dialog box will appear stating "Shutting down the system…Please wait".
   e. Once Shutdown completes, the analyzer automatically turns off.

f. Power off the CV-11 sampler using the main power switch on the front of the sampler. Hold the main power switch on the front of the CV-11 until a beep is heard and the indicator light has turned off.

2. Start up:
   a. Check physical status of the analyzer and CV-11.
   b. Clear racks that may be present on the left or right pool areas.
   c. Check if there is sufficient rinse water.
   d. Press the CV-11 power switch-this turns on the conveyor and UF-5000.
   e. The CV-11 will turn on. The green status light will illuminate when ready.
      1) **NOTE**: If an error occurs during start-up, the operator must log onto the instrument using the keyboard to resolve the error.
   f. The UF-5000 will begin start-up and perform a self-check.
   g. When the logon dialog box appears:
      1) User: See site specific login
      2) Password: See site specific password
      3) Touch [OK]
   h. Verify background check
      1) **NOTE**: Analysis is performed for background check without sample aspiration to check the effectiveness of rinsing. This is repeated up to 3 times. If background check fails after 3 analyses, a background check error occurs.
         a) **If a background check error occurs, perform cleaning procedure according to the UF-5000 Troubleshooting manual.**
   i. All parameter values outside of acceptable ranges are displayed with a red background on the UF-5000.

Acceptable Background Check Values for UF-5000	
Parameter	Acceptable Limit
RBC	1.0 [/µL] or less
WBC	1.0 [/µL] or less
EC	1.0 [/µL] or less
Cast	1.0 [/µL] or less
Path Cast	1.0 [/µL] or less
Bacteria	5.0 [/µL] or less
X'Tal	1.0 [/µL] or less
YLC	1.0 [/µL] or less
Sperm	1.0 [/µL] or less
Mucus	1.0 [/µL] or less
SF_TC	3,000 counts or less
CW_TC	300 counts or less
CB_TC	3,000 counts or less

3. Checking for fluid in the trap chamber
   a. Open the upper and lower front covers of the analyzer by lifting the upper cover and pushing the buttons to release the lower cover.
   b. Check to see if any fluid has accumulated in the Trap Chamber.
   c. If there is no fluid in the trap chamber, close the covers.
   d. If there is fluid in the trap chamber, follow the procedure below:
      1) Shut down the analyzer.
      2) Turn the trap chamber clockwise to remove it and dispose of the fluid collected in the chamber.
      3) Reinstall the O-ring and the float, pointed side up.
      4) Install the trap chamber by turning it counterclockwise.
      5) Close the upper and lower front covers.
      6) Start-up the UF-5000.

7) **NOTE**: Reference the UF-5000 troubleshooting guide for additional troubleshooting guidance.
8) **NOTE**: If fluid continues to accumulate in the trap chamber, contact Sysmex Technical Assistance Center for assistance.

B. Weekly:
1. Cleaning the Rinse Water container
   a. Remove the cap from the rinse water container and pull the dispensing set straight up.
   b. Discard the rinse water in the container.
   c. Use tap water to wash the inside of the container and then rinse with DI water.
   d. Fill the container with DI water then place the dispensing set and cap back in place.

C. As Needed:
1. Replenish the Rinse Water
   a. Discard any remaining DI water from the bottle and fill with fresh DI water.
2. Cleaning:
   a. **NOTE**: Cleaning is automatically performed when shutdown is executed. Additional cleaning can be performed without repeating the full daily shutdown procedure.
   b. Make sure the instrument is in the ready state for sampler analysis or STAT analysis.
   c. Touch the [Rinse] icon on the [Maintenance Menu] screen.
   d. Touch [Yes]
3. Rinsing the Flow Cell:
   a. Make sure the instrument is in the ready state for sampler analysis or STAT analysis.
   b. Touch the [Rinse Flow cell] icon on the [Maintenance Menu] screen.
   c. Dispense CELLCLEAN into a sample tube or sample cup.
      1) **NOTE**: When using the sample cup, set the sample cup in adapter.
   d. Set the sample tube or sample cup into the STAT sample holder.
   e. Push in the STAT sample tube holder.
   f. Touch [Execute].
   g. The process takes approximately 8 minutes. When finished, the dialog box closes
4. Rinsing/replacing the sample filter (See UF-5000 Troubleshooting Manual):
   a. If the sample filter is clogged or dirty, the specified amount of sample cannot be aspirated, and an error occurs. When an error occurs, rinse or replace the sample filter.
      1) **NOTE**: Be sure to shut down the analyzer before rinsing or replacing the sample filter.
   b. Make sure the instrument is in the ready state for sampler analysis or STAT analysis.
   c. Touch the [Maintenance] icon on the MENU screen.
   d. Touch the [Sample filter] icon.
   e. Touch [Execute].
   f. Wait 1 minute to allow the pressure to fall inside the instruments.
   g. Open the front upper cover.
   h. Remove the front lower cover.
   i. Remove the sample filter case from the holder. Have a dry cloth ready in case fluid leaks from the tube when removing the filter.
   j. Remove the tube adapters from the top and bottom of the sample filter by turning the top adapter counterclockwise and the bottom adapter clockwise.
   k. Remove the cap from the sample filter being careful not to drop the filter inside the case
   l. Remove the filter from the sample filter case and rinse it with DI water.
   m. Carefully dry the filter and inspect for clogging inside the hole. If filter is still clogged – repeat the rinsing. If clog cannot be removed, replace the filter.
   n. Set the rinsed or new filter in the sample filter case, and attach the cap.
   o. Install the tube adapters onto the top and bottom of the filter.
   p. Install the sample filter case into the holder.
   q. Attach the analyzer covers.
   r. Turn on the analyzer.
   s. Perform QC analysis and check the following points.

1) A short sample error does not occur.
2) There is no fluid leakage from the filter.
3) There is no abnormality with the QC analysis.

t. If any of the above errors occur, reassemble the sample filter.

D. Emergency Shutdown:

1. In case of an emergency, the power will be disrupted to the analyzer by pressing the main power switch located at the back of the analyzer.

10. UD-10 (TTW Excluded)

A. Daily

1. Shutdown
   a. Make sure the UD-10 is in the “Ready State”.
   b. Touch the [Menu] button on the toolbar, then touch [Shutdown] button.
   c. Dispense 2 ml of CELLCLEAN™ into a sample cup.
   d. Set the sample cup in the black adapter.
   e. Press the release button on the sampler section. The STAT sample tube holder slides out.
   f. Set the CELLCLEAN cup and adapter into the STAT sample holder.
   g. Push in the STAT sample holder, then touch [Execute] in the Shutdown dialog box.
   h. Shutdown takes approximately 10 minutes.
   i. Press the [stat] release button on the sampler section. The STAT sample tube holder slides out.
   j. Remove the CELLCLEAN from the STAT sample holder.
   k. Press the CV-11 start-up switch for 2 seconds. The status indicator LED goes out, and the power of the sampler section turns OFF.
2. Checking for fluid in the trap chamber on the UD-10
   a. Open the top front cover of the UD-10.
   b. Check to see if any fluid has accumulated in the trap chamber.
   c. If there is no fluid in the trap chamber, close the cover.
   d. If there is fluid in the trap chamber, follow the procedure below:
      1) Shutdown the analyzer.
      2) Turn the trap chamber clockwise to remove it.
      3) Reinstall the O-ring and the float, pointed side up.
      4) Install the trap chamber by turning it counterclockwise.
      5) Close the upper and lower front covers.
      6) Start up the UD-10.
   e. **NOTE**: If fluid continues to accumulate in the trap chamber, contact Sysmex Technical Assistance Center for assistance.
3. Start up:
   a. Check physical status of the analyzer and conveyor unit.
   b. Turn on the computer to the IPU.
   c. Logon to the IPU.
   d. When the logon dialog box appears:
      1) User: See site specific login
      2) Password: See site specific password
      3) Touch [OK]
   e. The UD-10 will begin start-up and perform a self-check.

UD-10 Acceptable Background Checks	
Parameter	Acceptable Limit
Class 1	80 or less
Class 2	15 or less
Class 3	15 or less
Class 4	10 or less

Class 5	5.0 or less
Class 6	5.0 or less
Class 7	5.0 or less
Class 8	5.0 or less

f. Press the CV-11 power switch. The conveyor turns on. The green status light on the conveyor will illuminate.

B. Weekly
1. Clean the Rinse Water container
a. Remove the cap from the rinse water container and pull the dispensing set straight up.
b. Discard the rinse water in the container.
c. Use tap water to wash the inside of the container and then rinse with DI water.
d. Fill the container with DI water then place the dispensing set and cap back in place.

C. As Needed:
1. Performing cleaning:
a. Cleaning consists primarily of rinsing the analysis line and pipette.
b. Make sure the instrument is in the ready state for sampler analysis or STAT analysis.
c. Touch the [Rinse] icon on the [Maintenance Menu] screen.
d. Touch [YES].
2. Cleaning the imaging cell:
a. Make sure the instrument is in the ready state for sampler analysis or STAT analysis.
b. Touch the [Cell Rinsing] icon on the [Maintenance Menu] screen.
c. Dispense CELLCLEAN into a sample cup.
d. Set the sample cup in the adapter.
e. Place the CELLCLEAN in the STAT sample holder.
f. Push in the STAT sample tube holder until it locks.
g. Touch [Execute].
1) Rinsing starts.
2) The progress dialog box appears.
3) Once CELLCLEAN is complete, the STAT sampler tube holder lock is automatically released.
h. Press the release button on the sampler section.
i. Imaging cell clearing takes about 10 minutes. Once complete, the [Background Check] dialog box appears, and a background check starts.
j. Check the results of the Background count.
3. Replenish the rinse water
a. Discard any remaining DI water from the bottle and fill with fresh DI water.

D. Emergency Shutdown:
1. In case of an emergency, the power will be disrupted to the analyzer by pressing the main power switch located at the back of the analyzer.

11. Urinalysis Data Manager (UDM)

A. Turn off the UDM – Daily:
1. From the main screen touch [exit]. A dialog box appears.
2. Click [OK].
3. Shut down windows. The computer will now turn off.

B. Start Up:
1. Power on while UF-5000/UD-10 start up:
a. Power on the UDM computer.
b. When the logon dialog box appears:
1) User: See site specific login
2) Password: See site specific password
3) Touch [OK]

12. Annual Maintenance

Entities will reference associated Documentation contained within this document as applicable
Printouts of this document may be out of date and should be considered uncontrolled.

A. Carryover Studies:
   1. Annual or more frequently as needed.
   2. Performed after major maintenance or repair of the pipetting assembly.
   3. Performed on both the Novus and UF-5000.
   4. Acceptable samples include:
      a. QC Material
      b. Patient samples
         1) Novus
            a) Low – “Negative” sample
            b) High – “Positive” sample
         2) UF-5000
            a) Low -Saline
            b) High - Samples with elevated particle counts
               1. WBC > 10000
               2. RBC >10000
               3. Bacteria > 1000
         3) Run in the following order
            a) Low
            b) High
            c) High
            d) Low
         4) First and last low control should match within 10% for quantitative results or plus or minus 1 unit of measure for qualitative or semi-qualitative results.

13. Revisions

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

14. References

A. UF-5000 Basic Operation, Sysmex Corporation, N. American Edition, Kobe, Japan
B. UF-5000 General Information, Sysmex Corporation, N. American Edition, Kobe, Japan
C. UD-10 Basic Operation, Sysmex Corporation, N. American Edition, Kobe, Japan
D. UD-10 General Information, Sysmex Corporation, N. American Edition, Kobe, Japan
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F. Material Safety Data Sheets, Sysmex Corporation, Kobe, Japan
G. Product inserts and reagent packaging. Sysmex Corporation, Kobe, Japan
H. CLINITEK Novus Automated Urine Chemistry Operator’s Guide. Siemens Healthcare Diagnostics, Elkhart IN. 46515
I. National Committee for Clinical Laboratory Standards (NCCLS). Clinical Laboratory Procedure Manuals – Third Edition (GP2-A3), 1996.
J. Urine Sample Transportation Unit [CV-11] Urine Sample Decapper Unit [TH-11] Instructions for Use.

15. Procedure Development and Approval

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16. Keywords

Not Set