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Table of Contents

Siemens Clinitek NOVUS Automated Urine Chemistry Analyzer Operation Manual and Maintenance

Purpose

This procedure provides instructions to perform testing and maintenance procedures on the Siemens Clinitek NOVUS analyzer.

Principle

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.

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.

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 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.

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	Clinitek Novus 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.

Continued on next page

Clinitek NOVUS Operation and Maintenance Procedures, Continued

Principle, Continued

Test Name	Clinitek Novus Chemical Principle
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 Gran 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.

Scope

This procedure is intended to be used by all personnel trained and competent (e.g., Clinical Laboratory Scientists, Medical Laboratory Technicians, and Laboratory Assistants) to perform and implement any of the activities described in this procedure.

Specimen sources

Acceptable specimen requirements:

1. Uncentrifuged urine without preservative.
2. Sampler mode requires a minimum of 2.0 ml of urine.
3. If analysis is not possible within one hour of collection, the urine may be refrigerated for up to 24 hours.

Specimen collection and transport

- Follow established regional procedures for specimen collection and transport.

Continued on next page

Clinitek NOVUS Operation and Maintenance Procedures, Continued

Specimen stability

Specimen Stability

1. Urine analysis should be performed as soon as possible, preferably within 1 hour of collection.
   - Formed elements may disintegrate at varying rates depending on pH, osmolality, and storage conditions.
   - Chemical changes can occur if samples are left at room temperature for 2 hours or more.
2. Samples that have been exposed to sunlight can deteriorate.
3. If analysis is not possible within one hour of collection, the urine may be refrigerated for up to 24 hours.

Specimen rejection

Unacceptable urine specimens including those listed below should not be analyzed:

1. Turbid samples containing high number of WBC, RBC, bacteria, or crystals.
2. Urine that is visibly mucoid or has visible large particles.
3. Urine containing visible foam.
4. Urine past stability requirements (24 hours refrigerated; 2 hours ambient temperature).

Reagents

Follow the manufacturer's instructions for the storage and expiration date for all reagents. Record date received and date opened on reagent container.

All reagents are azide-free and intended for in vitro diagnostic use as directed.

REAGENT	ANALYZER(S)	OPEN STABILITY
CLINITEK Novus 10™ Urinalysis Cassette	Siemens CLINITEK Novus	14 days
CLINITEK Novus Rinse Additive	Siemens CLINITEK Novus	2 weeks after dilution with distilled water

Supplies

The following is the list of required 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 adapter No. 368.
5. Plastic squeeze bottles.
6. 5.25% Sodium Hypochlorite.

Safety or Special Safety Precautions

All human samples should be handled and disposed of as if they were potentially infectious. Laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their safety and the safety of others in the lab.

All staff members performing these procedures must adhere to regional and local workplace safety policies. These will include but may not be limited to:

- Equipment safety, proper body mechanics, sharps exposure
- Proper use of gloves/personal protective equipment while performing these procedures
- Exposure to body fluids
- Proper handling of regular and biohazardous waste
- Proper cleaning of the work area
- Proper handwashing
- Proper storage and disposal of hazardous chemical waste

Calibration

1. **Calibration Frequency**
   1) Analyzer is initially installed.
   2) 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.**
   3) You load a new cassette lot. The status bar display **Not Ready.**
   4) The system displays error messages requiring you to calibrate the system. The status bar displays **Not Ready.**
   5) You enable the Report Clarity setting and the last calibration did not include clarity reporting.
   6) You upgrade the software.
   7) You replace the pipette, SG sensor, or syringe.
   8) After performing weekly and monthly maintenance procedures.

2. **Calibration Preparation**
   Important: Before calibrating, be sure the SG well has hydrated for at least one hour if the instrument is newly installed or if the power has been off for longer than one hour.
   1) Ensure that at least 9 tests remain in the Cassette.
      I. If there are only 9 tests remaining in the Cassette, check to see if there are unopened lots that are of the same lot#. If not – load the cassette with a different lot # and proceed with calibration.
   2) 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.

3) 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.
   - **NOTE:** if you disable the Report Clarity setting, you do not need to use CAL #4 for calibration. Refer to Section 7 – System Configuration, in the CLINITEK Novus Automated Urine Chemistry Analyzer Operator's Guide for additional information on the Report Clarity Setting
4) Allow all solutions to equilibrate to room temperature before you use them.

3. Calibration Procedure

Step	Action
1	Press the start/stop switch on the conveyor. The LED status display will illuminate yellow.
2	Place the rack with the calibrator tubes on the right pool of the Novus.
3	Select [System] from the Home screen.
4	Select [Calibration].
5	If necessary, enter the operator ID (initials).
6	To change or add a lot number, touch [Change], then enter the information. Touch [Next].
7	Follow the instructions on the screen to place the tubes in the rack: Bleach Pos 1 at least 3 mL Cal 4 Pos 2 at least 5 mL Cal 1 Pos 3 at least 3 mL Cal 2 Pos 4 at least 3 mL Cal 3 Pos 5 at least 3 mL
8	Select [Start] and the screen will count down from 3:13 to zero.
9	The analyzer updates the progress of the run.
10	Select [Print] to print the calibration report.
11	Select [Exit] to return to the system menu.
12	If calibration passes, the status bar will return to "Ready" and the system will be ready to process quality control and patient samples.

Continued on next page

Clinitek NOVUS Operation and Maintenance Procedures, Continued

Recording/ Storage of Quality Control Data

Follow laboratory protocol for troubleshooting Quality Control results exceeding the upper or lower limit of acceptability.

- **Siemens CLINITEK Novus**

Step	Action
1	At the home screen, click on **[Results]**.
2	Select **[Control]**.
3	Select the search option that best suits your search criteria. • Date Range – enter desired date range. • Control lot – enter Control lot# you wish to view. • Cassette lot – enter the cassette lot #. • All results – the results from all QC runs will be available. • Sequence – enter the sequence range.
4	After the search criteria is entered, a list of controls will be available.
5	Highlight the control and select **[View]**.
6	If a flag was generated during testing, a symbol denoting the flag is displayed adjacent to the result:
7	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.

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

Continued on next page

Clinitek NOVUS Operation and Maintenance Procedures, Continued

Operating Procedure

Follow the instrument start-up steps below for the:

NOTE: The Novus should never be powered off as the SG well continually needs to be hydrated. If analyzer has been turned off, turn it back on and allow the SG well to hydrate and stabilize for 1 hour.

Step	Action
1	If the System displays "Not Ready", review the messages in the status Log. Complete the necessary troubleshooting to bring the system to "Ready" Status.
2	Check the status of the reagent cards. If necessary, load a new reagent cassette.
3	Check the external supply of rinse.
4	Check the card waste container and the liquid waste container. Empty if necessary.
5	Clear any racks that may be present in pool areas.
6	Press the CV-11 power switch. • The conveyor will turn on. The green status light will illuminate when ready.

Sample Processing

Follow these steps to perform patient sample processing:

Step	Action
1	Confirm 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.
5	With unpreserved samples, for the most accurate results, test within two hours.
6	Prepare a well-mixed urine sample into a clean sample tube labelled with the appropriate barcode. • Novus minimum sample requirements - 2.0 mL

Continued on next page

Clinitek NOVUS Operation and Maintenance Procedures, Continued

Sample Processing, Continued

Step	Action
7	Place tubes(s) in rack with barcode visible within the rack opening. ◦ If using wide mouth tubes, place the tubes in every other rack position.
8	Load the rack with the groove to the right onto the right sampler pool of the first analyzer on the automation line. ◦ 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. – Press the alarm reset switch. – Reposition the rack. – Press the play button. ▷Rack will advance.
9	Rack movement behavior ◦ If there is more than one identical analyzer on the line, the system will load balance the racks and distribute to analyzers equally. – The first rack will proceed to the [identical] analyzer on the right; the second rack will proceed to the [identical] analyzer on the left. – When analysis is complete and analyzers go into standby, the next rack loaded will always move to the [identical] right analyzer. ◦ The racks will then move onto the second type of analyzer (reflex analyzer) and will load balance in the same fashion. – All tubes will be presented to the reflex analyzer(s). – The barcode will be read and will query for an order. ▫ If no order, no aspiration and the rack proceeds to next sample. ▫ If there is an LIS or reflex order from the UDM, the sample will be analyzed. ◦ 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. – When 10 racks have been collected, a "rack full" error code will display with an alarm on the CV-11.

Continued on next page

Siemens Clinitek NOVUS Automated Urine Chemistry Analyzer Operation Manual and Maintenance, Continued

Reviewing test results

The results summary, sequence number, and status are displayed for each of ten samples on each page of the Patient Results screen, starting with the most recent sample. The following status indicators are possible:

- Completed: The sample was completed.
- Low Volume: the sample volume in the tube is low.
- Dispense error: the system could not dispense the sample.
- Tube error: the tube is capped or too high.

Displaying Results Summaries

Step	Action
1	To display all results or results by type, select an option: • All: displays all the patient test results. • Error: displays the patient test that had errors. • Send error: displays only when the system could not send the patient test results to the LIS, and if you configured the Host Data setting to send the results automatically to the LIS>.
2	Use the scroll arrows to navigate the summary.
3	To view the details, print the summary or the details, or send the summary to the LIS, select a function button.

Displaying Results Details

Step	Action
1	Select the [Details] function button on the Patient Results screen to display the Patient Result Details screen.
2	Select [View] on the Patient Results Details screen. Detailed results for the first sample are displayed.
3	Use the scroll buttons to the right of the summary to navigate the list. Information is displayed in the Analytes area.
4	If the system cannot determine a valid analyte value, a result value of Error is displayed for the analyte.
5	A symbol represents an analyte flag, which displays next to an analyte for a sample that meets the following criteria.

Symbol	Description
^	Range adjusted
*	Abnormal
†	Sample quality

Continued on next page

Siemens Clinitek NOVUS Automated Urine Chemistry Analyzer Operation Manual and Maintenance, Continued

Reviewing test results, Continued

Step	Action
6	To display patient comments, print the details, or send the details to the LIS, select a function button.
7	For more information on the results, refer to the Tables of Results section in the appendix of the CLINITEK Novus Automated Urine Chemistry analyzer Operator's Guide.

Reference Ranges and Reportable Values

The table below lists the respective reference ranges and reportable values for the Clinitek NOVUS analytes.

Test Code	Reference Range	Reportable Values
Urobilinogen	0.2-1.0 mg/dL (Negative)	0.2,1.0,2.0,4.0,>=8.0
Blood	Negative	Neg, Trace, Small, Mod, Large, NHT
Bilirubin	Negative	Neg, Small, Mod, Large
Ketone	Negative	Neg, Trace, 15, 40, 80, >=160
Glucose	Negative	Neg, 100, 250, 500, >=1000
Protein	Negative	Neg, Trace, 30, 100, 300, >=1000
pH	5.0-8.0	5.0 - >=9.0, in increments of 0.5
Nitrite	Negative	Neg/Pos
Leukocytes	Negative	Neg, Trace, Small, Mod, Large
Specific Gravity	1.005 – 1.030	1.000->=1.045, in increments of 0.001

Alert Values

Glucose >=500 Critical flag for pediatric patients

Continued on next page

Siemens Clinitek NOVUS Automated Urine Chemistry Analyzer Operation Manual and Maintenance, Continued

Limitations

- Clinitek Novus Optical System
  - 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 can detect 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.
  - 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:
    - Visible levels of blood or bilirubin
    - Drugs containing dyes
    - Nitrofurantoin
    - Riboflavin

Continued on next page

Clinitek NOVUS Operation and Maintenance Procedures, Continued

Maintenance Procedures

Loading reagent cassettes

Step	Action
1	Select [System] then [Load & Unload]
2	Select [Yes] to confirm unloading of a cassette.
3	Open the system cover.
4	Turn the lock on the cassette door counterclockwise then open the door.
5	Hold the cassette by the handle and slide it towards you to remove. • Use the foil tab to peel the foil seal off the tray. • Remove the cassette from the tray. • Pull the shipping card out of the cassette. • Do not turn the cassette upside down, as the cards may fall out. **NOTE:** Determine if the analyzer will require calibration, and plan accordingly, prior to removing the foil seal. If calibration is required, the seal should not be removed until calibration and quality control material are warmed to room temperature and are ready to process.
6	Load the new cassette onto the rails and slide it into the instrument.
7	Close the door and turn the lock clockwise to lock the door.
8	Close the system cover. The system reads the log number and expiration date from the cassette.

Refill the rinse bottle

The system is configured with an external rinse bottle. It must be checked visually.

Step	Action
1	Remove the cap and empty the remaining rinse.
2	Fill the rinse bottle with 2000 mL. distilled or deionized water.
3	Add 4 mL. of CLINITEK Novus Rinse Additive. Gently swirl to mix trying to avoid excess bubbles.
4	Replace the cap.
5	Prime the pump.

Continued on next page

Siemens Clinitek NOVUS Automated Urine Chemistry Analyzer Operation Manual and Maintenance, Continued

QC File Maintenance

Preparation of QC files – CLINITEK Novus

Step	Action
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: QC lot entry for the CLINITEK Novus is ***REQUIRED.***

Daily SG Well Cleaning

The cleaning cycle takes about 3 minutes to process. The system cleans the SG well as part of the calibration procedure.

Step	Action
1	Pour at least 2 mL of 5.25% sodium hypochlorite (house bleach) into a sample tube and label "Bleach".
2	Place the tube of bleach in the 1st test position in a rack.
3	Press the start/stop switch on the conveyor. The indicator light will turn orange
4	Please the rack on the right sampler pool.
5	Select [System] > [Clean SG Well].
6	Select [Start].
7	After the system finished cleaning, a message displays that the cleaning cycle is complete.

Daily Maintenance Tasks

Disinfection might be required on several parts of the system, such as the rack handler, card platform, display, sensor windows, and racks. Disinfect the system using 70% isopropyl alcohol or a solution of 10% bleach and 90% water.

Step	Action
1	Wipe the system components (rack handler, card platform, display, sensor windows, and racks) with a cloth moistened with disinfectant solution, or spray a cloth or hand towel with the aerosol disinfectant.
2	Wait the appropriate length of time for the solution, as noted by the manufacturer.
3	Wipe off the component with water and dry it.

Weekly Maintenance

SG/Clarity Sensor Cleaning on the Siemens CLINITEK Novus

Step	Action
1	Turn the Novus off using the power switch.
2	Open the system door.
3	Fill a beaker, cup, or suitable vessel with hot tap water (90° - 110°F / 32° - 43°C.
4	Use a plastic pipette or dropper to manually dispense the hot water into the SG well. **Notes:** • Do NOT remove the SG/clarity sensor from the instrument. • Place the tip of the plastic pipette over the sensor well making sure that the tip doesn't touch the SG sensor. • Dispense the hot water into the SG well with three full plastic pipettes of hot water.
5	Close the system door and switch the power back on.
6	Run the [Clean SG well] procedure in the [System] menu.
7	Calibrate the system.

Monthly SG Well Cleaning

Monthly SG well cleaning steps include removing the old sensor, flushing and re-installing the sensor.

Step	Action
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: • Push the connector down. • Turn the collar counterclockwise ¼-turn. • Lift the connector.
9	After you remove all the connectors, select Next.

Continued on next page

Siemens Clinitek NOVUS Automated Urine Chemistry Analyzer Operation Manual and Maintenance, Continued

Monthly SG Well Cleaning, Continued

Step	Action
10	To flush the sensor: • Rinse 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. • Dry the sensor with a paper towel, making sure that the connector ends are free of water.
11	Re-install the SG sensor by sliding the SG sensor (facing up) into the sensor well, until you hear a click.
12	Select Next.
13	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.
14	Attach the connectors, starting at one end and working to the opposite end: • Holding the connector collar, align the tab to the slot in its matching color socket. • Push the collar down and turn it clockwise ¼-turn. • To ensure the connector is locked, gently try to lift the connector.
15	Select Done and close the cover.
16	After complete hydration, calibrate the system.

Controlled Documents

The following controlled documents support this procedure.

• SCPMG-PPP-0550 Urinalysis Specimen Handling
• SCPMG-PPP-0597 Handling Urine Color Interference Job Aid
• SCPMG-PPP-0569 Manual Microscopic Urinalysis
• SCPMG-PPP-0546 Urinalysis Autoverification Rules
• SCPMG-PPP-0626 Sysmex UDM Settings

Continued on next page

Siemens Clinitek NOVUS Automated Urine Chemistry Analyzer Operation Manual and Maintenance, Continued

Non-Controlled Documents

The following non-controlled document supports this procedure.

- Sysmex UN Series CLSI Procedure, Document Number 1519-LSS, Rev.2, Oct 2020
- Clinitek Novus Automated Urine Chemistry Analyzer Operator's Guide. 10697759 Rev. F
- Clinitek Novus 10 Urinalysis Cassette. 10844207 EN Rev.F, 2020-02
- Clinitek Quickguides CF-07640, Rev.1 3/2023

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Operations Director Approval

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Medical Director Approval

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