Procedure

Procedure Title:	Clinitek Status®+ Operating Procedure – Point of Care Testing (POCT)	
Applies To:	Health Care Professionals performing POCT using the Siemens Clinitek Status®+	
Governing Policy:	Point of Care Testing Operations - DT-POC-001	
Approved:	**Effective:**	**Next Review:**
July 13, 2023	August 8, 2023	July 13, 2027
Sponsor:	Senior Medical Director, Diagnostic and Therapeutic Services Senior Director, Clinical Networks	
Approval Authority:	Senior Medical Director, Diagnostic and Therapeutic Services Senior Director, Clinical Networks	
Number: DT-POC-010	**Manual:** Diagnostic Testing	

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PURPOSE

This procedure provides information and instruction to operate the Siemens Clinitek Status®+ to perform urinalysis testing with Multistix® 10 SG test strips and pregnancy testing with Clinitest ® hCG cassettes.

GUIDELINES

1. The Clinitek Status®+ is intended for use in situations when results are needed immediately.
2. Consider all patient specimens, as well as the materials they contact, as biohazardous and capable of transmitting infection or cross contamination.
3. Follow consistent inventory management practices, such as proper storage and labelling of supplies, and inventory rotation to support quality POCT results, and patient safety.

COMPETENCY REQUIREMENTS

1. The Health Care Professional is responsible to demonstrate competency in the use of this device prior to performing patient testing, or any part of this procedure, as per POCT Training and Competency Assessment - DT-POC-002.

PROCEDURE

Equipment and Supplies Handling

1. Perform required device maintenance as per Appendix B.
    1.1. Document completed tasks on maintenance checklist.
2. Follow Table 1 for maintaining stability and proper storage of reagents/supplies.

Table 1: Stability and Storage Instructions for Reagents/Supplies

Reagents/Supplies	Stability and Storage
Multistix® 10 SG	○ Store at 15 to 30 degrees Celsius (ºC) in the original bottle until manufacturer expiration date. ○ After opening, record the date opened on the bottle. ○ Ensure opened bottle is tightly capped when stored. **Do not:** ○ Remove the desiccant(s) from the bottle. ○ Store test strips in containers other than the original bottle. ○ Expose to light, heat, and ambient moisture.
Clinitest® hCG	○ Store at 2 to 30ºC until manufacturer expiration date. ○ If refrigerated, allow cassette to sit for five minutes to come to room temperature prior to opening the pouch. ○ Do not remove cassette from pouch until time of testing.

3. Follow Table 2 for liquid quality control (QC) practices.

Table 2: Liquid QC for Clinitek Status®+

Control	Levels	Stability and Storage	Frequency
Bio-Rad qUAntify Plus	1 and 2 Level 1 is negative; Level 2 is positive	○ Store at 2 to 8ºC. Protect from light. **Unopened:** ○ Stable until manufacturer expiration date. **Opened:** ○ Stable for: ● 14 days if using with Multistix® 10 SG ● 30 days if using with Clinitest® hCG ○ After opening, record the open expiry date on the vial. **Note:** ○ Once a control vial has been used for Multistix® 10 SG testing, do not use it for Clinitest® hCG testing. ○ Multistix® and Clinitest® must have separate QC vials.	○ Every seven days ○ After switching to a new lot number of reagent, or after receiving new reagents

4. Gather the following materials and equipment to prior to testing, as required:
    - Multistix® 10 SG test strips
    - Clinitest® hCG cassettes
    - Pipette
    - Liquid QC level 1 and 2
    - Paper towel or gauze
    - Protective Gloves
    - Clinitek Status®+
    - Thermal paper

Quality Control Testing (as per frequency in Table 2.)

> **Note:** It is recommended to perform any required maintenance procedures, prior to performing QC.

1. Ensure QC and supplies are not expired. Discard any outdated supplies. See Table 1 and Table 2.
2. Remove the QC from storage and let sit for 15-30 minutes at room temperature. Don clean gloves.
3. Turn the device on.
4. Select **QC Test** from the Select Ready screen.
5. On the QC Test screen, select:
    - **QC Strip Test** if using Multistix® 10 SG
    - **QC Cassette Test** if using Clinitest® hCG.
6. Position the table insert in the test table appropriately. Ensure it is clean and dry.
7. Scan or manually enter operator ID and press **Enter.**
8. Select **Enter Lot and Expiration Date**.
9. Scan or manually enter the lot number of the control and press **Enter**.

> **Note:** Always perform Level 1 (negative) control first.

10. Enter the open expiry date written on the vial using the arrow keys, and press **Enter**. Do not enter the manufacturer expiry date.
11. Select **Enter New Lot and Expiration Date**.
12. Scan the lot number:
    - On the bottle of Multistix® 10 SG, if doing a Strip Test, or
    - On the Clinitest® hCG cassette pouch, if doing a Cassette Test
13. Verify that the lot number and expiry date that is displayed is correct.

14. If doing a strip test, open the bottle of strips and remove a strip and recap immediately.
15. If doing a cassette test, open the pouch and remove the cassette and pipette. Place the cassette on the test table.
16. Gently mix the QC vial by inversion to ensure homogeneity of the solution. **Do not shake**. Open the QC.
17. Press **START**.

> **Note:** After **START** is pressed, the device will automatically pull in the test table in **eight seconds**.

18. If performing a strip test:
    18.1. Dip the strip in the control, ensuring all test pads are wet.
    18.2. Drag the edge of the strip against the side of the container while removing it.
    18.3. Blot the edge of the strip on the paper towel to remove excess.
    18.4. Place the strip in the test table channel with the test pads facing up.
    18.5. Slide or push the strip to the end of the channel.
19. If performing a cassette test:
    19.1. Using the pipette provided, squeeze the upper bulb, and draw enough urine to fill the stem completely. Any overdrawn amounts will go into the overflow reservoir.
    19.2. Discharge the urine in the pipette into the sample well on the cassette.

> **Note:**
>
> The device will perform a calibration prior to analysis. Analysis takes approximately:
>
> - 60 seconds for a strip test
> - Five minutes for a cassette test

20. Close the control vial.
21. After analysis is complete, remove and discard the used strip, or cassette, in the garbage.
22. Repeat this procedure for second QC solution.
23. Interpret Liquid QC Results.
    - **PASS** must be obtained for both levels of QC to proceed with patient testing.
    - If a FAIL result is obtained, do not perform patient testing, and repeat the control that failed. Refer to Appendix C.
    - If an error code is displayed, refer to Siemens' Clinitek Status®+ Operators Guide for appropriate action.

Patient Testing

Note:

Patient testing requires a written or verbal order from an Authorized Prescriber, or an approved care directive.

1. Ensure all required maintenance and QC procedures are complete before performing patient testing.
2. Ensure supplies are not expired. Discard any outdate supplies. Refer to Table 1.
3. Verify there is a written or verbal order from an Authorized Prescriber, or as per direction in an approved care directive.
4. Identify patient, as per Patient Identification - NSHA CL-SR-025.
5. Ask the patient to collect a freshly voided urine sample in a clean, dry container.
6. In the presence of the patient, label the container with at least two person-specific patient identifiers.
7. Document the date and time the specimen was collected as per local work instructions.
8. Perform hand hygiene and don clean gloves.
9. Ensure specimen is suitable for testing. See Appendix D.
10. Turn the device on.
11. On the Select Ready screen, select:
    - **Strip Test**, to do a urinalysis test.
    - **Cassette Test**, to do a pregnancy test
12. Position the table insert in the test table appropriately. Ensure it is clean and dry.
13. Scan or manually enter operator ID and press Enter.
14. Select Enter New Patient.
15. Scan or manually enter the patient's account number from the specimen container.
16. Select Enter New Lot and Expiration on the Strip Lot screen.
17. Scan the lot number:
    - On the bottle of Multistix® 10 SG, if doing a Strip Test.
    - On the Clinitest® hCG cassette pouch, if doing a Cassette Test.
18. Verify that the lot number and expiry date that is displayed is correct.
19. If performing a strip test, open the bottle of strips and remove a strip and recap immediately.
20. If performing a cassette test, open the pouch and remove the cassette and pipette. Place the cassette on the test table.
21. Mix the specimen gently and open the specimen container.

22. Press START.

> **Note:** After START is pressed, the device will automatically pull in the test table in eight seconds.

23. If performing a strip test:
    23.1. Dip the strip in the specimen, ensuring all test pads are wet.
    23.2. Drag the edge of the strip against the side of the container as you remove it
    23.3. Blot the edge of the strip on the paper towel to remove excess.
    23.4. Place the strip in the test table channel with the test pads facing up and Slide or push the strip to the end of the channel.
    23.5. During analysis, the Select Appearance screen displays.
    23.6. Assess the colour and clarity of the specimen. Select the appropriate colour and clarity from the choices displayed.
    23.7. Press Next.
24. If performing a cassette test:
    24.1. Using the pipette provided, squeeze the upper bulb, and draw enough urine to fill the stem completely. Any overdrawn amounts will go into the overflow reservoir.
    24.2. Discharge the urine in the pipette into the sample well on the cassette.

> **Note:**
>
> The device will perform a calibration prior to analysis. Analysis takes approximately:
>
> - 60 seconds for a strip test
> - Five minutes for a cassette test

25. Close specimen container.
26. After analysis is complete, remove and discard the used strip, or cassette, in the garbage and wipe the test table insert with gauze.

> **Note:** If an error code is displayed, refer to Siemens Clinitek Status®+ Operators Guide for appropriate action. Repeat testing, and document in the patient chart.

27. Interpret Results.
    - Results outside the reference range will be flagged with an asterisk (*) on the analyzer screen and on the printed report. For reference ranges, refer to Appendix E.
    - Clinitest® hCG tests can detect hCG concentrations of 25 IU/L or higher. Refer to Table 3 for interpretation of hCG test results.
28. Results will print and automatically transfer to the patient's electronic record. During downtime, or if results do not appear in electronic records:

28.1. Label a Point of Care Testing Results Form. with at least two Person-Specific Patient Identifiers and attach the result printout from Clinitek Status®+ to the result form.

28.2. Make a photocopy of the result form and place the photocopied result form in the patient's chart.

> **Note:** Thermal printer paper will fade over time. The result form must be photocopied to create a permanent record.

29. Dispose of specimen and any other contaminated materials in biohazard waste and clean work area.

30. Remove gloves and perform hand hygiene.

Table 3: Interpretation of hCG Results

Result	Interpretation
POSITIVE	HCG detected at a concentration of 25 IU/L or higher.
BORDERLINE	Result is indeterminate. Quantitative hCG testing is suggested. Send appropriate specimen to the laboratory.
NEGATIVE	HCG not detected. HCG may be present at a concentration of less than 25 IU/L.
INVALID	Procedural error or test reagent deterioration has occurred. Repeat test.

Note:

- If the patient's symptoms are inconsistent with results, refer to Appendix C.
- Substances that cause abnormal urine colour may affect the readability of strip test pads. These substances include visible levels of blood, bilirubin and drugs containing dyes (example: pyridium, nitrofurantoin or riboflavin).
- Clinitest® hCG cassette tests are not intended to detect conditions other than pregnancy. Several conditions other than pregnancy, can cause elevated levels of hCG.
- In very early stages of pregnancy, the lag between conception and the appearance of hCG in urine, may occasionally produce false negative results. To exclude pregnancy with the highest degree of certainty, submit a specimen to the lab for quantitative hCG testing.
- Refer to the Siemens' Clinitek Status®+ Operator's Guide, and reagent Instructions for Use, for specific principles of testing, performance characteristics and list of interfering substances.

REFERENCES

Siemens Clinitek Status®+ Operator's Guide

Multistix® 10 SG instructions for use

Clinitest® hCG instructions for use

Accreditation Canada. (2019). *Qmentum program point of care testing*. Ver. 14.

RELATED DOCUMENTS

Policies

POCT Operations - NSHA DT-POC-001

POCT Training and Competency Assessment – DT-POC-002

Venipuncture for Blood Specimen Collection - NSHA CL-BP-040

Patient Identification - NSHA CL-SR-025

Hand Hygiene – NSHA IPC-RP-020

Routine Practices – NSHA IPC-RP-005

Waste Management – NSHA ENV-WS-001

Sharps Safety – NSHA AD-OHS-005

Forms

Point of Care Testing Results Form

Clinitek Status+ Care and Maintenance Log

Appendices

Appendix A: Definitions

Appendix B: Maintenance

Appendix C: Troubleshooting

Appendix D: Specimen Requirement and Rejection Criteria

Appendix E: Reference Ranges

Appendix A: Definitions

Authorized Prescriber	A Regulated Health Care Professional who is permitted by legislation, their regulatory college, Nova Scotia Health/IWK Health, and practice setting (where applicable) to prescribe medications/treatments and order diagnostic tests within their scope of practice or employment. To have the authority to prescribe in Nova Scotia, the authorized prescriber must be a Regulated Health Care Professional, registered (in good standing), and practicing within the Nova Scotia Health/IWK Health/First Nations Health Service Delivery structure and has a Contractual Arrangement with, hold privileges with, or employed by Nova Scotia Health/IWK Health to provide health care services to Nova Scotians. Prescribers external to and have no contractual arrangement with Nova Scotia Health/IWK Health/First Nations Community Health Centre may not prescribe within Nova Scotia Health practice settings.
Health Care Professional (HCP) performing Point-of-Care Testing	A professional recognized as qualified by the appropriate professional college or association and pursuant to the professional legislation in force, following appropriate training, to perform the duties of collecting samples and determining the result of POCT as well as counselling the client if necessary. This healthcare professional may be a Physician, Nurse Practitioner, Medical Laboratory Technologist, Registered Nurse, Licensed Practical Nurse, Pharmacist, Paramedic, Respiratory Therapist or Medical Radiation Technologist provided they are members of their professional associations and have received appropriate training.
Point-of-Care Testing (POCT)	Testing that is performed near or at the site of the patient with the result leading to possible change in the care of the patient.
Quality Control (QC)	The set of procedures designed to monitor the test method and the results to assure test system performance by detecting gradual or sudden changes in performance.

Appendix B: Maintenance

Daily/As Needed

1. Turn device off.
2. Dampen a piece of gauze and clean the exterior of the instrument. If it is visibly contaminated, clean and disinfect as indicated under monthly maintenance.
3. Check that paper supply is adequate. If not, replace paper.
4. To replace paper:
    4.1. Open the printer cover by pulling up on the tab. Pull out the cover.
    4.2. Lift the paper holding arm into the open, upright position. Remove old roll.
    4.3. Place new roll into the printer paper compartment with the paper unrolling from underneath and toward compartment wall.
    4.4. Feed paper up along the wall and through the printer until 10cm of paper is through. Feed the edge through the printer cover.
    4.5. Push the holding arm down into the closed position.
    4.6. Close paper roll and printer covers by clicking into position.
5. Document actions on maintenance checklist.

Weekly

1. Turn the device on.
2. Remove the test table by pulling it slowly out of the analyzer.
3. Remove the test table insert and rinse with water. Use gauze or cotton-tipped swab to remove visible residue.
4. Clean the test table with wet gauze, except for the white calibration bar.
5. Dry the test table thoroughly.
6. Examine the white calibration bar carefully under good lighting for dirt, discolouration, or scratches. If it appears, dirty, discoloured or scratched, contact POCT specialist.

Note: Do not touch the calibration bar during the examination, or when cleaning the test table. Fingerprints, dirt, or lint can cause unreliable test results.

7. Insert the test table back into the analyzer with the white calibration bar facing upwards. Push it in slowly until it is just over halfway into the analyzer.
8. Re-insert the test table insert.
9. Document actions on maintenance checklist.

Monthly

1. Prepare one of the following solutions in a container (such as an empty Multistix® bottle) to a depth of 10cm:
   - Bleach (5% sodium hypochlorite - can be diluted up to 1:20), **or**
   - 70 – 85% isopropyl alcohol
2. Turn the device on.
3. Remove the table insert from the test table and remove the test table from the analyzer.
4. Place the table insert and test table into the solution. Ensure the cleaning solution does not contact the white calibration bar.
5. Soak the table insert and test table for at least two minutes but not more than 10 minutes.
6. Using the same solution, wipe the solution on the display screen and let it remain for 10 minutes.
7. Rinse the table insert and test table thoroughly with water and dry thoroughly with gauze.
8. Wipe the display with a clean cloth or gauze dampened with water and then dry with a separate clean cloth or gauze.
9. Insert the test table back into the analyzer.
10. Insert the test table insert into the test table.
11. Document actions on maintenance checklist.

Cleaning the White Calibration Bar

1. If the white calibration bar appears dirty or discoloured:
   1.1. Wet a piece of gauze or cotton-tipped swab with distilled water and gently wipe and clean the calibration bar.
   1.2. Allow to air dry.
2. If the white calibration bar is scratched or cannot be completely cleaned, replace it.
3. Document actions on maintenance checklist.

Appendix C: Troubleshooting

Patient Testing Troubleshooting
1. If questioning the validity of the result: • Ensure strips or cassettes used were stored in proper conditions and are not expired. • Repeat testing using a test strip from an unopened bottle. • Repeat testing with a new specimen. • Follow up with laboratory testing. • Contact POCT Specialist, if required. 2. Document actions in the patient chart.
Liquid Quality Control Testing Troubleshooting
1. If a “FAIL” result is obtained: • Ensure QC and strips or cassettes were stored in proper conditions and are not expired. • Repeat testing using a previously unopen bottle of Multistix® 10 SG. • Repeat testing using a previously unopen vial of QC. 2. If a “PASS” result is not obtained: • **Do not** perform patient testing. • Contact POCT Specialist.
When to Contact POCT Specialist
1. Contact POCT Specialist if: • The patient’s symptoms are inconsistent with results from the device and troubleshooting has been performed. • Testing was performed which led to results on a wrong patient record. • A “PASS” result cannot be obtained during QC testing and troubleshooting has been performed. • Unable to resolve problems or error messages after troubleshooting. • The device will not turn on. • There is any physical damage to the device.

Appendix D: Specimen Requirements and Rejection Criteria

Specimen Requirements

1. 10mL freshly voided urine in a clean dry container
2. Tested within two hours of collection.

> **Note:** First morning collection is preferred.

Specimen Rejection Criteria

1. Reject the specimen if:
   - The specimen is not labelled with two Person Specific Patient Identifiers.
   - There is insufficient volume to properly dip a Multistix® 10 SG test strip.
   - There is insufficient volume to properly load a Clinitest® hCG cassette.
   - The specimen is older than two hours.

Appendix E: Reference Ranges

Urinalysis

Analyte	Reference Range	Units
Glucose (GLU)	Negative	mmol/L
Bilirubin (BIL)	Negative	µmol/L
Ketones (KET)	Negative	mmol/L
Specific Gravity (SG)	1.005–1.025	
Blood (BLD)	Negative	/µL
pH	5.0–8.5	
Protein (PRO)	Negative	g/L
Urobilinogen (UBG)	3.2–16	µmol/L
Nitrite (NIT)	Negative	
Leukocytes (LEU)	Negative	/µL

Pregnancy

Analyte	Units
Human Chorionic Gonadotropin (hCG)	IU/L

Note:

- The detectable level of hCG concentration of the Clinitest® hCG Pregnancy Test is as low as 25 IU/L. The following are possible limitations of this assay:
- Positive, but very low levels of hCG can be present shortly after implantation.
- If the level of hCG at the time of collection is below the sensitivity of the test (25 IU/L), a false negative or slightly positive is possible.
- False positive results are possible due to conditions other than pregnancy and interference by human anti-mouse antibodies (HAMA).
- Any questionable result or result reported as Borderline should be confirmed with a 48-72 hour repeat or a quantitative plasma hCG.

Version History

Version:	Effective:	Approved by:	What's changed:
Original	2018-03-21	VP Integrated Health Services Program of Care 2	N/A
Standard Review	2023-08-08	Senior Medical Director, Diagnostic and Therapeutic Services Senior Director, Clinical Networks	○ Updated QC product names, definitions ○ Added Appendix for troubleshooting ○ Simplified test procedure instructions