Procedure

IWK Health

Procedure Title:	Point of Care Testing – Stat Strip Lactate Meter	
Applies To:	Certified Stat Strip Lactate Meter Users (Laboratory Technologists, Birth Unit Registered Nurses)	
Location Applicability:	Women's Newborn Health Program	
Approved: July 11, 2023	**Effective:** November 14, 2023	**Next Review:** November, 2027
Sponsor:	Chief of Pathology and Lab Medicine	
Approval Authority:	Policy and Practice Committee	
Number: 3103	**Manual:** Laboratory	

Contents

PURPOSE

Point of Care (POC) lactate testing is specifically indicated for use in clinical settings by health care professionals as an aid to monitor fetal well-being in utero in response to labour.

The Nova StatStrip™ Lactate Hospital Meter system is intended for use by healthcare professionals for clinical use and point-of-care usage for the quantitative determination of lactate (LAC) as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis.

The manufacturer of the Nova StatStrip™ Lactate Meter states it is not for use on capillary blood specimens. Laboratory experience in health centers across Canada have illustrated it is fit for the purpose of fetal scalp blood lactate.

This procedure provides information and instruction on certification, training, and use of the Nova StatStrip™ lactate meter.

GUIDELINES

CERTIFICATION and TRAINING

The Point of Care Coordinator (POCC) works collaboratively with clinical staff at the point of care to implement Point-of-Care Testing (POCT) safely, to assist with achieving and maintaining competency and adhering to the Department of Pathology and Laboratory Medicine quality management program. The POCC monitors and tracks the compliance with competency for the POC lactate meter in collaboration with the specific unit Clinical Leader of Development (CLD)/Clinical Leader (CL).

Initial Certification for use of the StatStrip™ Lactate Meter consists of successfully completing the online training/learning module/quiz on the Learning Management System (LMS) and attending a hands-on training session with a lactate meter super user, Point of Care Coordinator (POCC) or laboratory (lab) designate. The training checklist, which includes employee name, employee identification (ID) number (your operator ID), care area, and date of completion, must be signed by the employee and a copy sent to the POCC. Each operator will be certified for one year. A copy will also be maintained on the individual's staff education record.

Re-certification for the StatStrip™ Lactate Meter includes successfully completing the online certification quiz for the lactate meter on a yearly/annual basis.

Non-compliance will result in the operator being inactivated until recertification is completed. This will include completing the online education module and a hands-on review of quality control (QC) and patient testing.

PROCEDURE

1. **Gather equipment/materials**
    - Fetal blood sampling (FBS) kit
    - Nova StatStrip™ lactate test strips
    - Nova StatStrip™ lactate meter

- Prep sponges
- Hospital approved disinfecting wipe
- Quality Control Solutions (obtain from lab)

Refer to Appendix B for additional information on the Nova StatStrip™ Lactate Meter components, test strips and control solutions.

2. **Power up device**
   Press the power on/off button located below the center of the touch screen. The welcome screen or main screen displays. The main screen displays the meter's assigned location, date, time, status of battery charge (battery is fully charged when symbol is blue) and Login key.

3. **Enter Operator ID**
   Press the Login icon on the screen (or OK button) and scan or manually enter your Operator ID (press Accept/OK)

   3.1. **Bar Code Scanning:** Touch the Scan button (or OK) below the touch screen. Position the scanning beam approximately 4-6 inches from your operator ID barcode.
   3.2. **Manual Entry:** Input operator ID using the touch screen. Touch the OK button on the touch screen to progress to the next screen. The Patient Test screen will appear.

4. **Run StatStrip™ Lactate Quality Control (QC) Solutions**
   Two different levels of the StatStrip Lactate Control Solution should be run:

   - each 24 hours
   - prior to testing a patient specimen
   - and under the following circumstances:

     - If a patient test has been repeated and the blood lactate results are still lower or higher than expected
     - When a new vial of strips is opened
     - When the strip vial cap has been left opened
     - If there are indications that the system is not working properly indicated by alerts on the screen or difficulties with the meter operation. Refer to Appendix C for Troubleshooting recommendations.
     - If problems are identified (storage, operator, instrument)
     - If the meter is dropped or exposed to extreme temperatures, humidity, heat, etc
     - If meter infrequently used, QC must be performed a minimum of twice a week (Monday/Thursday)

Once QC is completed by clinical staff, the QC results will be stored electronically when the meter is docked on the docking station.

4.1. Turn the meter on. The Welcome screen will indicate if the meter is locked out “Lac LOCKED” which indicates the need for a QC to be performed before a patient test can be processed.
4.2. Login with your operator ID (Press Accept or OK) .
4.3. From the Patient Test screen, press the QC soft key.
4.4. Enter Strip Lot screen displays. Enter the strip lot number by scanning the barcode. To scan press Scan or OK and scan the barcode on the test strip vial. Press Accept or OK if the lot number is correct.
4.5. If the Strip Lot Number is invalid, the screen displays the invalid number with “is not a valid Strip Lot # Try again”. Touch the Back Button to return to the Enter Strip Lot screen to rescan the lot number.
4.6. Enter QC Lot screen displays. Enter the QC lot number by scanning the barcode. To scan press the Scan soft key or OK and scan the barcode on the QC vial. Press Accept or OK if the lot number is correct.

    4.6.1. If the QC lot Number is invalid, the screen displays the invalid number with “is not a valid QC Lot Try again” Touch the Back Button to return to the Enter QC Lot screen to rescan the lot number.

4.7. The Insert Strip screen displays. Insert a test strip in the strip port.
4.8. The Apply Sample screen displays. Gently shake the StatStrip™ Lactate Control Solution before each use and discard the first drop of control solution from the bottle to avoid contamination.
4.9. Place a drop of control solution to the end of the test strip until the solution is drawn into the well of the test strip. When enough solution has been drawn into the strip, an audible beep sounds and a 13 second countdown begins.
4.10. Recap the control solution.
4.11. When the meter completes the test, a PASS or FAIL will appear on the screen.

    4.11.1. If PASS - Press Accept or OK.
    4.11.2. If FAIL – a comment must be added to the results - Examples include: Procedure Error, Wrong Control, Repeat Control and then refer to Appendix C for Troubleshooting for the Nova StatStrip™ Meter

4.12. Remove the strip and discard into sharps container.
4.13. Patient Test screen displays a reminder of the level of QC still required to be run. Repeat the above steps for the next level.

NOTE: Patient specimens cannot be tested until both levels of QC have passed

5. Run Patient Test using the StatStrip™ Lactate Meter

5.1. Put on gloves for patient testing as per *IWK Health Policy #201.1 Application of Routine Practices*.

5.1.1. Put on personal protective equipment (PPE), if indicated, based on identification of the need for additional precautions as per *IWK Health Policy # 301.2 Application of Additional Precautions*

5.1.2. Place meter in isolation sleeve, if indicated for additional precautions

5.2. Turn on the Nova StatStrip™ Lactate Meter and Login by scanning or manually entering operator ID

5.3. Perform QC if necessary

5.4. From the Patient Test screen press the Accept or OK key

5.5. The Enter Strip Lot screen displays. Scan the strip lot number on the vial. Confirm lot number and press Accept.

5.6. The Enter Patient Identification (ID) screen will display. Confirm patient ID using two unique identifiers. Scan the armband barcode (patient's account number) or manually enter the patient's hospital identification number and press the accept key

5.7. For patients that have not been assigned a hospital identification number or an account number (i.e. during health centre downtime procedures, triage, newborns, patients from out of country, or no patient identification), a unique identifier (HCN or name), must be manually entered.

5.8. The Insert Strip screen displays. Insert a test strip as shown on the screen.

5.9. The fetal scalp blood sample will be collected as outlined in *IWK Heath Policy # 7076 Fetal Scalp Blood Lactate Determination*. The specimen will be handed to the approved user for the lactate meter.

5.10. Gently wipe the outside of the collection tube with a tissue to remove excess blood or paraffin on the end of the tube. Quickly dab the end of the collection tube to the tissue to remove a small amount of blood in order to have a "clean" sample.

Note: Do not hold a sponge or tissue to the end of the collection tube as this will potentially empty the tube.

5.11. Touch/tap the end of the collection tube to the end of the test strip until the well of the test strip is completely filled. The meter will beep (if the sound is turned on) and a 13 second countdown begins.

5.12. Keep the meter in a horizontal position to prevent any excess blood from entering the meter strip port.

> **Note: DO NOT** touch the test strip to the blood sample a second time – a flow error may occur. If a flow error occurs, discard the test strip and repeat with a new strip.

5.13. View test result. It will appear in 13 seconds.

5.14. Add comments, as appropriate, from a predefined list, prior to accepting the result (Press comment, select from the list, press accept, then accept the result). Choose comments that pertain to the situation only. Patient Comments Include:

- Unit policy/Dr order
- Repeat sample
- Procedure Error
- Train/Recert sample

5.15. To accept the result, press the Accept or OK button**.**

5.16. Communicate patient results to doctor. Refer to Appendix D - Interpreting Fetal Scalp Blood Lactate Results and Appendix E - Limitations/Interferences for the Lactate Meter

5.17. Document results on patient health record indicating POC Scalp Lactate result, unit of measure (millimoles/litre), date, time, and initials of both the tester and sample collector.

5.18. Log off the meter and remove isolation sleeve (if applicable)

5.19. Clean and disinfect the meter. Refer to Appendix F - Cleaning and Disinfection and Meter Maintenance.

5.20. Discard collection tube and test strip in appropriate sharps disposal container. The gauze and the isolation sleeve (if used) in the garbage.

5.21. Return the meter to the docking station for charging and uploading of test results. Refer to Appendix G – Data Management for the Nova StatStrip™ Lactate Meter.

6. **Review Previous Results, as needed.**

400 results can be recalled and reviewed for 30 days

6.1. From the Patient Test screen, press Review. The review Result screen displays

6.2. Select how to sort the results by pressing ID, Time/Date, or Type

6.3. Press Page Down or Page Up to scroll through the stored results

6.4. Select the result that you want to review

6.5. Press View to view the selected results

REFERENCES

Nova BioMedical (2012). *StatStrip Lactate Hospital Meter Instructions for Use Manual. Retrieved on June 30th, 2023 from* NOVA BIOMEDICAL STATSTRIP QUICK REFERENCE MANUAL Pdf Download | ManualsLib

RELATED DOCUMENTS

Policies

IWK Health Policy 3101- Point of Care Testing

IWK Health Policy 201.1 - Application of Routine Practices

IWK Health Policy IC 301.2 - Application of Additional Precautions

IWK Health Policy 1100 - Patient Identification

IWK Health Policy 1900 - Unidentified (Unknown) Patients Identification Process

IWK Health Policy IC 205.2 - Hand Hygiene

IWK Health Policy 7076 - Fetal Scalp Blood Lactate Determination

Appendices

Appendix A – Definitions

Appendix B – Nova StatStrip™ Lactate Meter Components, Test Strips and Control Solutions

Appendix C – Troubleshooting for the Nova StatStrip™ Lactate Meter

Appendix D - Interpretation of Fetal Scalp Blood Lactate Results

Appendix E - Limitations/Interferences

Appendix F - Cleaning and Disinfection and Meter Maintenance

Appendix G – Data Management for the Nova Stat Strip Lactate Meter

APPENDIX A - Definitions

Nova StatStrip Lactate Hospital Meter: A handheld, battery powered, in vitro diagnostic laboratory instrument that works in conjunction with Nova Biomedical lactate electrochemical test strips to measure lactate in a whole blood sample, a Quality Control solution, linearity, or proficiency solutions**.**

Point-of-Care Testing (POCT): Testing performed outside a central laboratory environment, by authorized health care personnel, generally nearer to, or at the site of the patient/client, with the result leading to possible change in the care of the patient.

Certified users for the Nova StatStrip™ Lactate Meter are Laboratory Technologists and Birth Unit Registered Nurses, who have completed both certification requirements.

Quality Control (QC) is defined as 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.

Quality Control Solutions are external control materials available from Nova Biomedical for verifying the integrity of the Lactate Hospital meters and test strips. Two levels (L1 and L3) of ready-to-use liquid controls, formulated at clinically relevant levels, are used for the lactate meter.

Point of Care Coordinator (POCC) is a senior technologist in the Core Lab who works collaboratively with health professionals at the point of care to implement POCT safely, to help achieve/maintain staff competency, and to adhere to the Department of Pathology and Laboratory Medicine quality management program.

Point-of-Care Testing (POCT) is testing that is performed outside of the laboratory, by authorized health care personnel, near or at the site of the patient with utilization of the results leading to possible change in the care of the patient.

Operator Identification (ID) Each operator will have a unique identifier. This identifier must be entered into the StatStrip™ meter before any testing can be performed. It is a breach of security to allow another person to use his/her operator ID. All results can be traced to the end operator.

Patient ID Code The patient ID Code will either be the patients' 6-digit hospital identification number which must be entered manually or scan the barcode on the patient's armband which is linked to the account number (consisting of 11 characters [2 letters and 9 digits). Patient ID length must be between 5 and 20 characters long.

APPENDIX B - Nova StatStrip™ Meter Components, Test Strips and Control Solutions

Nova StatStrip™ Meter Components

Test Strip Port: Located at the top of the meter where the strip is inserted; avoid exposure to liquids

- Temperature sensor, located above the test strip port, will indicate errors outside the range of 15-40°C
- Touch Screen: Front panel of the meter
- On/Off Button: Located on the front bottom of the meter; powers the meter
- Soft Key at base of touch screen – can be used to enter through screens
- Scanner: Infrared laser scanner for barcodes located at the bottom of the meter; avoid eye contact, scanner turns off in 5 seconds if not used
- Battery Pack: Located in the back of the meter; allows the meter to hold its' charge
- Docking Station/Base Unit: Recharges battery and for downloading/uploading data; keep meter docked to keep battery fully charged and for data transferring, indicated by a green light

StatStrip™ Test Strips

- Always store unused test strips in their original container with the cap tightly closed
- Store at room temperature (<30°C), do not refrigerate or freeze
- Do not store in high heat and humidity
- **Always** date bottle when opened and include discard date
- Once opened the bottle is good for 90 days (3 months)
- Discard expired strips
- Unopened strips can be used until manufacturer expiry date
- Discard test strips in the sharps container

StatStrip™ Control Solutions (Level 1 and Level 3)

- Store at room temperature
- QC Material is stable unopened until the expiry on the bottle, when stored at 15°- 30°C
- **Always** date bottle with the expiry date when opened
- Once opened the QC is stable for 3 months
- Before each use the controls must be mixed gently, do not shake.
- If the tip becomes crystallized with the QC solution wipe with a tissue
- Distributed by the POCC or lab designate

APPENDIX C - Troubleshooting for the Nova StatStrip™ Meter

Meter alerts:

- **Battery Low**- Charge the battery in the Docking Station.
- **Test Strip Was Removed**- The test has been cancelled, repeat the test with a new test strip. Leave the test strip in place until the result is displayed on the screen.
- **Temperature**- The meter will only work within the temperature range of 15°C to 40°C.
- **Bad Sample**- Insert a new strip and rerun the test. If the error code persists, perform the test using an alternate test strip vial, meter, or alternate method and inform the POCC.
- **Replace Strip** – Occurs after insertion of strip or occurs during analysis. Insert another strip and retest. If the error code persists, perform the test using an alternate test strip.
- **Flow Error** – The specimen was incorrectly drawn into the test strip due to either insufficient or incorrect sample application. Repeat the test with a new strip. If the error code persists, perform the test using an alternate test strip vial, meter, or alternate method and inform the POCC.
- **Transfer Failed** – Server refuses to allow dialog with meter, or Connections to server was broken. Please check the network settings, status of your network or contact POCC.
- **Transfer Failed**- The meter was removed before data transfer was complete. Please re-dock the meter.
- **Quality Control (QC) Failed –** Repeat QC test and be sure the correct QC level was used. Mix QC solution gently and discard first drop ensuring there are no bubbles in the application. If QC continues to fail, try another vial of test strips. If the meter continues to fail, take the meter out of service and notify the POCC.

APPENDIX D – Interpretation of Fetal Scalp Blood Lactate (FSBL) Results

If the FSBLS result is:	Interpretation:	Action:
Less than 3.5 mmol/L	NORMAL	Repeat the fetal scalp blood sampling in 1 hour if the electronic fetal monitor (EFM) abnormality persists, or sooner if required. If the EFM returns to normal, there is no need to repeat sampling.
3.5 – 4.8 mmol/L	PRE-ACIDOTIC	Repeat fetal scalp blood sampling in 30 minutes or consider delivery if a significant change has occurred since the previous fetal scalp blood sampling measurement.
Greater than 4.8 mmol/L	ACIDOTIC/ABNORMAL	Stop oxytocin. Immediate delivery is indicated. Notify attending physician if not already done.
LOW	Result is less than 0.3 mmol/L and outside of the measurable range	N/A
HI	Result is more than 20.0 mmol/L and outside of the measurable range	N/A

APPENDIX E - Limitations/Interferences

Interfering Substances
Lactate Interferences

The StatStrip™ Lactate Hospital Meter exhibits no interference from the following substances, up to the following concentration levels:

Tested Interfering Substances Concentration Level in millimoles/litre (mmol/L)
Acetaminophen 0.66 mmol/L
Ascorbic Acid 0.57 mmol/L
Bilirubin 0.26 mmol/L
Cholesterol 12.9 mmol/L
Creatinine 0.53 mmol/L
Dopamine 0.53 mmol/L
Ephedrine 0.055 mmol/L
Glucose 49.7 mmol/L
Ibuprofen 2.33 mmol/L
L-Dopa 0.25 mmol/L
Methyl-Dopa 0.042 mmol/L
Salicylate 1.87 mmol/L
Tetracycline 0.62 mmol/L
Tolazamide 0.48 mmol/L
Tolbutamide 1.67 mmol/L
Triglycerides 8.78 mmol/L
Uric Acid 1.05 mmol/L

APPENDIX F - Cleaning and Disinfection and Meter Maintenance

Nova StatStrip™ Meter Isolation Sleeves Isolation sleeves are designed to fit the StatStrip™ meter and are used to provide an added barrier to help prevent excessive contamination. They must be used for all patients who require additional precautions. Lactate meters are to be inserted into the isolation sleeves prior to entering the patient's room. The meter must be thoroughly cleaned and disinfected with a hospital approved disinfectant wipe after removing the isolation sleeve. Whenever possible, a meter should be dedicated to the patient requiring additional precautions.

CLEANING AND DISINFECTION

- Always wear appropriate Personal Protective Equipment (PPE) when handling contaminated equipment
- Always clean and disinfect the meter after patient use (before placing in docking station)
- Clean the outside of the meter with a hospital approved disinfectant wipe ensuring cloth is damp, **not saturated** and allow to air dry for the appropriate contact time. Several wipes may be required if the meter is heavily soiled.
- **Avoid** getting fluid/moisture in the test strip port or base connector.
- Dispose of wipes and gloves
- Clean hands using alcohol-based hand rub or soap and water

MAINTENANCE

- Meters that do not function correctly (i.e. do not turn on, battery issues, etc) are to be returned to the Point of Care Coordinator. A replacement meter will be assigned to the unit.
- Additional cleaning of the strip port may be required if QC solution or blood enters the strip port. Use a Nova StatStrip™ wrapped in an alcohol wipe to clean the inside of the strip port. Allow to dry thoroughly and run QC.

APPENDIX G - Data Management for the Nova StatStrip Lactate Meter

The Nova StatStrip™Lactate Meter stores patient test data, Quality Control (QC) test data, and other information relating to the patient test. The Docking Station is used to send results to the POCT middleware software (Aegis) in the laboratory and recharge the meter battery.

Currently at IWK Health, all results will be manually recorded by the operator. The results will be clearly defined with units of measure, as a point of care test (POCT) signed and dated by the tester on the patients chart according to *IWK Health Policy #7076 Fetal Scalp Blood Lactate Determination*.

All data for the StatStrip™ meter is held on the POCT middleware software database within the laboratory. The database allows for a complete audit trail of Nova StatStrip™ Lactate Meter testing which includes but is not limited to dates, times, operators, patient results and QC. QC is reviewed by the Point of Care Coordinator or laboratory designate. The clinical Division Head of Biochemistry reviews the QC results monthly or whenever problems occur.

Audits will be performed for QC and patient testing compliance. Certification may be revoked during audit reviews if there is a repeated non-compliance to policies and procedures.

As part of the Quality Management system**,** all new lactate meters will be validated for linearity, accuracy and precision studies prior to implementation.

Version History

(To Be Completed by the Policy Office)

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)