Fetal Scalp Blood Lactate Test Using Nova Statstrip™ Lactate Meter Policy

**Purpose**
To provide fetal scalp blood lactate testing at patient bedside, aiding in the clinical management of women in labour. The Nova Lactate Stat Strip has the same calibration, maintenance and quality control criteria as equivalent accredited laboratory devices.

**Scope**
- **Includes:** Delivery Suite midwives and medical staff only.
- **Excludes:** Other parts of the DHB

**Definitions**

**Certified staff**
Staff who have attended training and been approved to operate the system.

**Point of care testing (POCT)**
Medical laboratory testing performed near or at the site of the patient with the result leading to possible change in the care of the patients.¹

**Calibration**
The process of testing and adjusting values obtained from an instrument or other measuring device to provide a known relationship between the response measurement and the value of the analyte measured by the procedure.

**Quality control QC**
To monitor the status of an analysis to maintain its performance within desired limits

**External quality assessment (EQA) or Proficiency testing (PT)**
To assess the performance of an analyser by an external challenge of a blind sample, results of which are assessed against a reference or peer review.

Equipment

Nova StatStrip Lactate™ Hospital Meter and docking station

A connectable lactate meter that interfaces to middleware NovaNet with the capability to connect to Concerto.

Consumables
All consumables (except Fetal Scalp Kits) for the meters are held and issues by the laboratory. Contact Biochemistry Ext 8660

<table>
<thead>
<tr>
<th>Item</th>
<th>Name</th>
<th>Supplied by</th>
</tr>
</thead>
</table>
|                      | LAC – Test strips 2 pottles of 25 strips REF 47486 | NZMS
NZ Medical and Scientific
2a Fisher Crescent
Mt Wellington
Auckland 1060
P.O. 132400
Sylvia Park
Auckland 1644 |
| Strips                | Stat_Strip LAC control level 1 REF 47553
Stat_Strip LAC control level 2 REF 47554 |                                                 |
| Control Solutions     | Battery for Lactate Meter Spare found at back of docking station. Battery for Lactate Meter Ref NB46827-1 |                                           |
Fetal Scalp Kits held and ordered by Delivery Suite

<table>
<thead>
<tr>
<th>Fetal Scalp Kits</th>
<th>Rocket Fetal Scalp Kits Code:R57024 Compatible with Radiometer ABL90</th>
<th>USL Medical Order from Stores</th>
</tr>
</thead>
</table>

Clinical background
Fetal scalp blood lactate is used in cases of non-reassuring or abnormal fetal heart rate pattern during labour to help diagnosis fetal hypoxia.

Test principle
The test strip is an electrochemical sensor, using the enzyme lactate oxidase to convert lactate to a current. The amount of current that is produced depends on how much lactate is in the blood. The strips are calibrated to be equivalent to laboratory plasma lactate.

The strip has a multi well system
- One well measures electrochemical interferences e.g. ascorbic acid, uric acid, paracetamol, oxygen saturation, and bilirubin.
- One well measures Haematocrit
- Lactate well subtracts electrochemical interferences and corrects for Hct providing a true interference free result

The strips have a Gold backing. Gold is stable so
- No variance lot by lot
- No calibration required
- No check strip required
- Strip is stable environmentally and on handling

No result if strip is short sampled. No result if air bubbles present

Limitations
Sample:
- Fresh whole blood venous or arterial specimens.
- It is not for use with capillary specimens. The performance characteristics have not been determined for capillary samples.
- Not used to test newborns in the USA

---

2 NOVA biomedical REF47486 package insert LPN-485005D 2012-06
• It has not been verified for fetal scalp samples. ³

Fetal scalp sampling is shown on the video below: Rocket Fetal Scalp sampling video

Samples should be analysed as soon as possible post collection. Lactate concentrations increase in whole blood samples post collection due to continued metabolism of glucose and production of lactic acid.

**Interferences**
No interference from common substances, see above.

Lactate measurement range 0.7-20 mmol/L
- Meter will display LO if result is <0.7
- Meter will display HI if result is >20.0

Temperature range the meter reads at is 15° C to 40° C

**Roles and responsibilities**
The overall responsibility for and risk from using the Nova Lactate Stat Strip is with Delivery Suite. The laboratory acts as resource to help maintain the quality of lactate results.

It is the Delivery Suites responsibility to:
- Maintain the analyser
- Ensure meter is fully charged
- Ensure staff who use the meter are trained, and records are kept of that training.
- Maintaining supply of in date strips and controls

Point of Care Co-ordinator (or other trained Laboratory Scientist) and vendor is responsible for:
- Training the certified trainers.
- Run QC Twice weekly and remove non performing meter
- Approving QA practice
- Auditing POCT QA compliance
- Providing PT samples

All operators are responsible for:
- The quality of the testing they perform
- Use their operator ID and patient NHI in Nova StatStrip when performing a test.

³ personal communication Trish Snegirev NZMS 26 April 2013.
**Staff training**
All staff using the Nova Lactate Stat Strip must receive training in the use of the equipment including the quality and maintenance programmes. Competence is maintained and accessed annually.

Training
- Hands on training
- E learning Quiz

Recertification
- QC and at least one patient sample within twelve months
- E Learning Quiz

**Quality Assurance**

**QC**
LAC control 1 (low) and LAC control 2 (Normal) are run twice weekly by the Point of Care Co-ordinator (or other trained Laboratory Scientist)

**EQA**
A whole blood comparison is run monthly by the Laboratory

**Calibration**
Not required

**Stock control**
Test strips and controls must be within date and have been opened no longer than 90 days

- Lot number and expiry date can be found on outer box and bottle of strips and on box and bottle of QC material
- Test strips and controls should be stored at room temperature but below 30°C
- Test strips and controls are viable for 90 days after opening.

Midwives responsible for opening new bottle of strips must write open date and discard date and initial

Midwives opening a new bottle of control solution should write the date opened and initial
**Maintenance and troubleshooting**

**Docking/Charging Station**

When the meter is not in use, place it into the Docking/Charging Station. This enables the meter to remain fully charged and connects the meter to the computer network.

- The right light is **green** when the battery is fully charged or **amber** when charging

**Testing Errors**

Analysis error - The test strip was removed or lost electrical contact with the meter before completing the test. Insert a new test strip and repeat the test.

Flow error - Insufficient sample. Sample was applied incorrectly to the test strip. Do not pull the pipette away until the countdown begins.

Battery Low - Replace the battery or, place the meter into the Docking Station.

**Battery Replacement**

If there is a spare fully charged battery, it can be changed to allow for continuous operation.

1. Press the Power Button to place the meter into Sleep Mode. This allows the operator approximately 20 seconds to change the battery without losing the Date/Time settings.
2. Push down on the two cover latches to release the cover. Take the battery cover off the back of the meter. (Fig. 1)
3. Push up on the battery latch. Remove the drained battery. (Fig 2)
4. Replace with a fully charged battery. (Fig 3)
5. Replace the battery cover.
6. Place the drained battery into the Charging Station.
7. Dock the meter.
**Infection Control**

All PoCT Lactate Stat Strip testing complies with Infection Control standards and Hutt Valley DHB Infection Control policy.

Clean the meter using hospital wipes and dry after every patient test.

- Do NOT immerse the meter or hold the meter under running water
- Do NOT spray the meter with a disinfectant solution
**Procedures**

**Patient samples**  
1. Take the meter off the docking station. Turn meter on by pressing power button (1) if necessary. If message on screen press **OK**.

2. Enter your operator ID (computer login number) by selecting ‘LOGIN’ on the screen or by pressing the **OK** button (2). Enter your number manually or Select ‘SCAN’ or press **OK** to scan your operator ID. The scanning laser is at the bottom of the meter (3).

3. ‘Patient Test’ is on top right corner. Accept or press **OK** (NB you cannot proceed with patient testing if control tests are required to be performed).

4. Follow screen instructions to analyse a patient sample. Scan strip lot. The barcode is on the potsles.

5. At Enter Patient mothers NHL. Accept **OK**

6. The strip is inserted into the port on top of the meter (4)

7. **Clinician to collect sample**

---


5 Nova StatStrip Lactate Monitoring System Quick Operating Guide
8. Make sure you use the “clean” end of the capillary tube for testing. The end that was against the fetal head MAY be contaminated with paraffin, ethyl glycine or amniotic fluid. This may affect the result you may get.

9. Touch end of capillary to test strip and expel in one fluid movement. Results will appear in 13 seconds.

   **Keep Meter flat during analysis**

10. Accept **OK** results.
11. Refer to clinical policy for interpretation of the results.
12. Log out of meter

<table>
<thead>
<tr>
<th>Lactate result</th>
<th>Interpretation of Result</th>
<th>Action based on Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 4.2 mmol/l</td>
<td>Reassuring</td>
<td>Continue to observe CTG</td>
</tr>
<tr>
<td>4.2 – 4.8 mmol/l</td>
<td>Suspicious</td>
<td>Repeat FBS in 30 minutes</td>
</tr>
<tr>
<td>&gt; 4.8 mmol/l</td>
<td>Pathological</td>
<td>Deliver urgently</td>
</tr>
<tr>
<td>&gt; 5.7 mmol/l</td>
<td>Pathological</td>
<td>Category 1 CS</td>
</tr>
</tbody>
</table>

13. Wipe down the meter using hospital wipes and dry. Place back on the docking station for charging.
1. Take the meter off the docking station and if necessary turn meter on by pressing power button (1)

2. Enter your operator ID by selecting ‘LOGIN’ on the screen or by pressing the OK button (2). Enter your login number manually or Select ‘SCAN’ or press ‘OK’ to scan your operator ID. The scanning laser is at the bottom of the meter (3).

3. Select ‘Control Test’ on the screen to proceed

4. Follow screen instructions to analyse control samples. The strip is inserted into the port on top of the meter (4).

5. Apply QC samples

6. Check QC results against the control ranges stated on the control material. If within the acceptable ranges, continue to use.

7. If outside the acceptable ranges, repeat. Continue if within range.

8. If still outside range, repeat using fresh QC material. Continue to use if within range.

9. If still outside the acceptable ranges, remove lactate meter from use and notify on duty nurse manager. The lactate meter may give false results if used further,
Contacts and HELP
Hutt Valley DHB POCT coordinator  Bernice Smith Ext 8660
NZMS representative  Kevin Holwill 09 259 4062 or mobile 022 410 4977
During day shift hours  Karen Waklin ACNM
Out of day shift hours  Midwife in charge

References:
CCDHB Policy ID 1.8254 Fetal Heart Monitoring
RANZCOG Fetal surveillance Education Program – Maternal Heart Rate accessed 11/09/2012

Appendix:
Appendix 1: Nova StatStrip Lactate Hospital Meter OPERATOR ACCREDITATION FORM

Hutt Maternity Policies provide guidance for the midwives and medical staff working in Hutt Maternity Services. Please discuss policies relevant to your care with your Lead Maternity Carer.