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Facilitated by: Karen Daniels, CMM	Last reviewed: December 2018
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Fetal Scalp Blood and Cord Blood Lactate Test Using Nova Statstriptm Lactate Meter Policy

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.

Purpose

To provide fetal scalp blood and cord 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: Midwives, theatre nurses, theatre technicians and medical staff.

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

¹ ISO 22870 (2006) Point-of-care testing (POCT) – Requirements for quality and competence.

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.

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Equipment

Nova StatStrip
Lactate™ Hospital Meter
and docking station



Touch screen



Test strip port

OK accept keys



Sleep mode On/Off

Scanner

A connectable lactate meter that interfaces to middleware NovaNet and Bioconnect. This middleware holds all the operator, device, reagent and results data. Fetal scalp results are available electronically in Concerto only.

Consumables

All consumables (except Fetal Scalp Kits) for the meters are held and issues by the laboratory. Contact Ext 8512

Item	Name	Supplied by
 Strips	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
Control Solutions	Stat_Strip LAC control level 1 REF 47553 Stat_Strip LAC control level 2 REF 47554	
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

Fetal Scalp Kits	Rocket Fetal Scalp Kits Code:R57018 Compatible with Radiometer ABL90	USL Medical Order from Stores
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Clinical background

Fetal scalp blood lactate is used in cases of 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. ² 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 short samples or if there are 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
- It has not been verified for fetal scalp samples. ³

Fetal scalp sampling is shown on the video below:

² NOVA biomedical REF47486 package insert LPN-485005D 2012-06

³ personal communication Trish Snegirev NZMS 26 April 2013.

[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 0.3-20 mmol/L
Meter will display LO if result is <0.3 mmol/L
Meter will display HI if result is >20.0 mmol/L

Temperature range the meter reads at is 15° C to 40° C
Strips should be stored at Room Temperature 15° C to 30° C

Roles and responsibilities

The overall responsibility for testing and result management of the Nova Lactate Stat Strip is with the trained operators with a valid certificate. The laboratory acts as resource to help maintain the quality of lactate results.

It is the Operators responsibility to:

- Maintain the analyser
- Ensure meter is fully charged
- Ensure staff who use the meter are trained.(Clinical Nurse Educators or other certified trainers
- Maintaining supply of in date strips and controls
- Running weekly QC
- The quality of the testing they perform
- Use their operator ID and patient NHI in Nova StatStrip when performing a test.
-

Point of Care Co-ordinator (or other trained Laboratory Scientist) and vendor is responsible for:

- Training the certified trainers.
- Approving QA practice
- Auditing POCT QA compliance
- Reviewing Ko Awatea ELearning and loading new operators and recertifying operators.
- Replacing the QC every 3 months

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 through annual recertification

Training

- Hands on training
- E learning Quiz

Recertification

- E Learning Quiz
- Hands on training if returning after >1 year lapse in certification

Quality Assurance

QC

LAC control 1 (low) and LAC control 2 (Normal) are run once per week by the ACMMs.

EQA

A whole blood comparison at three levels is run weekly 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 pottle 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.

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.
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.

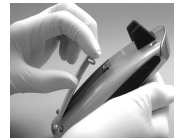


Fig 1

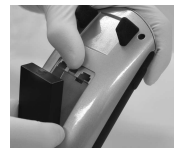


Fig 2



Fig 3

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 microfibre 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



Sample Collection

Trained and credentialed clinicians collect two samples from the fetal scalp.

The cord should be double clamped and arterial and venous cord blood samples taken as soon as possible after birth and within 10 minutes. Use a blood gas syringe to collect at least 2 mls of blood (this ensures you can send to the laboratory for further analyser if required) Take further samples if the venous and arterial sample have a lactate <0.6 difference.



Procedures

Patient samples

Refer to the "Performing a Patient Lactate Test" quick guide

QC Samples

Refer to the "Performing a QC Test" quick guide

Fetal Scalp Sample Application to strip



Remove capillary tube from fetal scalp kit holder.



Move blood down to clean end of capillary tube.



Position the capillary tube vertically so a drop forms at the end of the tube so a drop forms strip.

Clinical t ion

Lactate result	Action based on Result
< 4.2 mmol/l	Continue to observe CTG
4.2 – 4.8mmol/l	Repeat FBS in 30 minutes time
> 4.8 mmol/l	Deliver urgently
> 5.7 mmol/l	Category 1 delivery

Contacts and HELP

Hutt Valley DHB POCT coordinator Bernice Smith Ext 9518 or

During day shift hours Maternity ACNM

Out of day shift hours Midwife in charge

References:

Heinis, A.M.F., Spaanderman, M.E.A., Klien Gunnewiek, Lotgering, F.K. Scalp blood lactate for intra-partum assessment of fetal metabolic acidosis. ACT Obstetrica et Gynaecologia Scandinavia 2011; 90: 1107-1114

Heinis, A.M.F., Dinnissen, D., Spaanderman, M.E.A., Lotgering, F.K., Klien Gunnewiek, J.M.T. Comparison of two point of care testing (POCT) devices for fetal lactate during labor. Clin Chem Lab Med 2012; 50(1) 89-93

ISO 22870 (2006) Point-of-care testing (POCT) – Requirements for quality and competence.

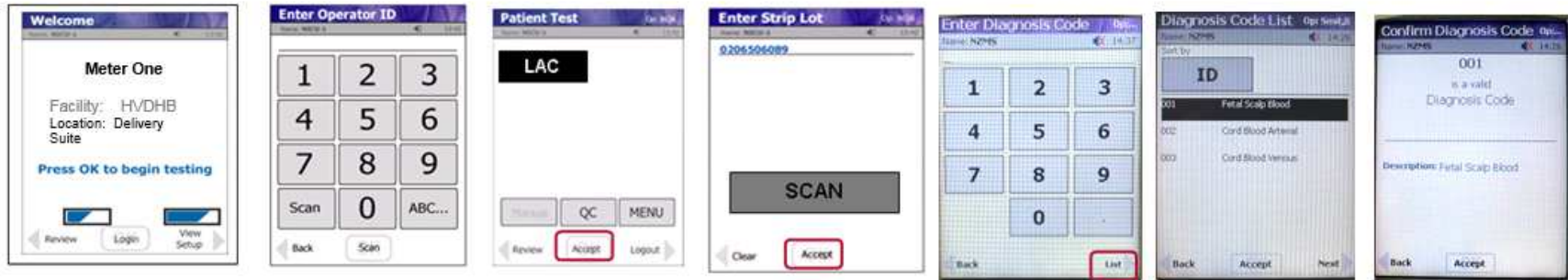
RANZCOG Fetal surveillance Education Program – Maternal Heart Rate accessed 11/09/2012

Seymour, C.W. et al Temperature and time stability of whole blood lactate: implications for feasibility of pre-hospital measurement. BMC Research Notes 2011; 4: 169

Appendix 1



PERFORMING A PATIENT LACTATE TEST

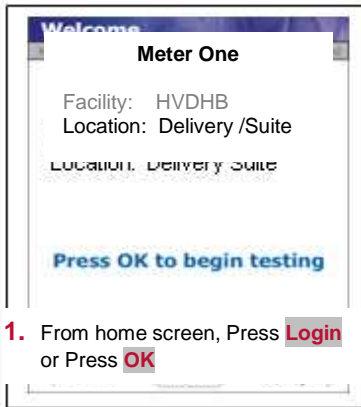


1. From home screen, Press **Login** or Press **OK**
2. Enter Operator ID by pressing **Scan** or enter via keypad
3. From Patient Test screen, press **Accept**.
4. Enter Lot number of strips by pressing **Scan**.
5. Press **LIST** to put in sample type
6. Select sample type from list and press **accept**.
7. Confirm sample type by pressing **accept**.



8. Enter or scan baby or mothers NHI (remember this is where the results will reside in MAP).
9. Confirm patient identification by pressing **Accept**. Or back to change or if "not valid patient ID" check NHI if correct use either Override If incorrect press back and enter correct NHI
10. Insert strip into meter. Close **cap** of strips firmly
11. When prompted on screen apply sample collected according to hospital protocol
12. Results available after 13 seconds. To accept result press **Accept** or to reject it press **Reject**
You can add comments if you wish.

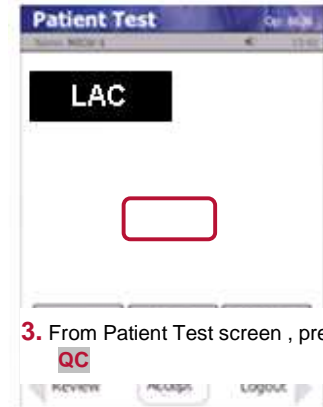
PERFORMING A QC LACTATE TEST



1. From home screen, Press **Login** or Press **OK**



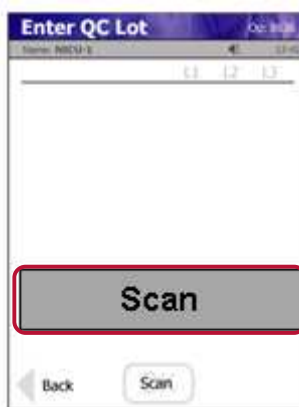
2. Enter Operator ID by pressing **Scan** or enter via keypad.



3. From Patient Test screen , press **QC**



4. Enter Lot number of strips by pressing **Scan**.



5. Enter QC lot no by pressing **Scan**.



6. Insert strip into meter. Close pottle of strips firmly



7. Gently invert QC bottle three times. Remove lid and wipe top of dropper. Apply end of dropper to test strip.



8. Results available after 13 seconds. To accept result press **Accept** or to reject it press **Reject**

Informed Consent

The right of a consumer to make an informed choice and give informed consent, including the right to refuse medical treatment, is enshrined in law and in the Code of Health and Disability Consumers' Rights in New Zealand. This means that a woman can choose to decline treatment, referral to another practitioner, or transfer of clinical responsibility. If this occurs follow the process map on page 18 of the Referral Guidelines (Ministry of Health, 2012).