FETAL SCALP LACTATE TESTING TO ASSESS FETAL STATUS DURING DELIVERY
Comparison of Two Point of Care Meters to confirm existing clinical guidelines

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The current Canadian guideline on fetal health surveillance (JOGC 29 Suppl 4, 2007) recommends use of fetal scalp pH to assess fetal acidemia during delivery. Recent international studies and guidelines have supported the use of fetal scalp lactate as a valid and viable alternative to fetal scalp pH. Most supportive evidence has been based on work using the Lactate Pro meter.

In July 2011, the Lactate Pro meter (5uL), (Arkray USA, Inc., Medina MN) was implemented at the point of care, in the delivery suites. Decision cut-offs for this application as reported in the literature had been determined using the Arkray Lactate Pro.

The recent discontinuation in the manufacture of the current Lactate Pro meter, and unavailability in the North American market have prompted us to evaluate the Nova StatStrip Lactate (0.6uL), (Nova Bionmedical, Waltham, MA) which was recently approved for whole blood lactate by Health Canada. Currently the laboratory is engaged in a study with nursing to evaluate the use of the Nova StatStrip Lactate in the application of Fetal Scalp Lactate and the assessment of fetal acidemia during delivery.

Methods: Phase 1: NOVA StatStrip Lactate and Lactate Pro meters were evaluated for precision, accuracy and linearity. Comparison of lactate was performed using residual venous, arterial, and capillary whole blood specimens. Testing is performed in the laboratory against the GEM® Premier™ 4000.
Phase 2: (September 2013 – September 2014). Ward implementation of the NOVA StatStrip Lactate comprised of NOVA StatStrip Lactate training of the bedside nurse with supportive documentation and training materials. Currently both meters are being compared at the clinical setting with simultaneous testing using the same fetal scalp sample obtained according to usual practices, from a woman in active labour who has an atypical or abnormal tracing requiring fetal acidemia evaluation. Published clinical guidelines for fetal scalp lactate will be assessed using current cut-off values: normal <4.2 mmol/L; 4.2 – 4.8 mmol/L repeat within 30 minutes; and >4.8 mmol/L where immediate delivery is indicated.

Results of Laboratory Evaluation:
Phase 1: Precision for aqueous QC, NOVA StatStrip Lactate at levels of 0.6 mmol/L and 6.4 mmol/L showed 7.0% CV and 4.9% CV respectively. Precision for aqueous QC, Lactate Pro Arkray at levels of 3.4 mmol/L and 8.8 mmol/L showed 2.8% CV and 2.3%CV respectively. Comparison with GEM4000 showed a regression of NOVA StatStrip Lactate = 0.96*GEM + 0.84, r2 = 0.99, versus Lactate Pro Arkray = 0.95*GEM + 0.15, r2 = 0.95.

Phase 2: Estimated sample of 350 fetal scalp collections over a 12 month period with 10-15 samples between 4.2-4.8 mmol/L and >4.8 mmol/L is planned. Preliminary data from same fetal scalp samples (n=123) showed good agreement, NOVA StatStrip LAC = 1.03*Lactate Pro + 0.02 and r2 = 0.85. Of n= 123 < 4.2 mmol/L n= 108; 4.2-4.8 mmol/L n=6; >4.8 mmol/L n=9. Concordance of values for clinical cut-off NOVA StatStrip Lactate versus Lactate Pro results < 4.2 mmol/L (104/107 compared; 1 sample 4.2-4.8; 2 samples >4.8); Lactate Pro results 4.2-4.8 mmol/L (4/7 compared; 2 samples < 4.2; 1 sample >4.2) >4.8mmol/L (9/9 compared with 1 sample < 4.2).

Conclusion: At BC Women's Hospital, preliminary findings found the NOVA StatStrip Lactate to display excellent analytical performance and to yield similar values to the Lactate Pro Arkray, indicating that the same clinical decision cut-offs may be adopted as per current literature.