

# Analytical evaluation of a POC lactate meter for measurement of fetal scalp lactate concentrations intrapartum

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**Background:** A request was made to the POC director, by an Obstetrician for the implementation of POC fetal scalp lactate testing in the birthing units of The Ottawa Hospital. Fetal scalp lactate measurement can be used intrapartum as an early marker of anaerobic metabolism which can lead to neonatal hypoxia and metabolic academia. Previous studies have shown that fetal scalp lactate concentrations can help to guide clinical decisions during labour, with elevated fetal scalp lactate concentrations (> 4.8 mmol/L) indicative of the presence of academia. This suggests the need for expedient delivery, often via operative delivery.

Here, we evaluated the analytical performance of the Nova StatStrip POC lactate meter prior to use of the meter as part of a clinical study in the birthing unit at The Ottawa Hospital.

**Methods:** The analytical evaluation included precision and linearity studies along with a method comparison to lactate measured by the GEM 4000 blood gas instrument, used in the central lab at The Ottawa Hospital. Two concentrations of quality control material were measured (n=20) to calculate within-day imprecision. Commercial linearity material, supplied by the manufacturer, was used for linearity studies. A mixture of arterial and venous whole blood specimens were used for the method comparison. Lactate concentrations were measured by the Nova StatStrip Lactate meter in a mixture of arterial and venous specimens (n=34) received in the central laboratory for routine blood gas analysis (including lactate measurement). The specimens were analyzed first by the GEM4000 blood gas instrument, followed immediately by analysis using the StatStrip Lactate meter.

**Results:** Within-day imprecision of the StatStrip Lactate meter was 13% (CV) at a lactate concentration of 0.7 mmol/L and 2.6% (CV) at a lactate concentration of 6.0 mmol/L. The StatStrip lactate measurement strips demonstrated linearity between lactate concentrations of 0.6-17.0 mmol/L. When compared to lactate measured by the GEM 4000 blood gas instrument, the StatStrip Lactate measurements agreed well for lactate measurements < 5.0 mmol/L. The StatStrip Lactate demonstrated a negative bias, compared to the GEM 4000, for measurements > 5.0 mmol/L, ranging from 0.3-1.7 mmol/L (measured lactate values ranging from 5.7-12.1 mmol/L).

**Conclusions:** The analytical evaluation established that the Nova StatStrip lactate meter is suitable for use in a clinical study in the birthing units at The Ottawa Hospital. The aim of the clinical study will be to determine whether the operative delivery rate is decreased when obstetricians have the ability to measure fetal scalp lactate at the POC. The StatStrip Lactate meter shows suitable precision and linearity for this purpose. There is no reference measurement method for lactate; however a comparison of lactate measured by the StatStrip Lactate to that measured by the GEM4000 blood gas instrument demonstrated suitable agreement within the range of lactate concentrations relevant for use intrapartum.