

# Clinical evaluation of Statstrip® Lactate for use in fetal scalp blood sampling

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**Introduction:** Point-of-Care Testing (POCT) of fetal scalp blood lactate is used as an alternative for pH analysis (gold standard) in fetal scalp blood sampling (FBS) during labor. Lactate measurements have not been standardized and values vary with each device used. The aim of this study was to evaluate POCT by StatStrip Lactate (SSL) in the clinical setting in comparison to pH (RLpH) and lactate (RLL) by RapidLab.

**Materials and methods:** A total of 325 FBS samples were obtained from 139 women. Parallel sampling of SSL and RLpH/RLL was performed in 247 samples. Outcome measures were failure rate of both methods and the agreement between RLpH, RLL and SSL. Sensitivity, specificity, positive (PPV) and negative predictive value (NPV) for SSL cut-off values indicating either reassuring fetal status or immediate intervention were calculated.

**Results:** Failure rates for RLpH, RLL and SSL were 22%, 40% and 8% respectively. SSL showed poor agreement with RLpH ( $R^2 = 0.204$ ) and excellent agreement with RLL ( $R^2 = 0.742$ ). Sensitivity specificity, PPV and NPV for SSL  $\leq 5.7$  mmol/l to predict RLL  $\leq 5.4$  mmol/L were 97%, 73%, 95% and 80% respectively. For a cut-off  $\geq 7.0$  mmol/l to predict RLL  $\geq 6.6$  mmol/L these were 100%, 98%, 70% and 100% respectively.

**Conclusions:** SSL had a higher success rate compared to RLpH/RLL and showed excellent agreement with RLL. Test characteristics to predict normal or low pH were moderate, but high to predict normal or high lactate. As such, we implemented POCT fetal scalp lactate by SSL in conjunction with pH in FBS on our ward and monitored this process. Additional performance and reliability data from this two-year period will be presented.