

## Total bilirubin assay using GEM Premier 4000: promising results for jaundice diagnosis in maternity wards.

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**Background:** Newborn jaundice, an usually benign condition that typically resolves with appropriate nutritional intake and phototherapy, can progress to severe hyperbilirubinemia in 8 -10 % of healthy newborn infants leading in some cases to kernicterus. Kernicterus results from fixation of bilirubin on brain when total serum bilirubin (TSB) concentration exceeds the infant's neuroprotective defenses, stressing the need for accurate TSB measurement. This assay should be available quickly for a safe management of newborn jaundice.

**Objective:** To develop bilirubin measurement with an equipment available in maternity wards: GEM Premier 4000 a compact blood gas CO-Oximeter and electrolyte analyzer for point-of-care and laboratory testing (Instrumentation Laboratory). After a first step of adaptation of bilirubin measurement on the GEM premier 4000, the CNRHP (Centre National de Référence en Hémobiologie Périnatale) evaluated the accuracy of this assay and its potential impact on monitoring of the jaundice in newborn.

**Methods:** Blood specimen of neonates sent to CNRHP were tested at the same time with the reference method in use in CNRHP (diazotation methodology on Synchron CX4-CE-Beckman-Coulter) using plasma and on GEM 4000 using whole blood (two volumes were tested: 150 or 100 µl) . On GEM 4000, total bilirubin was measured simultaneously with total haemoglobin and haemoglobin fractions. The spectrophotometric assay on the GEM 4000 used the CO-Oximetry module. Spectral measurements between 480 and 650 nm and multi-variate regression were used for the bilirubin assay.

**Results:** A total of 67 samples were analysed with TSB concentration ranging from 30 to 393 µmol/l. Whole blood total bilirubin levels on GEM 4000 were well correlated with those on plasma obtained with reference method on CX4-CE analyzer ( $r=0.95$ ),  $y=1.12x -27.86$  (Deming regression). The correlation was found to be stronger with high values of TSB (over 100 µmol/l). No significative difference was found between the results obtained with the two different whole blood volumes.

**Conclusion:** This new assay system requires only a small volume of whole blood to perform quantitative analysis of bilirubin (100 µl instead of 500 µl required for the reference method). Furthermore, haemoglobin concentration is measured on the same blood sample and the coupling of the two analysis is an advantage for monitoring haemolytic disease of newborn. GEM 4000 provides accurate values for high levels of TSB and can substitute the evaluation of transcutaneous bilirubin currently used in maternity departments. At last, the main advantage of this analyzer in maternity wards is the short delay needed for accurate TSB ensuring paediatricians better management of jaundiced newborns.