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Analytical performance evaluation of the Diazo Total Bilirubin assay on the Atellica CH Analyzer for use in neonates

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Background

Total bilirubin (TBil), a byproduct of hemoglobin catabolism, is a critical biomarker in the evaluation of neonatal hyperbilirubinemia. In newborns, even modest elevations in bilirubin levels are closely monitored due to the risk of kernicterus, a serious and potentially irreversible neurological complication associated with excessive bilirubin exposure. Accurate measurement of TBil is therefore essential for early identification, risk stratification, and clinical management of hyperbilirubinemia in neonates. This study evaluated the reference range and method comparison of the Diazo TBil (D_TBil) assay[1] on the Atellica CH analyzer using prospectively collected neonatal serum samples.

Material and Methods

Reference Interval

- Healthy neonatal serum samples with no history of hyperbilirubinemia were prospectively collected (23 samples: 0–1 day; 27 samples: 1–2 days; 26 samples: 3–5 days).
- All samples were tested using the Atellica CH D_TBil assay.
- Results were compared with published reference ranges, and ranges were considered verified if ≤10% of the samples fell outside of the established limits.

Method Comparison

- A total of 113 prospectively collected serum samples from healthy neonates and those diagnosed with hyperbilirubinemia, along with 11 contrived samples prepared by spiking neonatal serum with unconjugated bilirubin, were tested using the Atellica CH 930 D_TBil and Roche COBAS 8000 TBIL (BILT3) assays.
- Weighted Deming regression was used to assess slope, y-intercept, and correlation between the two methods.
- Method comparison studies were conducted consistent with the governing standard *CLSI EP09C-ED3: Measurement Procedure Comparison and Bias Estimation Using Patient Samples*. Individual neonate serum samples were tested on the Atellica CH system and Roche COBAS 8000 system. The method comparison was completed with the Atellica CH D_TBil assay as the test assay and the Roche COBAS 8000 TBIL assay as the predicate assay. Individual samples were obtained from outside vendors through the external testing site and specimen acquisition group. Eleven samples were spiked with unconjugated bilirubin material supplied with Certificate of Analysis from Frontier Specialty Chemicals to cover the assay measuring interval. A single replicate was processed for each sample on both systems.

Results

Reference Interval

- The Atellica CH D_TBil assay demonstrated complete concordance with physician-assigned classifications of healthy versus hyperbilirubinemic neonates when evaluated against the established clinical nomogram.[2]
- Age specific expected TBil values were verified for healthy neonates aged 0–1 day (<8.00 mg/dL), 1–2 days (<12.00 mg/dL), and 3–5 days (<16.00 mg/dL), consistent with clinical expectation.

Table 1. Reference interval verification summary

Specimen Type	Neonate Age (Day)	Reference Interval (SI)	# of Samples	# of Samples > RI[a]	% Samples > RI
Serum	0–1	< 8.00 mg/dL (< 136.80 µmol/L)	23	0	0
Serum	1–2	< 12.00 mg/dL (< 205.20 µmol/L)	27	0	0
Serum	3–5	< 16.00 mg/dL (< 273.60 µmol/L)	26	0	0

[a]*Reference Interval*

The verification testing data for healthy neonates were acceptable and met the acceptance criteria, consistent with clinical expectation.

Table 2. Reference interval acceptance criteria for healthy neonates were verified for the D_TBil assay on the Atellica CH Analyzer

Neonate Age (Day)	Reference Interval
0–1	< 8.00 mg/dL (< 136.80 µmol/L)
1–2	< 12.00 mg/dL (< 205.20 µmol/L)
3–5	< 16.00 mg/dL (< 273.60 µmol/L)

Method Comparison

The Atellica CH D_TBil assay demonstrated agreement with the Roche COBAS TBIL assay across the neonatal concentration range, 0.10–21.81 mg/dL, with a regression of y = 1.06x – 0.02 mg/dL and r = 0.997, indicating strong analytical concordance within clinically relevant bilirubin levels.

Table 3. Performance of the Atellica CH D_TBil assay compared to the Roche COBAS TBIL (BILT3) assay.

Sample Type	Comparison Assay	Comparison Analyzer (x)	n	r	Regression Equation	Sample Range
Serum	Roche COBAS TBIL (BILT3)	Roche COBAS 8000	124	0.997	y = 1.06x – 0.02 mg/dL (y = 1.06x – 0.34 µmol/L)	0.10–21.81 (1.71–372.95)

n: number of samples; r: correlation coefficient.

The design requirements for method comparison were met for the Atellica CH D_TBil assay compared to the Roche COBAS TBIL (BILT3) assay. When analyzed by Weighted Deming regression, the two measurement methods recovered samples spanning the measuring interval, with a slope of 1.00 ± 0.10, intercept 0.00 ± 0.10 mg/dL, and a correlation coefficient (r) ≥ 0.950.

Weighted Deming fit and percent difference plots on the Atellica CH Analyzer for sample range indicated in Table 3 are shown for the Atellica CH D_TBil assay versus the Roche COBAS TBIL (BILT3) assay in Figure 1.

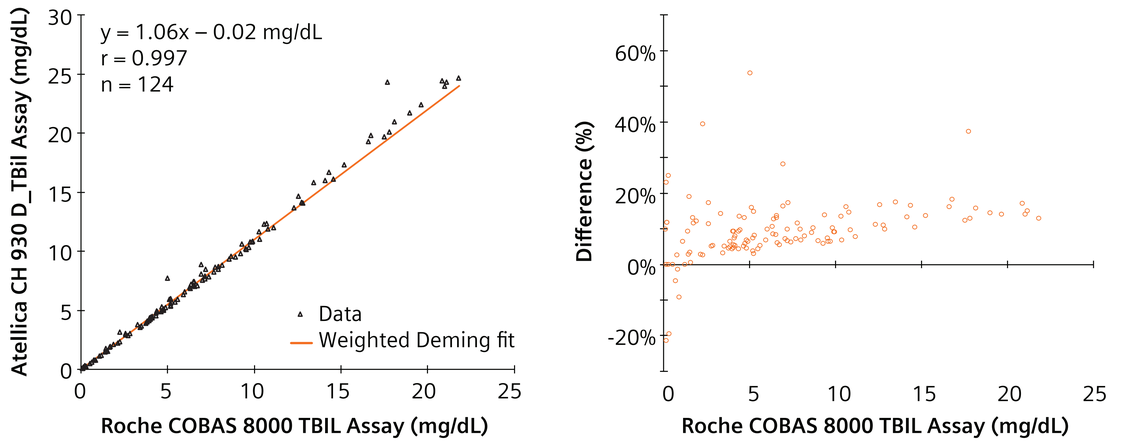

Figure 1. Weighted Deming regression and difference plot for the Atellica CH D_TBil assay compared to the Roche COBAS TBIL (BILT3) assay

Conclusion

Using neonatal serum samples, the Atellica CH D_TBil assay demonstrated clinically acceptable agreement with the Roche COBAS TBIL (BILT3) assay and verified age-appropriate neonatal reference values, supporting its use for accurate assessment and management of neonatal hyperbilirubinemia.

References

1. *Diazo Total Bilirubin (D_TBIL) assay. Atellica CH Analyzer. 11537552_EN Rev. 02, 2026-XX Draft 2026-01-26 20:05:23*
2. *Kemper A.R., et al. Clinical Practice Guideline Revision: Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation. Pediatrics 2022:150(3).*

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