NSW Health

Variations in Serum Bilirubin assay method and results in neonates

SAFETY INFORMATION 012/25

Issue date:	4 September 2025
Content reviewed by:	Expert advisory group for Neonatal Hyperbilirubinaemia and Jaundice Identification and Management review, Senior Neonatal Advisor, Senior Neonatologist, NSW Health Pathologist
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	Inform clinicians of variation in Serum bilirubin (SBR) results between different analysers, pathology services and assay methods.
ACTION REQUIRED BY:	Maternity, Neonatal and Paediatric Managers and Clinicians
REQUIRED ACTION:	1. Distribute this safety notice to all relevant clinicians and clinical departments who screen for or treat neonatal hyperbilirubinaemia. 2. Ensure relevant staff are aware of risks when interpreting or comparing Serum Bilirubin results from different pathology laboratories, analysers and assay methods. 3. Ensure that staff are aware of risks when a neonate is transferred between healthcare facilities. Different pathology laboratories may use differing assay methods and variation in SBR result may delay urgent treatment. 4. When there is clinical concern from Point of Care Testing (POCT) verify with SBR. POCT is only to be used to screen and guide treatment.
DEADLINE:	N/A
We recommend you also inform:	Directors, Managers and Staff of: • Neonatal services • Newborn and paediatric Emergency Transport Service (NETS) • Maternity services (including midwifery home) • Emergency Departments • Paediatric services • Pathology services
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	September 2027

Contact: Agency Clinical Innovation
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Situation

During the NSW Health *Neonatal Jaundice and Hyperbilirubinaemia Identification and Management in Neonates ≥ 32 weeks gestation* guideline review, the expert advisory group was alerted to potential risks in neonatal serum (total) bilirubin levels (SBR) due to variability between assays from different manufacturers. Two types of risk were noted:

1. Specimens collected at different locations, e.g. when a neonate is transferred from one facility to another
2. Comparability between Point of Care Testing (POCT) whole blood bilirubin (BR) and laboratory serum bilirubin (SBR).

Both risks are due to inadequate international standardisation of bilirubin assays. The safest approach is to use the same testing method for monitoring serial results.

Background

Jaundice is a common condition in neonates caused by elevated levels of bilirubin, a by-product of haemoglobin degradation. Approximately 60% of term and 80% of preterm neonates will develop jaundice. The presence of visible jaundice is an unreliable indicator of hyperbilirubinaemia because the interpretation of colouring is subjective. Some neonates may need treatment to prevent hyperbilirubinaemia related neurotoxicity caused by unconjugated bilirubin which can cross the blood brain barrier, resulting in permanent brain injury.

Serum Bilirubin (SBR) remains the reference standard for diagnosing hyperbilirubinaemia and is the recommended test for guiding management, including escalation and de-escalation of care for neonates with jaundice.

There are two different analysers (Abbott and Roche) used for measuring SBR in NSW Health pathology laboratories. These analysers may produce discordant SBR results in neonates who are transferred between hospitals.

The use of POCT (whole blood BR) enables prompt results for monitoring neonatal jaundice and are a valuable tool as the whole blood volume requirement is very small (65uL). However, if significant discordance between POCT BR and SBR values are found repeat testing is indicated. SBR results are more reliable than POCT BR and should be used as the preferred reference in clinical decision-making.

A recent publication from Sydney reported a neonate who was transferred to a tertiary hospital for severe hyperbilirubinaemia but on arrival was reclassified into a lower risk category due to 20% difference in SBR between laboratories (2). The variation between laboratory BR methods in Sydney is shown (see appendix 1).

Assessment

This difference in analyser results may lead to unnecessary treatment and transfer of neonates. The treatment or transfer of a neonate may separate mother from her baby, causing maternal and family distress, disruption to bonding and breastfeeding challenges.

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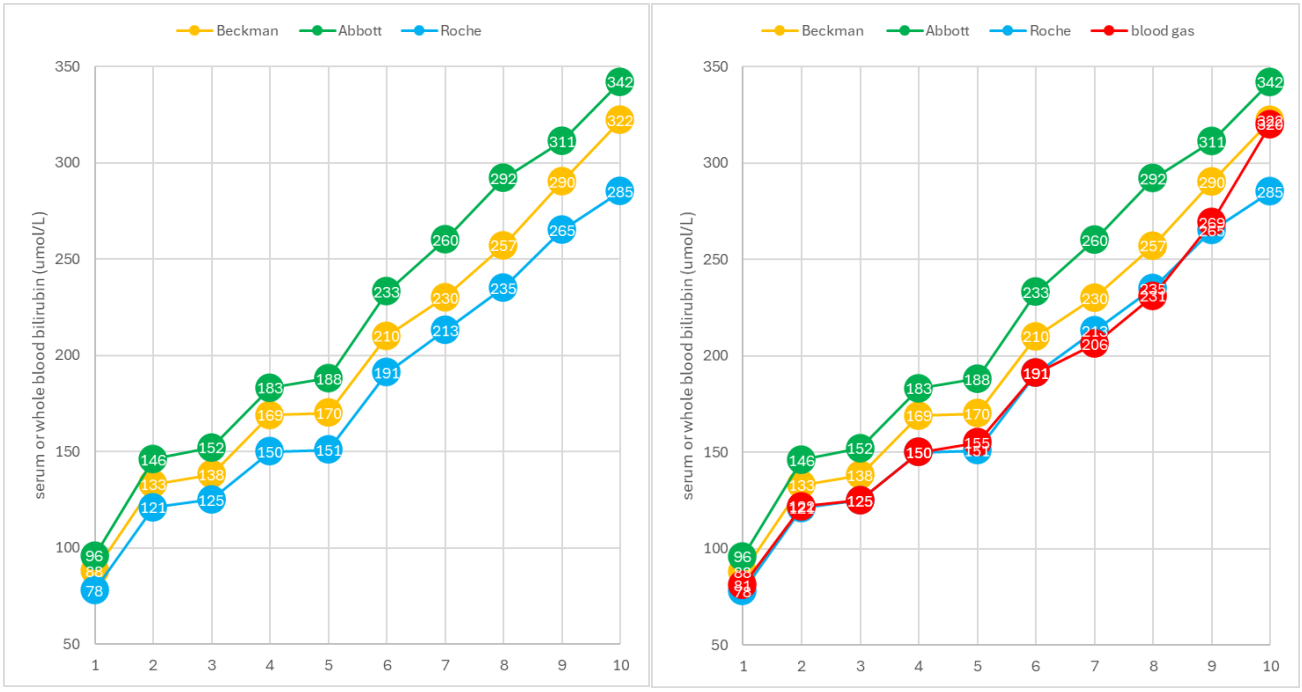
Recommendations

- Review and update education packages to ensure awareness of the potential variation of results between analysers, assays and methods used at local facilities. Ensure local procedures in place to follow up discrepancies.
- Educate staff that neonatal SBR results are not interchangeable between laboratories, and that clinical judgement is used to guide treatment when discordant SBR results are received.
- Ensure POCT of bilirubin (e.g. blood gas analyser) is used to screen and guide treatment only, always verify with an SBR if there are clinical concerns.
- Do not delay treatment if there is clinical concern.
- Establish processes that ensure regular calibration of point of care and laboratory devices.

Further information

Appendix 1



Figures above. 10 neonatal samples were analysed and across the concentration range. A. Serum BR methods (Beckman, Abbott and Roche). B. Same graph with POCT whole blood BR (ABL90) added in red. The Abbott method (green) is consistently the highest and Roche method (blue) the lowest. The POCT. The whole BR reads closer to the Roche SBR but exceed Roche method when > 200 umol/L when it is closer to the Abbott SBR (green) (ref 1; adapted with permission).

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References

1. Berthe AMvdG, de Graaf JP, Bertens LCM, et al. Screening and treatment to reduce severe hyperbilirubinaemia in infants in primary care (STARSHIP): a factorial stepped-wedge cluster randomised controlled trial protocol. BMJ Open. 2019;9(4). DOI: https://doi.org/10.1136/bmjopen-2018-028270
2. Thomas, D., Warner, J., Jones, G., Chung, J., Macey, D., Screnci, A. & Ryan, J. (2022). Total bilirubin assay differences may cause inconsistent treatment decisions in neonatal hyperbilirubinaemia. *Clinical Chemistry and Laboratory Medicine (CCLM)*, *60*(11), 1736-1744. https://doi.org/10.1515/cclm-2022-0749
3. Review on “Evolution of Methods of Bilirubin Estimation” Dr. P.V.Puppalwar1, Dr Kalyan Goswami2, Dr. Archana Dhok IOSR Journal of Dental and Medical Sciences (IOSRJDMS). ISSN: 2279-0853 Volume 1, Issue 3 (Sep-Oct. 2012), PP 17-28