Technical Bulletin

APPLICATION NOTE – JAUNDICE AND KERNICTERUS

Diagnostic Need: There is a growing concern that Hyperbilirubinemia and the disease it causes, Kernicterus, is reemerging in the newborn population. According to health care agencies, reported cases are on the rise. Hospital nurseries, Neo-natal clinics, and Pediatricians' offices are the first line of defense to detect and treat for this disease. Early detection and treatment are critical, and have been proven extremely effective in the prevention of this condition.

Practical Need: Point of Care (POC) test dramatically reduces patient wait time and eliminates follow-up calls and the associated time and effort spent by the staff. Reimbursement covers disposables and instrument costs.

The Problem: Kernicterus, a lifelong brain syndrome, can include cerebral palsy, mental retardation, hearing loss, and death. It is caused by Hyperbilirubinemia, a severe and untreated elevation in a newborn's bilirubin concentration. Bilirubin is a natural, toxic byproduct of decomposing red blood cells. In newborns, the liver may not be developed well enough to effectively filter the blood and rid the body of this excess bilirubin. Visual detection of one of the main symptoms, jaundice, has been proven to be dangerously unreliable and not a good indicator of the level of this toxin. To this end, various skin colors can mask the jaundice symptom.

The Solution: A POC test for Total Bilirubin is needed to measure all neonates, particularly those in high-risk groups. Reichert UNISTAT® Bilirubinometers have performed this test for over 40 years. It incorporates direct spectrophotometry to measure Total Serum Bilirubin, resulting in rapid answers with results that correlate at 0.99r^2 with the "Gold Standard" HPLC laboratory method.[1] Obtaining this measurement quickly and accurately will allow the physician to make an appropriate diagnosis and to begin necessary treatment immediately.

[1] H A Barko, G L Jackson, W D Engle;Evaluation of a point-of-care direct spectrophotometric method for measurement of total serum bilirubin in term and near-term neonates;Journal of Perinatology; 01 Feb 2006; 26, 100 – 105.

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The UNISTAT® Bilirubinometer has been FDA cleared since 1992 as a device to measure the levels of bilirubin (total and unbound) in the blood (serum) of newborn infants and to aid in calculating the risk of bilirubin encephalopathy (kernicterus).

Key features and benefits of this instrument: ✓ Easy to use with limited training. ✓ POC testing reduces patient wait time and eliminates costly follow-up activities. ✓ Small sample of 20uL required and no dilution. ✓ Reimbursable test with low disposable cost of < $1.30 per test.

✓ Corrects for Oxyhemoglobin and results are not typically impacted by hemolyzed samples.

Product Recommended:

Reichert UNISTAT® Bilirubinometer, 115v, Reichert Cat # 1310310C

Reichert UNISTAT® Bilirubinometer, 230v, Reichert Cat # 1310311C

Why choose Reichert to solve this important measurement:

- ✓ Unparalleled accuracy for a POC test that matches wet laboratory testing.
- ✓ No dilutions and chemistry reagents required, making the Reichert instrument less complicated and less costly to operate. ✓ Automatic calibration setting simply places a reusable calibration standard (supplied with the unit) into the sample chamber.
- ✓ The Reichert UNISTAT® Bilirubinometer is the standard for POC measurement. A large installed customer base is further testament to the quality and performance that our Bilirubinometer delivers. ✓ Produced in Depew, New York, USA to the highest standards of quality. ✓ Best-In-Class warranty. ✓ Technical, demonstration, rental, and service support. ✓ Service contracts available.
- ✓ Expertise and knowledge in optical measurements for over 100 years.

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