



Frequently Asked Questions (FAQs) about the Reichert UNISTAT® Bilirubinometer

Can you provide references from UNISTAT® Bilirubinometer endusers? – The UNISTAT® Bilirubinometer has been used by medical practitioners since the 1970s and has been evaluated in several independent studies that have resulted in published papers. The UNISTAT® Bilirubinometer is accurate to HPLC standards, considered the Gold Standard for Accuracy. Since Reichert sells this instrument through Clinical/Scientific Distributors, we do not have a database of endusers from which to supply references. We can, however, reference the work of Dr. Gregory Jackson, MD at the University of Texas Southwestern Medical Center/Parkland Hospital in Dallas TX. He and his team evaluated the UNISTAT® Bilirubinometer to determine if it was a suitable Point of Care (POC) instrument for the determination of Total Serum Bilirubin (TSB). This study was initiated after the American Academy of Pediatrics (AAP) published the guideline entitled “Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation.” The results of the study, co-authored by Dr. Jackson and Dr. William Engle, were published on-line on the website of The Journal of Perinatology in January 2006 at <http://www.nature.com/jp/journal/v26/n2/abs/7211436a.html>. An internet search of both Drs. Engle and Jackson will find numerous studies and published papers regarding pediatric bilirubin.

Why is the Reichert UNISTAT® Bilirubinometer better than other instruments or test methods? – First, it is well accepted that a TSB measurement is the most accurate. Blood is drawn via a heel stick and centrifuged. The undiluted serum is then inserted into the UNISTAT® Bilirubinometer for measurement, completed and accurate in under five seconds. Since our instrument measures undiluted serum, no expensive reagents, chemicals, or dilutions are required to obtain a measurement. The only recurring cost is the disposable specimen cuvette, used to carry the serum, which costs less than \$1.00 USD each. The UNISTAT® has been found to correlate very well against the diazo Jendrassik-Grof with blank method commonly found in Hospital Chemistry Laboratories. Using Bland-Altman analysis, our UNISTAT® correlates to the Olympus AU640 analyzer (common in the hospital laboratory) to $r=0.99$. As a Point of Care provider, most pediatric practices would want their TSB results to correlate to results a hospital lab would obtain. In fact, we have recently placed several UNISTAT® Bilirubinometers in pediatric practices because their TSB measurements on competitive instruments were not matching the hospital lab test results.

Does the Reichert UNISTAT® Bilirubinometer offer a good return on investment? With no reagents, chemicals, and dilutions required, the cost of ownership is reduced. The only recurring expense is the specimen cuvette. The calibration cuvette is glass; therefore, it can be used over and over.

Is testing for TSB really that important? It certainly is. The AAP Guidelines recommend POC testing. It is also known that bilirubin concentration actually peaks in a neonate at 72 hours. Most newborns have been discharged from the hospital well before that time so the follow-up visit to the pediatrician’s office is the opportunity to measure TSB. Left unmeasured, a newborn with high bilirubin levels could develop hyperbilirubinemia. Left untreated, hyperbilirubinemia can lead to kernicterus, a brain disorder that can result in cerebral palsy, mental retardation and even death. This can be preventable if it is detected and the newborn is treated for it. **What is the CPT Reimbursement Code and how much is it?** – The CPT Code is # 82247 for Total Serum Bilirubin (TSB). The reimbursement may vary from state to state. The amount of \$9.00 USD per test was reported to us by an end user in Kentucky.

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