Technical information

Sample Features

Sample Type	Newborn infant whole blood
Sample Size	35 µL
Hematocrit	25 – 70%

Bilistick Reader

Units	mg/dL and µmol/L
Range	1 mg/dL to 40 mg/dL / 17.1 µmol/L to 684.0 µmol/L
Measure System	Photometric based in two wavelength at 465 nm and 570 nm
Resolution	± 0.1 mg/dL / 1.0 µmol/L
Repeatability	Till 25 mg/dL: Within ± 0.2 mg/dL / 3 µmol/L Over 25 mg/dL: Within ± 0.6 mg/dL / 10 µmol/L
Test Time	< 2 minutes depending on hematocrit
Sensors	Optical sensor
Optical filters	Glass protection inside the optical chamber
Calibration	Standard for periodic calibration Blank self-calibration after Test Strip insertion
Hemolysis	Automatic system for hemolysis detection
Results Report	Color display, dimension 36.0 x 29.0 mm
Interface	Mini B - USB port
Operating Conditions	Temperature: 15°C to 40°C Relative Humidity (non-condensing): 5 to 75%
Storage Conditions	10 °C to 40 °C low humidity, non-corrosive gas atmosphere.
Long-term Storage	1- In case of long-term storage, store the reader at 15-25 °C, low humidity, non-corrosive gas atmosphere. 2- When storing the reader for a period longer than six months, charge the battery at least once a month
Power Supply	Mini B - USB – DC 5V – 0.5A – 2.5 W
Charging Conditions	Average charging time: 4 hours (while no bilirubin test are been performed) Charging temperature: 15 – 40 °C (Recommended 15-25°C) Voltage: 5V
Dimensions	31.3 mm H x 72.9 mm W x 140 mm D
Net Weight	220 gr.
Shipping Weight	760 gr.

Power Supply

Power Supply	USB – DC 5V – 1.5A - 7.5 W UL Certificated Accessory
USB Cable	Type A - Mini B (5pin) M/M USB 2.0 UL Certificated Accessory

Bilistick Test Strips

Cell-Plasma Separator	Glass fiber
Reading membrane	Nitrocellulose
Plastic Cassette	High Impact Polystyrene (HIPS)
Dimensions	3.70 mm H x 15.00 mm W x 48.65 mm D
Net Weight	1.86 gr.

Bilistick Sample Transfer Pipettes

Composition	Plastic and Glass
Total Length	70.00 ± 0.20 mm
Glass Tube Diameter	1.60 ± 0.02 mm
Drawing Capacity	35.00 ± 2.00 µL

Contact information

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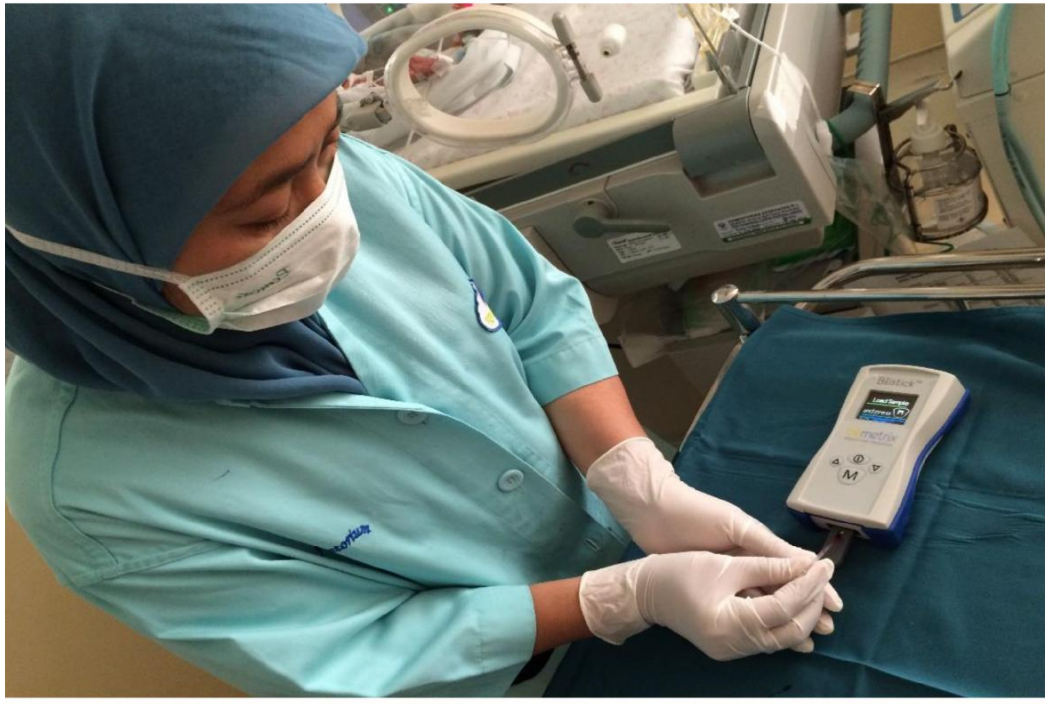

Bilistick® System

In Vitro POC Bilirubin Assay

Measuring what needs to be measured

Measuring what needs to be measured

The Bilistick® System is a Point of Care bilirubin assay able to provide early diagnosis of hyperbilirubinemia by measuring total serum bilirubin concentration.

It is composed by the Bilistick® Reader, a portable rechargeable battery reflectance reader; Bilistick® Test Strips, test strips with a cell-plasma separator coupled with a nitrocellulose membrane, both encased in a plastic cassette; and Bilistick® Sample Transfer Pipettes, used for loading the appropriate volume of blood on the test strip.

The test requires collection of a small blood sample directly from a heel stick or a test tube, by using a Sample Transfer Pipette, and its application on a Test Strip once it was already inserted in the Reader.

Bilistick® System benefits

Portable and usable everywhere, afterwards a short training

Minimally invasive, requiring only one blood drop

Does not need the use of reagents and results are immediate

Comparable to laboratory exams, diagnose immediately the hyperbilirubinemia

Able to measure in blood samples with wide range of PCV

Applicable to newborn babies of all ethnicities

Bilistick® Reader Maintenance products

Bilistick® Calibration Kit

Bilistick® Cleaning Kit

Simple Steps for trustable results

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1

Insert Bilistick® Strips

2

Collect blood sample

3

Load sample

4

Press M key and wait for result

5

Check bilirubin concentration in the display

6

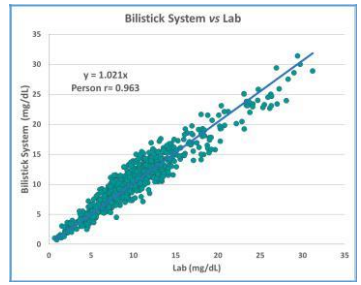
Check the Bilistick Test Strip

Because precision matters…

The Bilistick® System has been extensively validate both in Western Countries as well as in Low and Middle Income Countries, covering different environments and condition in which it can be used around the world.

By comparing Bilistick® bilirubin results with classic methodologies routinely used in high quality laboratories of hospitals, it has been demonstrated an excellent correlation of bilirubin results.

Several studies supports the use of Bilistick® System for routine Total Serum Bilirubin screening. It may facilitate early identification of newborns requiring phototherapy treatment thus contributing to substantial reduction of the prevalence of ABE/kernicterus in LMICs.



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- EClinicalMedicine 1 (2018) 14–20 – "Diagnostic Performance Analysis of the Point-of-Care Bilistick System in Identifying Severe Neonatal Hyperbilirubinemia by a Multi-Country Approach"