Pediatric Total BILIRUBIN

**Intended Use**
Spectrum Diagnostics Total Bilirubin single reagent is intended for in-vitro quantitative, diagnostic determination of Total Bilirubin in human serum on both manual and automated systems.

**Background**
The average level of the bilirubin produced in humans from different sources ranges between 250 to 300 mg/day, of which 85% is derived from the heme moiety of the haemoglobin released from senescent erythrocytes that are destroyed in the reticuloendothelial system. The remaining 15 % is produced from erythrocytes destroyed in the bone marrow and from catabolism of other heme containing proteins such as cytochromes and myoglobin.

After it is produced in the peripheral tissues, bilirubin is transported to the liver in association with albumin. In the liver, bilirubin is conjugated with glucuronic acid for solubilization and subsequent transport through the bile duct and elimination via the digestive tract.

Disease or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it, cause the levels of unconjugated (indirect) bilirubin to increase in the circulation. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

**Method**
Modified Bergh & Muller method (Colorimetric, End point)

**Assay Principle**
The azobilirubin produced by the reaction between bilirubins and the diazonium salt of 3,5-dichlorophenyl diazonium tetrafluoroborate shows maximum absorption at 540 nm. The intensity of the colour produced is proportional to the quantity of bilirubin which has reacted. In the presence of caffeine and surfactants as accelerators, conjugated and free bilirubin participate in the reaction in the same way, so that the level of total bilirubin is determined.

**Reagents**

**Reagent (R)**
- 3,5-dichlorophenyl diazonium tetrafluoroborate: 0.2 mmol/L
- Caffeine: 50 mmol/L
- Surfactants and stabilizers: < 3%

**Serum Blank Reagent (SB)**
Buffered Saline

For further information, refer to the Pediatric Total Bilirubin reagent material safety data sheet.

**Precautions and Warnings**
Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

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Quality Control
Normal & abnormal commercial control serum of known concentrations should be analyzed with each run.

Methods Comparison
A comparison between Spectrum Diagnostics Total Bilirubin reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.978 was obtained.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 0.1 mg/dl (1.71 µmol/l)

Linearity
The reaction is linear up to Bilirubin concentration of 25 mg/dl (427.5 µmol/l)

Interfering substances
Serum, plasma

Haemolysis
Avoid haemolysis since it interferes with the test.

Lipemia
Lipemic specimens interfere with the test.

Drugs
Theophyllin and propranolol may cause artificially low total bilirubin levels.

Expected Values
Total Bilirubin
Newborns premature (3-5 d) 10-14 mg/dL (171-239 µmol/l)

Newborns:
(>48 h) 4.0 - 8.0 mg/dL (68-137 µmol/l)
(<48 h) 6.0 - 10.0 mg/dL (103-171 µmol/l)
(<24 h) 2.0-6.0 mg/dL (34-103 µmol/l)

Analytical Range
0.1 - 25 mg/dl.

Waste Disposal
This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal. S56: dispose of this material and its container at hazardous or special waste collection point. S57: use appropriate container to avoid environmental contamination. S61: avoid release in environment. refer to special instructions/safety data sheets.

References


ORDERING INFORMATION

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<th>QUANTITY</th>
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Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the reults is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.