Bilirubin Total Kit
CliniQuant - FSR
DCA Method

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Bilirubin Total Reagent	R2 Sodium Nitrite Reagent
TBLFSR-01	4 x 25ml	4 x 25ml	1 x 6ml
TBLFSR-02	2 x 200ml	2 x 200ml	1 x 12ml

INTENDED USE
This reagent is intended for quantitative determination of total bilirubin concentration in human serum or plasma.

CLINICAL SIGNIFICANCE
Bilirubin a breakdown product of hemoglobin in the reticulo-endothelial system is transported to the liver in association with albumin. This bilirubin is water insoluble known as indirect or unconjugated bilirubin. In liver, bilirubin is conjugated to glucuronic acid to form direct bilirubin or conjugated bilirubin and excreted into intestine via biliary system.

TOTAL BILIRUBIN = INDIRECT BILIRUBIN + DIRECT BILIRUBIN

Total Bilirubin is elevated in obstructive conditions of bile duct, hepatitis, cirrhosis of liver and hemolytic disorders. Indirect Bilirubin is elevated by pre-hepatic causes such as hemolytic disorders or liver diseases. Monitoring of indirect bilirubin in neonates is of special importance as it is the indirect (free) bilirubin bound to albumin that is able to cross the blood brain barrier more easily increasing the danger of cerebral damage.

PRINCIPLE OF THE METHOD
Total (conjugated and unconjugated) bilirubin couples with a DCA reagent in the presence of a surfactant to form azobilirubin. The diazo reaction is accelerated by the addition of surfactant as a solubilizing agent. The increase in absorbance at 546 nm due to azobilirubin is directly proportional to the total bilirubin concentration.

KIT COMPONENTS
Composition :

R1 - Bilirubin Total Reagent : Surfactant 5%, Sulfanilic Acid 6.24 g/l, HCl 10 ml/l, 2,4 Dichloroaniline 0.22 g/l

R2 - Sodium Nitrite Reagent : Sodium Nitrite : 0.075 g/l

MATERIALS REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY
Reagents are ready to use. Keep away from direct light sources.

Stability: unopened bottle up to expiration date on labels +15 to +30°C.

REAGENT DETERIORATION
Discard the working reagent if it fails to achieve assigned assay values of fresh control sera.

WARNINGS AND PRECAUTIONS
1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN
Serum, plasma (heparinate only). Bilirubin in serum is stable for one month at -20°C or 7 days at 2-8 °C.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Factor	12
Filter 1 (nm)	546
Filter 2 (nm)	670
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	5
Reaction Direction	Increase
Reference Low	0.1
Reference High	1.2
Linearity Limit	30

CE
Meril Diagnostics Pvt. Ltd., Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India. T+91-260-3052100, F +91-260-3052125, W www.merillife.com
EC REP Obelis s.a., Bd General Wahis 53, 1030, Brussels, Belgium. T +(32) 2 732-59-54, F +(32) 2 732-60-03, E mail@obelis.net

TEST PROCEDURE

Dispense	Blank	Test
Reagent 1	1 ml	1 ml
Reagent 2	25 µl	25 µl
Distilled water	100 µl	-
Sample	-	100 µl
Mix, incubate for 5 min at 37°C. Read absorbance at 546/ 670 nm against reagent blank. Reading should be taken immediately after incubation is over (2 minutes maximum).		

RESULT CALCULATION

Serum/plasma:

Total Bilirubin mg/dl = Abs. of Test- Abs. of Blank x 12

SI conversion factor: 1 mg/dl x 17.1 = 1 µmol/l

EXPECTED VALUES

Total Bilirubin:

Adults: 0.1 – 1.2 mg/dl OR 1.7 – 20.5 µmol/l

Infants: 1.2 – 12 mg/dl OR 20.5 – 205 µmol/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

When using the recommended Calibrator (BioCal), calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 30 mg/dl or 513 µmol/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection of Total Bilirubin is 0.2 mg/dl.

The limit of quantification of Total Bilirubin is 0.6 mg/dl.

3. Interferences

Gross hemolysis and/ or lipaemia may cause falsely low and/ or elevated results.

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	0.77	0.03	3.68
sample 2	4.04	0.05	1.18

Inter-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	0.69	0.03	4.69
sample 2	3.97	0.17	4.4

5. Methods Comparison

Comparison was done between reference Total Bilirubin Reagent and CliniQuant - FSR Total Bilirubin Reagent (test).

N = 21 $y = 1.934x - 0.024$

$r^2 = 0.961$

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 1458 - 1470.

2. Data on file: Meril Diagnostics.

IFU/TBLFSR01/00

05-12-2018

Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged
EC REP	Authorized European Representative in the European Community		