Bilirubin (T & D) Test Kit

REF	Pack Size	Reagent 1	Reagent 2
BLTLMB01	1 x 60 + 1 x 15 ml	1 x 60 ml	1 x 15ml
BLDLMB01	1 x 60 + 1 x 15 ml	1 x 60 ml	1 x 15ml

INTENDED USE
Bilirubin (T & D) is used for the quantitative estimation of Bilirubin (T & D) in human serum or plasma.

CLINICAL SIGNIFICANCE
Bilirubin is a breakdown product of hemoglobin. It is transported from the spleen to the liver and excreted into bile duct. Hyperbilirubinemia results from the increase of bilirubin concentrations in plasma. Causes of hyperbilirubinemia colon, total bilirubin (T)colon increased hemolysis genetic errors, neonatal jaundice, ineffective erythropoiesis and drugs. Direct bilirubin(D) colon Hepatic cholestasis, genetic errors, hepatocellular damage. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

METHOD: JENDRASSIK(MODIFIED)

TEST PRINCIPLE:
In the determination of total bilirubin, bilirubin is coupled with diazotized Sulphanilic acid in the presence of Caffeine to give an azo dye. No caffeine is added when direct bilirubin is determined.

KIT CONTENTS/COMPONENTS
Reagent 1: Total Reagent/ Direct Reagent
Reagent 2: Activator

MATERIAL REQUIRED BUT NOT PROVIDED:
Fully Auto Biochemistry Analyzer: LM1016-400TPH.
Calibrator
Controls.

REAGENT PREPARATION, STORAGE AND STABILITY
Reagent ready to use and are stable up to the expiry date specified when stored at room temperature. Always keep the bottles tightly closed after each withdrawal.

ON - BOARD REAGENT STABILITY-
On board reagent stability is 15 days.

APPLICATION For LM1016-400 TPH

Method	End Point
Blank	Reagent blank
Primary filter	546
Secondary filter	620
R1 Volume	300
R1 Position	*
Incubation time (Sec)	144
R2 Volume	15
R2 Position	*
Incubation time (Sec)	260
Sample Volume	15
Read Time	40
Calibrator Concentration	As on the vial label
Mix speed set	Middle
Unit	mg/dl
Decimal	2

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CALIBRATION
For calibration, it is recommended to use any multi calibrator.

CALCULATION
Calculations Fully automated systems automatically calculate the Bilirubin concentration of each sample.

NORMAL VALUE
Total bilirubin: Adult: 0.1-1.2 mg/dl; Infants:1.2-12 mg/dl
Direct bilirubin: Adult: & infants 0 - 0.3 mg/dl

LIMITATIONS
If the value (T & D) exceeds 20 mg / dL, dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not use the reagent after the expiration date printed on the kit.
3.Avoid reagents contamination.
4.These Reagent kits meant for laboratory/professional use only, not for Drug use.

QUALITY CONTROL AND CALIBRATION
It is recommended to perform internal quality control with assayed normal and assayed abnormal to confirm the validity of the test and assure the accuracy of patient result. Using the recommended multi calibrator, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

PRECISION
Reproducibility was determined using quality control sera as shown below

	Intra run				Inter run			
Control	Level 1		Level 2		Level 1		Level 2	
	T	D	T	D	T	D	T	D
n	20	20	20	20	20	20	20	20
Mean (gm/dl)	1.33	0.39	1.32	0.40	1.33	0.41	1.34	0.39
SD	0.04	0.04	0.08	0.04	0.06	0.03	0.02	0.02
CV (%)	0.03	0.09	0.06	0.10	0.05	0.08	0.02	0.04

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

REF	Catalog No.		Instruction for use
LOT	Batch No.	IVD	*In-vitro* Diagnostics
	Manufacturing Date		Storage temperature
	Expiry Date		Manufacturer

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