

Bilirubin (T & D) Test Kit

REF	Pack Size	Reagent 1	Reagent 2	Activator
BILLMS01	2x50 ml	1x50 ml	1x50 ml	1x 5 ml
BILLMS02	4x25 ml	2x25 ml	2x25 ml	2 x 2.5 ml
BILLMS03	4x50 ml	2x50 ml	2x50 ml	2 x 5 ml

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
Reagent 2: Direct Reagent
Reagent 3: Activator

MATERIAL 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 tubes/rack, heating bath, controls, saline.

SAFETY PRECAUTIONS & WARNINGS

- 1.For in-vitro diagnostics use only.
- 2.Do not pipette by mouth. Avoid contact with skin and eyes. If spilt thoroughly wash affected area with water.
- 3.Do not use the reagent after the expiration date printed on the kit.

REAGENT PREPARATION, STORAGE AND STABILITY

Reagent 1, 2 and 3 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.

REAGENT DETERIORATION

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

METHOD FOR TOTAL

Reaction Mode	End point
Primary Wavelength	546 nm
Secondary Wavelength	630 nm
Light Path	10 mm
Blanking	Reagent
Total Reagent Volume	1000 µl
Sample Volume	50 µl
Incubation	5 min. at 37°C
Factor	23
Linearity	20 mg/dl

METHOD FOR DIRECT

Reaction Mode	End point
Primary Wavelength	546 nm
Secondary Wavelength	630 nm
Light Path	10 mm
Blanking	Reagent
Direct Reagent Volume	1000 µl
Sample Volume	50 µl
Incubation	5 min. at 37°C
Factor	17
Linearity	20 mg/dl

PROCEDURE FOR TOTAL

Addition Sequence	Sample
Reagent 1	1000 µl
Reagent 3	50 µl
Sample	50 µl

Mix well & incubate for 5 minutes at 37°C read absorbance of sample (A_{TB}) against reagent blank.

PROCEDURE FOR DIRECT

Addition Sequence	Sample blank
Reagent 2	1000 µl
Reagent 3	50 µl
Sample	50 µl

Mix well & incubate for 5 minutes at 37°C read absorbance of sample (A_{DB}) against reagent blank.

CALCULATION

For Total Bilirubin

Conc. in Serum or Plasma (mg/dl) = $ATB \times 23$ mg/dl

For Direct Bilirubin

Conc. in Serum or Plasma (mg/dl) = $ADB \times 17$ mg/dl

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.

QUALITY CONTROL AND CALIBRATION

It is suggested 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 calibrator or the Standard included, calibrate the assay.

WASTE DISPOSAL










This Product is made to be used in professional laboratories.

HIGHLIGHTS

- 1.Storage condition mentioned on the kit is to be used.
- 2.Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- 3.Before testing bring the reagents to the RT.
- 4.Avoid reagents contamination.
- 5.Every time use new pipette-tips for pipetting out the reagents.
- 6.These Reagent kits meant for laboratory/professional use only, not for Drug use.

REFERENCES

Tietze NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24
Jendrassik L & Groff., Biochem. 2.297,81(1938)
Practical Clinical Biochem Vol 5th ed., H. Varley, P101291980
Lords Data File.

	Catalog No.		Contain Sufficient for test
	Batch No.		Instruction for use
	Manufacturing Date		In-vitro Diagnostics
	Expiry Date		Storage temperature
	Manufacturer		

IFU/BIL/01 Rev.: 02; Rev Dated.: 22/07/2024

