# Bilirubin (T & D) Test Kit

| REF | Pack Size | Reagent 1 | Reagent 2 |
|---|---|---|---|
| BILLMA01 | 2x20+2x20 +2x5 ml | 1 x 20 ml | 1 x 5ml |

## 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: LM1015-200TPH.
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 LM1015-200 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 |

*** Customer Detrive.**

## 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 (mg/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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