SBio TOTAL BILIRUBIN KIT

(Mod. Jendrassik and Grof's Method)

(For invitro diagnostic use only)

REF	91222275	91232150	91244250
Pack Size	2 x 75 ml	2 x 150 ml	4 x 250 ml

CE

30°C / 15°C Store at 15 - 30°C (R.T.)	Manufacturer	This way up	Modified Jendrassik & Grof's — Modified Jendrassik & Grof's Method
Use by (Last day of stated month)	Consult Instructions for use	L1	Total Bilirubin Reagent
Date of Manufacture	REF Catalogue Number	L2	Total Nitrite Reagent
LOT Batch Number	IVD *In vitro* Diagnostic Medical Device	EC REP Authorised Representative in the European Community	

INTENDED USE

SBio Total Bilirubin kit is used for the determination of total bilirubin in serum.

CLINICAL SIGNIFICANCE

Bilirubin is mainly formed from the heme portion of aged or damaged RBC'S. It then combines with albumin to form a complex, which is not water-soluble. This is referred to as indirect or unconjugated Bilirubin. In the liver this Bilirubin complex is combined with glucuronic acid into a water-soluble conjugate. This is referred to as conjugated or direct Bilirubin. Elevated levels of bilirubin are found in liver diseases (Hepatitis, cirrhosis), excessive haemolysis / destruction of RBC (hemolytic jaundice) obstruction of the biliary tract (obstructive jaundice) and in drug induced reactions. The differentiation between the direct and indirect bilirubin is important in diagnosing the cause of hyperbilirubinemia.

PRINCIPLE OF THE TEST

Bilirubin reacts with diazotised sulphanilic acid to form a coloured azobilirubin compound. The unconjugated bilirubin couples with the sulphanilic acid in the presence of a caffein- benzoate accelerator. The intensity of the colour formed is directly proportional to the amount of bilirubin present in the sample.

Bilirubin + Diazotized Sulphanilic Acid ⟶ Azobilirubin Compound

PRESENTATION	2 x 75 ml	2 x 150 ml	4 x 250 ml
L1 : Total Bilirubin Reagent	2 x 75 ml	2 x 150 ml	4 x 250 ml
L2 : Total Nitrite Reagent	4 ml	2 x 4 ml	30 ml

COMPOSITION

Hydrochloric Acid 185 mM; Sulfanillic Acid 17 mM; Caffeine 230 mM; Sodium Benzoate 480 mM; Sodium Nitrite 15 mM.

STORAGE / STABILITY

Contents are stable at R.T. till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum. Bilirubin is reported to be stable in the sample for 4 days at 2-8°C protected from light, as it is photosensitive.
Do not pipette with mouth.

REAGENT PREPARATION

Reagents are ready to use.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.
This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.
Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.
Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength/filter : 546 nm / Yellow - Green
Temperature : R.T.
Light path : 1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

Total Bilirubin Assay:

Pipette into clean dry test tubes labeled as Blank (B) and Test (T):

Addition Sequence	B (ml)	T (ml)
Total Bilirubin Reagent (L1)	1.0	1.0
Total Nitrite Reagent (L2)	--	0.05
Sample	0.1	0.1

Mix well and incubate at R.T for 10 minutes. Measure the absorbance of the Test Samples (Abs.T) immediately against their respective Blanks.

CALCULATIONS

Total Bilirubin in mg/dl = Abs. T x 13

QUALITY CONTROL

The following process is recommended for QC during the assay of SBio Total Bilirubin. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

This procedure is linear upto 20 mg/dl. If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:

The limit of detection for Total Bilirubin is 0.03 mg/dl.

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	1.49	5.20	1.31	4.76	2.8	9.96
Control 2	5.51	6.67	5.21	3.05	10.72	9.72

Method comparison:

Comparative studies were done to compare our reagent with another commercial Total Bilirubin Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Serum : upto 1.0 mg/dl

It is recommended that each laboratory establish its own normal range representing its patient population*.

NOTE

In case of neonates where the sample quantity is a limitation, and the samples have high bilirubin (above 3 mg/dl), only 0.05 ml / 0.02 ml of the sample may be used for bilirubin estimation. The calculation factor in this case would be 24.9 / 60.5 respectively instead of 13. The reagent may be used in several automated analyzers. Instructions are available on request. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Jendrassik, L., Grof, P., (1938) Biochem. 2,297: 81.
2. Sherlock S. (1951) p.204 in Liver Disease, Churchill, London.

Mfd. for:

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EC REP

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