# **TOTAL BILIRUBIN liquid**

Modified Jendrassik method

R1: 1 x 100 ml + R2: 1 x 10 ml CI 10-110 R1: 3 x 100 ml + R2: 3 x 10 ml CL10-330

#### **INTENDED USE**

Kit for quantitative determination of Total Bilirubin in serum.

# **CLINICAL MEANING**

Analysis of total and fractioned bilirubin is made to determine the presence of hepatic damages or diseases e.g. obstruction of bile ducts, haemolytic amenias, metabolic issues, stones. A typical sign of high bilirubin levels is jaundice, which manifests with yellow skin and sclerae

#### **PRINCIPLE**

In presence of quaternary ammonium salt in an acid medium, total bilirubin reacts with diazotized sulphanilic acid to form a diazo pink compound (azobilirubin), whose intensity is proportional to the concentration of total bilirubin present in the sample.

#### **SAMPLE**

Non hemolyzed serum

Analyze samples within 2 hours from collection. Protect samples from light. STABILITY: 12 hours in the fridge at 2-8°C, 3 months at -20°C if protected from

#### **REAGENTS**

Only for in Vitro diagnostic use. Liquid monoreagent ready to use

Package content	CL10-110	CL10-330
REAGENT 1 Sulphanilic acid 3,5 mmol/L, hydrochloric acid 0,09 mmol/L; CTAB 7 g/L	1 x 100 ml	3 x 100
REAGENT 2 Sodium nitrite 7 mmol/L	1 x 10 ml	3 x 10

Stability: Store at 15-30°C and protect from light to keep the reagents stable up to the expiration date on the label. Keep bottles closed when not in use. Do not use turbid reagents

#### **NECESSARY ITEMS - NOT PROVIDED**

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

# MANUAL ASSAY PROCEDURE

Method: increasing endpoint

Wavelength: 546 nm Optical path: 1 cm Temperature: 37°C Reaction time: 10 minutes Reading against blank sample

Sample/reagent ratio:

Bring reagents to the chosen temperature for the analysis.

Pipette in cuvette:

	Blank sample	Sample
Reagent 1	1,5 ml	1,5 ml
Reagent 2		100 μΙ
De-mineralized water	100 μΙ	
Sample	100 µl	100 μΙ

Stir carefully. After exactly 10 minutes of incubation at 37°C, read the sample absorbance (AbsS) against the blank sample (AbsSB). The color is stable for about 60 minutes at room temperature and protected from direct light.

Reaction volumes can be proportionally varied without any change in calculation.

# **CALCULATION**

Calculate the concentration in the sample using the following formula:

[mg/dl] total bilirubin = (AbsS - AbsSB) x 20,4 [ $\mu$ mol/I] total bilirubin = (AbsS – AbsSB) x 349

### REFERENCE VALUES

 $0.2 \div 1.2 \text{ mg/dl } (3.4 \div 20.5 \mu\text{mol/l})$ 

Each laboratory should define its own reference values for this method.

# **QUALITY CONTROL - CALIBRATION**

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:

PRE-NORM serums with normal values

PRE-PATH serums with pathological values

If the method requires it, a multiparameter calibrator of human origin is available. Contact FAR for further information.

# PERFORMANCE CHARACTERISTICS

Sensitivity: the sensitivity of the method is 0,05 mg/dl.

Linearity: up to 25 mg/dl (427 µmol/L).

For higher values, dilute the samples with saline solution and multiply the result by the dilution factor.

#### Precision:

Within run (n=10)	Average [mg/dl]	SD	CV %
Sample 1	1,05	0,024	2,37
Sample 2	5,22	0,172	3,30

Between run (n=20)	Average [mg/dl]	SD	CV %
Sample 1	1,04	0,016	1,57
Sample 2	5.30	0.118	2.23

Interferences: up to 150 mg/dl of hemoglobin does not interfere.

Direct light can cause a decrease of direct bilirubin up to 50% in an hour.

Correlation against a reference method: the correlation of FAR method (Y) against a reference method (X) gives this equation:

Y = 0.975X + 0.042

# **DISPOSAL**

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

### WARNINGS AND PRECAUTIONS

Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behaviour in laboratory.

#### **REFERENCES**

- 1. Pearlman F.C., Lee R.T.Y., Clin. Chem. 20, 447, (1974)
- 2. Blumenfeld T.A. et al., Am. J. Clin. Path. 69, 388 (1978)

# **MANUFACTURER**

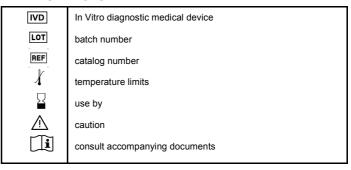
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#### **KEY SYMBOLS**



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