

TOTAL BILIRUBIN liquid

Modified Jendrassik method

R1: 1 x 100 ml + R2: 1 x 10 ml
R1: 3 x 100 ml + R2: 3 x 10 ml

CL10-110
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 anemias, 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 light.

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: 1/16

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 µl
De-mineralized water	100 µl	---
Sample	100 µl	100 µl

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:

$$[\text{mg/dl}] \text{ total bilirubin} = (\text{AbsS} - \text{AbsSB}) \times 20,4$$

$$[\mu\text{mol/l}] \text{ total bilirubin} = (\text{AbsS} - \text{AbsSB}) \times 349$$

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:

$$Y = 0,975X + 0,042$$

$$r = 0,9994$$

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

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

MANUFACTURER

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

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KEY SYMBOLS

	In Vitro diagnostic medical device
	batch number
	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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