

BioMed-Bilirubin (Total&Direct)

Colorimetric method with sample blank



REF: BIL102160 (160 ml)
BIL102320 (320 ml)

INTENDED FOR USE:

For the quantitative determination of direct bilirubin in serum .

Principle :

Total bilirubin reacts in acid medium with diazotized sulfanilic acid to form a red colored azobilirubin .

The intensity of color produced results is directly proportional to the amount of bilirubin present in the sample .

Direct bilirubin consists of glucuronic acid conjugated derivatives , is water soluble and it reacts directly .

Total bilirubin is obtained by the presence of an accelerating agent which unconjugates bilirubin bound to serum albumin .

Indirect bilirubin can be calculated by subtracting direct bilirubin from total bilirubin .

SPECIMEN COLLECTION :

Non haemolized fresh serum.

Samples must be analyzed within two hours of collection and kept at room temperature and not exposed to light . Direct Bilirubin (BIL-D) in serum is stable for 12 hours when stored in the refrigerator at +2/8° C and 3 months at -20° C, if not exposed to sunlight . Direct sunlight may cause up to 50% decrease in BIL-D within 1 hour .

Shake and bring the samples at room temperature (+15-25°C) before using.

REAGENT COMPOSITIONS:

R1	Sulfanilic Acid Hydrochloric Acid 23%	< 1% <5%
R2	Sodium Nitrate	0-1%
R3	Caffeine Sodium benzoate	0.28 mol/l 0.55 mol/l
R4	Tartrate NaOH	0.99 mol/l 2.0 N

PACKAGE : Collection & Storage .

Store at room temperature indicated upon the label .

Stable until the expiration date reported upon the package.

After the unsealing and the taking of the reagent , it is advised to close up the bottle immediately in order to avoid evaporation , direct light exposure and bacterial contamination .

PRECAUTIONS & WARNING

Avoid pipette with mouth .

The preparation , according to current regulation . is classified as not dangerous.

The Reagent (R1) contains : sulphanilic acid : may produce an allergic reaction .

The total concentration of non active components (preservatives , detergents ,stabilizers) is below the minimum required for citation .

Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes .

. The samples must be handle as potentially infected from HIV or Hepatitis .

REAGENT PREPARATION & STABILITY :

Liquid reagents must be at room temperature (+15-25° C) before using .

The Reagent is limpid and colourless .

Liquid reagent ready to use .

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations .

PROCEDURE :

Wavelength

Total Bilirubin 578 nm (560-600 nm)

Direct Bilirubin 546 nm (530-555 nm)

Optical path 1 cm

Incubation temperature 20-25°C

Zero adjustment Specimen blank

Total Bilirubin

	Specimen blank	Specimen
R₁	0.2 ml	0.2 ml
R₂	—————	1 drop
R₃	1.0 ml	1.0 ml
Specimen	0.2 ml	0.2 ml
Mix, and incubate for 10 minutes at 20 - 25°C.Add		
R₄	1.0 ml	1.0 ml
Mix, and incubate for 5 minutes at 20-25°C. Read absorbance of specimen (A _{specimen}) against specimen blank. The color intensity is stable for 30 min.		

Direct Bilirubin

	Specimen blank	Specimen
R₁	0.2 ml	0.2 ml
R₂	—————	1 drop
NaCl (0.9%)	2.0 ml	2.0 ml
Specimen	0.2 ml	0.2 ml
Mix and incubate for exactly 5 minutes at 20-25°C. Read absorbance of specimen (A _{specimen}) against specimen blank.		

CALCULATION :

$$\text{Total Bilirubin (mg/dl)} = A_{\text{specimen}} \times 10.8$$

$$\text{Direct Bilirubin (mg/dl)} = A_{\text{specimen}} \times 14.4\text{IB}$$

EXPECTED VALUES :

Total Bilirubin:	Up to 1.2 mg/dl
Direct Bilirubin:	Up to 0.3 mg/dl

The above mentioned values are to be considered as a reference.

It is strongly recommended that each laboratory establish its own normal range according to its geographic area, according to IFCC protocol.

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

REFERENCESE :

1. Malloy H.T. & Evelyn K.A., J.Biochem. 119(481), 1937.
2. Jendrassik L. & Grof P., Biochem Z. 291(81), 1938.
3. Walters M.I. & Gerarde H., Microchem J.15 (231) 1970.

PERFORMANCE :

MEASURE INTERVAL INEARTY :	0.1-25 mg/dL
DETECTION LIMIT :	0.0558 mg/dL
SENSITIVITY :	0.1mg/dL= 0.00652A a546 nm

INTER-ASSAY PRECISION : n=30

LOW LEVEL	M = 0.19 mg/dL	C.V = 2.78%
MEDIUM LEVEL	M = 0.65 mg/dL	C.V = 1.20%
HIGH LEVEL	M = 3.12 mg/dL	C.V = 0.95%

INTRA-ASSAY PRECISION : n=30

LOW LEVEL	M = 0.20 mg/dL	C.V = 5.12%
MEDIUM LEVEL	M = 0.66 mg/dL	C.V = 1.52%
HIGH LEVEL	M = 3.16 mg/dL	C.V = 1.27%
CORRELATION	r = 0.998	n= 40
LIN. REGRESSION	Y = 1.04 x + 0.07	N = 40



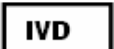


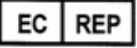



INTERFERENCE:

Interferences are negligible up to :	
Hemoglobin	500 mg/dL
Triglycerides	2000 mg/dL

LIMITATIONS:

For concentration higher than 25 mg/dL, repeat the measure on a sample diluted 1:2 with saline solution e multiply the result x 2.

for a thorough evaluation of the interfering substances, consult: Young, D. S., et al, Clin,

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

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