PATHOZYME DIAGNOSTICS

LIQVIPATH BILIRUBIN

[(Modified Bergh & Muller Method) / Single Reagent]

CAT NO.: BIS

Reagent kit for quantitative estimation of Bilirubin in Serum or Plasma.

DIAGNOSTIC SIGNIFICANCE:

Total & Direct Biliruibin determination in serum is used for the diagnosis. The conjugated Bilirubin is predominantly increased in obstructive jaundice due to regurgitation while hepatic jaundice is associated with increase in both conjugated & unconjugated Bilirubin in sample.

PRINCIPLE:

Bilirubin couples directly with a Diazonium salt in an acid medium to form Azobilirubin. Which has the maximum absorption peak at 546nm, and the absorption is proportional to the Bilirubin in the specimen.

Bilirubin + Diazonium Salt ⟶ Azobilirubin (Coloured Complex)

SPECIMEN COLLECTION:

Serum free from hemolysis.or Heparinized Plasma.

KIT PRESENTATION:

PACK SIZE	2 X 25 ml	2 X 50 ml	4 X 50 ml
Total Bilirubin Reagent	1 X 25 ml	1 X 50 ml	2 X 50 ml
Direct Bilirubin Reagent	1 X 25 ml	1 X 50 ml	2 X 50 ml

WORKING REAGENT PREPARATION:

Both Bilirubin Reagents are ready to use.

REAGENT STORAGE AND STABILITY:

Bilirubin Reagents are stable at 2-8°C until the expiry date stated on the label.

ASSAY PARAMETERS:

Reaction	: End Point	Sample Volume	: 50 µl
Wavelength -I	: 546 nm	Reagent Volume	: 1000 µl
Wavelength-II	: 630 nm	Zero Setting	: Reagent
Flow Cell Temp.	: 37°C	Total Bilirubin Factor	: 30
Incubation Time	: 5 Minutes	Direct Bilirubin Factor	: 15
Incubation Temp.	: 37°C	Linearity	: 20 mg/dl

PROCEDURE *FOR TOTAL BILIRUBIN*:

Pipette into TT	Blank	Test
Total Bilirubin Reagent	1000 µl	1000 µl
Sample (Test)	--	50 µl

Mix & incubate at 37°C for 5 minutes. Read absorbance of Test (**T**) after 5 minutes against reagent blank at 546 nm & 630 nm (546 nm is primary filter and 630 nm secondary filter).

CALCULATION:

Total Bilirubin (mg/dl) = Abs T X 30

For Direct Bilirubin:

Pipette into TT	Blank	Test
Direct Bilirubin Reagent	1000 µl	1000 µl
Sample (Test)	--	50 µl

Mix & incubate at 37°C for 5 minutes. Read absorbance of Test (**T**) after 5 minutes against reagent blank at 546 nm & 630 nm (546 nm is primary filter and 630 nm secondary filter).

CALCULATION:

Direct Bilirubin (mg/dl) = Abs T X 15

NORMAL VALUES:

Total Bilirubin : 0.3 – 1.2 mg/dl (Adults & children over 10 days)
Direct Bilirubin : < 0.2 mg/dl

Each laboratory should determine its own expected values as dictated by good laboratory practice.

LINEARITY:

This method is linear up to **20 mg/dl**. For values above 20 mg/dl, dilute the sample suitably with 0.9 % saline, and repeat the assay. Apply dilution factor to obtain final result.

IMPORTANT NOTE:

For severely haemolyzed or lipemic sera, serum correction is required by performing serum blank. Use normal saline as serum blank reagent.

REFERENCES:

1. Tietz, N.W., Fundamentals of Clinical Chemistry, 2nd ed., W.B. Saunders, Philadelphia, 1976, p. 1028-1044.
2. Annino, J.S., Clinical Chemistry Principles and Procedures, 2nd ed., Little, Brown and Company, Boston, 1960, p. 203.
3. Van den Bergh, A. and Mueller, P., Biochem. Z. 77, 1916, p. 90.
4. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 3rd ed., AACC Press, Washington, D.C., 1990, p. 3-61 - 3-72.
5. Wachtel M et al, Creation and Verification of Reference Intervals. Laboratory Medicine 1995; 26:593-7.

IFU No.: 006/00 | Rev No.: 00/120723

Expiry Date | IVD In-Vitro Diagnostics Use | Storage | Mfg. Date | LOT Batch Number | REF Catalogue Number | See Package Insert

PATHOZYME DIAGNOSTICS
An ISO 9001:2015, ISO 13485:2016, CE & GMP Certified Company
A-115, Kagal Five Star MIDC, Kagal, Dist. Kolhapur-416 216.
Tel: 0231-2305072, Cell: +91 88058 67810, E-mail: contactus@pathozyme.com, Website: www.pathozyme.com