BILIRUBIN DIRECT

4 x 50 mL, 3 x 100 mL, 5 x 100 mL
51003001, 51003006, 51003007

INTENDED USE

This reagent is intended for *in vitro* quantitative determination of Bilirubin in serum or plasma .

- Modified Diazo Method
- Linear up to 20 mg/dL
- Fast incubation 5 minutes at room temperature.
- Sample volume only 50 µL.

CLINICAL SIGNIFICANCE

Bilirubin is formed by the break down of RBC's in the spleen, liver & bone marrow. Small amount of bilirubin circulates in the plasma loosely bound to albumin, which is not water soluble. This is referred to as indirect or unconjugated bilirubin. In the liver bilirubin is conjugated with glucuronic acid, which forms a soluble compound. This is referred to a direct bilirubin.

Elevated levels are found in Hepatitis, Cirrhosis, Haemolytic jaundice, obstruction of biliary tract & drug induced reactions.

PRINCIPLE

Sulfanilic acid reacts with sodium nitrite to form diazotized sulfanilic acid. Direct Bilirubin reacts with diazotized sulfanilic acid to form azobilirubin.

REAGENT COMPOSITION

DIRECT BILIRUBIN REAGENT	**4 x 50 mL**	**3 x 100 mL**	**5 x 100 mL**
Sulfanilic acid	28.9 mmol/L		
Hydrochloric acid	165 mmol/L		
Preservatives and stabilizers			
DIRECT BILIRUBIN ACTIVATOR	**2 x 4 mL**	**2 x 8 mL**	

BILIRUBIN ARTIFICIAL STANDARD	**1 x 4 mL**
Direct Bilirubin Standard Concentration	7.7 mg/dL

STORAGE AND STABILITY

The sealed reagents are stable up to the expiry date stated on the label, when stored at RT. The standard & activator should be stored at 2 - 8°C

LINEARITY

This reagent is linear up to 20 mg/dL.

If the concentration is greater than linearity (20 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

NORMAL RANGE

It is recommended that each laboratory establish its own reference values.

The following value may be used as guide line.

Direct Bilirubin up to 0.4 mg/dL

PREPARATION AND STABILITY OF WORKING REAGENT

Reagents are ready to use.

PRECAUTION

To avoid contamination, use clean laboratory wares.

Avoid direct exposure of reagent to light.

SAMPLE

Serum / plasma (free of haemolysis)

GENERAL SYSTEM PARAMETER

Mode of Reaction	End point
Slope of reaction	Increasing
Wavelength	546/532 nm
Temperature	30°C
Factor (Direct)	16.0/18.0
Blank	Sample blank
Linearity	20 mg/dL
Reaction time	5 min
Sample volume	50 µL
Reagent volume	1000 µL
Activator	20 µL
Cuvette	1 cm light path

LABORATORY PROCEDURE

	Sample Blank	Test
Direct bilirubin reagent	1000 µL	1000 µL
Activator Direct	-	20 µL
Serum	50 µL	50 µL

Mix well and incubate for 5 minutes at room temperature. Measure the absorbance of test against respective Blank at 546/532 nm.

CALCULATION

With factor :

Direct Bilirubin = OD of test – OD of sample blank X Factor

With Artificial Standard

$$\text{Direct Bilirubin Conc.} = \frac{\text{OD of test} - \text{OD of sample blank}}{\text{OD of Standard}} \times \text{Concentration of Std.}$$

BIBLIOGRAPHY

1. Water, M., Gerard, H.; MICROCHEM JM 15, 231(1980)
2. Annino J. S.; C.C. Principles and procedure,1960
3. A.A. A.C.C.; Clin. Chem. 8 : 405,196

SYMBOLS USED ON THE LABELS

SYMBOLS USED ON THE LABELS : IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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