DELTA
BILIRUBIN TOTAL & DIRECT
(SINGLE REAGENT - MODIFIED BERGH & MULLER METHOD)

ORDER INFORMATION

CODE : DL0411 - T1 - 1 x 25 ML + D1 - 1 x 25 ML
DL0412 - T1 - 2 x 25 ML + D1 - 2 x 25 ML
DL0413 - T1 - 1 x 100 ML + D1 - 1 x 100 ML

INTENDED USE :

Reagent kit for the quantitative determination of Total and Direct Bilirubin in serum.

CLINICAL SIGNIFICANCE :

Approximately 80-85% of the bilirubin produced is derived from the heme moiety of the haemoglobin released from aging erythrocytes in the reticuloendothelial cells. Bilirubin bound to albumin is transported into the liver where it is rapidly conjugated with glucuronide to increase its solubility. Then it is excreted into biliary canaliculi and hydrolyzed in the gastrointestinal tract. Unconjugated bilirubin serum concentration increases in case of overproduction of bilirubin (acute or chronic haemolytic anemias) and in case of disorders of bilirubin metabolism and transport defects (impaired uptake by liver cells : Gilbert's syndrome; defects in the conjugation reaction : Crigler-Najjar syndrome). Reduced excretion (hepatocellular damage : hepatitis, cirrhosis…; Dubin-Johnson and Rotor syndrome) and obstruction to the flow of bile (most often produced by gallstones or by tumours) induce an important elevation of conjugated bilirubin and in a minor extent an increase of unconjugated bilirubin (conjugated hyperbilirubinemia).

REAGENT COMPOSITION :

Reagent T1 : Total Bilirubin reagent
Reagent D1 : Direct Bilirubin reagent

MATERIALS REQUIRED BUT NOT PROVIDED :

- Clean & Dry Glassware.
- Micropipettes & Tips.
- Colorimeter or Bio-Chemistry Analyzer.

SAMPLES :

Serum free of hemolysis. Heparinized plasma.
Care must be taken to fill heparinized tubes according to the manufacturer's instructions. An insufficient filling may lead to erroneous results. Protect the samples from light before and during the analysis.

STABILITY OF REAGENT :

When Stored tightly closed at 2° TO 8° C protected from light and contaminations prevented during their use; reagents are stable up to the expiry date stated on the label.

WORKING REAGENT :

The Reagent is ready for use.

GENERAL SYSTEM PARAMETERS :

Reaction type	End Point (Increasing)
Primary Wave length	546 nm
Secondary Wave length	630 nm
Light Path	1 Cm
Reaction Temperature	37°C
Blank / Zero Setting	Reagent Blank
Reagent Volume	1 ml
Sample Volume	50 µl
Incubation Time	5 Minutes
Total Bilirubin Factor	30
Direct Bilirubin Factor	15
Linearity	20 mg/dl

ASSAY PROCEDURE :

Total Bilirubin :

	Blank	Test
T. Bilirubin (T1)	1ml	1ml
Sample	-	50 µl

Direct Bilirubin :

	Blank	Test
D. Bilirubin (D1)	1ml	1ml
Sample	-	50 µl

Mix and read the absorbance of the tests against their respective reagent blanks after a 5 - minutes incubation at 37°C.

CALCULATION :

Total Bilirubin (mg/dl) = (Abs. Test - Abs. Blank) X 30
Direct Bilirubin (mg/dl) = (Abs. Test - Abs. Blank) X 15

LINEARITY :

Reagent is Linear up to 20 mg/dl.

Dilute the sample appropriately and re-assay if Total or Direct Bilirubin concentration exceeds 20 mg/dl. Multiply result with dilution factor.

REFERENCE NORMAL VALUE :

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

QUALITY CONTROL :

For accuracy it is necessary to run known controls with every assay.

BIBLIOGRAPHY :

Tietz, N.W., Clinical guide to laboratory tests. 3rd Ed., (W.B. Saunders eds. Philadelphia USA), (1995), 90. Vassault, A., et al., Protocole de validation de techniques.
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