Total Bilirubin (DPD Method)

IVD

(BR-120/BR-160)

PRODUCT
CODE CS022

INTENDED USE

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

CLINICAL SIGNIFICANCE

Bilirubin is a waste product derived from the heme moiety of the hemoglobin released from senescent or damaged erythrocytes that are destroyed in the reticuloendothelial cells. After production, bilirubin is transported to the liver in association with albumin. Inside the hepatocytes bilirubin is conjugated with glucuronic acid and it is excreted into bile. A number of inherited and acquired diseases affect production, uptake, metabolism, and excretion of bilirubin, resulting in hyperbilirubinemia [1,2]. Unconjugated hyperbilirubinemia is seen in newborns (physiological jaundice), in increased red cell destruction (hemolytic anemia, extensive hematoma), in ineffective erythropoiesis and in some rare genetic diseases (Gilbert's syndrome, Crigler-Najjar syndrome). Conjugated hyperbilirubinemia is associated to a decreased excretion of bile due to liver diseases (hepatitis or cirrhosis) or to intrahepatic or extrahepatic cholestasis. Jaundice is a clinical manifestation of hyperbilirubinemia, consisting of deposition of bile pigments in the skin, resulting in a yellowish staining of the skin and mucous membranes. Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE

Direct bilirubin in the sample reacts with 3.5-dichlorophenyl diazonium salt forming a colored complex that can be measured by spectrophotometry at 546 nm[3]. Both direct and indirect bilirubin couple with diazo in the presence of cetrimide [4,5]. The terms "direct" and "total" refer to the reaction characteristics of serum bilirubin in the absence or presence of solubilizing (accelerating) reagents. The "direct" and "indirect" bilirubin are only approximately equivalent to the conjugated and unconjugated fractions.

CONTENTS:

Reagent 1: Hydrochloric acid 170 mmol/L, cetrimide 40 mmol/L, pH 0,9.
Reagent 2:3.5-dichlorophenyl diazonium 1.5 mmol/L.

REAGENT PREPARATION

All reagents are ready to use.

REAGENT STORAGE AND STABILITY

Store at 2-8ºC. Components are stable once opened until the expiry date marked in the label if they are stored at the recommended temperature, well closed and care is taken to prevent contamination during their use.

SPECIMEN

Serum and plasma collected by standard procedures. EDTA may be used as anticoagulants. Bilirubin concentration in serum and plasma is stable for 1 days at 20-25ºC, 3 days at 4-8ºC and 6 months at −20ºC if protected from light

PRECAUTION

To avoid contamination, use clean laboratory wares. Avoid direct exposure of reagent to light.

APPLICATION ON AUTO BIOCHEMISTRY ANALYZERS

BR-160 AUTO BIOCHEMISTRY ANALYZER

TEST NAME	BIL.T			SAMPLE VOLUME	5	
FULL NAME	BILIURUBIN TOTAL					
					R1	R2
	PRI.	SEC.		REAGENT VOLUME	200	50
WAVE LENGTH	546	700				
		START	END			
ASSAY /POINT	1 POINT END	1	25			
DECIMAL PLACE	2					
UNIT	mg/dl					
	LOW	HIGH				
LINEARITY RANGE	0.201	38				

Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526, E-mail:info@bioresearch.com.jo

BR-120 AUTO BIOCHEMISTRY ANALYZER						
TEST NAME	BIL.T			SAMPLE VOLUME	5	
FULL NAME	BILIURUBIN TOTAL					
	PRI.	SEC.		REAGENT VOLUME	R1	R2
WAVE LENGTH	546	700			200	50
		START	END			
ASSAY /POINT	1 POINT END	1	39			
DECIMAL PLACE	2					
UNIT	mg/dl					
	LOW	HIGH				
LINEARITY RANGE	0.201	38				

- Detection limit: 0.201 mg/dL = 3.43 µmol/L.
- Linearity: 38 mg/dL = 650 µmol/L.
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
2.10 mg/dL = 36.0 µmol/L	2.9 %	6.1 %
4.72 mg/dL = 80.6 µmol/L	1.9 %	4.7 %

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

NORMAL RANGE

Adult: Up to 2.0 mg/dL = 34 µmol/
L Newborns:

Age	premature	full-term
Up to 24 h	1.0-8.0 mg/dL = 17-137 µmol/L	2.0-6.0 mg/dL = 34-103 µmol/L
Up to 48 h	6.0-12.0 mg/dL = 103-205 µmol/L	6.0-10 mg/dL = 103-171 µmol/L
3-5 days	10-14 mg/dL = 171-239 µmol/L	4.0-8.0 mg/dL = 68-137 µmol/L

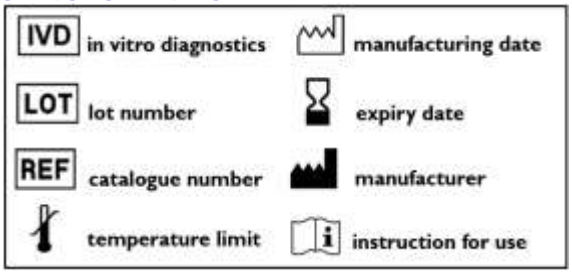
QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum Biotrol level I & Biotrol level
II

LIMITATION & PRECAUTIONS:

– Interferences: hemolysis (hemoglobin 500 mg/dL) do not interfere. Lipemia (triglycerides 1300 mg/dL) interfere. Other drugs and substances may interfere6.

SYMBOL ON LABELS



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Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526, E-mail:info@bioresearch.com.jo