



Total Bilirubin (BR120/ BR160) (DMSO Method)

IVD

PRODUCT
CODE CS024

INTENDED USE

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

CLINICAL SIGNIFICANCE

Bilirubin is mainly formed from the heme portion of aged or damaged RBC'S. It then combines with albumin to form complex, which is not water-soluble. This is referred to as indirect or unconjugated Bilirubin. In the liver this Bilirubin complex is combined with glucuronic acid into a water-soluble conjugate. This is referred to as conjugated or direct Bilirubin. Elevated levels of bilirubin are found in liver diseases (Hepatitis, cirrhosis), excessive hemolysis / destruction of RBC (hemolytic jaundice) obstruction of the biliary tract (obstructive jaundice) and in drug induced reactions. The differentiation between the direct bilirubin hyperbilirubinemia

PRINCIPLE

Bilirubin reacts with diazotized sulphanilic acid to produce azobilirubin (violet colour). DMSO catalyzes the formation of azobilirubin from free bilirubin. The violet color is proportional to bilirubin concentration measured at 546 nm (530-550nm).



CONTENTS

Total Bilirubin Reagent (R1)

Total Activator Reagent (R2)

REAGENT PREPARATION

All reagents are ready to use.

REAGENT STORAGE AND STABILITY

All reagents are stable to the given expiry date if stored at 2-25°C.

SPECIMEN

Fresh haemolysis- free serum or heparinized plasma may be used. Carefully protect from light until use. Bilirubin in sample is stable for 4 days when stored in the dark at 2-8° C.

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	20	
FULL NAME	BILIURUBIN TOTAL				
	PRI.	SEC.	REAGENT VOLUME	R1	R2
WAVE LENGTH	546	700	200	20	
ASSAY /POINT	1 POINT END	START 1	END 25		
DECIMAL PLACE	2				
UNIT	mg/dl				
LINEARITY RANGE	LOW 0	HIGH 20			



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BR-120 AUTO BIOCHEMISTRY ANALYZER					
TEST NAME	BIL.T		SAMPLE VOLUME	20	
FULL NAME	BILIURUBIN TOTAL				
	PRI.	SEC.	REAGENT VOLUME	R1	R2
WAVE LENGTH	546	700		200	20
ASSAY /POINT	1 POINT END	START	END		
		1	39		
DECIMAL PLACE	2				
UNIT	mg/dl				
LINEARITY RANGE	LOW	HIGH			
	0	20			

Linearity: This procedure is linear up to 20 mg/dl. If the values exceed this limit, dilute the sample with normal saline (NaCl 0.9%) and repeat the assay. Multiply result by dilution factor.

NORMAL RANGE

Total Bilirubin: up to 1.0 mg/dl

QUALITY CONTROL

All control sera with Bilirubin value estimated by this method can be used.

LIMITATION & PRECAUTIONS:

1. It is important to ensure through mixing of Bilirubin reagent and nitrite reagent before assay.
2. Bilirubin levels may be reduced if the sample are exposed to light. Hemolytic sample will also show low value.
3. It is important to ensure the working reagent and nitrite reagent are thoroughly mixed before adding the sample.

SYMBOL ON LABELS

IVD in vitro diagnostics	 manufacturing date
LOT lot number	 expiry date
REF catalogue number	 manufacturer
 temperature limit	 instruction for use

BIBLIOGRAPHY

- 1- H. varley, A. H. Gowen lock, Maurice Bell et. al. - Practical clinical Biochemistry. 5th edi. : P. 1022 to 1024.
- 2- Jendrassik L. & Grof P. Biochem 2.297, 81 (1938)

