

BILIRUBIN TOTAL

Diazo with Dichloraniline (DCA)

Inteded use :

For the in vitro quantitative determination of total bilirubin in serum.

Summary:

Total bilirubin is comprised of direct bilirubin and indirect bilirubin. The total bilirubin are increased in liver cell jaundice, as if acute jaundice hepatitis, critically ill hepatitis, slow live liver, liver cirrhosis and so on. The total bilirubin and the direct bilirubin are also elevated in the blocking jaundice, like biliary duct stone, biliary duct obstruction and so on. The total bilirubin and the indirect bilirubin are also elevated common in hemolytic jaundice.

Test principle:

Method: Diazo with Dichloraniline (DCA)

The bilirubin in acidic conditions reacts with the diazodichloraniline and product the color azo compound, the color diazo compound production quantity is proportional to the concentration of the total bilirubin in the sample.

Reagents – contents and concentrations:

R1:

Phosphate buffer solution 40 mmol/l
NaCl 9 g/L

surfactants

R2:

2,4-daizodichlorobenzenamine 1 mmol/L
HCl 30 mmol/L

surfactants

Preparation and stability:

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8°C.

The reagents are stable for 1 month on-board the analyser after opening.

Specimen:

Serum samples. Should be tested within 2 hours after the collection. Serum samples are stable for a 12 hours at 2-8 °C, or for 3 months at -20 °C. Be taken to avoid hemolysis and dark save.

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Hemoglobin: 300 mg/dl

TG: 1000 mg/dl

Ascorbic Acid: 30 mg/dl

Testing procedure :

Materials provided

- Working solutions as described above Additional materials required
- Calibrators and controls as indicated below
- NaCl 0.9%

Wavelength:	510 nm (allowed 490 + 520 nm)		
Lightpath:	1 cm		
Temperature:	25, 30 or 37°C		

dispense:	blank	calibrator	sample
reagent R1	1 ml	1 ml	1 ml
water	50 µl	-	-
calibrator	-	50 µl	-
sample	-	-	50 µl

Mix, incubate at 25, 30 or 37°C for 5 minutes.
Read absorbances of calibrator (Ac₁) and samples (Ax₁) against reagent blank.

dispense:	blank	calibrator	sample
reagent R2	250 µl	250 µl	250 µl

Mix, incubate at 25, 30 or 37°C for 5 minutes.
Read absorbances of calibrator (Ac₂) and samples (Ax₂) against reagent blank.

$$\text{Concentration} = \frac{\Delta A_{\text{sample}} - \Delta A_{\text{blank}}}{\Delta A_{\text{calibrator}} - \Delta A_{\text{blank}}} \times \text{Calibrator value}$$

Measuring /reportable range:

The method is linear up to 15 mg/dl.

If the sample above this concentration should be diluted with 0.9% NaCl and assay. Multiply the result by dilution factor

Analytical sensitivity (lower detection limit):

The minimum detectable level that can be distinguished from zero has been determined as 0.05 mg/dl.

EXPECTED VALUES

adults: 0.2 - 1.0 mg/dl (3.4 - 17.1 µmol/l)

newborns:

up to 24 h 2.0 - 6.0 mg/dl (34 - 103 µmol/l)

up to 48 h 6.0 - 10.0 mg/dl (103 - 171 µmol/l)

days 3-5 4.0 - 8.0 mg/dl (68 - 137 µmol/l)

Each laboratory should establish appropriate reference intervals related to its population.

Imprecision:

N=20	Level 1	Level 2
Mean	26.8	84.1
SD	0.13	0.89
CV	0.5 %	1.05 %

Intra Assay Precision		
N=5	Level 1	Level 2
Mean	30.6	80.1
SD	0.19	0.42
CV	0.63 %	0.53 %

Method comparison:

A comparison of the BIOANALYTIC BILIRUBIN TOTAL (y) with a commercial obtainable assay (x) gave the following result (mg/dl): Y=0.997x-0.212, R2=0.999; 319 patient samples were analyzed .

Quality Control:

Control Serum:

BIOCON N 5 x 5 ml # B10814

BIOCON P 5 x 5 ml # B10817

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration:

S1: 0.9% NaCl

S2: BIOCAL H 5 x 3 ml # B11895

Calibration frequency:

A two-point-calibration is recommended in case of:

- 1- Change of lot
- 2- Quality Control Requirements

BILIRUBIN TOTAL

Diazo with Dichloraniline (DCA)

SAFETY PRECAUTIONS AND WARNINGS

1. Dual-reagent method, the first step in the reaction can be deducted sample blank (to reduce interference from hemolysis and lipemia)
2. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
3. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
4. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
5. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

Literature:

1. Malloy HT.Eveleyn KA The Determination of bilirubin with the photoelectric colorimetric method J. Biol Chem.
2. Ehrlich, P., Charite-Annalen, 8: 140, 1883.

Order information (Cat No.):

CC350	BBTO250	B25060	B30060	B33061	B37061
SH350	BBTO500	B25061	B30061	B34060	B80060
CR350	B21060	B27060	B31060	B35060	B80061
OL350	B21061	B27061	B32060	B36060	
KL350	B22060	B28060	B32061	B36061	
AB350	B24060	B28061	B33060	B37060	

Manufacturer :








Diaclinica Diagnostik Kimya.San.Tic.Ltd.Şti

Adress : İkitelli O.S.B Mutsan San. Sit. M4 Blok No: 19

Başakşehir/İSTANBUL Tel:+90(212) 549 33 88- Fax:+90 (212) 549 55 50

Web :www.diaclinica.com

SYMBOLS

	for in vitro diagnostic use only
	lot of manufacturing
	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions