

Diazo with Dichloraniline (DCA)

Intended use:

For the in vitro quantitative determination of Direct Bilirubin in serum.

Summary:

Each types hepatitis, liver cirrhosis, the blocking jaundice obviously direct bilirubin increase, is more sensitive than the transaminase. It is especially suits in the chronic hepatitis prognosis appraisal and the early liver cirrhosis diagnosis. When serious anemia in the blood serum or the blood plasma direct bilirubin decreases.

Test principle:

In the blood serum the direct bilirubin reacts with the diazo-dichloraniline and the color azo compound is produced, the color diazo compound production quantity is proportional to the concentration of the direct bilirubin in the sample.

Reagents – contents and concentrations:

R1:

EDTA-Na2 0.70 mmol/l
NaCl 6.6 g/L
Amidosulfuric acid 70 mmol/l

R2:

2,4-daizodichlorobenzamine 0.09 mmol/l
HCl 130 mmol/l
EDTA-Na2 0.02 mmol/l

Preparation and stability:

R1 ready for use.

R2 ready for use.

Unopened kit components:

Up to the expiration date at + 2 to + 8°C.

Onboard Stability:

R1: 28 days.

R2: 28 days.

Specimen:

Serum. Samples should be tested within 2 hours after collection. Serum samples are stable for 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
Intralipid: 100 mg/dl
Ascorbic Acid: 10 mg/dl

Testing procedure:

Applications for automated systems are available on request.

Materials provided

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

TEST PROCEDURE (BY CALIBRATOR)

Wavelength: 546 nm (allowed 530 ÷ 560 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 re-assay. Multiply the result by dilution factor.

Sensitivity/limit of detection (LOD)

The limit of detection is 0.039 mg/dl.

Expected values in serum:

Serum : up to 5,16 µmol/L (0.3mg/dl)

Each laboratory should establish an expected range

with a set of standards.

Unit Conversion

mg/dL x 17.1 = µmol/L

PRECISION

The CV of the test should be CV ≤5%

Intra Assay Precision		
N=20	Level 1	Level 2
Mean	19.04	32.40
SD	0.123	0.278
CV	0.65 %	0.86 %

Intra Assay Precision		
N=20	Level 1	Level 2
Mean	19.70	30.61
SD	0.151	0.460
CV	0.77 %	1.50 %

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.

BILIRUBIN DIRECT

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Calibration:

S1: 0,9 % NaCl

S2: BIOCAL H 5x3 ml #B11895

Calibration frequency:

A two point – calibration is recommended case of:

1-Change of lot

2-Quality Control Requirements

Literature:

1. Tietz, N.W.(ed), Fundamentals of Clinical Chemistry, 3rd Edition, W.B. Saunders, 1987.

2.Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000

3. J.A. Lott and B.T. Doumas – Clin. Chem.

Order information (Cat No.):

CC355	AB355	B25055	B30055	B33056	B37056
SH355	BBDI250	B25056	B30056	B34055	B80055
CR355	B21055	B27055	B31055	B35055	B80056
OL355	B21056	B27056	B32055	B36055	B80057
KL355	B22055	B28055	B32056	B36056	
BBDI500	B24055	B28056	B33055	B37055	

Manufacturer

Diaclinica Diagnostik Kimya.San.Tic.Ltd.Şti

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Web :www.diaclinica.com

SYMBOLS

IVD for in vitro diagnostic use only

LOT lot of manufacturing

REF code number

 storage at temperature interval

 expiration date (year/month)

 warning, read enclosed documents

 Read the directions