CE IVD

Liquid Reagents – ready to use

BILIRUBIN AUTO DIRECT

DCA with ATCS*
2 Reagents

Diagnostic reagent for quantitative in vitro determination of direct bilirubin in human serum or plasma on photometric systems.

REF Cont.

D96543	**5 x 100 ml**	4 x 100 ml	Reagent 1
		1 x 100 ml	Reagent 2

Additionally offered:

D98485SV	1 x 3 ml	Calibrator	Diacal Auto
D98485	5 x 3 ml	Calibrator	Diacal Auto
D98481	12 x 5 ml	Control normal	Diacon N
D98482	12 x 5 ml	Control abnormal	Diacon P

TEST PARAMETERS

Method:	Colorimetric, Endpoint, Increasing Reaction, DCA
Wavelength:	Hg 546 nm, 540-560 nm
Temperature:	20 – 25 °C or 37°C
Sample:	Serum, heparinized plasma
Linearity:	up to 10 mg/dl
Sensitivity:	The lower limit of detection is 0.1 mg/dl

* **A**dvanced **T**urbidity **C**learing **S**ystem; minimizes turbidity caused by lipemia

REAGENT COMPOSITION

COMPONENTS	FINAL CONCENTRATION
Reagent 1	
EDTA-Na_2	0.07 mmol/L
NaCl	6.6 g/L
Sulfamine Acid	70 mmol/L
Reagent 2	
2.4-Dichlorphenyldiazoniumsalt	0.09 mmol/L
HCl	130 mmol/L
EDTA-Na_2	0.02 mmol/L

REAGENT PREPARATION

Substrate Start:
Reagents are ready for use.

Sample Start:
Not possible. (5 min stabilization of high lipemic sera)

REAGENT STABILITY AND STORAGE

Conditions: protect from light
close immediately after use

Substrate Start:
Storage: at 2 – 8°C
Stability: up to the expiration date

Maximum allowable absorbance of a mixture of 4 parts Reagent 1 and 1 part Reagent 2 measured at 546 nm against water as reference is 0.1.

SAMPLE STABILITY AND STORAGE

It is very important to store the sample protected from light!

Stability:	at 15 - 25 °C	2 days
	at 2 - 8 °C	7 days
	at - 20 °C *	3 months

*FREEZE ONLY ONCE!
Discard contaminated specimens.

INTERFERING SUBSTANCES

no interference up to:

ascorbic acid	30 mg/dl
hemoglobin	50 mg/dl
triglycerides	1000 mg/dl

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate Start:

Pipette into test tubes	Blank	Calibr.	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	-	-	100 µl
Calibrator	-	100 µl	-
Mix. Incubate for 3-5 min. (20 – 25 °C /37°C) and read A1 against Reagent Blank. Then add:			
Reagent 2	250 µl	250 µl	250 µl
Mix. Incubate for 5 min. (37°C) or 10 min. (20 – 25 °C) and read A2 against Reagent Blank. Calculate: ΔA=A2-A1.			

CALCULATION (light path 1 cm)

With calibrator:

$$\text{Bilirubin (mg/dl)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Cal}} \times \text{Conc. of Cal (mg/dl)}$$

UNIT CONVERSION

mg/dl x 17.1 = µmol/L

REFERENCE RANGE *(mg/dl)

up to 0.25

It is recommended that each laboratory establishes its own normal range.

TEST PRINCIPLE

Direct Bilirubin reacts with diazotized Dichloroaniline to form a colored azocompound.

PERFORMANCE CHARACTERISTICS

LINEARITY

The assay is linear up to 10 mg/dl.
Above this concentration, dilute the sample with NaCl (9 g/L sodium chloride in water) and reassay multiplying the result by the dilution factor.

PRECISION (at 37°C)

Intra-assay n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	0.34	0.01	3.24
Sample 2	0.73	0.01	1.51
Sample 3	2.05	0.03	1.27

Inter-assay n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	0.33	0.01	3.33
Sample 2	0.72	0.01	0.97
Sample 3	2.10	0.02	0.71

METHOD COMPARISON

A comparison between Dialab Bilirubin Auto Direct (y) and a commercially available test (x) using 76 samples gave following results: y = 0.95 x + 0.04 mg/dl; r= 0.995.

QUALITY CONTROL

All control sera with bilirubin values determined by this method can be used.
We recommend:

REF	Cont.		
D98481	12 x 5 ml	**DIACON N**	Assayed Control Serum Normal
D98482	12 x 5 ml	**DIACON P**	Assayed Control Serum Abnormal

CALIBRATION

The assay requires the use of a Bilirubin Standard or Calibrator.

We recommend:

REF	Cont.		
D98485SV	1 x 3 ml	**DIACAL AUTO**	Assayed Multi Calibration Serum
D98485	5 x 3 ml	**DIACAL AUTO**	Assayed Multi Calibration Serum

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNING AND PRECAUTIONS

Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Rand, R.N., Di Pasque, **A. Clin. Chem**., 8, 570 (1962).
2. Henry, J, Cannon, D.C, Winkelmann, J**.V.Clinical Chemistry, Principles and Tecnics**, Verlag Chemie 1042 (1974).

2°C 8°C IVD

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