

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.

<b>D96543</b>	<b>5 x 100 ml</b>	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

\* Advanced Turbidity Clearing System; minimizes turbidity caused by lipemia

### REAGENT COMPOSITION

COMPONENTS	FINAL CONCENTRATION
<b>Reagent 1</b>	
EDTA-Na <sub>2</sub>	0.07 mmol/L
NaCl	6.6 g/L
Sulfamine Acid	70 mmol/L
<b>Reagent 2</b>	
2,4-Dichlorophenyldiazoniumsalt	0.09 mmol/L
HCl	130 mmol/L
EDTA-Na <sub>2</sub>	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

$$\text{mg/dl} \times 17.1 = \mu\text{mol/L}$$

### REFERENCE RANGE \*(mg/dl)

up to 0.25
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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:  $y = 0.95x + 0.04$  mg/dl;  $r = 0.995$ .

### QUALITY CONTROL

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

We recommend:

REF	Cont.		
<b>D98481</b>	12 x 5 ml	<b>DIACON N</b>	Assayed Control Serum Normal
<b>D98482</b>	12 x 5 ml	<b>DIACON P</b>	Assayed Control Serum Abnormal

## CALIBRATION

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

We recommend:

REF	Cont.		
<b>D98485SV</b>	1 x 3 ml	<b>DIACAL AUTO</b>	Assayed Multi Calibration Serum
<b>D98485</b>	5 x 3 ml	<b>DIACAL AUTO</b>	Assayed Multi Calibration Serum

## AUTOMATION

Special adaptations for automated analyzers can be made on request.

## WARNING AND PRECAUTIONS

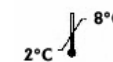
Take the necessary precautions for the use of laboratory reagents.

## 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 Tecnicis**, Verlag Chemie 1042 (1974).



DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.  
A – 2351 Wiener Neudorf, Austria  
IZ-NÖ Süd, Hondastrasse, Objekt M55  
Phone: ++43 (0) 2236 660910-0  
Fax: ++43 (0) 2236 660910-30 e-mail: [office@dialab.at](mailto:office@dialab.at)