CE IVD DIALAB

Liquid Reagents – ready to use

BILIRUBIN DIRECT

Jendrassik Grof
2 Reagents

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

REF Cont.

102002	**5 x 100 ml**	5 x 100 ml	Reagent 1
	(520 ml)	1 x 20 ml	Reagent 2
102012	**5 x 50 ml**	5 x 50 ml	Reagent 1
	(260 ml)	1 x 10 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, Increasing Reaction, Endpoint,. Jendrassik Grof
Wavelength:	555 nm
Temperature:	20 – 25°C, 37°C
Sample:	serum or plasma,
Linearity:	up to 20 mg/dl Total Bilirubin

REAGENT COMPOSITION

COMPONENTS	FINAL CONCENTRATION
Reagent 1:	
Sulfanilic Acid	32.2 mmol/L
Reagent 2:	
Sodium Nitrite	109 mmol/L

REAGENT PREPARATION

Substrate Start:
Reagents are ready for use.

Sample Start (Working Reagent):
Mix 150 parts of Reagent 1 with 1 part of Reagent 2.

REAGENT STABILITY AND STORAGE

Conditions:	protect from light close immediately after use
Storage:	at 2 – 8°C
Stability:	up to the expiration date

Working Reagent:

Stability: at 20 – 25°C 8 hours*
* in amber bottles.

SAMPLE STABILITY AND STORAGE

It is very important to store the sample protected from light!
Use only clear unhemolyzed serum.

Stability:	at 15 – 25°C	2 hours
	at 2 – 8°C	5 hours
	at - 20°C *	2 months

*in case of immediate freezing after use.
Discard contaminated specimens.

INTERFERING SUBSTANCES

no interference up to:

hemoglobin	1000 mg/dl

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Sample Start:

Pipette into test tubes	Sample blank	Sample	Calibr. blank	Calibr.
Reagent 1	1000 µl	-	1000 µl	-
Working R.	-	1000 µl	-	1000 µl
Sample	100 µl	100 µl	-	-
Calibrator	-	-	100 µl	100 µl
Mix without delay. Incubate for 3 minutes at 30 °C or for 2 minutes at 37 °C. Read absorbance of each test against the respective blank.				

Substrate Start:

Pipette into test tubes	Sample blank	Sample	Calibr. blank	Calibr.
Reagent 1	1000 µl	1000 µl	1000 µl	1000 µl
Sample	100 µl	100 µl	-	-
Calibrator	-	-	100 µl	100 µl
Reagent 2	-	10 µl	-	10 µl
Mix without delay. Incubate for 3 minutes at 30 °C or for 2 minutes at 37 °C. Read absorbance of each test against the respective blank.				

CALCULATION (light path 1 cm)

With Calibrator:

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

With Factor:

Bilirubin (mg/dl) = ΔA Sample x Factor

Factor = 12.9

The factor has to be checked by a calibration serum and adapted if necessary!

UNIT CONVERSION

mg/dl x 17.1 = µmol/L

REFERENCE RANGE *(mg/dl)

Conjugated (direct) bilirubin:	0.0 - 0.2
Unconjugated bilirubin:	0.2 - 0.8
Total bilirubin:	0.2 - 1.0

*It is recommended that each laboratory should establish its own reference range.

TEST PRINCIPLE

Bilirubin is formed from the heme portion of hemoglobin released by aged or damaged red blood cells.
It is then converted in the liver to bilirubin monoglucuronide and bilirubin diglucuronide.
Free bilirubin is not soluble in aqueous solution and requires solubilization by alcohols or other solvents to react.
Reactions carried out in these solvents provide measurements of total bilirubin.
Mono and diglucuronides of bilirubin are water soluble and measurements performed in aqueous solution measure what in this form is called direct bilirubin.
The assay of bound (direct) bilirubin is performed in an aqueous acid solution of diazotized sulfanilic acid.
The intensity of color of the diazo dye formed with bilirubin in aqueous solution is proportional to the concentration of direct bilirubin.

PERFORMANCE CHARACTERISTICS

LINEARITY

The assay is linear to 20 mg/dl.
Samples with bilirubin concentrations higher than 20 mg/dl should be diluted with distilled or deionized water and the assay should be repeated; multiply results by dilution factor.

PRECISION (at 37°C)

Intra-assay n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	0.31	0.01	3.59
Sample 2	2.57	0.02	0.58
Sample 3	5.33	0.01	0.09

Inter-assay n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	0.32	0.01	3.58
Sample 2	2.65	0.02	0.60
Sample 3	5.48	0.01	0.09

METHOD COMPARISON

A comparison between Dialab Bilirubin Total (y) and a commercially available test (x) using 55 samples gave following results: y = 0.989 x + 0.001 mg/dl; r= 0.998.

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
D98485	5 x 3 ml	**DIACAL AUTO**	Assayed Multi Calibration Serum

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

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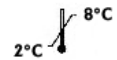

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