

## Bilirubin Auto Direct FS\*

Diagnostic reagent for quantitative in vitro determination of direct bilirubin in serum or plasma on DiaSys respons<sup>®</sup> 910

### Order Information

Cat. No. 1 0821 99 10 920

4 twin containers for 200 tests each

### Method

Photometric test using 2,4-dichloroaniline (DCA)

### Principle

Direct bilirubin in presence of diazotized 2,4-dichloroaniline forms a red colored azocompound in acidic solution.

### Reagents

#### Components and Concentrations

<b>R1:</b>	EDTA-Na <sub>2</sub>	0.1 mmol/L
	NaCl	150 mmol/L
	Sulfamic acid	100 mmol/L
<b>R2:</b>	2,4-Dichlorophenyl-diazonium salt	0.5 mmol/L
	HCl	900 mmol/L
	EDTA-Na <sub>2</sub>	0.13 mmol/L

#### Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents.

#### Warnings and Precautions

1. Reagents: S24/25: Avoid contact with skin and eyes.
2. In very rare cases, samples of patients with gammopathy might give falsified results.
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.

#### Waste Management

Please refer to local legal requirements.

#### Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

#### Specimen

Serum or heparin plasma

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

Stability [1]:

2 days	at	20 - 25 °C
7 days	at	4 - 8 °C
6 months	at	-20 °C

in case of immediate freezing.

Discard contaminated specimens. Freeze only once.

#### Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. This method has been standardized against the manual Jendrossik-Gróf test. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

### Performance Characteristics

Measuring range up to 7 mg/dL bilirubin (in case of higher concentrations re-measure samples after manual dilution or use rerun function).	
Limit of detection**	0.1 mg/dL direct bilirubin
On-board stability	6 weeks
Calibration stability	21 days

Interfering substance	Interferences < 10%	Direct bilirubin [mg/dL]
Ascorbate	up to 30 mg/dL	2.16
Naproxen	up to 1 mmol/L	0.15
Hemoglobin	< 5 mg/dL	0.27
	up to 25 mg/dL	5.35
Lipemia (triglycerides)	up to 400 mg/dL	0.44
	up to 2000 mg/dL	4.80
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.40	0.59	3.08
Coefficient of variation [%]	2.69	1.18	0.85
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.28	0.58	1.58
Coefficient of variation [%]	3.73	2.72	1.46

Method comparison (n=102)	
Test x	DiaSys Bilirubin AD FS (Hitachi 911)
Test y	DiaSys Bilirubin AD FS (respons <sup>®</sup> 910)
Slope	1.077
Intercept	-0.017 mg/dL
Coefficient of correlation	0.999

\*\* according to NCCLS document EP17-A, vol. 24, no. 34

#### Conversion factor

Bilirubin [mg/dL] x 17.1 = Bilirubin [µmol/L]

#### Reference Range [3]

Adults and children ≤ 0.2 mg/dL (≤ 3.4 µmol/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

#### Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1<sup>st</sup> ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
2. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.
3. Thomas L ed. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft, 1998; p. 192-202.
4. Tolman KG, Rej R. Liver function. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3<sup>rd</sup> ed. Philadelphia: W.B Saunders Company; 1999. p. 1125-77.
5. Rand RN, di Pasqua A. A new diazo method for the determination of bilirubin. Clin Chem 1962; 6: 570-8.

#### Manufacturer



DiaSys Diagnostic Systems GmbH  
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## Bilirubin Auto Direct FS

### Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel

Identification	
This method is usable for analysis:	Yes
Name:	DBIL
Shortcut:	
Reagent barcode reference:	018
Host reference:	

Technic	
Type:	Endpoint
First reagent:[ $\mu$ L]	180
Blanc correction	Yes
Second reagent:[ $\mu$ L]	45
Blanc correction	Yes
Main wavelength:[nm]	546
Secondary wavelength:[nm]	660
Polychromatic factor:	1.000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Substrate depletion: absorbance limit	
Endpoint	
Stability: largest remaining slope	-
Prozone Limit [%]	-

Sample	
Diluent	NaCl
Concentration technical limits-Lower	0.1
Concentration technical limits-Upper	7
SERUM	
Normal volume [ $\mu$ L]	8
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	15
Below normal dilution (factor)	1
Above normal volume [ $\mu$ L]	2
Above normal dilution (factor)	1
URIN	
Normal volume [ $\mu$ L]	8
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	15
Below normal dilution (factor)	1
Above normal volume [ $\mu$ L]	2
Above normal dilution (factor)	1
PLASMA	
Normal volume [ $\mu$ L]	8
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	15
Below normal dilution (factor)	1
Above normal volume [ $\mu$ L]	2
Above normal dilution (factor)	1
CSF	
Normal volume [ $\mu$ L]	8
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	15
Below normal dilution (factor)	1
Above normal volume [ $\mu$ L]	2
Above normal dilution (factor)	1

Results	
Decimals	1
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	All
Age	
SERUM	>= <=0.2
URINE	
PLASMA	>= <=0.2
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [ $\mu$ L]	
Contaminant 2	
Wash with	
Cycle	
Volume [ $\mu$ L]	

Calibrators details	
Calibrator list	Concentration
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
Max delta abs.	
Cal. 1	0.015
Cal. 2	0.005
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8
Calculations	
Model	X degree
Degree	1

\* Enter calibrator value