

## Bilirubin Auto Total FS\*

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

### Order Information

Cat. No. 1 0811 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. A specific mixture of detergents enables a safe determination of the total bilirubin.

### Reagents

#### Components and Concentrations

<b>R1:</b>	Phosphate buffer	50 mmol/L
	NaCl	150 mmol/L
	Detergent, stabilizers	
<b>R2:</b>	2,4-Dichlorophenyl-diazonium salt	5 mmol/L
	HCl	130 mmol/L
	Detergent	

#### 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. Reagent 1: S61: Avoid release to the environment. Refer to special instructions/safety data sheets.
3. In very rare cases, samples of patients with gammopathy might give falsified results.
4. 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]:

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

in case of immediate freezing.

Freeze only once!

Discard contaminated specimens.

### Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. The assigned values for total bilirubin have been made traceable to the SRM 916 reference material. 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 30 mg/dL bilirubin (in case of higher concentrations re-measure samples after manual dilution or use rerun function)	
Limit of detection**	0.11 mg/dL bilirubin
On-board stability	4 weeks
Calibration stability	3 days

Interfering substance	Interferences < 10%	Total Bilirubin [mg/dL]
Ascorbate	up to 30 mg/dL	2.26
Naproxen	up to 1 mmol/L	0.46
Hemoglobin	up to 100 mg/dL	1.17
	up to 500 mg/dL	15.2
Lipemia (triglycerides)	up to 1000 mg/dL	1.29
	up to 2000 mg/dL	13.3
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]	0.85	1.03	6.86
Coefficient of variation [%]	1.85	2.31	0.93
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.75	1.84	6.82
Coefficient of variation [%]	4.60	3.67	0.95

Method comparison (n=94)	
Test x	DiaSys Bilirubin AT FS (Hitachi 911)
Test y	DiaSys Bilirubin AT FS (respons <sup>®</sup> 910)
Slope	1.028
Intercept	0.036 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]



	[mg/dL]	[µmol/L]
<b>Neonates</b>		
24 h	< 8.8	< 150
2nd day	1.3 - 11.3	22 - 193
3rd day	0.7 - 12.7	12 - 217
4th - 6th day	0.1 - 12.6	1.7 - 216
<b>Children</b>		
> 1 month	0.2 - 1.0	3.4 - 17
<b>Adults</b>	0.1 - 1.2	1.7 - 21

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  
Alte Strasse 9 65558 Holzheim Germany

## Bilirubin Auto Total 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:	TBIL
Shortcut:	
Reagent barcode reference:	019
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]	09:00
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	0.11
Concentration technical limits-Upper	30
SERUM	
Normal volume [ $\mu$ L]	5
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	8
Below normal dilution (factor)	1
Above normal volume [ $\mu$ L]	2
Above normal dilution (factor)	1
URIN	
Normal volume [ $\mu$ L]	5
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	8
Below normal dilution (factor)	1
Above normal volume [ $\mu$ L]	2
Above normal dilution (factor)	1
PLASMA	
Normal volume [ $\mu$ L]	5
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	8
Below normal dilution (factor)	1
Above normal volume [ $\mu$ L]	2
Above normal dilution (factor)	1
CSF	
Normal volume [ $\mu$ L]	5
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	8
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	Male
Age	
SERUM	$\geq 0.1 \leq 1.2$
URINE	
PLASMA	$\geq 0.1 \leq 1.2$
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