respons®920

Bilirubin Auto Total FS*

Order Information

Cat. No.	Kit size
1 0811 99 10 920	Σ 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of total bilirubin in human serum or heparin plasma on automated DiaSys respons®920.

Summary

Bilirubin is a breakdown product of hemoglobin. Free, unconjugated bilirubin is extremely apolar and nearly insoluble in water, thus forming a complex with albumin for the transport in the blood from the spleen to the liver. In the liver, bilirubin is conjugated with glucoronic acid and the resulting water soluble bilirubin glucoronic acid is excreted via the bile ducts. Hyperbilirubinemia can be caused by increased bilirubin production due to hemolysis (pre-hepatic jaundice), by parenchymal damages of the liver (intra-hepatic jaundice) or by occlusion of bile ducts (post-hepatic jaundice). A chronic congenital (predominantly unconjugated) hyperbilirubinemia called Gilbert's syndrome is quite frequent in the population. High levels of total bilirubin are observed in 60 – 70% of neonates due to an increased postpartum breakdown of erythrocytes and because of delayed function of enzymes for bilirubin degradation. Common bilirubin methods detect either total bilirubin or direct bilirubin. Determinations of direct bilirubin measure mainly conjugated, water soluble bilirubin. Therefore, the value of unconjugated bilirubin may be estimated from the difference between total bilirubin and direct bilirubin. [1,2]

Method

Photometric test using 2,4-dichloroaniline (DCA)

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 [3].

Reagents

Components and Concentrations

R1:	Phosphate buffer	50 mmol/L
	NaCl	150 mmol/L
R2:	2,4-Dichloroaniline	5 mmol/L
	HCl	130 mmol/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze reagents and protect them from light.

Warnings and Precautions

1. ⚠ Reagent 1: Warning. H290 May be corrosive to metals. H315 Causes skin irritation. H319 Causes serious eye irritation. H410 Very toxic to aquatic life with long lasting effects. P234 Keep only in original packaging. P264 Wash hands and face thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection. P337+P313 If eye irritation persists: Get medical advice/attention. P391 Collect spillage.
2. ⚠ Reagent 2: Warning: H290 May be corrosive to metals. H319 Causes serious eye irritation. P234 Keep only in original packaging. P264 Wash hands and face thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. P390 Absorb spillage to prevent material damage.
3. In very rare cases, samples of patients with gammopathy might give falsified results [4].
4. Eltrombopag medication leads to falsely low or high results in patient samples.
5. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
6. 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.
7. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Protect sample from light.

Stability [5]:

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

in case of immediate freezing.

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. TruCal U calibrator values have been made traceable to the NIST SRM 916 reference material. Use DiaSys TruLab N and P for internal quality control. 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

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 30 mg/dL. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.01 mg/dL
Onboard stability	4 weeks
Calibration stability	4 weeks

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Hemoglobin	1000 mg/dL
Lipemia (triglycerides)	2000 mg/dL
Naproxen	1 mmol/L
For further information on interfering substances refer to Young DS [6,7].	

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	0.99	1.04	5.67
CV [%]	2.80	1.03	0.59
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	0.95	1.04	5.62
CV [%]	4.23	3.79	2.36

Method comparison (n=110)	
Test x	DiaSys Bilirubin Auto Total FS (Hitachi 917)
Test y	DiaSys Bilirubin Auto Total FS (respons®920)
Slope	1.00
Intercept	0.005 mg/dL
Coefficient of correlation	0.990

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

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

Reference Range [1]

	[mg/dL]	[µmol/L]
Neonates		
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
Children		
>1 month	0.2 – 1.0	3.4 – 17
Adults	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. Thomas L ed. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft, 1998: p. 192-202.
2. Tolman KG, Rej R. Liver function. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1125-77.
3. Rand RN, di Pasqua A. A new diazo method for the determination of bilirubin. Clin Chem 1962; 6: 570-8.
4. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
5. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
6. 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.
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DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
www.diasys-diagnostics.com

* Fluid Stable

respons®920

Bilirubin Auto Total FS

Application für serum und plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	TBIL				Auto Rerun	☐	
Report Name	:	Total Bilirubin				Online Calibration	☐	
Unit	:	mg/dL	Decimal Places	:	2	Cuvette Wash	☐	
Wavelength-Primary	:	546	Secondary	:	660	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Linear	Reagent R1	:	TBIL R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	TBIL R2
M2 Start	:	33	M2 End	:	33	**Consumables/Calibrators:**		
Sample Replicates	:	1	Standard Replicates	:	3	Blank		0
Control Replicates	:	1	Control Interval	:	0	Calibrator		*
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.0000			
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs. / Min.	:	0.0000			
Technical Minimum	:	0.01	Technical Maximum	:	30.0			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	TBIL		
Sample Type	:	Serum		

Sample Volumes

Normal	:	5.00	µL	Dilution Ratio	:	1	X
Increase	:	8.00	µL	Dilution Ratio	:	1	X
Decrease	:	2.00	µL	Dilution Ratio	:	1	X
Standard Volume	:	5.00	µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180	µL	R1 Stirrer Speed	:	High	
RGT-2 Volume	:	45	µL	R2 Stirrer Speed	:	High	

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	TBIL		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	0.10	1.20
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other