respons®920

Bilirubin Auto Direct FS*

Order Information

Cat. No.	Kit size
1 0821 99 10 920	Σ 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of direct 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 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. [3]

Reagents

Components and Concentrations

R1:	EDTA-Na_2	0.1 mmol/L
	NaCl	150 mmol/L
	Sulfamic acid	100 mmol/L
R2:	2,4-Dichloroaniline	0.5 mmol/L
	HCl	900 mmol/L
	EDTA-Na_2	0.13 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 and protect from light.

Warnings and Precautions

1. ⚠ Reagent 1 and 2: Warning. H290 May be corrosive to metals. P234 Keep only in original packaging. P390 Absorb spillage to prevent material damage.
2. In very rare cases, samples of patients with gammopathy might give falsified results [4].
3. Eltrombopag medication leads to falsely low or high results in patient samples.
4. 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.
5. The summary of safety and performance (SSP) may be accessed on the website of the European Databank on Medical Devices (EUDAMED) via the following link: …….
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]:

2 days	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. Calibrator values have been made traceable to the manual Jendrassik-Gróf test. 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 10 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
Lipemia (triglycerides)	1000 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]	0.34	0.57	2.25
CV [%]	3.35	1.13	0.59
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	0.32	0.68	3.00
CV [%]	3.65	1.21	0.96

Method comparison (n=110)	
Test x	DiaSys Bilirubin Auto Direct FS (Hitachi 917)
Test y	DiaSys Bilirubin Auto Direct FS (respons®920)
Slope	1.0
Intercept	0.0 mg/dL
Coefficient of correlation	0.960

** 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]

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. 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.
7. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in December 2020. Published by AACC Press and John Wiley and Sons, Inc.

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* Fluid Stable

respons®920

Bilirubin Auto Direct FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	DBIL				Auto Rerun		☐
Report Name	:	Direct 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	:	DBIL R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	DBIL R2
M2 Start	:	33	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.0000	Calibrator 1		*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	0.01	Technical Maximum	:	10.0			
Y = aX + b a =	:	1.0000	b=	:	0.0000			

*Enter calibrator value

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

Sample Volumes

Normal	:	8.00 µL	Dilution Ratio	:	1 X	
Increase	:	15.00 µL	Dilution Ratio	:	1 X	
Decrease	:	3.00 µL	Dilution Ratio	:	1 X	
Standard Volume	:	8.00 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	:	DBIL		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	0.00	0.20
Panic	:	0.00	0.00

Sample Types

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