respons®920

UIBC FS*

Diagnostic reagent for quantitative in vitro determination of the unsaturated iron binding capacity in serum or plasma on DiaSys respons®920

Order information

Cat. No. 1 1921 99 10 921
4 twin containers for 120 determinations each

Method

Photometric test using Ferene

Principle

A known ferrous ion concentration incubated with sample, binds specifically with transferrin at unsaturated iron binding sites. Remaining unbound ferrous ions are measured with the ferene reaction.
The difference between the amount of excess iron and the total amount added to the serum is equivalent to the quantity bound to transferrin. This is the UIBC (unsaturated iron binding capacity) of the sample.

$$2\ Fe^{2+}\ (known) + Transferrin \longrightarrow Transferrin\ (Fe^{3+}) + Fe^{2+}\ (excess)$$

$$Fe^{2+}(excess) + 3\ Ferene \longrightarrow Ferene\ (blue\ complex)$$

Reagents

Components and Concentrations

R1:	Buffer	pH 8.7	100 mmol/L
	Ammonium iron (II) sulfate		13 µmol/L
	Thiourea		120 mmol/L
R2:	Ascorbic acid		240 mmol/L
	Ferene		6 mmol/L
	Thiourea		125 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. Reagent 1: Danger. H318 Causes serious eye damage. P280 Wear protective gloves/protective clothing/eye protection/face 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. P310 Immediately call a poison center or doctor/physician.
2. Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
3. 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.
4. In very rare cases, samples of patients with gammopathy might give falsified results [7].
5. 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.
6. For professional use only!

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, heparin plasma
Separate serum/plasma at the latest 2 h after blood collection to avoid hemolysis.

Stability [1]	in serum:		
	5 days	at	20 – 25°C
	1 month	at	2–- 8°C
	1 month	at	−20°C
Stability [1]	in plasma:		
	1 month	at	2 – 8°C
	1 month	at	−20°C

Calibrators and Controls

DiaSys TruCal U calibrator is recommended for calibration. The assigned values of the calibrator have been made traceable to a measurement of transferrin and iron. Thereby, the transferrin value is traceable to ERM®-DA470k/IFCC and the iron value is traceable to NIST SRM 682. For internal quality control DiaSys TruLab N control 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 10 064	6 x	3 mL
	5 9100 99 10 063	20 x	3 mL
TruLab N	5 9000 99 10 062	20 x	5 mL
	5 9000 99 10 061	6 x	5 mL

Performance Characteristics

Measuring range up to 750 µg/dL UIBC (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	40 µg/dL UIBC
On-board stability	14 days
Calibration stability	4 days

Interfering substance	Interferences < 10%	UIBC [µg/dL]
Ascorbate	up to 30 mg/dL	146
Hemoglobin	up to 30 mg/dL	143
	up to 75 mg/dL	312
Bilirubin, conjugated	up to 60 mg/dL	126
	up to 60 mg/dL	320
Bilirubin, unconjugated	up to 60 mg/dL	127
	up to 60 mg/dL	325
Lipemia (triglycerides)	up to 2000 mg/dL	137
	up to 2000 mg/dL	299
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	168	395	825
Coefficient of variation [%]	2.94	1.51	0.73
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	142	284	795
Coefficient of variation [%]	3.88	3.37	1.36

Method comparison (n=101)	
Test x	DiaSys UIBC FS Hitachi 917
Test y	DiaSys UIBC FS respons®920
Slope	0.972
Intercept	-3.85 µg/dL
Coefficient of correlation	0.999

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

Conversion Factor

UIBC [µg/dL] x 0.1791 = UIBC [µmol/L]

Reference Range [3,4]

Taking into account reference values for iron and transferrin, the following reference range results for UIBC:

120 – 470 µg/dL (21 – 84 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. Data on file at DiaSys Diagnostic Systems GmbH.
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. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-20.
4. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 273-5.
5. Fairbanks VF, Klee GG. Biochemical aspects of hematology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1642–1710.
6. Wick M, Pingerra W, Lehmann P. Clinical aspects and laboratory. Iron metabolism, anemias. 5th ed. Wien, New York: Springer; 2003.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240–1243.

Manufacturer

IVD CE

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* fluid stable

respons®920

UIBC FS

Application for serum und plasma

Test Details		Test Volumes		Reference Ranges	
Test	: UIBC			Auto Rerun	☐
Report Name	: UIBC			Online Calibration	☐
Unit	: µg/dL	Decimal Places	: 1	Cuvette Wash	☐
Wavelength-Primary	: 578	Secondary	: 700	Total Reagents	: 2
Assay Type	: 2-Point	Curve Type	: Linear	Reagent R1	: UIBC R1
M1 Start	: 15	M1 End	: 15	Reagent R2	: UIBC 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	: 30	Technical Maximum	: 800		
$Y = aX + b$ a=	1 1.0000	b=	: 0.0000		

* Enter calibrator value.

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

Sample Volumes

				Dilution Ratio		
Normal	:	14.0	µL	Dilution Ratio	:	1 X
Increase	:	18.0	µL	Dilution Ratio	:	1 X
Decrease	:	10.0	µL	Dilution Ratio	:	1 X
Standard Volume	:	14.0	µL			

Reagent Volumes and Stirrer Speed

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

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

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

Reference Range

	Lower Limit (µg/dL)	Upper Limit (µg/dL)
Normal	: 120	470
Panic	: 0.00	0.00

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