respons®910

UIBC FS*

Diagnostic reagent for quantitative in vitro determination of the unsaturated iron binding capacity in serum or plasma on DiaSys respons®910

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 ⟶ Transferrin (Fe^{3+}) + Fe^{2+} (excess)

Fe^{2+}(excess) + 3 Ferene ⟶ 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. Use only disposable material to avoid iron contamination.
4. In very rare cases, samples of patients with gammopathy might give falsified results [7].
5. To avoid contamination and carryover, special care should be taken in combination with Ferritin SR reagent.
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

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.

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys TruCal U 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 640 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**	23 µg/dL UIBC
On-board stability	2 weeks
Calibration stability	1 week

Interfering substance	**Interferences < 10%**	**UIBC [µg/dL]**
Ascorbate	up to 30 mg/dL	146
Hemoglobin	up to 50 mg/dL	179
	up to 150 mg/dL	375
Bilirubin, conjugated	up to 60 mg/dL	139
	up to 60 mg/dL	318
Bilirubin, unconjugated	up to 65 mg/dL	204
	up to 50 mg/dL	404
Lipemia (triglycerides)	up to 2000 mg/dL	196
	up to 2000 mg/dL	369
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]	166	218	369
Coefficient of variation [%]	2.96	2.29	1.23
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	152	201	247
Coefficient of variation [%]	3.94	3.16	2.53

Method comparison (n=120)	
Test x	DiaSys UIBC FS Hitachi 917
Test y	DiaSys UIBC FS respons®910
Slope	1.02
Intercept	8.81 µg/dL
Coefficient of correlation	0.996

** 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

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

respons®910

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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
Twin reaction:	No
Name:	UIBC
Shortcut:	
Reagent barcode reference:	053
Host reference:	053

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	45
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	600
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
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 [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	23.0000
Concentration technical limits-Upper	640.0000
SERUM	
Normal volume [µL]	13.5
Normal dilution (factor)	1
Below normal volume [µL]	20.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
URINE	
Normal volume [µL]	13.5
Normal dilution (factor)	1
Below normal volume [µL]	20.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	13.5
Normal dilution (factor)	1
Below normal volume [µL]	20.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	13.5
Normal dilution (factor)	1
Below normal volume[µL]	20.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	13.5
Normal dilution (factor)	1
Below normal volume[µL]	20.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	1

Results	
Decimals	0
Units	µg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=120 <=470
URINE	
PLASMA	>=120 <=470
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0050
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value