respons®920

Iron FS* Ferene

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

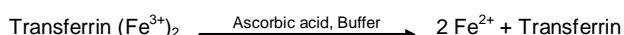### Order Information
Cat. No. 1 1911 99 10 921
4 twin containers for 120 determinations each

Method
Photometric test using Ferene

Principle
Iron bound to transferrin is released in an acidic medium as ferric iron and is then reduced to ferrous iron in the presence of ascorbic acid. Ferrous iron forms a blue complex with Ferene. The absorbance at 595 nm is directly proportional to the iron concentration.

$$\text{Transferrin (Fe}^{3+})_2 \xrightarrow{\text{Ascorbic acid, Buffer}} 2\,Fe^{2+} + \text{Transferrin}$$

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

Reagents

Components and Concentrations

R1:	Acetate buffer	pH 4.5	1 mol/L
	Thiourea		120 mmol/L
R2:	Ascorbic acid		240 mmol/L
	Ferene		3 mmol/L
	Thiourea		120 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 and contamination is avoided. Do not freeze the reagents! Reagents should be protected from light. DiaSys respons containers provide protection from light.

Warnings and Precautions
1. Reagent 1: Danger. H315 Causes skin irritation. H318 Causes serious eye damage. P264 Wash hands and face thoroughly after handling. 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. Use only disposable material to avoid iron contamination.
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 [8].
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 or heparin plasma
Separate serum/plasma at the latest 2 h after blood collection to minimize hemolysis.
Stability [1]:

7 days	at	20 – 25°C
3 weeks	at	4 – 8°C
1 year	at	−20°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls
DiaSys TruCal U calibrator is recommended for calibration. The assigned values of the calibrator have been made traceable to the NIST reference material SRM®-682. 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 1000 µg/dL iron (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	5 µg/dL iron
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by	
Hemoglobin up to 50 mg/dL	
Conjugated Bilirubin up to 60 mg/dL	
Unconjugated Bilirubin up to 60 mg/dL	
Lipemia (triglycerides) up to 2000 mg/dL	
Copper up to 200 µg/dL	
Zinc up to 400 µg/dL	
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]	87.2	175	277
Coefficient of variation [%]	1.27	0.74	0.40
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	90.5	174	279
Coefficient of variation [%]	0.97	1.20	0.63

Method comparison (n=111)	
Test x	DiaSys Iron FS Ferene (Hitachi 917)
Test y	DiaSys Iron FS Ferene (respons®920)
Slope	1.01
Intercept	3.07 µg/dL
Coefficient of correlation	0.998

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

Conversion factor
Iron [µg/dL] x 0.1791 = [µmol/L]

Reference Range [3]

	µg/dL	µmol/L
Children		
2 weeks	63 – 201	11 – 36
6 months	28 – 135	5 – 24
12 months	35 – 155	6 – 28
2 - 12 years	22 – 135	4 – 24
Women		
25 years	37 – 165	6.6 – 29.5
40 years	23 – 134	4.1 – 24.0
60 years	39 – 149	7.0 – 26.7
Pregnant women		
12th gestational week	42 – 177	7.6 – 31.6
at term	25 – 137	4.5 – 24.5
6 weeks postpartum	16 – 150	2.9 – 26.9
Men		
25 years	40 – 155	7.2 – 27.7
40 years	35 – 168	6.3 – 30.1
60 years	40 – 120	7.2 – 21.5

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

* fluid stable

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Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 34-5.
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. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 273-5.
4. Wick M. Iron metabolism and its disorders. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 268-73.
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. Higgins T. Novel chromogen for serum iron determinations. Clin Chem 1981; 27: 1619.
7. Artiss JD, Vinogradov S, Zak B. Spectrophotometric study of several sensitive reagents for serum iron. Clin Biochem 1981; 14: 311-15.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE DiaSys Diagnostic Systems GmbH
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respons®920

Iron FS Ferene
Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: FE			Auto Rerun	☐
Report Name	: IRON			Online Calibration	☐
Unit	: µg/dL	Decimal Places	: 2	Cuvette Wash	☐
Wavelength-Primary	: 578	Secondary	: 700	Total Reagents	: 2
Assay Type	: 2-Point	Curve Type	: Linear	Reagent R1	: FE R1
M1 Start	: 15	M1 End	: 15	Reagent R2	: FE 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	: 0.00	Calibrator 1	*
Prozone Limit %	: 0	Prozone Check	: Lower		
Linearity Limit %	: 0	Delta Abs./Min.	: 0.00		
Technical Minimum	: 5.00	Technical Maximum	: 1000.00		
$Y = aX + b$ a=	: 1.00	b=	: 0.00		

* Enter calibrator value

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

Sample Volumes

			Dilution Ratio		
Normal	:	11.00 µL	Dilution Ratio	:	1 X
Increase	:	15.00 µL	Dilution Ratio	:	1 X
Decrease	:	8.00 µL	Dilution Ratio	:	1 X
Standard Volume	:	11.00 µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	Medium
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	: FE		
Sample Type	: Serum		
Reference Range	: DEFAULT		
Category	: Male		

Reference Range

		Lower Limit (µg/dL)	Upper Limit (µg/dL)
Normal	:	35.00	168.00
Panic	:	0.00	0.00

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