respons®910

Iron FS* Ferene

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

Order Information

Cat. No. 1 1911 99 10 921
4 twin containers for 120 tests 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 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. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. 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.
5. 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. Feeze only once.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. 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**	4 µg/dL iron
On-board stability	6 weeks
Calibration stability	7 days

Interfering substance	Interferences < 10%	Iron [µg/dL]
Ascorbate	up to 30 mg/dL	97.9
Hemoglobin	up to 24 mg/dL	38.7
	up to 90 mg/dL	159
Bilirubin, conjugated	up to 65 mg/dL	40.0
	up to 65 mg/dL	143
Bilirubin, unconjugated	up to 70 mg/dL	50.5
	up to 70 mg/dL	144
Lipemia (triglycerides)	up to 1900 mg/dL	39.4
	up to 1900 mg/dL	140
Copper	up to 200 µg/dL	97.1
Zinc	up to 400 µg/dL	95.7
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]	71.6	148	309
Coefficient of variation [%]	1.66	2.73	1.34
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	65.5	143	317
Coefficient of variation [%]	3.54	1.87	1.52

Method comparison (n=113)	
Test x	DiaSys Iron FS Ferene (Hitachi 917)
Test y	DiaSys Iron FS Ferene (respons®910)
Slope	0.990
Intercept	–1.708 µg/dL
Coefficient of correlation	0.9997

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

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.

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

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respons®910

Iron FS Ferene

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:	FE
Shortcut:	
Reagent barcode reference:	042
Host reference:	042

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	4.0000
Concentration technical limits-Upper	1000.0000
SERUM	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	15.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
URINE	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	15.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	15.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume[µL]	15.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume[µL]	15.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	1

Results	
Decimals	2
Units	µg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Male
Age	25-40 a
SERUM	>=40.00 <=155.00
URINE	
PLASMA	>=40.00 <=155.00
CSF	
Whole blood	
Gender	Female
Age	25-40 a
SERUM	>=37.00 <=165.00
URINE	
PLASMA	>=37.00 <=165.00
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	0.002
Cal. 2	0.005
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value