BioMajesty

Iron FS* Ferene

Diagnostic reagent for quantitative in vitro determination of iron in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 1911 99 10 964
R1: 6 x 150 tests
R2: 6 x 150 tests

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, protected from light and contamination is avoided. Do not freeze the reagents!

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 trays.

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

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator have been made traceable to the NIST-SRM®682 reference material. 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 (179 µmol/L) 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**	2.2 µg/dL (0.39 µmol/L) iron
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 100 mg/dL
Bilirubin (conjugated and unconjugated) up to 60 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
Zinc up to 400 µg/dL
For further information on interfering substances refer to Young DS [7].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	78.2	169	261
Mean [µmol/L]	14.0	30.3	46.8
Coefficient of variation [%]	1.36	1.25	0.91
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	78.6	254	330
Mean [µmol/L]	14.1	45.4	59.0
Coefficient of variation [%]	2.23	1.53	0.98

Method comparison (n=143)	
Test x	Competitor Iron
Test y	DiaSys Iron FS Ferene
Slope	1.04
Intercept	-3.87 µg/dL (-0.694 µmol/L)
Coefficient of correlation	0.9999

** 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]

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Reference Range [2]

	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.
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3. Wick M. Iron metabolism and its disorders. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 268-73.
4. 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.
5. Higgins T. Novel chromogen for serum iron determinations. Clin Chem 1981; 27: 1619.
6. Artiss JD, Vinogradov S, Zak B. Spectrophotometric study of several sensitive reagents for serum iron. Clin Biochem 1981; 14: 311-15.
7. 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.
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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Iron FS

Chemistry code 10 191

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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	5.0
Sample vol (U)	5
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	FE
Digits	2
M-wave L.	596
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	5.0	5.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999