BioMajesty®

Iron FS* Ferene

Order Information

Cat. No.	Kit size
1 1911 99 10 964	900 (R1: 6 x 150, R2: 6 x 150)

Intended Use

Diagnostic reagent for quantitative in vitro determination of iron in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

Summary

Iron exists in the body as a component of hemoglobin and myoglobin as well as bound to transferrin for the transport in plasma and stored in ferritin. Increased iron concentrations occur in hemochromatosis and liver damage [1]. Malabsorption due to gastrointestinal diseases can cause decreased iron levels, and may thus lead to anemia. Blood loss after gastrointestinal lesions or heavy menstrual bleeding can generate anemia, too [2].

Method

Photometric test using Ferene

Iron bound to transferrin (Fe^{3+}) is completely released under acidic conditions and reduced to Fe^{2+}. 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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

1. Components contained in Iron FS Ferene are classified according to EC regulation 1272/2008 (CLP) as follows:

⚠ Reagent 1: Danger. Contains Dodecan-1-ol, ethoxylated and Alcohols, C9-11-iso-, C10-rich, ethoxylated. 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. 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/doctor.

2. In very rare cases, samples of patients with gammopathy might give falsified results [3].
3. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
4. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
5. Please refer to the safety data sheets (SDS) 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

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Separate serum/plasma at the latest 2 h after blood collection to minimize hemolysis.

Stability [4]:

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

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the NIST Reference Material SRM 682. Use DiaSys TruLab N and P for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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, linearity is given within ± 5%. 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
Onboard stability	6 weeks
Calibration stability	6 weeks

Interference by	**Interferences ≤ 10% up to**	**Analyte concentration [µg/dL]**
Ascorbic acid	30 mg/dL	85.0
Bilirubin (conjugated)	60 mg/dL	84.9
Bilirubin (unconjugated)	60 mg/dL	84.9
Hemolysis	100 mg/dL	84.2
Lipemia (triglycerides)	2000 mg/dL	84.3
Zinc	400 µg/dL	85.3

For further information on interfering substances, refer to the literature [5,6].

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Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	78.2	169	261
CV [%]	1.36	1.25	0.914
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	78.6	254	330
CV [%]	2.23	1.53	0.983

Method comparison (n=143)	
Test x	Competitor Iron (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Iron FS Ferene (BioMajesty® JCA-BM6010/C)
Slope	1.04
Intercept	-3.87 µg/dL
Coefficient of correlation	0.999

** 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 = Iron [µmol/L]

Reference Range [7]

	[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 week	42 – 177	7.6 – 31.6
At delivery	25 – 137	4.5 – 24.5
6 weeks post partum	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. Wick et al, Clinical Aspects and Lab Iron Metabolism, Anemias. Novel concepts, Springer,5th ed. Wien New York 2003 p141 – 147.
2. 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.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 34-5.
5. 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.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in March 2024. Published by AACC Press and John Wiley and Sons, Inc.
7. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 May 13]. https://www.clinical-laboratory-diagnostics.com

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

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* Fluid Stable

BioMajesty®

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