Iron FS* Ferene

Order Information

Cat. No.	Kit size		
1 1911 99 10 021	R1 5 x 20 mL	+	R2 1 x 25 mL
1 1911 99 10 026	R1 5 x 80 mL	+	R2 1 x 100 mL
1 1911 99 10 023	R1 1 x 800 mL	+	R2 1 x 200 mL
1 1911 99 10 704	R1 8 x 50 mL	+	R2 8 x 12.5 mL
1 1911 99 10 917	R1 8 x 60 mL	+	R2 8 x 15 mL
1 1911 99 10 930	R1 4 x 20 mL	+	R2 2 x 10 mL

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of iron in human serum or heparin plasma on automated photometric systems.

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. Use only disposable material to avoid iron contamination. When using glassware, rinse the material with diluted HCl and copious dist. water.
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. 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.
6. 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.
7. 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.

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.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	596/694 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	5.0 µL
Reagent 1	80 µL
Reagent 2	20 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Linear

Calculation

With Calibrator

$$\text{Iron [µg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Cal.}} \times \text{Conc. Cal. [µg/dL]}$$

Conversion Factor

Iron [µg/dL] x 0.1791 = Iron [µmol/L]

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the NIST Reference Material SRM 682. Iron Standard FS may be used alternatively for calibration. 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
Iron Standard FS	1 1900 99 10 030	6	x	3 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range up to 1000 µg/dL, linearity is given within ± 5%. When values exceed this range, samples should be diluted 1 + 2 with NaCl solution (9 g/L) and the result multiplied by 3.	
Limit of detection**	2.2 µg/dL

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].

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.

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

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