ISE S.r.l.
CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

IRON ferene – Instructions for use

R1: 4 x 50 mL • REF A-R0200000500
R2: 4 x 20 mL

CE IVD

SUMMARY

Iron exists in the biological fluid 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. Decreased iron levels can be caused by anemia due to malabsorption as consequence of gastrointestinal diseases or by blood loss as a result of gastrointestinal lesions or heavy menstrual bleeding. For the estimation of the body iron status, the measurement of transferrin and ferritin can provide more detailed information.

PRINCIPLE

In a pH 4.8 buffer system, iron is released from transferrin to which it is bound, and then quantitatively reduced to ferrous state. The iron++ forms with Ferene S {3-(2-pyridil)-5,6-bis-[2-(5-furylsulfonic acid)]-1,2,4-triazine} a stable coloured complex, which colour intensity is proportional to the amount of iron in the sample. The interference from copper is eliminated by particular reaction conditions and a specific masking agent.

REAGENTS

Kit R1: 4 x 50 mL R2: 4 x 20 mL Code A-R0200000500
Reagent 1: no. 4 vials x 48.50 mL
Reagent 2: no. 4 vials x 3 mL

Concentrations

Reagent 1:		
	Conc.	**U.M.**
acetate buffer Ph 4.8	1.4	mol/L
guanidine hydrochloride	≥ 4.5	mol/L
copper specific masking agent		
Reagent 2:		
ferene S	≥ 20	mmol/L
ascorbic acid	≥ 0.5	mol/L

Precautions

In addition to the eventual risk indications regarding the active components, the reagents may contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components is lower than the limits reported by the 67/548/EEC and 1999/45/EC directives and following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucos membranes and to use laboratory reagents according to good laboratory practice.

Storage

The components of the kit, stored at 2-8 °C in unopened vials, are stable up to the expiry date indicated on the package.

SAMPLE COLLECTION

Type of sample and storage

Serum or plasma (EDTA, heparin) not haemolyzed collected in plastic tubes or glassware washed with hydrocloric acid 2N solution and distilled water. Collect samples in accordance with the NCCLS procedure reported in the bibliography

7 days at 2-8 °C or 12 months at -20 °C.

Precautions

All human samples must be handled and disposed of as potentially infectious materials.

WARNING AND PRECAUTIONS

· For in vitro diagnostic use.
· Do not use components beyond the expiration date.
· Do not mix materials from different kit lot numbers.
· Safety Data Sheets are available at www.sentineldiagnostics.com or contact your local representative.

· **CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens2. Biosafety Level 23 or other appropriate biosafety practices4,5 should be used for materials that contain or are suspected of containing infectious agents.

REAGENT 1

DANGER: contains GUANIDINE HYDROCHLORIDE, ACETIC ACID, THIOUREA

Hazard statements:
· H315 Causes skin irritation.
· H319 Causes serious eye irritation.
Precautionary statements:
· P264 Wash thoroughly after handling.
· P280 Wear protective gloves/protective clothing/eye protection/face protection.
· P332+P313 If skin irritation occurs: Get medical advice/attention.
· P337+P313 If eye irritation persists: Get medical advice/attention.
· P362+P364 Take off contaminated clothing and wash it before reuse.

Procedure

Quality control

Human control serum with known levels of Iron is commercially available for quality control purposes. Data sheets are included, listing the values and the confidence limits. Normal and abnormal control sera are available from I.S.E. S.r.l. "Normal control serum" code R0400000006 and "Pathological control serum" code R0400000106. Obtained values must be within the range of acceptability. If erratic results occur, the following points should be checked:

- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation

This kit, though developed and manufactured to be used as manual assay and with I.S.E. S.r.l. analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions - Test procedure" Application sheets are available for automatic instruments.
All applications not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

STANDARDIZATION

NIST (National Institute of Standards and Technology).

Calibration

For calibration use the "Multicalibrator" I.S.E. S.r.l. code R0300000006.

Traceability:

The Iron ferene value is reported in the package insert supplied with the "Multicalibrator".

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Calibration Stability
For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Method for automated instrumentation

Analyzer:	**I.S.E. Miura**		
Analyte Name :	**IRON ferene**	Ref.:	A-R0200000500
Method Code:	**Fe**		
Type:	**Diff.sample blank / sub.start**		
Unit:	**µg/dL**		
Filter F1 / F2	**578 nm**		
Blank in:	**Not Used**		

Step	**Reaction volume**	**U.M.**
Volume reagent R1:	**180**	µL
Volume reagent R2:	**9**	µL
Sample volume:	**36**	µL
First uncubation	**36**	Sec.
Final incubation	**360**	Sec.

Reagents included in the kit
The reagents are described above.

Materials required but not supplied in the kit
Calibrators and controls.

NORMAL VALUES
Men: 65 - 175 µg/dL
Women: 50 - 170 µg/dL
The serum iron level can show a 30% diurnal variation, with a peak early in the morning.

It is recommended that each laboratory establish its own expected range. For diagnostic purposes, results obtained should always be evaluated taking into consideration the patient's history and all other clinical findings.

CONVERSION FACTOR
Fe [µg/dL] x 0.179 = Fe [µmol/L]

ANALYTICAL CHARACTERISTICS/PERFORMANCE
Linearity
1000 µg/dL.
Samples with concentrations higher than 1000 µg/dL must be diluted 1:10 with normal saline and the result multiplied by 10.

Interferences
the test is not affected by the presence of bilirubin (conjugated and unconjugated) up to 15 mg/dL and lipids (intralipid) up to 1500 mg/dL.

Precision of the method
Intra-assay:
was determined on 20 replicates of each control (3 levels - L1/L2/L3). The results were as follows:

µg/dL	**L1**	**L2**	**L3**
mean	82.2	103.6	146.8
SD	1.46	2.87	1.96
CV%	1.8	2.8	1.3

Inter-assay:
was determined from 12x1x3 tests (day x run x rep) on each control (5 levels - L1/L2/L/L4/L5). The results were as follows:

	mean	**Total Imprecision**		**Between Days**		**Repeatability**	
	µg/dL	**SD**	**CV%**	**SD**	**CV%**	**SD**	**CV%**
L1	110.8	4.01	3.7	4.06	3.7	0.53	0.5
L2	248.4	6.41	2.6	6.33	2.5	1.00	0.4
L3	101.0	1.50	1.5	0.79	0.8	1.27	1.3
L4	154.0	1.82	1.2	1.74	1.1	0.55	0.4
L5	302.0	3.19	1.1	3.10	1.0	0.75	0.2

Sensitivity
5.0 µg/dL. Sensitivity was calculated on 20 replicates x 2 runs of normal saline and reported as the "mean zero value + 3 SD".

Comparative method
this test (y) was compared with a commercially available method (x).
The results were as follows:
N = 51, r = 0.997, y = 1.00x - 4.90

Disposal of reagents
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

The product is in conformity with D.L: 8 September 2000, no. 332 "Actuation of the directive 98/79/EC regarding in vitro medical diagnostic devices".

Symbols used on labels and packaging

IVD = In vitro diagnostic medical device
REF = Catalogue Number
LOT = Lot Number
= Manufacturer
= Expiration date
= Temperature limitation
= Instruction for use

Reference

1) NCCLS Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Fifth Edition (H3-A5). Wayne, PA: The National Committee for Clinical Laboratory Standards, 2003.
2) Pesce, A.J., Kaplan, L.A.: "Methods in Clinical Chemistry", Mosby Ed. (1987).
3) Burtis C.A., Ashwood E.R.: "Tietz Textbook of Clinical Chemistry", W.B. Saunders Company Ed. (3rd edition, 1999).
4) Guder W.G.: "The Quality of Diagnostic Sample". Recommendations of the Working Group on Preanalytical Quality of the German Society for Clinical Chemistry and the German Society for Laboratory Medicine. (1st Edition - 2001).
5) Jakobs, D.S., Kasten, Jr., B.L., DeMott, W.R., Wolfson, W.L.: "Laboratory Test Handbook", Lexi-Comp and Williams & Wilkins Ed. (2nd Edition -1990).
6) Winsten S, Cehelyk B. Clin Chim Acta 1969; 25: 441- 446.
7) Martinek RG. Clin Chim Acta 1966; 13: 161-170.

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