Iron Ferene – Instructions for use

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

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

R1: 3 x 18,5 mL – R2: 1 x 18,5 mL • REF R3330000020

IVD CE

INTENDED USE
Direct colorimetric determination without deproteinization of the concentration of iron in serum and plasma. The test results should always be interpreted with reference to the hospital clinical context. For professional use only.

CLINICAL SIGNIFICANCE
Iron is present in biological fluids as a component of hemoglobin and myoglobin and is bound in plasma to transferrin, which acts as a transport protein.. Ferritin constitutes the plasma reserve of iron and allows the regulation of the level in the plasma. Increased iron values are an indication of hemochromatosis and liver damage. Low iron levels can be caused by malabsorption anaemia as a result of gastrointestinal disorders or due to blood loss resulting from gastrointestinal injuries or major menstrual losses. For control of martial metabolism, determining transferrin and ferritin levels can provide more detailed information.

PRINCIPLE
Iron in the presence of a pH 4.8 buffer system is first released from transferrin, its carrier protein, and then quantitatively reduced to the ferrous state. The ferro++ thus obtained forms with the specific complexant Ferene S {3-(2-pyridyl) -5,6-bis-[2-(5-furylsulfonic acid)]-1,2,4-triazine} a stable colored compound, whose color intensity is proportional to the amount of iron present in the test sample. Interference due to copper is eliminated using special reaction conditions and a specific mask.

REAGENTS
A-R0200000500- R1: 4x50 – R2: 4x20 mL
Reagente 1: n° 4 vials x 35,0 mL ready for use
Reagente 2: n° 4 vials x 3,5 mL ready for use
R3330000020 - R1: 3x18,5 – R2: 1x18,5 mL
Reagente 1: n° 3 vials x 12,5 mL ready for use
Reagente 2: n° 1 vials x 2,2 mL ready for use

Concentrations

Reagent 1:			
	Conc.	**U.M.**	
Acetate buffer pH 4.8	1.4	mol/L	
Guanidine Hydrochloride	≥ 4.5	mol/L	
Specific masking for copper			
Reagent 2:			
	Conc.	**U.M.**	
Ferene S	≥ 20	mmol/L	
Ascorbic acid	≥ 0.5	mol/L	


*GHS07

* *Warning:* **DANGER**
Contains Guanidine Hydrochloride (CAS 50-01-1); Acetic Acid (64-19-7); Tiourea (62-56-6)
H315 - Causes skin irritation.
H319 - Causes severe eye irritation.
P264 - Wash thoroughly after use.
P280 - Wear protective gloves/clothing/Eye/face protection.
P332+P313 - In case of skin irritation: consult a doctor.
P337+P313 - If eye irritation persists, consult a doctor.
P362+P364 - Remove all contaminated clothing and wash it before wear them again.

Precautions
In addition to risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentration of these components is lower than the limits reported in the EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle reagents according to the standards of good laboratory practice

Reports of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Conservation and stability
Store at 2 - 8 °C away from direct light. When stored as described above, reagents are stable until the expiry date stated on the label**.** A slight variation in the composition of the reagents can occur from batch to batch, without affecting the test results. After opening, they are stable for 30 days if closed immediately and protected from contamination, evaporation, direct light and stored at the correct temperature.

SAMPLE COLLECTION
Type of sample and storage
Serum, plasma (EDTA, heparin) not emolyzed and collected in disposable plastic tubes and glassware washed with 2N hydrochloric acid and distilled water. Collection of the sample in accordance with the NCCLS procedure referred to in the bibliography 1.

Precautions
This product requires handling of human samples. It is recommended that all samples of human origin be considered potentially infectious and be handled in accordance with the OSHA Blood-Transmitted Pathogen Standards.2 For materials containing, or suspected to contain, infectious agents, Biosafety Level 23 should be developed or appropriate biosecurity practices implemented.

Procedure
Quality Control
Control sera known as Ferene Ferro are commercially available for quality control, including certificates of analysis showing the values and confidence limits. Normal and pathological control sera "Normal control serum" cod. R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:
- Glassware cleaning.
- Wavelength.
- Expiration date of reagents.

Automation
Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique". All applications not explicitly approved by. cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

Calibration
For calibration use the kit "Multicalibrator" code R0300000006.
Calibration Stability
7 days at 2-8 °C or 12 months at -20 °C.
Traceability
The value of Ferene Iron is visible in the insert of the calibration serum package.

Reaction condition
Primary wavelength: 600 nm
Secondary wavelength: 700 nm
Temperature: 37 °C

Bring the reagents to working temperature before use. A proportional change in the indicated reaction volumes has no effect on the results obtained.

Technique – Procedure with Reagent B as starter

	U.M.	**Sample**	**Blanck**	**Calib.Serum**
Reagent 1	µL	1000	1000	1000
Sample	µL	80	-	-
Distilled Water	µL	-	80	-
Calib. Serum	µL	-	-	80
Mix and after 5 min. read the Absorbance (Reading 1), add				
Reagent 2	µL	80	80	80
Mix and after 5 min. read the Final Absorbance (Reading 2)				

The reaction volumes can be varied proportionally, the calculation remains unchanged

Risultati

$$\frac{\Delta \text{ D. O. Campione}}{\Delta \text{ D.O. Siero di Calibrazione}} \times \text{Concentrazione Calibratore} = \text{µg/dL di Ferro}$$

Materials included in the kit
Reagent as described.

Sclavo Diagnostics International
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
Phone +39 0577 39041 - Fax +39 0577 390 444

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Necessary materials not included in the kit
Controls and calibrators.

REFERENCE RANGE
Men: 65 - 175 µg/dL
Women: 50 - 170 µg/dL
Serum iron levels can show a circadian variation of 30% with a peak in the early morning. Each laboratory should determine its own reference values. For diagnostic purposes, the results obtained should always be evaluated in conjunction with the patient's medical history, examinations and other clinical findings.

Sensitivity:
5.0 µg/dL. The sensitivity was calculated on 20 replicates x 2 analytical sessions of saline and expressed as "mean value of zero + 3 SD".

Accuracy in series (serum):
Determined on 20 replicates of each control (3 levels L1/L2/L3). The results obtained were as follows:

ug/dL	L1	L2	L3
Media	82.2	103.6	146.8
DS	1.46	2.87	1.96
CV%	1.8	2.8	1.3

Accuracy between series (serium):
Determined on 12x1x3 assays (days x analytical session x replicated) for each control (5 levels L1/L2/L3/L4/L5). The results obtained were as follows:

	Media	Total inaccuracy		Between days		Repeatability	
	µg/dL	DS	CV%	DS	CV%	DS	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

Correlation:
The comparison between this assay (y) and a method of trade (x), gave the following results: N = 51, r = 0.997, y = 1.00x - 4.90

Interferences:
No bilirubin influence (conjugated and unconjugated) up to 15mg/dL as well as lipids (intralipids) up to 1500 mg/dL.

Measurement range:
5 - 1000 µg/dL. For samples above 1000 µg/dL, repeat the determination on diluted sample 1:10 with saline and
Multiply the result by 10.

Manufacturer:
Sclavo Diagnostics International
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
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Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

References

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) US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. Bloodborne Pathogens.

3) US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. Washington,DC: US Government Printing Office, January 2007.

4) World Health Organization. Laboratory Biosafety Manual, 3rd ed.Geneva: World Health Organization, 2004.

5) Sewell DL, Bove KE, Callihan DR, et al. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline — Third Edition (M29-A3). Wayne, PA: Clinical and Laboratory Standards Institute, 2005.

6) Kaplan, L.A., Pesce, A.J.: "Clinical Chemistry", Mosby Ed. (1996).

7) Burtis C.A., Ashwood E.R.: "Tietz Textbook of Clinical Chemistry", W.B. Saunders Company Ed. (3rd edition, 1999).

8) 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).

9) 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)

REVISION	DATE	CHANGE
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