Iron - method Iron "Ferene S"
Instructions for use (IFU)

IVD CE

ORDERING INFORMATION

	Code	Composition
CHEMILAB	REF B81180111	n° 3 vials x 24 mL (R.A) n° 1 vial x 6 mL (R.B)
	REF B81180112	n° 6 vials x 24 mL (R.A) n° 2 vials x 6 ml (R.B)

INTENDED USE
Product for use in the quantitative determination in vitro of the iron concentration in human serum and plasma. The results of the test must always be interpreted in conjunction with the clinical context. FOR PROFESSIONAL USE ONLY.

CLINICAL SIGNIFICANCE
Iron is present in body fluids as a component of haemoglobin and myoglobin. It is transported in the plasma by a protein, transferrin. Ferritin constitutes the plasma reserve of iron and allows regulation of the plasmatic concentration. High increases in plasma iron values are an indication of hemochromatosis and liver damage. Low iron levels may be caused by anemia due to malabsorption because of gastrointestinal disease or to significant losses through menstruation. In order to control iron metabolism and obtain more detailed information it is advisable to determine the transferrin and ferritin concentrations.

PRINCIPLE OF THE METHOD
Method Iron "Ferene S". In the presence of a buffer system (pH 4.5), the iron is first freed by transferrin and then reduced by ascorbic acid to the ferrous state. The $iron^{2+}$ thus obtained forms a stable-coloured compound with the specific "Ferene S" complexing agent. The intensity of the colour formed, read at λ 600 nm, is proportional to the amount of iron present in the test sample.

$$(Fe^{3+} \text{ - Transferrin}) + (\text{Buffer - -Thiourea}) \xrightarrow{\text{pH 4.5}} Fe^{3+} + \text{Transferrin}$$

$$Fe^{3+} + \text{Ascorbic Acid} \xrightarrow{\text{Reducing}} Fe^{2+} + \text{Complexing} \xrightarrow{\text{Ferene}} \text{Coloured complex}$$

Storage and stability
= storage temperature 2-8°C
Stored closed at the indicated temperature avoiding direct light, evaporation and contamination of any kind, intact reagents are stable until the expiry date indicated on the label.

Concentrations
(Referred to the reagent ready for use)

Reagent A:			
	Conc.	**U.M.**	
Acetate buffer (pH 4,8)	**1.4**	mol/L	*GHS07
Guanidine hydrochloride	>4,5	mol/L	
Specific masking for copper			
Reagent B:			
Ferene-S	>20.0	mmol/L	
Ascorbic acid	≥ 0.5	mol/L	

* Warning **CAUTION** - Contains: GUANIDINE HYDROCHLORIDE, ACETIC ACID, THIOUREA
H315 Causes skin irritation.
H319 Causes serious eye irritation.
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.

Reagents included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Controls, calibrators and pipettes with adequate volume.

PRECAUTIONS and WARNINGS
1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles)
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting 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.

PROCEDURE
Quality control
Control sera with a known titer of Iron are commercially available for quality control, with values and confidence limits included. Sclavo Diagnostics Normal and pathological control sera are available: Clinicontrol N 5x5mL cod. B35181700 and Clinicontrol A 5x5 mL code B35181701. The values obtained must be within the acceptability range.

Calibration
For calibration use the "Calibrator serum Sclavo" Code B35181702.

Traceability
The Iron traceability is reported in the package insert supplied with the calibrator serum.

SAMPLE
Type of sample and storage.
Serum and plasma samples should be used. Do not use haemolysed samples.
Samples can be stored for 7 days at 25°C or 1 month at 4°C.

REAGENT PREPARATIONS
Reagent A and B are ready for use. Reagent B has a yellow coloration that over time may tend to brown; this change in color does not involve changes in the performance of the product. A slight difference in color, from batch to batch, does not affect the test results.

ANALYTICAL TECHNIQUE
For automatic procedures, please refer to the user manual and application notes of the CHEMILAB analyzer. All applications not explicitly approved by Sclavo Diagnostics cannot be guaranteed in terms of performance and must therefore be evaluated by the user.

Calculation of results
The results are automatically calculated by the analyzer using the calibration line. The analyzer automatically picks up the appropriate amount of a primary standard as set in the application method. The calibration line is obtained by interpolating the values obtained with an appropriate calculation algorithm.

Calculation of Ferro Ferene concentration:

$$\frac{\text{O.D. Sample}}{\text{O.D. Calibrator serum}} \times \text{Calibrator Serum Concentration} = \mu\text{g/dL of Iron}$$

Automation
The results are automatically calculated by the analyzer based on the calibration line. The analyzer automatically performs calibration in accordance with the method protocol. The calibration line is calculated automatically by single instruments.

REFERENCE RANGE
Serum and Plasma:
- Males: 65 - 175 µg/dL (11,6 - 31,3 µmol/L)
- Females: 50 - 170 µg/dL (9,00 – 30,4 µmol/L)

Each laboratory must establish its own normal-range values based on its population.

ANALYTICAL CHARACTERISTICS/PERFORMANCE
Linearity
The reaction is linear up to 1000 µg/dl. For samples with higher concentrations, repeat the determination with a 1:10 diluted sample in physiological solution and multiply the result by the dilution factor.

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Recovery
Commercial control sera were analyzed with the kit in question following the guidelines of the CLSI protocol. The data obtained are shown in the table below.

Range	Replicates	Mean (µg/dL)	DS	CV%	Recovery
Low	5	69,4	2,408	3,47	94,2 %
High	5	226,4	1,817	0,80	97,2 %

Interferences

Interference	Limits
Triglycerides	**300 mg/dL**
Bilirubin	**58 mg/dL**

Precision of the method

Accuracy in the series (Within-run precision) – Repeatability					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	g/dL	237	3.62	1.52	30
High	g/dL	67.9	1.38	2.04	30
Total precision (Within-lab precision)					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	g/dL	229	1.89	0.82	20
High	g/dL	65.2	1.02	1.57	20

Limit of 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".

Comparison between methods
The method was compared with a similar commercially available method, analyzing 200 human samples. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	-4.403
Correlation Coeff. (R)	0.991

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

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REVISION	DATE	CHANGE
Rev.A	01/2023	New Issue for IVDR Regulation (UE) 2017/746 compliance

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