IRON FERENE Liquid

Colorimetric Method with Ferene

2 x 100 ml + 2x 25 ml **CL30-250S**

INTENDED USE

Kit for quantitative determination of Iron in serum.

CLINICAL MEANING

The majority of Iron that transits in plasma derives from the destruction of red blood cells. The rest derives from reserve iron and, only in a small percentage, from the individual's diet.
The dosage of total iron in serum is the determination of the quantity of plasmatic transport iron, linked to transferrin. Iron deficit causes microcytic anemia: low values of haemoglobin and of average corpuscular volume of red blood cells should always lead to investigation on iron exchange.
On the contrary, high levels of total iron are caused by massive blood transfusions, hemochromatosis, aplastic and hemolytic anemia, thalassemia, lead poisoning, vitamin B6 deficiency, excessive iron therapy.

PRINCIPLE

Iron, liberated by proteins and especially by transferrin in particular ionic conditions (buffer at pH 2.0), is reduced to bivalent state. This bivalent Iron bounds to Ferene to form a stable colored complex, whose intensity is proportional to the quantityof Iron in the sample.

SAMPLE

Fresh, non hemolized serum. Do not use hemolized samples.
STABILITY: 4 days at room temperature (15-25°C), up to 7 days at 2-8°C.
Separate serum from the clot as soon as possible. Shake the samples and bring them to room temperature before use.

REAGENTS

Only for in Vitro diagnostics. Liquid reagents ready to use.

Package Contents	**CL30-250S**
REAGENT 1 (Liquid) Citric Acid 180 mmol/L, Ascorbic acid 100 mmol/L, copper-specific masking agent 100 mmol/L, surfactants.	2 x 100 ml
REAGENT 2 (Liquid) Citric Acid 180 mmol/L, Ferene 6 mmol/L, surfactants and preservatives.	2 x 25 ml
STANDARD (Liquid) Iron 100 µg/dl (17,9 µmol/L)	1 x 4 ml

STABILITY: if kept away from light at 2-8°C, reagents are stable up to the expiration date on the label.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

PREPARATION OF WORKING REAGENT

Bring the reagents to room temperature before use.
Reagent 1 is clear, colorless or yellowish (yellowing of reagent does not undermine its efficiency).
Reagent 2 is clear, the color varies from yellowish-green to brown.

MANUAL ASSAY PROCEDURE

Wavelength:	593 nm (578 – 600)
Optical path:	1 cm
Reading:	against blank reagent
Temperature:	37°C
Analysis:	increasing endpoint
Sample/Reagent Ratio	1/40

Bring the reagents to the chosen temperature.

Pipette in cuvette:

	Blank	Sample	Standard
Reagent 1	1000 µL	1000 µL	1000 µL
Distilled Water	200 µL		
Sample		200µL	
Standard			200 µL

Mix and incubate for 5 minutes at 37°C. Then read the extinction of the sample against reactive blank.

Reagent 2	250 µl	250 µl	250 µl

Mix and incubate for 5 minutes at 37°C. Then read the extinction of the sample and the standard against blank.
The coloration is stable for at least 15 minutes at room temperature.

Reaction volumes can be proportionally varied without any change in calculation.
The calibration with aqueous standards may cause a systematic error in the utilization of certain automatic instruments. The use of a human proteic calibrator is recommended.

CALCULATION

$$\frac{\text{Abs Sample - Abs Blank Sample}}{\text{Abs Standard – Abs Blank Standard}} \times 100 = \text{Iron µg/dL}$$

REFERENCE VALUES

Men: 60 - 150 µg/dl 10,8 - 28,6 µmol/L
Women: 40 - 145 µg/dl 7,1 - 26 µmol/L

Each laboratory should define its own reference values for this method.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:
PRE-NORM serums with normal values
PRE-PATH serums with pathological values
If the method requires it, a multiparameter calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Linearity: 4,2 - 800 µg/dl

Measurable limit: 4,2 µg/dl

Sensitivity: 1 µg/dl.at 593 nm

Method limits: if the concentration is higher than 800 µg/dl, repeat the analysis on a diluted sample (1:2) and multiply the result by 2. .
Precision:

Within run (n=30)	Average µg/dl	SD	CV %
	54,5		2,1
	122,3		1,4
	285,3		1,1

Between run (n=30)	Average µg/dl	SD	CV %
	55,7		1,5
	124,4		1,8
	284,3		1,8

Analysed range: 14.4 – 280,4 µg/dl

Correlation: r = 0,9975

Linear Regression: y=0,95 x + 1,02

Interferences:

Bilirubin (20 mg/dl) does not interfere

Triglycerides (1000 mg/dl) do not interfere

Zinc (400 µg/dl) does not interfere

Copper (400 µg/dl) does not interfere

Cobalt (400 µg/dl) does not interfere

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The product, according to current legislation, is not classified as dangerous. The total concentration of non-active components (preservatives, detergents, stabilisers) is lower than the required limits. Nonetheless, please handle the product with care, according to the usual laboratory rules. Avoid ingestion, contact with skin, eyes or mucous membranes. The samples must be handled as potentially infected by HIV or hepatitis.

REFERENCES

1. Hinggins, T., et al. Clin. Chem., 27, 1619, (1981)
2. Vassault, A.et al. Ann. Biol. Clin., 44,686, (1986)
3. Young D.S., et. al., Clin. Chem. 21 :1D (1975).

MANUFACTURER

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KEY SYMBOLS

IVD	in Vitro diagnostic medical device
LOT	batch number
REF	catalogue number
	temperature limits
	use by
	caution
	consult accompanying documents

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