IRON F

Colorimetric Method with Ferene

REF. 0089 4x50 ml
REF. 0086 8x50 ml

CE IVD

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

quantitative determination of iron in the serum.

PRINCIPLE

Serum iron bound to transferrine is released in acid enviroment. Fe (III) ions are then reduced to Fe (II), which binds to the Ferene to give a stable colored complex, whose color intensity is proportional to the amount of iron in the sample.

SAMPLE

Fresh serum. Do not use hemolyzed samples.
Separate serum from clot as soon as possible.
The iron in the sample is stable 4 daysi at room temperature and at least one week at 2-8°C.

KIT COMPONENTS

Reagent (A) Fe F Volume = 45 ml	Buffer Complexing Guanidine hydrochloride	100 mmol/l 130 mmol/l 1.3 mmol/l
Reagent (B) Fe F Powder + dispenser	Reducing	10 mmol/l
Reagent (C) Fe F Volume = 20/40 ml	Buffer Ferene	50 mmol/l 19 mmol/l
Standard Fe Volume = 10 ml	Iron	100 µg/dl (17.9 µmol/l)

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C.
Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided.

REAGENT PREPARATION

Bring all reagents at room temperature before use.
Take a measuring cup with the proper dispenser of powder, Reagent (B), and pour into the bottle of Reagent (A). Mix until completely dissolved.
The working solution (A+B) is stable 5 days at room temperature and 4 weeks in refrigerator (2-8 °C).
The Reagent (C) and the Standard are liquid, ready to use.

PRECAUTIONS AND WARNINGS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Use the normal precautions required in the laboratory.
Dispose of waste according to local laws.

PROCEDURE

Wavelength:	593 nm (578 – 700)
Lightpath :	1 cm
Temperature:	37°C
Reading:	against blank
Method:	Increasing End Point

pipette:	blank	sample	standard
Reagent (A+B)	900 µl	900 µl	900 µl
water	200 µl		
sample		200 µl	
standard			200 µl

Mix, read the absorbance of blank sample (Abx) against blank reagent.
Add in the same tubes:

Reagent (C)	100 µl	100 µl	100 µl

Mix, incubate at 37°C for 5 minutes and read the absorbance of the sample (Ax) and the standard (As) against blank reagent.
Reaction volumes can be proportionally varied.
In the manual procedure prepare a series of test-tubes for blanks reading.
For automated procedure, ask for specific applications.

RESULTS CALCULATION

Iron µg/dl = (Ax – Abx)/(As – Abs) x 100 (Standard value)

EXPECTED VALUES

Men:	**60 – 160**	**µg/dl**	**(10.6 – 28.3 µmol/l)**
Women:	**37 – 145**	**µg/dl**	**(6.6 – 26 µmol/l)**

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of control sera: PRECISENORM (REF.6000) and PRECISEPATH (REF.6001).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 5 µg/dl.
Linearity: the method is linear up to 800 µg/dl. For higher values, dilute the sample 1:2 and multiply the result by 2.
Precision intra-assay:

	Level1	Level 2	Level 3
Mean (µg/dl)	70.45	115.7	326.5
DS	1.29	1.16	1.84
CV %	1.83	0.75	0.56

Precision inter-assay:

	Level 1	Level 2	Level 3
Mean (µg/dl)	76.07	167.5	336.0
DS	1.38	1.72	2.45
CV %	1.81	1.02	0.73

Interferences: the copper does not interfere up to 400 µg/dl.
Bilirubin up to 10 mg/dl does not interfere.
Hemoglobin interferes with the test. Do not use hemolyzed samples.
Correlation against a reference method: Y = 1.0099x + 0.982 r = 0.9872

REFERENCES

1. Higgins T., 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).

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