GENESIS

Instructions For Use

Iron (Kinetic Enzymatic Method)

Cat no.	size
1307 101	2*25
1307 102	2*50
1307 103	4*25

INTENDED USE
Iron reagent is intended for in-vitro quantitative determination of Iron in human serum or heparinized plasma.

DIAGNOSTIC CHARACTERISTICS
The iron is the component of a great number of enzymes. The myoglobin, muscular protein, contains iron, as well as the liver.
Iron is necessary for the hemoglobin production, molecule that transports oxygen inside red globules. Their deficit in the last causes the ferropenic anemia. High levels of iron are found in hemochromatosis, cirrhosis, hepatitis and in increased transferrin levels.
The variation day to day is quite marked in healthy people.
Clinical diagnosis should not be made on a single test result; it should cintegrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD
The iron is dissociated from transferring-iron complex in weakly acid medium. Liberated iron is reduced into the bivalent form by means of ascorbic acid. Ferrous ions give with Ferrozine a colored complex:

$Transferrin\ (Fe^{3+})_2 + e^- \xrightarrow{Ascorbic\ acid} 2\ Fe^{2+} + Transferrin$

$Fe^{2+} + Ferrozine \rightarrow Colored\ complex$

The intensity of the color formed is proportional to the iron concentration in the sample.

COMPOSITION

Reagent (R1)	Acetate pH 4.9 Ascorbic acid	100 mmol/L 20 mmoll/L
Reagent (R2)	Ferrozine	40 mmol/L
Standard (S)		100 µg/dL

STORAGE AND STABILITY.
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contaminations prevented during their use. Do not use reagents over the expiration date.

REAGENT PREPARATION
working reagent: mix 4 volumes of R1 + 1 volume of R2.
Stable for 6 months at 2-8ºC

ADDITIONAL EQUIPMENT
– Analyzer, spectrophotometer able to read at 578 nm.

SPECIMEN
Serum or heparinized plasma.
Stability of serum samples:
- 3 weeks at 2-8ºC
- 7 days at 15-25ºC

PRECAUTIONS AND WARNING
Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries, seek medical advice immediately.

PROCEDURE
1. Assay conditions:
Mode ……end point
Wavelength: . . . . . 578 nm
Cuvette: . . . . . 1 cm light path
Constant temperature . . . . . .…..37ºC
2. Adjust the instrument to zero with distilled water.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

3. Pipette into a cuvette:

	WR Blank	Standard	Sample
Sample	-----	------	200 µL
Distilled water	200 µL	-----	------
Standard	-----	200 µL	------
Working Reagent	1000 µL	1000 µL	1000 µL

4. Mix, and allow to stand for 5 min at room temperature.
Read absorbance of reagent blank, standard and sample (A).

CALCULATIONS

$$\text{Conc. of Iron} = \frac{A\ sample - A\ blank}{A\ standard - A\ blank} \times \text{Standard conc.}$$

REFERENCE VALUES

Male	65 - 175 µg/dL ≅ 11.6 – 31.3 µmol/L
Female	40 - 150 µg/dL ≅ 7.16 - 26.85 µmol/L

QUALITY CONTROL
It is recommended to use the Control Serum level I And II to verify the performance of the measurement procedure.
Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS
Measuring range: From detection limit of 0,850 µg/dL to linearity limit of 1000 µg/dL. If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.
Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (µg/dL)	113	250	111	249
SD	0.89	0.72	3.51	6.29
CV (%)	0.79	0.29	3.17	2.52

Sensitivity: 1 µg/dL = 0.00104 A.
Accuracy: Results obtained using Genesis reagents did not show systematic differences when compared with other commercial reagents. The results obtained using 50 samples were the following:
Correlation coefficient $(r)^2$: 0.9934.
Regression equation: y= 1.0243x – 3.877.
The results of the performance characteristics depend on the analyzer used.

INTERFERENCES
- Hemolyzed samples are rejected, since erythrocytes contain iron and therefore falsely elevate the serum results.
- A list of drugs and other interfering substances with iron determination has been reported by Young.

BIBLIOGRAPHY

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