

PACKAGING

Ref.: 101-0007	Cont.: 100 tests
----------------	------------------

Store at 2 - 8° C

CLINICAL SIGNIFICANCE

The iron is the component of a great number of enzymes. The myoglobin, muscular protein, contain iron, as well as the liver Iron is necessary for the hemoglobin production, molecule that transports oxygen inside red globules. Serum iron is almost always accompanied by a measurement of (TIBC) and denotes the available iron-binding sites of the serum. We can found high levels in the ferropenic anemia. Their deficit may be due to a hemochromatosis, cirrhosis or hepatitis. The variation day to day is quite market in healthy people^{1,5,6}.

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Serum transferrin is saturated with an excess of Fe³⁺ and the unbound portion is precipitated with magnesium carbonate. The total amount of iron is then determined. The difference between the total iron-binding capacity (TIBC) and initial seric iron(SI) yields the unsaturated iron-binding capacity (UIBC)^{1,2}.

REAGENTS

R 5 Saturating solution	Iron solution	500 µg/dL
R 6 Precipitating agent	Magnesium carbonate	

Optional (not included in the kit)

Contro-N	Ref.: 101-0252	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0083	20 x 5 mL	
Contro-P	Ref.: 101-0253	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0084	20 x 5 mL	

ADDITIONAL REAGENTS

The supernatant will be processed according to the instructions of iron determination:

Iron FerroZine Ref: 101-0374, 101-0455, 101-0625

PREPARATION

The reagents are ready to use.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2 - 8° C, protected from light and contaminations prevented during their use.

Do not use reagents over the expiration date.

Signs of reagent deterioration:

- Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- Samples centrifuge.
- General laboratory equipment^(Note 1).

SAMPLES

Serum or heparinized plasma.

Free of hemolysis and separated from cells as rapidly as possible.

Stability of the sample: Iron is stable at 2 - 8° C for 7 days¹.

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

It is recommended to use disposable material. If glassware is used the material should be soaking for 6 h in diluted HCl (20 % v/v) and then thoroughly rinsed with distilled water and dried before use.

The supernatant is stable up to 1 hour at room temperature. If appear turbid, centrifuge again.

Pipette into the tubes:

Sample (mL)	0.5
R 5 Saturating solution (mL)	1.0

- Mix well and incubate for 10 min. at room temperature (15 - 25° C).
- Add to each tube:

(*) R 6 Precipitating agent (spoonful)	3
--	---

(*) Powder: Dispense using the enclosed spoon. (Dosage: aprox. 70 mg)

- Mix well and incubate for 10 min. at room temperature (15 - 25° C).
- Centrifuge 15 min. at 3000 r.p.m.
- Collect the supernatant carefully and measure the iron concentration^(Note 2). See: ADDITIONAL REAGENTS

CALCULATIONS

The calculations are indicating in the Iron Insert determination.

$$TIBC = \text{Iron concentration in the supernatant} \times 3 \text{ (Dilution factor)}$$

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES⁴

Serum or plasma:

$$200 - 400 \mu\text{g/dL} \cong 36 - 72 \mu\text{mol/L}$$

These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: From detection limit of 3 µg/L 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)	SD	Mean (µg/dL)	SD
Mean (µg/dL)	367	567	359	565
SD	2.82	9.43	7.16	9.46
CV (%)	0.77	1.66	1.99	1.67

Sensitivity: 1 µg/dL = 0.00026 A.

Accuracy: Results obtained using CHRONOLAB reagents (y) did not show systematic differences when compared with other commercial reagents (x).

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 results¹.

A list of drugs and other interfering substances with iron determination has been reported by Young et. al^{3,4}.

BIBLIOGRAPHY

1. Baadenhuijsen H et al. Modification in Ramsay's method for correct measurement of total iron-binding capacity. Clin. Chim 1988; (175): 9-16.
2. Perrotta G. Iron and iron-binding capacity. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1063-1065.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
4. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.