

Store at: +15-25°C.

Presentation:

Cod. SU023 CONT: 50 Test.

Procedure

Total iron-binding capacity (TIBC) saturating – precipitating reagent.

Only for in vitro use in clinical laboratory (IVD)

TEST SUMMARY

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 serum iron (SI) yields the unsaturated iron-binding capacity (UIBC)^{1,2}.

REAGENTS COMPOSITION

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

ADDITIONAL REAGENTS

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

Ref. SU022 Iron Ferrozine

REAGENT PREPARATION AND STABILITY

The reagents are ready to use.

All the components of the kit are stable until the expiration date on the label when stored at 15-25°C, protected from light and contamination prevented during their use.

Do not use reagents over the expiration date.

Signs of reagent deterioration:

- Presence of particles and turbidity.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8°C. Do not use reagents over the expiration date.

SPECIMEN

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.

MATERIAL REQUIRED BUT NOT PROVIDED

- Samples centrifuge.

General laboratory equipment.

TEST PROCEDURE

1. Pipette into the tubes:

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

2. Mix well and incubate for 10 min. at room temperature (15-25°C).

3. Add to each tube:

(*) R 6 Precipitating agent (spoonful)	3
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(*) Powder: Dispense using the enclosed spoon. (Dosage: aprox. 70 mg)

4. Mix well and incubate for 10 min. at room temperature (15-25°C).

5. Centrifuge 15 min. at 3000 r.p.m.

6. 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 = Iron concentration in the supernatant x 3 (Dilution factor)

QUALITY CONTROL

Control sera are recommended to monitor the performance of the procedure, Control Normal Ref. QC001 and Control Pathological Ref. QC002. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

REFERENCE VALUES

Serum or plasma:

200 – 400 µg/dL ≅ 36-72 µmol/L

(These values are for orientation purpose).

It is suggested that each laboratory establish its own reference range.

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 find 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.

REAGENT PERFORMANCE

- Measuring Range:

From detection limit of 3 µg/dL. to linearity limit of 1000 µg/dL., under the described assay conditions.

If results obtained were greater than linearity limit, dilute the sample ½ with NaCl 9 g/L. and multiply result by 2.

- Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
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 GPL reagents did not show systematic differences when compared with other commercial reagents.

The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES

Hemolyzed samples are rejected, since erythrocytes contain iron and therefore falsely elevate the serum results¹.

Other substances may interfere. A list of drugs and other substances that could interfere has been reported by Young et al.^{3,4}.

NOTES

1. 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.

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

BIBLIOGRAPHY

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