

IN VITRO DIAGNOSTIC USE



REF	03010	2 x 100 ml (100 T)	R1: 2 x 100 ml	R2: 1 x 2.5 g	R3: 1 x 5 ml	R4: 1 x 10 ml
REF	03027	2 x 200 ml (200 T)	R1: 4 x 100 ml	R2: 1 x 5 g	R3: 1 x 10 ml	R4: 2 x 10 ml
REF	03041	2 x 50 ml (50 T)	R1: 2 x 50 ml	R2: 1 x 2.5 g	R3: 1 x 5 ml	R4: 1 x 10 ml

CLINICAL SIGNIFICANCE

In humans, 70% of the body's iron is bound to haemoglobin, the rest is bound to transport proteins such as ferritin (or transferrin), or stored in certain tissues such as the liver and bone marrow. Low serum iron levels may be seen in iron deficiency anemia (martial deficiency) or in patients with inflammatory anemia.

Conversely, iron overload may occur during hemochromatosis or acute liver dysfunction.

PRINCIPLE

At pH 4.8 ferric iron (Fe⁺⁺⁺) is instantly released from transferrin. Ascorbic acid reduces it to ferrous iron (Fe⁺⁺). Ferrozine forms with ferrous iron a soluble colored complex, measurable from 560 to 580 nm.

The presence of thio urea eliminates the interference of cuprous ions.

REAGENT COMPOSITION

Reagent 1	Guanidine, HCl Acetate Buffer	4,5 mmol/l pH 5
Reagent 2	Ascorbic acid	40 mmol/l
Reagent 3	Ferrozine	1 mg/l
Reagent 4	Standard	17,9 µmol/l

SAFETY CAUTIONS

Biomaghreb reagents are intended for use by qualified personnel for in vitro use (do not pipette by mouth).

- Refer to the current MSDS available on request or on www.biomaghreb.com.
- Check the integrity of the reagents before use.
- Disposal of waste: comply with applicable legislation.

For safety reasons, treat any specimen or reagent of biological origin as potentially infectious. Observe the applicable legislation.

REAGENT PREPARATION

Dissolve the contents of a spatula of ascorbic acid (approximately 250 mg) in 50 ml of Reagent 1 (Reagent A). Add 40 µl ferrozine to 1 ml of Reagent A (Reagent B). Reagent B is prepared extemporaneously.

SAMPLE COLLECTION AND HANDLING

Serum, plasma heparinized and non hemolysed

PRESERVATION AND STABILITY

- Before opening: Until the expiry date indicated on the label of the box at + 4°C.
- After opening: Reagents A and B are stable: 3 days at 20 - 25°C;
2 weeks at 2 - 8°C.

ADDITIONAL EQUIPMENT

- Basic equipment of the medical analysis laboratory;
- Spectrophotometer or Clinical Biochemistry Analyzer.

LIMITS

The use of glass materials requires soaking for several hours in 2N hydrochloric acid and then rinsing carefully with distilled water. It is therefore preferable to use disposable plastic material. High doses of anticoagulants (Heparin) can cause disturbances in the reaction mixture.

QUALITY CONTROL

External quality control program.

It is recommended to control in the following cases:

- At least one test per series.
- Change of reagent bottle.
- After maintenance work on the analyzer.

If a control value is outside the confidence limits, repeat the procedure using the same control.

Use normal and pathological control sera.

CALIBRATION

- Standard (Reagent 3)

The calibration frequency depends on the performance of the analyzer and the storage conditions of the reagent.

Recalibration is recommended in the following cases:

- changing the reagent lot;
- after maintenance work on the analyzer; and
- the control values are outside the confidence limits.

LINEARITY

The reaction is linear up to 1000 µg/dl (179.7 µmol/l). Above this limit, dilute the sample with 9 g/L NaCl solution and repeat the determination taking the dilution into account in the calculation of the result. The linearity limit depends on the sample/reagent volume ratio.

PROCEDURE

Wavelength: 578 nm (530-590).

Temperature: 20 - 25°C.

Tank: 1 cm thick.

Adjust the spectrophotometer zero by:

- Reagent A for Sample Whites;
- Reagent blank Reagent for standard and samples

	Blank Reagent	Standard	white Sample	Sample
Distilled water	200µl	-	-	-
R4	-	200µl	-	-
Sample	-	-	200µl	200µl
Reagent A	-	-	1ml	-
Reagent B	1ml	1ml	-	1ml

Mix and wait 10 minutes
Measuring absorbances at 578 nm

Staining stability: 30 minutes.

CALCULATION

$$\text{Serum iron} = \frac{\text{DO. Sample} - \text{DO. White sample}}{\text{DO Standard}} \times n$$

n = 1 mg/l;

n = 17,9 µmol/l.

REFERENCE VALUES

Women	69 - 158 µg/dl 12.5 - 28.3 µmol/l
Men	59 - 145 µg/dl 10.7 - 26 µmol/l

REFERENCES

Persijn et al Clin. Chem. Acta 35,91 (1971);
Stookey L. Anal. Chem. 42,779 (1970);
Williams et al. Clin. Chem. 23,237(1977).

