IRON - FERROZINE

COD 12509 5 x 50 mL
Only for *in vitro* use in the clinical laboratory

Automated Systems

BioSystems

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FERROZINE

INTENDED USE

Reagent for the measurement of iron concentration in human serum or plasma. The obtained values are useful as an aid in the diagnosis and treatment of diseases such as iron deficiency anemia and hemochromatosis.

This reagent is for use in the BioSystems A25 and A15 analyzers or in other analyzer with similar performance characteristics.

CLINICAL SIGNIFICANCE

Iron is distributed in the body in a number of different compartments: hemoglobin, myoglobin, tissues (mainly in liver, spleen, bone marrow). Only 0.1% of total body iron is present in plasma.

Serum iron concentration is affected by many physiological or pathological conditions. Day-to-day variation is quite marked in healthy people.

Iron deficiency and iron overload are the major disorders of iron metabolism. However, altered iron metabolism is also related to a number of other diseases.

Serum iron is increased in hemochromatosis, in acute iron poisoning, in active cirrhosis or acute hepatitis and as a result of increased transferrin levels[1,2].

Serum iron concentration is decreased in many but not all patients with iron deficiency anemia and in chronic inflammatory disorders. Measurement of serum iron should not be used as a test for identification of iron deficiency[1,2].

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

PRINCIPLE OF THE METHOD

Transferrin-bound ferric ions in the sample are released by guanidinium and reduced to ferrous by means of ascorbic acid. Ferrous ions react with ferrozine forming a coloured complex that can be measured by spectrophotometry[3,4,5].

CONTENTS AND COMPOSITION

A. Reagent: 5 x 40 mL. Guanidinium chloride 1.0 mol/L, acetate buffer 0.4 mol/L, pH 4.0.

B. Reagent: 5 x 10 mL. Ferrozine 8 mmol/L, ascorbic acid 200 mmol/L.

STORAGE AND STABILITY

Store at 2-8 ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 2 months.

Indications of deterioration: Absorbance of the blank over the limit indicated in "Test Parameters".

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Reagents are provided ready to use.

SAMPLES

Serum or heparinized plasma collected by standard procedures.

Iron in serum or heparinized plasma is stable for 3 weeks at 4-8ºC[6].

CALIBRATION

A reagent blank should be done every day and a calibration at least every 2 months, after reagent lot change or as required by quality control procedures.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007. 18010 and 18043) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum and plasma[7]

Men: 70 – 180 µg/dL = 12.5 – 32.2 µmol/L
Women: 60 – 180 µg/dL = 10.7 – 32.2 µmol/L

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using a A25 analyzer and following the guidelines of the Clinical & Laboratory Standards Institute (CLSI).

- Detection limit: 6.17 µg/dL = 1.10 µmol/L. Quantification limit: 33.2 µg/dL = 5.94 µmol/L.
- Linearity limit: 1000 µg/dL iron = 179 µmol/L. Measuring range: 33.2 - 1000 µg/dL.
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
61.9 µg/dL = 11.1 µmol/L	7.5 %	7.9 %
98.8 µg/dL = 17.7 µmol/L	4.1 %	5.8 %
315 µg/dL = 56.4 µmol/L	1.6 %	2.1 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: bilirubin (up to 20 mg/dL) and lipemia (triglycerides up to 1500 mg/dL) do not interfere. Hemolysis interferes. Other drugs and substances may interfere[8].

BIBLIOGRAPHY

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2. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
3. Stookey LL. Ferrozine-A new spectrophotometric reagent for iron. Anal Chem 1970; 42: 779-81.
4. Itano M. Serum Iron Survey. Am J Clin Pathol 1978; 70: 516-522.
5. Artiss JD, Vinogradov S, Zak B. Spectrophotometric study of several sensitive reagents for serum iron. Clin Biochem 1981; 14: 311-315.
6. World Health Organization (WHO). Use of anticoagulants in diagnostic laboratory investigations. Document WHO/DIL/LAB/99.1, Rev.2; 2002.
7. Clinical and Laboratory Standards Institute (CLSI). Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard. CLSI document H17 A. Wayne, PA: Clinical and Laboratory Standards Institute; 1998.
8. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

TEST PARAMETERS

These reagents may be used in several automatic analyzers. Specific instructions for application in many of them are available on request.

R1: use Reagent A.

R2: use Reagent B.

	A25	A15
GENERAL		
Name	**IRON FERROZINE**	**IRON FERROZINE**
Sample type	SER	SER
Analysis mode	differential bir.	differential bir.
Units	µg/dL	µg/dL
Turbidimetry test	no	No
Decimals	1	1
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	monoch.	monoch.
Main filter	560	560
Reference filter	-	-
Sample	40	40
Vol. R1	240	240
Vol. R2	60	60
Washing	1.2	1.2
Reading 1 (cycle)	5	4
Reading 2 (cycle)	26	18
Reagent 2 (cycle)	6	5
Predilution factor	-	-
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.080	0.080
Kinetic blank limit	-	-
Linearity limit	1000	1000
Substrate depletion	-	-

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