IRON CROMAZUROL CE

REF 1135105
2 x 50 mL
CONTENTS
R1. Reagent 2 x 50 mL
CAL. Standard 1 x 3 mL

For *in vitro* diagnostic use only

IRON
CROMAZUROL
Colorimetric method
ENDPOINT

PRINCIPLE

The method is based on the properties of Chromazurol S (CAS), a chromogenic iron-binding dye, that under acidic conditions in presence of cetrimide (CTAB) forms an intense purple complex proportional to the concentration of iron present in the sample.

$$Fe^{+3} + 3\ CAS + CTAB \xrightarrow{pH\ 4.7} Fe(CAS)_3\ complex$$

REAGENT COMPOSITION

R1 **Chromazurol reagent.** Acetate buffer 1 mol/L pH 4.7, chromazurol 200 µmol/L, cetrimida 740 µmol/L, Mg2+ 2.3 g/L, thiourea 1 mmol/L, Tween 20 0.1 mL/L (v/v).
C R:35/10 S :26-37/39-45

CAL **Iron standard.** Ferric ion 100 µg/dL (17.9 µmol/L). Concentration value is traceable to Standard Reference Material NIST 937.

STORAGE AND STABILITY

Store at 2-8ºC.
All the kit compounds are stable until the expiry date stated on the label. Do not use reagents over the expiration date.
Store the vials tightly closed, protected from light and prevented contaminations during the use.

Discard If appear signs of deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 635 nm > 0.575 in 1cm cuvette.

REAGENT PREPARATION

The Reagent and Standard are ready-to-use.

SAMPLES

Serum or heparinized plasma. Centrifuge specimen as soon as possible after collection.
Hemolyzed samples are rejected. Ruptured red cells falsely elevate the serum results.
Iron in serum is stable for 3 weeks at 2-8ºC and for about 7 days at 20-25ºC. Freeze for longer storage.

INTERFERENCES

- Lipemia (intralipid >1.25 g/L) may affect the results.
- Bilirubin (< 10 mg/dL) does not interfere.
- Hemoglobin may affect the results.
- Other drugs and substances may interfere[3].

MATERIALS REQUIRED

- Photometer or colorimeter capable of measuring at 635 ± 20 nm.
- Pipettes with disposable plastic tips to measure reagents and samples.
- Disposable plastic tubes for the tests.

PROCEDURE

1. Bring reagents and samples to room temperature.
2. Pipette into labelled test tubes:

TUBES	Blank	Sample	CAL. Standard
R1.Reagent	1.0 mL	1.0 mL	1.0 mL
Sample	–	50 µL	–
CAL. Standard	–	–	50 µL

3. Mix and let the tubes stand 3 minutes at 37ºC.
4. Read the absorbance (A) of the samples and the standard at 635 nm against the reagent blank.

CALCULATIONS

$$\frac{A\ Sample}{A\ Standard} \times C\ Standard = \mu g/dL\ iron$$

Samples with concentrations higher than 1000 µg/dL should be diluted 1:2 with saline and assayed again. Multiply the results by 2.

If results are to be expressed as SI units apply:
µg/dL x 0.179 = µmol/L

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REFERENCE VALUES[4]

Serum

Men	60 - 175 μg/dL (10.7 - 31.3 μmol/L)
Women	50 - 170 μg/dL (9.0 - 30.4 μmol/L)

It is recommended that each laboratory establishes its own reference range

QUALITY CONTROL

The use of a standard to calculate results allows to obtain an accuracy independent of the system or instrument used.
To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

REF **1980005** HUMAN MULTISERA NORMAL
Borderline level of iron. Assayed.

REF **1985005** HUMAN MULTISERA ABNORMAL
Elevated level of iron. Assayed.

If the values are found outside of the defined range, check the instrument, reagents and procedure.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

CLINICAL SIGNIFICANCE

Following intestinal absoption of iron or erythrocyte destruction, iron ions are released into the plasma where they bind to either apotransferrin or apoferritin proteins to form transferrin and ferritin, respectively. The former helps transport iron to bone marrow for *erythropoiesis*; the latter stores iron in tissues, until is needed.

An *increase* in the iron level in plasma due to rapid destruction of erythrocytes or excesive uptake of iron may also lead to iron overload. The latter causes iron deposition disorders in tissue known as *hemosiderosis* or *hemochromatosis*.

Conversely, a *decrease* in the iron level in plasma due to malnutrition or malabsorbtion may lead to excesive depletion in iron storage, resulting in *anemia* such as iron-deficiency anemia.

NOTES

- Contamination of glassware with iron will affect the test. Use acid-washed glassware or plastic tubes.
- This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

ANALYTICAL PERFORMANCE

- ***Detection Limit :*** 10.10 μg/dL
- ***Linearity :*** Up to 1000 μg/dL
- ***Precision:***

μg/dL	Within-run		Between-run	
Mean	118.8	204.6	118.8	204.6
SD	0.95	1.21	2.71	3.71
CV%	0.81	0.59	2.28	1.81
N	10	10	10	10

- ***Sensitivity :*** 1 mAbs / μg/dL iron.
- ***Correlation:*** This assay (y) was compared with a similar commercial method (x). The results were:
  N = 49 r = 0. 97 y = 0.97x + 0.10

The analytical performances have been generated using on automatic instrument. Results may vary depending on the instrument.

REFERENCES

1. Carter, P. Anal. Biochem. 40 : 450 (1971).
2. Artiss, J.D., Vinogrador, S., and Zak, B. Clin. Biochem. 14 : 311 (1981).
3. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
4. Tietz, N.W., Fundamentals of Clinical Chemistry, p.940. W.B. Saunders Co., Philadelphia , 1987.

B11351-2/1304
R1.ing

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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