BIOTECHNOLOGY PRODUCTS
MenidiMedica Medical Instruments, Tools & Supplies

IRON CROMAZUROL

REF 10130
100 mL.
CONTENTS
Reagent R, 5 x 20 mL.

IRON
CROMAZUROL
Colorimetric method
Endpoint

For in vitro diagnostic use only

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.

REAGENT COMPOSITION
R Chromazurol reagent.
Acetate buffer, chromazurol, cetrimide, Mg2+, thiourea, Tween 20.
C R:35/10 S :26-37/39-45

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 is 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

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.
R	1000 uL.	1000 uL.	1000 uL.
Sample	-	50 uL.	-
Cal.	-	-	50 uL.

3. Mix and let the tubes stand 10 minutes at 37ºC.
4. Read the absorbance (A) of the samples and the standard at 635 nm against the reagent blank.

CALCULATIONS
A Sample/A Standard x C Standard = ug/dL iron

Samples with concentrations higher than 1000 ug/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: ug/dL x 0.179 = umol/L

REFERENCE VALUES
Men = 60 - 175 ug/dL (10.7 - 31.3 umol/L)
Women = 50 - 170 ug/dL (9.0 - 30.4 umol/L)

Note: 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.

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 ug/dL
Linearity : Up to 1000 ug/dL
Precision (expressed in ug/dL):
Within-run
Mean - 118.8, 204.6
SD - 0.95, 0.59
CV% - 0.81, 0.59
N - 10, 10
Between-run
Mean - 118.8, 204.6
SD - 2.71, 3.71
CV% - 2.28, 1.81
N - 10, 10
Sensitivity : 1.6 mAbs / ug/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).
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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.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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