IRON CRX

FE 0100 CH	2 x 50 ml
FE 0500 CH	4 x 125 ml

INTENDED USE

Reagent for quantitative in vitro determination of iron in biological fluids.

SUMMARY OF TEST

Serum iron concentration connotes the Fe(III) bound to serum transferrin and does not include the iron contained in serum as free hemoglobin.

PRINCIPLE OF THE METHOD

Serum iron reacts with chromazurol-B and CTMA-Br to form a complex deeply blue colored. The absorbance measured at 630 nm is directly proportional to the amount of iron in the sample.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

FE CRX R1 **0100: 2 x 50 ml (liquid) blue cap**
0500: 4 x 125 ml (liquid) blue cap

Composition: chromazurol-B 0.13 mM, CTMA-bromide 0.82 mM, acetate buffer pH 4.75.

Standard: iron(III) solution 200 µg/dl - 5 ml

Store all components at 15-25°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Reagent R1: ready to use.
Stability of reagent: up to expiration date on labels at 15-25°C
Stability since first opening of vials: preferably within 60 days at 15-25°C.

PRECAUTIONS

FE CRX R1: Warning. Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

Standard: It is not classified as hazardous.

SPECIMEN

Serum. Samples are stable 4 days at 2-8°C.
Separate serum/plasma from clot within 1 hour.

TEST PROCEDURE

Wavelenght:	630 nm (allowed 620 ÷ 640 nm)
Lightpath:	1 cm
Temperature:	25, 30 or 37°C

dispense:	blank	calibrator	sample
reagent R1	2.5 ml	2.5 ml	2.5 ml
water	100 µl	-	-
standard	-	100 µl	-
sample	-	-	100 µl

Mix, incubate at 25, 30 or 37°C for 5 minutes.
Read absorbances of standard (Ac) and samples (Ax) against reagent blank.

RESULTS CALCULATION

serum/plasma sample:

$$\text{iron } \mu g/dl = \frac{Ax}{Ac} \times 200 \text{ (standard value)}$$

EXPECTED VALUES

men	59 - 158 µg/dl	(10.6 - 28.3 µmol/l)
women	37 - 145 µg/dl	(6.60 - 26.0 µmol/l)

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
QUANTINORM CHEMA
with normal or close to normal control values
QUANTIPATH CHEMA
with pathological control values.

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity
the method is linear up to 500 µg/dl.
If the limit value is exceeded, it is suggested to dilute sample 1+9 with distilled water and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)
the limit of detection is 12 µg/dl.

Interferences
no interference was observed by the presence of:

hemoglobin	interferes
bilirubin	≤ 50 mg/dl
lipids	interferes

Precision

intra-assay (n=10)	mean (µg/dl)	SD (µg/dl)	CV%
sample 1	111.70	2.31	2.10
sample 2	172.10	2.28	1.30

inter-assay (n=20)	mean (µg/dl)	SD (µg/dl)	CV%
sample 1	111.79	2.66	2.40
sample 2	170.58	2.53	1.50

Methods comparison
a comparison between Chema and a commercially available product gave the following results:

Iron CRX Chema = x
Iron competitor = y
n = 95

$y = 1.08x - 8.71$ µg/dl $r^2 = 0.97$

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Garcic A. - Clin. Chim. Acta 94, 115 (1979)
Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

MANUFACTURER

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use