IRON FZ

FE F245 CH	12 x 20 ml
FE F400 CH	8 x 50 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 bound to transferrine is released in acidic environment. Fe(III) ions are then reduced to Fe(II), which reacts with ferrozine to give a violet colored complex. The absorbance measured at 560 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 FZ R1 **F245: 12 x 16 ml (liquid) blue cap**
F400: 8 x 40 ml (liquid) blue cap
Composition: acetate buffer 500 mM pH 4.50, thiourea ≥ 50 mM, guanidine hydrochloride ≥ 100 mM, surfactant.

FE FZ R2A **F245: 2 x 24 ml (liquid) red cap**
F400: 2 x 40 ml (liquid) red cap
Composition: ferrozine 6 mM.

FE FZ R2B **F245: 2 vials powder for 24 ml**
F400: 2 vials powder for 40 ml
Composition: sodium ascorbate ≥ 50 mM.

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

Store all components at 2-8°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.
Reagent R2: add all the content of reagent R2B to reagent R2A and let to stay 20 minutes, mixing occasionally by inversion. Do not shake. Stable 90 days at 2-8°C.
Caution: keep well closed and refrigerated.

Stability of unmixed reagents:
up to expiration date on labels at 2-8°C.
Stability of unmixed reagents since first opening of vials: preferably within 60 days at 2-8°C.

PRECAUTIONS

FE FZ R1: Danger. Causes serious eye damage (H318). 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). Immediately call a doctor (P310).

FE FZ R2A: It is not classified as hazardous.

FE FZ R2B: It is not classified as hazardous.

Standard: It is not classified as hazardous.

SPECIMEN

Serum, plasma heparinate.
Samples are stable 7 days at 15-25°C, 3 weeks at 2-8°C and several months at -20°C.
Separate serum/plasma from clot within 1 hour.
Anticoagulants as EDTA or oxalate could yeld too low recovery values.

TEST PROCEDURE

Wavelenght: 560 nm (allowed 540 ÷ 580 nm)
Lightpath: 1 cm
Temperature: 25, 30 or 37°C

dispense:	blank	calibrator	sample
reagent R1	1 ml	1 ml	1 ml
water	250 µl	-	-
standard	-	250 µl	-
sample	-	-	250 µl

Mix, incubate at 25, 30 or 37°C for 5 minutes.
Read absorbances of standard (Ac_1) and samples (Ax_1) against reagent blank.

dispense:	blank	calibrator	sample
reagent R2	250 µl	250 µl	250 µl

Mix, incubate at 25, 30 or 37°C for 5 minutes.
Read absorbances of calibrator (Ac_2) and samples (Ax_2) against reagent blank.

RESULTS CALCULATION

serum/plasma sample:

$$\text{iron } \mu g/dl = \frac{Ax_2 - Ax_1}{Ac_2 - Ac_1} \times 200 \text{ (standard value)}$$

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 1000 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 25 µg/dl.

Interferences
no interference was observed by the presence of:

hemoglobin	interfers
bilirubin	≤ 19 mg/dl
lipids	≤ 1000 mg/dl

Precision

intra-assay (n=10)	mean (µg/dl)	SD (µg/dl)	CV%
sample 1	106.41	2.12	1.99
sample 2	178.48	1.54	0.86

inter-assay (n=14)	mean (µg/dl)	SD (µg/dl)	CV%
sample 1	107.69	6.65	6.20
sample 2	179.15	4.65	2.60

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

Iron FZ Chema = x
Iron competitor = y
n = 100

$y = 0.947x + 0.387$ µg/dl $\quad r^2 = 0.973$

WASTE DISPOSAL

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

REFERENCES

Paul Carter - Anal. Biochem. 40, 450-458 (1971).
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

CE