

# 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 transferrin 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  $\geq$  50 mM, guanidine hydrochloride  $\geq$  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  $\geq$  50 mM.

**Standard:** iron(III) solution 200  $\mu$ g/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 micro-pipettes. 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). Harmful to aquatic life with long lasting effects (H412).  
**IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). Wear protective gloves / eye protection / face protection (P280). Immediately call a POISON CENTER / doctor (P310). Wash with water thoroughly after handling (P264). Avoid release to the environment (P273).

**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 yield too low recovery values.

## TEST PROCEDURE

Wavelength: 560 nm (allowed 540  $\div$  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 $\mu$ l	-	-
standard	-	250 $\mu$ l	-
sample	-	-	250 $\mu$ l

Mix, incubate at 25, 30 or 37°C for 5 minutes.  
Read absorbances of standard ( $A_{c1}$ ) and samples ( $A_{x1}$ ) against reagent blank.

dispense:	blank	calibrator	sample
reagent R2	250 $\mu$ l	250 $\mu$ l	250 $\mu$ l

Mix, incubate at 25, 30 or 37°C for 5 minutes.  
Read absorbances of calibrator ( $A_{c2}$ ) and samples ( $A_{x2}$ ) against reagent blank.

## RESULTS CALCULATION

serum/plasma sample:

$$\text{iron } \mu\text{g/dl} = \frac{A_{x2} - A_{x1}}{A_{c2} - A_{c1}} \times 200 \text{ (standard value)}$$

## EXPECTED VALUES

men	59 - 158 $\mu$ g/dl	(10.6 - 28.3 $\mu$ mol/l)
women	37 - 145 $\mu$ g/dl	(6.60 - 26.0 $\mu$ mol/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 - MULTINORM CHEMA**

with normal or close to normal control values

**QUANTIPATH CHEMA - MULTIPATH CHEMA**

with pathological control values.

Please contact Customer Care for further information.

## TEST PERFORMANCE

### Linearity

the method is linear up to 1000  $\mu$ g/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  $\mu$ g/dl.

### Interferences

no interference was observed by the presence of:

hemoglobin	interferes
bilirubin	$\leq$ 19 mg/dl
lipids	$\leq$ 1000 mg/dl

### Precision

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

inter-assay (n=14)	mean ( $\mu$ g/dl)	SD ( $\mu$ g/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:

$$\begin{aligned} \text{Iron FZ Chema} &= x \\ \text{Iron competitor} &= y \\ n &= 100 \end{aligned}$$

$$y = 0.947x + 0.387 \mu\text{g/dl} \quad r^2 = 0.973$$

## 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, Bur-tis-Ashwood (1994).

## MANUFACTURER

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## SYMBOLS

	<i>in vitro</i> diagnostic medical device
	batch code
	catalogue number
	temperature limit
	use-by date
	caution
	consult instructions for use