

Liquick Cor - FERRUM

	(EN)
Kit name	Cat. No
Liquick Cor-FERRUM mini	3-247
Liquick Cor-FERRUM 30	3-257
Liquick Cor-FERRUM 60	3-258
Liquick Cor-FERRUM 500	3-323

INTENDED USE

Diagnostic kit for determination of iron concentration used both for manual assay and in several automatic analysers.

The reagents must be used only for *in vitro* diagnostic, by suitably qualified laboratory personnel, only for the intended purpose, under appropriate laboratory conditions.

INTRODUCTION

Iron is the most abundant trace element in the organism. Most of the iron in humans is located within heme molecule which is incorporated into hemoglobin, myoglobin, catalase, peroxidase and cytochromes. Iron is stored bound to ferritin or hemosiderin and is transported by transferrin. Measurement of iron level is valuable especially in diagnosis of different types of anemia.

METHOD PRINCIPLE

Colorimetric method with ferrozene, without deproteinization. Iron ions (Fe^{3+}), bounded in blood to transferrin are released in acid solution and in the presence of detergents and reduced to Fe^{2+} by ascorbate. Fe^{2+} forms with 3-(2-pyridyl)-5,6-bis(2-[4-phenyl sulfonic acid])-1,2,4-triazine sodium salt (ferrozene) coloured complex, Cu^{2+} ions are bound by thiourea. The colour intensity is directly related to the iron concentration.

REAGENTS

Package	Liquick Cor-FERRUM mini	Liquick Cor-FERRUM 30
1-FERRUM	2 x 25 ml	5 x 25 ml
2-FERRUM	1 x 10 ml	1 x 25 ml
3-STANDARD	1 x 1 ml	1 x 2 ml

	Liquick Cor-FERRUM 60	Liquick Cor-FERRUM 500
1-FERRUM	5 x 50 ml	3 x 417 ml
2-FERRUM	1 x 50 ml	1 x 250 ml

3-STANDARD is iron ions standard solution – 10 $\mu\text{mol/l}$ (56 $\mu\text{g/dl}$).

The reagents are stable up to expiry date printed on the package, if stored at 2-8°C. The reagents are stable for 11 weeks on board the analyser at 2-10°C.

Concentrations in the reagent

1-FERRUM	
citric acid (pH 1.9)	≤ 240 mmol/l
thiourea	≤ 108 mmol/l
detergent	≤ 7 %
2-FERRUM	
sodium ascorbate	≤ 150 mmol/l
3-(2-pyridyl)-5,6-bis(2-[5-furyl sulfonic acid])-1,2,4-triazine sodium salt (ferrozene)	≤ 6 mmol/l
preservative	
stabilizer	

Warnings and notes

- Protect from direct sunlight and avoid contamination!
- When using the manual method, use disposable cuvettes.
- Reagent 1-FERRUM (Cat. No 3-261) can be ordered separately.
- 1-FERRUM and 3-Standard meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Ingredients:

1-FERRUM contains polyethylene glycol monoalkyl ether.

3-Standard contains hydrochloric acid.

Danger



H314 Causes severe skin burns and eye damage.
EUH208 Contains thiourea. May produce an allergic reaction (1-FERRUM).
EUH208 Contains 1-[1,3-Bis (hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis

(hydroxymethyl) urea. May produce an allergic reaction (2-FERRUM).

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P533 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor.

ADDITIONAL EQUIPMENT

- automatic analyzer or photometer able to read at 550 nm;
- thermostat at 37°C;
- general laboratory equipment.

SPECIMEN¹³

Serum free from hemolysis, collected in plastic tubes.

Serum should be separated from red blood cells as soon as possible after blood collection.

Serum can be stored up to 7 days at 15-25°C or up to 3 weeks at 2-8°C.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

Applications for analyzers are available on request.

Manual procedure

wavelength	550 nm
temperature	37°C
cuvette	1 cm

Reagent Start method

Pipette into the cuvettes:

	blank (B)	test (T)	standard (S)
1-FERRUM	1000 μl	1000 μl	1000 μl

Bring up to the temperature of determination. Then add:

standard	-	-	80 μl
serum	-	80 μl	-
distilled water	80 μl	-	-

Mix well and after 5 minutes of incubation read the absorbance A1 of test (T) and standard (S) against blank (B). Then add:

2-FERRUM	200 μl	200 μl	200 μl
----------	-------------------	-------------------	-------------------

Mix well and after 10 minutes of incubation read the absorbance A2 of test (T) and standard (S) against blank (B). The intensity of colour is stable for 30 minutes.

Calculate ΔA for the test and standard:

$$\Delta A = (A2 - 0.84A1)$$

The 0.84 coefficient compensate the decrease of absorbance after 2-FERRUM addition.

Calculation

$$\text{iron concentration} = \frac{\Delta A(T)}{\Delta A(S)} \times \text{standard concentration}$$

REFERENCE VALUES^{8, 10}

serum	$\mu\text{g/dl}$	$\mu\text{mol/l}$
newborns	100 – 250	17.9 – 44.8
infants	40 – 100	7.2 – 17.9
children	50 – 120	9.0 – 21.5
adult females	50 – 170	9.0 – 30.4
adult males	65 – 175	11.6 – 31.3

Samples should be taken in the morning from patients in a fasting state, since iron values decrease by 30% during the course of the day.

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.

For calibration when using the manual method IRON STANDARD 56 (Cat. No 5-133) or 3-STANDARD attached to the kit is recommended.

For calibration of the automatic analysers systems CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) or CORMAY MULTICALIBRATOR LEVEL 2 (Cat. No 5-175; 5-177) is recommended depending on the calibrator lot number. The calibration curve should be prepared every 11 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using automatic analyser Biolis 24i Premium. Results may vary if a different instrument or a manual procedure is used.

- Sensitivity:** 3.6 $\mu\text{g/dl}$ (0.644 $\mu\text{mol/l}$).
- Linearity:** up to 1000 $\mu\text{g/dl}$ (179 $\mu\text{mol/l}$).

For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

Specificity / Interferences

Ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl, triglycerides up to 1000 mg/dl and copper up to 500 $\mu\text{g/dl}$ do not interfere with the test. Haemoglobin interferes even in small amount with the determination.

Precision

Repeatability (run to run) n = 10	Mean [$\mu\text{g/dl}$]	SD [$\mu\text{g/dl}$]	CV [%]
level 1	33.86	0.47	1.39
level 2	317.54	1.76	0.55
Reproducibility (day to day) n = 10	Mean [$\mu\text{g/dl}$]	SD [$\mu\text{g/dl}$]	CV [%]
level 1	243.77	1.97	0.81
level 2	65.91	1.39	2.10

Method comparison

A comparison between ferrum values determined at Biolis 24i Premium (y) and at Hitachi 912 (x) using 102 samples gave following results:

$$y = 0.9325x + 7.8482 \mu\text{g/dl};$$

$$R = 0.9925 \quad (R - \text{correlation coefficient})$$

TRACEABILITY

IRON STANDARD 56 is traceable to the direct spectrophotometric reference method.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

- Stookey L.L.: Anal. Chem. 42/7, 779-781 (1970).
- Williams H.L., Johnson D.J., Haut M.J.: Clin. Chem. 23/2, 237-240 (1977).
- Duffy J.R., Gaudin J.: Clin. Biochem. 10/3, 122-123 (1977).
- Cerioti F., Cerioti G: Clin. Chem. 26/2, 327-331 (1980).
- Valcour A., Krzymowski G., Onoroski M., Bowers G.N. Jr., McComb R.B.: Clin Chem. 36/10, 1789-1792 (1990).
- Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders, 2062 (1994).
- Tietz N.W., Textbook of Clinical Chemistry, Philadelphia, PA: WB Saunders, 3:24, (1990).
- Kaplan L.A., Pesce A.J., ed. Clinical chemistry, theory, analysis and correlation, 3rd ed. St Louis, MO: Mosby, 714 (1996).
- Dembińska-Kieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumed, 24-25, (1998).
- Alan H.B. Wu: Tietz Clinical Guide to Laboratory Tests, 4th ed. WB Saunders, 634, (2006).
- Tietz NW, Rinker AD, Morrison SR. Clin Chem. 40(4):546-51 (1994).
- Br J Haematol. 75(4):615-6 (1990).
- Ehret W., Heil W., Schmitt Y., Töpfer G., Wisser H., Zawta B., et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. WHO/DIL/LAB/99.1 Rev. 2, p. 36

Date of issue: 01.2020.