

## DIAGNOSTIC KIT FOR DETERMINATION OF IRON CONCENTRATION



### HC – FERRUM

#### 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 ferrozine, without deproteinization.

Iron ions ( $\text{Fe}^{3+}$ ), bounded in blood to transferrin are released in acid solution and in the presence of detergents and reduced to  $\text{Fe}^{2+}$  by ascorbate.  $\text{Fe}^{2+}$  forms with 3-(2-pyridyl)-5,6-bis(2-[4-phenyl sulfonic acid])-1,2,4-triazine sodium salt (ferrozine) coloured complex,  $\text{Cu}^{2+}$  ions are bound by thiourea. The colour intensity is directly related to the iron concentration.

#### REAGENTS

##### Package

1-Reagent	6 x 88 ml
2-Reagent	6 x 18.5 ml

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. Protect from light and avoid contamination!

#### Concentrations in the test

##### 1-Reagent

citric acid (pH 1.9)	200 mmol/l
thiourea	90 mmol/l
detergent	6 %

##### 2-Reagent

sodium ascorbate	125 mmol/l
sodium chloride	50 mmol/l
3-(2-pyridyl)-5,6-bis(2-[5-furyl sulfonic acid])-1,2,4-triazine sodium salt (ferrozine)	≥ 5 mmol/l
preservatives	0.2 %

#### Warnings and notes

- Product for in vitro diagnostic use only.
- Contaminated glassware is the greatest source of error. The use of disposable plastic ware is recommended. Glassware should be soaked for a few hours in 2M HCl solution and then thoroughly rinsed with distilled water.
- 1-Reagent is classified as an irritant!

**Xi** – Irritant.

**R 36:** Irritating to eyes.

**S 25-26:** Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water and see medical advice.

#### SPECIMEN

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 6 hours at 15-25°C or up to 3 days at 2-8°C.

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

#### PROCEDURE

The reagents are ready to use.

These reagents may be used in automatic analyser Hitachi 911/912.

Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

#### REFERENCE VALUES <sup>10</sup>

serum	µg/dl	µmol/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

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 the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.

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 the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Limit of detection:** 0.69 µg/dl (0.124 µmol/l).  
Limit of detection is reflecting the lowest measurable concentration of analyte which can be distinguished from zero. It is calculated as mean value increased with triple standard deviation of sample with no analyte, for 21 repeats.
- **Sensitivity:** 7.9 µg/dl (1.41 µmol/l).
- **Linearity:** up to 1000 µg/dl (179 µmol/l).  
For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.
- **Measuring range:** 0.69 – 1000 µg/dl (0.124 – 179 µmol/l).

▪ **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 µg/dl do not interfere with the test. Haemoglobin interferes even in small amount with the determination.

▪ **Precision**

Repeatability (run to run) n = 10	Mean [µg/dl]	SD [µg/dl]	CV [%]
level 1	67.33	1.65	2.45
level 2	244.42	1.00	0.41

Reproducibility (day to day) n = 10	Mean [µg/dl]	SD [µg/dl]	CV [%]
level 1	249.72	3.65	1.46
level 2	65.37	1.46	2.23

▪ **Method comparison**

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 130 samples gave following results:

$$y = 0.9223 x + 3.4774 \text{ µg/dl};$$

$$R = 0.9976 \quad (R - \text{correlation coefficient})$$

**WASTE MANAGEMENT**

Please refer to local legal requirements.

**LITERATURE**

1. Stookey L.L.: Anal. Chem. 42/7, 779-781 (1970).
2. Williams H.L., Johnson D.J., Haut M.J.: Clin. Chem. 23/2, 237-240 (1977).
3. Duffy J.R., Gaudin J.: Clin. Biochem. 10/3, 122-123 (1977).
4. Ceriotti F., Ceriotti G: Clin. Chem. 26/2, 327-331 (1980).
5. Valcour A., Krzymowski G., Onoroski M., Bowers G.N. Jr., McComb R.B.: Clin Chem. 36/10, 1789-1792 (1990).
6. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders, 2062 (1994).
7. Tietz N.W., Textbook of Clinical Chemistry, Philadelphia, PA: WB Saunders, 3:24, (1990).
8. Kaplan L.A., Pesce A.J., ed. Chemistry Theory, Analysis, and Correlation, 3rd ed. St Louis, MO: Mosby, 714 (1996).
9. Dembińska-Kieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumes, 24-25, (1998).
10. Alan H.B. Wu: Tietz Clinical Guide to Laboratory Tests, 4th ed. WB Saunders, 634, (2006).
11. Tietz NW, Rinker AD, Morrison SR. Clin Chem. 40(4):546-51 (1994).
12. Br J Haematol. 75(4):615-6 (1990).

**Date of issue:** 09. 2012.

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09/12/09/12