Cat. No 4-502

DIAGNOSTIC KIT FOR DETERMINATION OF UNSATURATED IRON BINDING CAPACITY

HC – UIBC

INTRODUCTION

The total iron content of the body is about 3 to 3.5 g. Of this amount about 2.5 g contained in erythrocytes or their precursors in the bone marrow. Plasma contains only about 2.5 mg of iron. Iron is transported as Fe (III) bound to the plasma protein apotransferrin. The apotransferrin-Fe (III) complex is called transferrin. Normally only about one third of the iron binding sites of transferrin are occupied by Fe (III). The additional amount of iron that can be bound is the unsaturated (or latent) iron-binding capacity (UIBC). The sum of the serum iron and UIBC represents total iron binding capacity (TIBC). TIBC is a measurement for the maximum iron concentration that transferrin can bind.
Serum UIBC levels vary in disorders of iron metabolism where iron capacities are often increased in iron deficiency and decreased in chronic inflammatory disorders or malignancies.

METHOD PRINCIPLE

Colorimetric method with ferene:

$2\ Fe^{2+}$ (known) + transferrin ⟶ transferrin-(Fe^{3+}) + Fe^{2+} (excess)

Fe^{2+} (excess) + 3 ferene ⟶ ferrous ferene (blue complex)

A known ferrous ion concentration incubated with serum, binds specifically with transferrin at unsaturated iron binding sites. Remaining unbound ferrous ions are measured with the ferene reaction.
The difference between the amount of excess iron and the total amount added to the serum is equivalent to the quantity bound to transferrin. This is the UIBC (unsaturated iron binding capacity) of the sample.

REAGENTS

Package

1-Reagent	1 x 76.5 ml
2-Reagent	1 x 19.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. Do not freeze the reagents. Protect from light and avoid contamination!

Concentrations in the test

buffer (pH 8.7)	100 mmol/l
ammonium iron (II) sulfate	13 µmol/l
thiourea	120 mmol/l
ascorbic acid	240 mmol/l
ferene	6 mmol/l

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- 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.
- Products contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum, heparin plasma.
Separate serum/plasma at the latest 2 h after blood collection to avoid hemolysis.
Discard contaminated specimens.
Serum can be stored up to 5 days at 20-25ºC, up to one month at 4-8ºC or also up to month at -20ºC.
Plasma can be stored up to one month at 4-8ºC or also up to month at -20ºC.
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 [4, 5]

serum / plasma	µg/dl	µmol/l
adults	120 – 470	21 – 84

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 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 Hitachi 912. Results may vary if a different instrument is used.

- **Sensitivity:** 17.2 µg/dl (3.08 µmol/l).

- **Linearity:** up to 660 µg/dl (118.14 µmol/l).
  For higher concentration dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 0.04 g/dl, ascorbate up to 300 mg/l, conjugated and free bilirubin up to 60 mg/dl, triglycerides up to 2000 mg/dl, RF up to 350 IU/ml, copper up to 15 mg/dl and zinc up to 15 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [µg/dl]	SD [µg/dl]	CV [%]
level 1	117.97	2.50	2.12
level 2	167.96	2.51	1.49

Reproducibility (day to day) n = 80	Mean [µg/dl]	SD [µg/dl]	CV [%]
level 1	129.24	11.58	8.96
level 2	175.01	10.03	5.73

- **Method comparison**

A comparison between UIBC values determined at Hitachi 912 (y) and at Cobas Integra 400 PLUS (x) using 61 samples gave following results:
y = 0.9923 x + 12.571 µg/dl;
R = 0.9917 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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MANUFACTURER

PZ CORMAY S.A.
22 Wiosenna Street
05-092 Łomianki, POLAND
tel.: +48 (0) 22 751 79 10
fax: +48 (0) 22 751 79 14
http://www.pzcormay.pl

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