CORMAY UIBC

DIAGNOSTIC KIT FOR DETERMINATION OF UNSATURATED IRON BINDING CAPACITY

Kit name	Cat. No
CORMAY UIBC 500	1-311
CORMAY UIBC "bulk"	1-258

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, malignancies or in course of hemochromatosis.

METHOD PRINCIPLE

Direct, colorimetric method with ferrozine:

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

Fe^{2+} (excess) + ferrozine ⟶ Fe2+-ferrozine (coloured complex)

In an alkaline environment known ferrous ion concentration incubated with serum, binds specifically with transferrin at unsaturated iron binding sites. Remaining unbound ferrous ions are measured with the chromogen 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

	CORMAY UIBC 500	CORMAY UIBC "bulk"
1-Reagent	3 x 400 ml	--*
2-Reagent	1 x 300 ml	--*

*reagent volume is printed on the label.

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 8 weeks on board the analyser at 2-10°C. Do not freeze the reagents. Protect from light and avoid contamination!

Concentrations in the test

1-Reagent	
buffer (pH 8.4)	0.25 mol/l
ammonium iron (II) sulfate	20 µmol/l
thiourea	90 mmol/l
detergent	0.1 %
sodium azide	<0.1 %
2-Reagent	
sodium ascorbate	150 mmol/l
sodium chloride	75 mmol/l
3-(2-pyridyl)-5,6-bis(2-[5-furyl sulfonic acid])-1,2,4-triazine sodium salt (ferrozine)	≥ 10 mmol/l
preservatives	0.3 %

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for intended purpose, 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.
- The negative UIBC value will occur when the patient's serum iron level exceeds the binding capacity of the transferrin.
- For the diagnostic purpose UIBC determination should be perform at the same time with iron determination. Obtained result have to be interpreted in relation to the result of iron concentration and the percentage saturation of transferrin with iron ions[7].
- 1-Reagent contains thiourea. May produce an allergic reaction (EUH208).
- 2-Reagent contains 1-[1,3-Bis (hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis (hydroxymethyl) urea. May produce an allergic reaction (EUH208).

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN

Serum, heparin plasma.
Separate serum/plasma at the latest 2 h after blood collection to avoid hemolysis.
Samples should be taken in the morning from patients, since iron values decrease during the course of the day.
Discard contaminated specimens.
Anticoagulants such as EDTA, oxalate and citrate must not be used, as they bind iron ions and prevent reaction with chromogen [4].
Serum can be stored up to 3 days at 20-25ºC, 7 days at 4-8ºC or up to one month at -20ºC. Plasma can be stored up to 7 days at 4-8ºC or up to month at -20ºC [4].
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in several automatic analysers. Applications for them are available on request.

REFERENCE VALUES [5, 6]

The reference values were calculated from the serum iron (SI) and TIBC ranges reported in literature, in accordance with mathematic formula:
UIBC=TIBC-SI
Reference values for UIBC are listed in table below:

serum / plasma	µg/dl	µmol/l
Females	80 – 375	14 – 67
Males	75 – 360	13 – 64

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.

The calibration curve should be prepared every week, 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 Biolis 24i Premium. Results may vary if a different instrument is used.

- **Sensitivity:** 17 µg/dl (3.04 µmol/l).

- **Linearity:** up to 550 µg/dl (98.45 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 interfere even in small amounts, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl, triglycerides up to 1000 mg/dl, copper up to 3.5 mg/dl and zinc up to 15 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [µg/dl]	SD [µg/dl]	CV [%]
level 1	90.00	3.89	4.32
level 2	149.00	1.63	1.10

Reproducibility (day to day) n = 10	Mean [µg/dl]	SD [µg/dl]	CV [%]
level 1	94.85	3.21	3.39
level 2	157.45	2.14	1.36

- **Method comparison**

A comparison between UIBC values determined at Biolis 24i Premium (y) and at Cobas Integra 400 Plus (x) using 73 samples gave following results:

y = 0.9774 x - 1.6176 µg/dl ;

R = 0.992 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Fairbanks VF, Klee GG. Biochemical aspects of hematology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1642-1710.
2. Wick M, Pingerra W, Lehmann P. Clinical aspects and laboratory. Iron metabolism, anemias. 5th ed. Wien, New York: Springer; 2003.
3. Guder Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 46.
4. Perrotta, G., Iron and Iron-Binding Capacity, In: Pesce, A.J., Kaplan, L.A. eds., Methods in Clinical Chemistry, C.V. Mosby, St. Louis, 1258 - 1261,1987
5. Tietz NW (ed). Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA: WB Saunders; 1701-1703; 1821t (1999).
6. Burtis CA, Bruns DE. Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics. 7th ed. St. Louis, p. 306. 2014
7. Schreiber WE. „Iron and Porphyrin Metabolism" in Pesce, A.J., Kaplan, L.A. editors. Clinical Chemistry: Theory, Analysis, Correlation. Mosby Inc., an affiliate of Elsevier Inc., St. Louis, 755-770, 2010.

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