AU

Instructions For Use

UIBC
UIBC

REF OSR61205 4 x 27 mL R1
4 x 3 mL R1a
4 x 6 mL R2
4 x 2 mL R2a

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED USE

Photometric colour test for the quantitative determination of unsaturated iron binding capacity (UIBC) in human serum and plasma on Beckman Coulter analysers.

SUMMARY AND EXPLANATION

Reference[1,2,3]

Iron participates in a variety of vital processes in the body varying from cellular oxidative mechanisms to the transport and delivery of oxygen to body cells. It is a constituent of the oxygen-carrying chromoproteins, haemoglobin and myoglobin, as well as various enzymes, such as cytochrome oxidase and peroxidases. The remaining body iron is present in the flavoproteins, the iron-sulphur proteins, as well as storage iron-ferritin, and transport iron-transferrin.

Measured serum iron concentration is principally the Fe(III) bound to serum transferrin and does not include the iron contained in serum as free haemoglobin. Since normally only about one-third of the iron-binding sites of transferrin are occupied by Fe(III), serum transferrin has considerable reserve iron-binding capacity. This is called the serum unsaturated or latent iron-binding capacity. UIBC measurements can be used in conjunction with serum iron concentration to obtain the total-iron binding capacity (TIBC) i.e. the maximum concentration of iron that serum proteins, principally transferrin, can bind.

TIBC is decreased in chronic infections, malignancy, in iron poisoning, renal disease, nephrosis, kwashiorkor and thalassemia. Common causes for an increase in TIBC include iron deficiency anemia, late pregnancy, oral contraception and viral hepatitis.

METHODOLOGY

Fe^{2+} from reagent 1 reacts with Nitroso-PSAP from reagent 2 to form an intense green complex. If sample is added a part or all of the iron ions bind specifically with transferrin at unsaturated iron binding sites at alkaline pH. They are thus not available for the colour reaction with Nitroso-PSAP. The difference between the resulting changes in the measured absorbances with or without samples is equivalent to the iron quantity bound to transferrin. This is the unsaturated iron binding capacity (UIBC).

SPECIMEN

TYPE OF SPECIMEN

Serum and heparinised plasma. Do not use EDTA, oxalate or citrate plasma.

Stable in serum and plasma for 3 weeks when stored at 2…8°C and 7 days when stored at 15…25°C.[4]

Haemolysed samples should be avoided. Remove serum from red cells immediately to avoid haemolysis.

Samples should be taken in the morning from patients in a fasting state, since iron values can decrease by 30% during the course of the day.[5]

REAGENTS

WARNING AND PRECAUTIONS

Dispose of all waste material in accordance with local guidelines.

Exercise the normal precautions required for handling all laboratory reagents.

REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

Tris Buffer (pH 8.1)	180 mmol/L
Iron	6.9 µmol/L
Nitroso-PSAP	176 µmol/L
Hydroxylammonium chloride	36 mmol/L
Preservative	

The concentrations of the reactive components of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 vials. The reagent composition which is shown in the Instructions For Use is the final concentration of these components in the reaction cuvette after addition of R1, Sample, and R2.

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

UIBC R1	WARNING	
	H316	Causes mild skin irritation.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
		Tris(hydroxymethyl)– aminomethane 1 - 5%
UIBC R1a	WARNING	

	H316	Causes mild skin irritation.
	H317	May cause an allergic skin reaction.
	H351	Suspected of causing cancer.
	H373	May cause damage to organs through prolonged or repeated exposure.
	H411	Toxic to aquatic life with long lasting effects.
	P201	Obtain special instructions before use.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
	P391	Collect spillage.
		Hydroxylamine Hydrochloride 1 - 5%
UIBC R2	WARNING	
		
		
	H316	Causes mild skin irritation.
	H317	May cause an allergic skin reaction.
	H351	Suspected of causing cancer.
	P201	Obtain special instructions before use.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		Tris(hydroxymethyl)– aminomethane 1 - 5%
		Hydroxylamine Hydrochloride 0.1 - 0.2%

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

REAGENT PREPARATION

R1: The entire contents of bottle R1a must be transferred into the entire volume of R1. Mix by gentle inversion before placing on board the instrument.

R2: The entire contents of bottle R2a must be transferred into the entire volume of R2. Mix by gentle inversion before placing on board the instrument.

STORAGE AND STABILITY

The reagents are stable, unopened, up to the stated expiry date when stored at 2…8°C. Once prepared, reagents stored on board the instrument are stable for 30 days.

CALIBRATION

CALIBRATOR REQUIRED

System Calibrator Cat. No. 66300.

The calibrator value is traceable to the National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 937.

Recalibrate the assay every 14 days or when the following occur:

Change in reagent bottle or significant shift in control values;

Major preventative maintenance was performed on the analyser or a critical part was replaced.

QUALITY CONTROL

Controls Cat. No. ODC0003 and ODC0004 or other control materials with values determined by this Beckman Coulter system may be used.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement.

CALCULATIONS

The Beckman Coulter analysers automatically compute the UIBC concentration of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

Reference[6]	
Adults	27.8 – 63.6 µmol/L (155 – 355 µg/dL)

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

PROCEDURAL NOTES

INTERFERENCES

Results of studies conducted to evaluate the susceptibility of the method to interference were as follows:

Icterus:	Interference less than 6% up to 40 mg/dL or 684 µmol/L bilirubin
Haemolysis:	Interference less than 10% up to 2 g/L haemoglobin
Lipemia:	Interference less than 5% up to 1,000 mg/dL Intralipid. AU5800 / DxC 700 AU: Interference less than 10% up to 1,000 mg/dL Intralipid.

Refer to Young[7] for further information on interfering substances.

Eltrombopag and its metabolites may interfere with this assay causing erroneously high patient results.

PERFORMANCE CHARACTERISTICS

PERFORMANCE CHARACTERISTICS

Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

LINEARITY

The test is linear within a concentration range of 10 – 100 µmol/L (55 – 550 µg/dL).

SENSITIVITY

The lowest detectable level on an AU2700 analyser was estimated at 2.30 µmol/L.

The lowest detectable level represents the lowest measurable level of UIBC that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

METHODS COMPARISON

Patient serum samples were used to compare this UIBC OSR61205 assay on the AU640 against another commercially available UIBC assay. Results of linear regression analysis were as follows:

y = 0.988x + 1.956	r = 0.992	n = 115	Sample range = 11.21 – 75.63 µmol/L

PRECISION

The following data was obtained on an AU2700 using 3 serum pools analysed over 20 days.

n = 80	Within-run		Total	
Mean µmol/L	**SD**	**CV%**	**SD**	**CV%**
24.56	0.54	2.19	0.82	3.35
35.57	0.39	1.10	0.68	1.93
72.54	0.47	0.65	0.73	1.01

ADDITIONAL INFORMATION

DxC 700 AU requires that each reagent application has a standard format of abbreviated Closed Test Name. This Closed Test Name is required to allow automated loading of the calibrator information for each application as part of the DxC 700 AU Closed System. Refer to the table below for the Closed Test Name assigned to each application for this assay.

Test Name	Description
UBC1N	UIBC (Serum)

Setting Sheet Footnotes
User defined
† System Calibrator Cat. No.: 66300
* Values set for working in SI units (µmol/L). To work in µg/dL multiply by 5.585.

REVISION HISTORY

Added new languages

Preceding version revision history

Revised GHS section

Revised Interferences section.

REFERENCES

1. Tietz NW, ed. Clinical guide to laboratory tests, 3rd ed. Philadelphia: WB Saunders Company,1995:376-377.

2. Fairbanks VF, Klee GG. Biochemical aspects of hematology. In: Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry. Philadelphia: WB Saunders Company, 1999;1698-1703.

3. Woo J, Henry JB. Metabolic intermediates and inorganic ions. In: Henry JB, ed. Clinical diagnosis and management by laboratory methods. Philadelphia:WB Saunders Company, 1996:188-190.

4. 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.2:36pp.

5. Perrotta G. Iron and total iron binding capacity. In: Kaplan LA, Pesce AJ, eds. Clinical chemistry theory, analysis, and correlation. St Louis: Mosby, 1996:714pp.

6. Data on file at Beckman Coulter Biomedical Ltd..

7. Young DS. Effects of Drugs on Clinical Laboratory Tests, AACC, 5th ed. AACC Press, 2000.

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