UIBC (UNSATURATED IRON BINDING CAPACITY)

En

REF DMU10	1.200	Tests
REF 8AU300	5.192	Tests
REF 8AU301	3.358	Tests
REF BYU300	5.192	Tests
REF BYU301	3.358	Tests
REF AT305	1.816	Tests

Test for the quantitative determination of the unsaturated iron-binding capacity in human serum and heparinized plasma. Liquid. Dual reagents. Store at +2/+8°C. Do not freeze. For in Vitro Diagnostic Use.

INTENDED USE [1, 2, 3]

The test is applied for quantitative determination of unsaturated iron-binding capacity (UIBC) in human serum and plasma.

In the determination of various iron disorders, the measurement of unsaturated iron binding capacity (UIBC) in combination with serum iron is defined as a useful diagnostic tool.

The total iron binding capacity (TIBC) is obtained by the combined values of UIBC and serum iron. TIBC is the maximum amount of iron that can be bound to transferrin.

It is the representation for the maximum concentration of iron that serum proteins can bind.
Transferrin is a plasma iron-transport protein, also called siderophilin, formed in the liver that has a half-life of 7–10 days. Transferrin is capable of binding more than its own weight in iron (That is, 1 g of transferrin can carry 1.43 g of iron).[2]

Variation is seen in serum UIBC levels in disorders of iron metabolism, where iron binding capacities are often increased in iron deficiency and decreased in chronic inflammatory disorders or malignancies.
Not only the findings of a single test result but also an integration of both clinical and laboratory data should be used in clinical diagnosis.

TEST PRINCIPLE [9, 10]

Direct determination with FerroZine.4,5

$$Fe(II) + \text{transferrin} \xrightarrow{\text{Alkaline buffer}} \text{transferrin-}Fe(III) + Fe(II)\ (\text{excess})$$

$$Fe(II)\ (\text{excess}) + 3\ \text{FerroZine}\ Fe(II) \longrightarrow (\text{FerroZine})3$$

The color intensity is directly proportional to the unbound excess iron concentration and indirectly proportional to the unsaturated iron-binding capacity.

TEST PARAMETERS

Method	: Ferrozine, End Point.
Wavelength	: Main: 570 -600 nm, Sub: 700-750 nm
Temperature	: 37 ºC
Sample	: Serum and heparinized plasma
Linearity	: 20 µg/dL-600 µg/dL

REAGENT COMPOSITION

Components	Concentrations
Reagent 1	
Buffer	≥ 0.2 mol/L
Ferrous ammonium sulphate	≥ 8.4 µmol/L
Hydroxylamine hydrochloride	≥ 0.1 mol/L
Nonionic surfactant	
Reagent 2	
Ferrozine	≤ 24.3 mmol/L
Preservative	< 0.1%

REAGENT PREPARATION

Reagents are ready to use, liquid.

REAGENT STABILITY AND STORAGE

Store at +2/+8°C.
Reagents are stable till the expiration date stated on the label which is only for closed and uncontaminated vials.

On board stability:

Once opened vials are stable 30 days at +2/+8°C at optimum conditions. There is a strong relation between on board stability and auto analyzer's cooling specification and the carry-over percentage.

SAMPLES

Serum:
Use fresh serum samples. Samples should preferably be analyzed on the day of collection. Serum collected by standard procedures. [13]
Serum and plasma are stable for:

4 days at +15/+25 ºC,
7 days +2/+8ºC.[11, 5]

Don' t use samples with EDTA, Oxalate, Citrate. Don't use hemolysed samples. To avoid hemolyse; centrifuge and separate samples immediately, after collecting samples. Samples should be taken in morning. Otherwise results may be decreased %30 within daytime.[16]

PROCEDURE

Materials provided

UIBC Liquid reagent:
REF DMU10 (for Dimension),
REF 8AU300 or 8AU301 (for Advia 1800),
REF BYU300 or BYU301 (for Advia 2400),
REF AT305 (for Atellica CH).
Archem UIBC Calibrator,
REF: A301S (for Advia 1800, Advia 2400 and Dimension)

Materials required but not provided

Archem Arcal Auto Calibrator:
REF: A39051 (for Advia Chemistry XPT and Atellica CH)

REFERENCE INTERVALS (NORMAL VALUES) (Based on CLSI EP28A3/Transference) [16]

UIBC : 120 to 370 µg/dL
TIBC : 127 to 450 µg/dL

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.[6, 15]

QUALITY CONTROL

Commercially available control material with established values determined by this method may be used.
Quality control is recommended every day.
Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

CALIBRATION

Use UIBC calibrator. We recommend:
Archem UIBC Calibrator (Standard): REF: **A301S**
Archem Arcal Auto Calibrator: REF: **A39051**

The UIBC kit must be calibrated using the calibrator included in the same pack. UIBC Archem calibrator values are lot specific.

Note: The calibrator value for the UIBC Liquid Calibrator must be entered as a **negative** number.
Archem Arcal Auto Calibrator should be preferred for devices whose the calibrator value is not entered as a negative number.

Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is minimum 5 days. Calibration is not recommended if QC values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity (LoQ) (Values are based on CLSI Standard EP17A and LoQ CV% values ≤ 20%): 20 µg/dL UIBC.

High Linearity: The test is linear up to 600 µg/dL UIBC.

Precision Studies* (Based on CLSI EP05A3):

Repeatability (within run) (intra-assay) Within-run reproducibility was established by assaying two levels of control serum 40 runs.

Mean (µg/dL)	Std. Dev.	CV%	N
121.9	2.5	2.05	40
220.4	1.6	0.72	40

Repeatability (Run to run) (inter-assay) Run-to-run reproducibility was established by assaying three levels of control serum for 40 runs.

Mean (µg/dL)	Std.Dev.	CV%	N
124.0	2.96	2.38	40
216.2	1.88	0.87	40

Method Comparison and Correlation:

Correlation with a comparative method is: r= 0.999
Regression analysis according to Passing-Bablok Fit: [7]
Slope: 1 **Intercept:** -1.01

Interferences: [12]

The acceptable interference limit is set 10% below the highest interferent concentration that is within ±10% recovery of the target.
No significant interaction was observed for hemoglobin, conjugated bilirubin, lipemia up to the interferant concentration given in the table. Other drugs and substances may interfere.

Reference observed results in the table below.

Interferent and Concentration	UIBC Liquid Target (µg/dL)	N	Observed Recovery %
Bilirubin (Conjugated) 31,5 mg/dL	118	3	109%
	279	3	108%
Triglycerides 1125 mg/dL	120	3	104%
	273	3	104%
Hemoglobin 540 mg/dL	225	3	91%
Hemoglobin 1035 mg/dL	419	3	96%

The effect of interfering substances has only been evaluated for those listed in this table.
A biochemistry analyzer has been used to obtain these performance characteristics. Usage of different biochemistry auto analyzers or manual procedure may cause the variance in results.
Intralipid has been used for Triglycerides interferences studies.

NOTES

1. For in vitro diagnostic use only. Mouth pipetting is prohibited. Avoid contact with skin and mucous membranes.

2. All the calibrators and controls must be considered as human or animal-sourced substances and thus they are potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet (SDS) will be provided upon request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general GLP guidelines.
R22: Harmful if swallowed.
H302: Harmful if swallowed.

Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

UIBC	: Unsaturated Iron Binding Capacity
TIBC	: Total Iron Binding Capacity
CLSI	: Clinical and Laboratory Standards Institute
CV%	: Coefficient of Variation Percentage
EP	: Evaluation Protocols
GLP	: Good Laboratory Practice
mA	: miliabsorbance
mL	: mililiter
QC	: Quality Control
dL	: deciliter
µg	: Microgram

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies products to be used together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration date
	Temperature limitation
	Consult instructions for use
	Caution
	Sufficient for