UIBC DIRECT (For TIBC)

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

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A300G2	5 x 100 ML	BYU300	6459 Tests	KUIB10	4364 Tests	MUIB11	1675 Tests
A300G1	5 x 50 ML	BYU301	4306 Tests	KUIB11	2182 Tests	SUIB10	2667 Tests
01R85-41	3082 Tests	DMU10	1200 Tests	NUIB10	784 Tests	SUIB11	1280 Tests
01R85-31	1614 Tests	VUIB10	2500 Tests	NUIB11	549 Tests	LUIB10	3500 Tests
01R85-21	1159 Tests	VUIB11	1190 Tests	MUIB10	2512 Tests	LUIB11	1867 Tests

* 01R85-41 / 01R85-31 / 01R85-21 Ref Number Products are Produced Specifically for Abbott Architect Biochemistry Analyzer Series

INTENDED USE

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.

It is the representation for the maximum concentration of iron that serum proteins can bind.

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

TEST PRINCIPLE

Direct determination with FerroZine.4,5

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

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

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

TEST PARAMETERS

Method	: Ferozine
Wavelength	: Main: 570 -600 nm, Sub: 700-750 nm
Temperature	: 2-8°C
Sample	: Serum, heparinised plasma
Linearity	: 30 µg/dL - 600 µg/dL

REAGENT COMPOSITION

Components	Final concentrations
Reagent 1	
Buffer	≥ 0.2 mol/L pH : 8.45
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 for use.

Preparation ratio is R1/R2:4 (R1: 4 ML, R2:1 ML) *Every laboratory can mix according to double or triple of written amounts by the same ratio.

For manual working procedures; if working reagent will be used; first shake Reagent 2 vial gently then pouring its contents to reagent 1 vial. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

Working reagents are stable at 2-8ºC for 1 day when they are stored in closed vials and avoiding contamination after preparation.

REAGENT STABILITY AND STORAGE

Reagent I is stable for 30 days, opened and stayed on the analyzer in well cooling conditions.

Reagent II is liquid and ready to use. It is stable for 90 days, opened and refrigerated on the analyzer.

Calibrator is stable until the expiration date written on the label.

There is a strong relation between on board stability and auto analysers cooling specification and carry-over values.

SAMPLES

Serum collected by standard procedures.
Serum is stable for 4 days at 15-25 ºC ,7 days 2-8ºC. Use serum or heparinised plasma. 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.

TEST PROCEDURE

Sample Start
In case of request, ready application procedures dedicated to different kind of photometers and ready manual working procedures can be supplied.

In case of request, ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied.

Substrate Start
In case of request, ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied.

CALCULATIONS

$$\frac{\text{A Sample}}{\text{A Standard}} \text{ x conc. of standard (calibrator)}$$

= µg/dL UIBC in sample.

Unit Conversion

UIBC (µg/dL) = TIBC – Fe µg/dL
µmol/L x 5.59 = µg/dL
µmol/L x 0.0559 = mg/L
µg/dL x 0.179 = µmol/L
µg/dL x 0.010 = mg/L

REFERANCE INTERVALS (NORMAL VALUES)

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

*It is recommended that each laboratory establish its own normal range.

QUALITY CONTROL AND CALIBRATION

All control sera with UIBC values determined by this method can be used. We recommend:

Assayed Control Serum Normal
Cat. No: A3910 ARCON N
Assayed Control Serum Abnormal
Cat. No: A3920 ARCON P

Or
LIQUID CONTROL LEVEL I 5*5 ML
Cat No: ZA93A
LIQUID CONTROL LEVEL II 5*5 ML
Cat No: ZA93B

Calibrator:
We recommend: ARCHEM Calibrator (Standard) Ref.No. A301S. (Kit includes calibrator)

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 2 days**.**

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity (LOQ) (Based on CLSI EP17A2E document and ARCHITECT c Systems, Also LOQ values are based on CV% values lover %20): 30 µg/dL UIBC. Considerable variation may be seen in linearity depending on the analyzer model and application method.

Sensitivity (LOD) (Based on CLSI EP17A2E document): 20 µg/dL

High Linearity: 600 µg/dL. Considerable variation may be seen in linearity depending on the analyzer model and application method.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run) (intra-assay) Within-run reproducibility was established by assaying three levels of control serum 20 runs.

	Mean (µg/dL)	Std. Dev.	CV%
L1	72	1.5	2.1
L2	169	1.8	1.06
L3	332	4.3	1.05

Reproducibility (Run to run) (inter-assay) Run-to-run reproducibility was established by assaying three levels of control serum for 10 runs.

	Mean	Std.Dev.	CV%

	(µg/dL)		
L1	81	4.27	5.54
L2	186	6.8	3.66
L3	430	14.08	3.28

Correlation: Corr with a reference reagent is: r=0,99 (Between 50 µg/dL to 500 µg/dL)

Trueness: No systematic differences seen in results obtained with this reagent when compared with reference reagents. It's available to get details of comparison experiments in case of requirement.

İnterferences:

Bilirubin: 30 mg/dL

Intralipid ≤1000 mg/dL

Hemoglobin: 350 mg/dL do not interfere. Other drugs and substances may interfere.

An analyzer has been used to obtain these performance characteristics. Usage of different analyzer or a manual procedure may cause the variance in results.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. 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 linearity limit depends on the sample to reagent ratio.

PRECAUTION 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.

R36/38 : Irritating to eyes and skin.

S20/21 : When using, do not eat, drink or smoke.

S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 : After contact with skin wash immediately with plenty of water.

S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

S45 : In case of accident or if you feel unwell, seek medical advice immediately.

S56 : Dispose of this material and its container at hazardous or special waste collection point.

S57 : Use appropriate container to avoid environmental contamination.

S61 : Avoid release in environment. Refer to special instructions/safety data sheets.

Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control
UIBC : Unsaturated Iron Binding Capacity

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
SN	Serial Number
REF	Reference Number (Catalog No)
	Expiration Date
	Storage temperature interval
	Read the directions
	Biological risk

CE

Archem Diagnostics Industry LTD. ŞTİ.
Organize Sanayi Bölgesi, Mutsan Sanayi Sitesi
M8 Blok No: 48 Başakşehir / ISTANBUL TURKEY
Tlf: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr
www.archem.com.tr