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
A300	5X100 ML	BYU301	4306 Tests	KUIB11	2240 Tests	SUIB10	2667 Tests
A301	5X50 ML	DMU10	780 Tests	NUIB10	784 Tests	SUIB11	1280 Tests
TUIB10	3300 Tests	RUIB10	1591 Tests	NUIB11	549 Tests	LUIB10	3500 Tests
TUIB11	1750 Tests	RUIB11	527 Tests	MUIB10	2512 Tests	LUIB11	1867 Tests
BYU300	6459 Tests	KUIB10	4480 Tests	MUIB11	1671 Tests		

INTENDED USE

The test is applied for quantitative determination of unsaturated iron-binding capacity (UIBC) in human serum and plasma. The measurement of unsaturated iron binding capacity (UIBC) in combination with serum iron is a useful diagnostic tool in the determination of various iron disorders. The combined value of UIBC and serum iron gives a value for the total iron binding capacity (TIBC). This represents the maximum concentration of iron that serum proteins can bind. Serum UIBC levels vary 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. It is determine

TEST PARAMETERS

Method	: Ferozine (Mod. Presijn Method)
Wavelength	: 700
Temperature	: 2-8°C
Sample	: Serum, heparinised plasma
Linearity	: 41 µg/dL - 600 µg/dL

REAGENT COMPOSITION

Components	Final concentrations
Reagent 1	
Tris Buffer	≥ 0.2 mol/L pH : 8.45
Ferrous ammonium sulphate	≥ 8.4 µmol/L
Hydroxylamine hydrochloride	≥ 0.1 mol/L
Nonionic surfactant, Thiourea, Dilute Sulfiric acid	
Reagent 2	
Ferrozine	≤ 24.3 mmol/L
Preservative	< 0.1%

REAGENT PREPARATION

Reagents are ready for use.
14 days opened and refrigerated on the analyzer.

Reagent II: Liquid ready to use. 90 days opened and refrigerated on the analyzer.

Preparation ratio is R1/R2:4 (R1: 4 ML, R2:1 ML) Reagent I: Every laboratory can mix according to double or triple of write ratio. For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. 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 in case of closed vials and avoiding contamination after preparation.

REAGENT STABILITY AND STORAGE

Once opened vials are stable minimum 30 days at 2-8 C at optimum conditions. On board stability is strongly related to auto analysers cooling specification and carry-over values.

SAMPLES

Serum collected by standard procedures.
Serum is stable for 7 days at room temparature. Serum is stable for 3 weeks 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 taken morning. Otherwise results may be decreased %30 within daytime.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATIONS

$$\frac{\text{AbsorbanceSample}}{\text{AbsorbanceStandard}} \times \text{Conc. of Standard(500)} =$$

µg/dl UIBC in sample.

UIBC (µg/dL) = TIBC – Fe

REFERANCE INTERVALS (NORMAL VALUES)

(Based on rules CLSI C28-P Document)*

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

*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: 30 µg/dL

High Linearity: 600 µg/dL

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 times.

	Mean (µg/dL) / (µmol/L)	Std. Dev.	CV%
L1	72/12.9	1.98/0.35	2.75
L2	195/34.9	0.95/0.17	0.49
L3	665/119.0	3.71/0.66	0.56

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

	Mean (µg/dL) / (µmol/L)	Std.Dev.	CV%
L1	68/12.2	3.75 / 0.67	5.51
L2	191/34.2	4.38 / 0.78	2.29
L3	662/118.5	6.84 / 1.22	1.03

Sensitivity (LOD) (Based on CLSI EP17 document): 20µg/dL

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

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 "Good Laboratory Practice" (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 Capasity

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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