UIBC (UNSATURATED IRON BINDING CAPACITY)

En

REF 08V5725

REF 08V5720

Alinity c

Diagnostic reagent for the determination of UIBC (Unsaturated Iron Binding Capacity) concentration.
Liquid. Dual reagent (Ratio: 4/1). Store at +2/+8°C. For In Vitro Diagnostic use. **Do not freeze.**
The products with 08V5725/08V5720 reference numbers provided are compatible for use with Abbott Alinity biochemistry autoanalyzer series.

Changes made in the instructions for use are marked as gray.

The instructions must be followed carefully. The reliability of the test results cannot be guaranteed unless these instructions are followed.

NAME

UIBC

INTENDED USE

UIBC assay is used for the quantitative determination of UIBC concentration in human serum and plasma on Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST

Iron (Fe) is an essential element for almost all organisms, including humans, and its level is tightly controlled in nearly all biological processes.[1] Most of the iron (Fe) in the body (3-5 g) including also hemoglobin (2.5 g) and myoglobin (130 mg) is found in oxygen transport and storage proteins containing a heme molecule, Only small amounts of Fe, as little as 150 mg, are found in enzymes such as peroxidase, catalase, ribonucleotide reductase, crebs cycle and electron transport chain enzymes that contain heme or Fe-sulfur clusters in the active site. Most of the Fe (1 g in adult males) not included in the heme molecule is stored in macrophages and hepatocytes as ferritin or hemosiderin. Only a very small amount (3 mg) of Fe binds to the circulating serum protein transferrin (TF).[2]

Circulating Fe binds to free sites on TF, an iron transport protein in plasma. TF keeps Fe unreactive in the circulation and extravascular fluid, and transmits it to the cells via TF receptors. Iron binding capacity means TF's binding capacity to Fe. Iron binding capacity is of two types: total iron binding capacity (TIBC) and unsaturated iron binding capacity (UIBC).[2]

Iron status can be assessed by several natural serum-based indicators, including serum ferritin, TF and TF receptor.[3] Abnormal serum ferritin level indicates iron storage disorder, while both TF and soluble Transferrin Receptor (sTfR) tests are used to diagnose iron deficiency anemia or iron overload.[4,5]

TF can be measured directly using immunologic techniques,[6] but some laboratory tests are also used to determine serum TF status, including serum iron, TIBC, transferrin saturation (TS) and UIBC.[7] While TIBC measures the iron binding capacity of TF in blood, TS measures the calculated iron-filled TF percentage using "serum iron / TIBC x 100" ratio. UIBC is a rapid, reliable multistep alternative to TS that measures the empty iron binding capacity of TF.[8] Ferrozine used in UIBC measurements is a compound that can form a red colored complex by forming chelates with $Fe2^{+}$,[9] and therefore can be measured colorimetrically.[10]

When Fe stores are depleted, TF levels in the blood rise. Since only one third of TF is saturated with Fe, TF in serum has an extra binding capacity (67%). This refers to UIBC.[11] TIBC is the sum of serum Fe and UIBC.[11,12]

A practical and chemical method for the determination of TIBC from serum or plasma samples was first developed in 1957.[13] In 1978, this method of measurement was further developed by the International Committee for Standardization in Haematology[14] and subsequently revised and defined as a recommended procedure in 1990.[15] Instead of this three-step colorimetric method, more direct measurement methods were developed in the 1990s.[16,17]

Most biochemistry analyzers nowadays detect TIBC computationally via UIBC measurement, which is more easily adapted to the automated systems.[12,18] TIBC value can then be obtained from the sum of the UIBC and Fe measured values.[19] In one study, it was reported that the UIBC test generally produced more accurate results than TF, TS and Fe measurements in the diagnosis of empty iron stores.[20]

However, conditions such as hemolysis, which alters serum content, and liver diseases such as cirrhosis and hepatitis, in which TF production is altered, can have adverse effects on UIBC results.[21,22]

Iron binding studies are important in the diagnosis of iron deficiency and iron overload. In iron-deficient states, the TS value declines below 15% and the UIBC and TIBC values are high due to the relative increase in transferrin content compared to iron content.[23] When Fe overload occurs in the body, as in hemochromatosis, the amount of free transferrin in the blood decreases and UIBC and TIBC values decline accordingly.[23] Low serum iron and TIBC values (ferrozine measurement method) occur in anemia due to chronic diseases, malignant tumors and infections. In liver diseases such as cirrhosis, iron binding capacity is reduced as transferrin is synthesized by the liver. TIBC levels may be low in multifactorial anemias or anemias of chronic inflammation. In iron overload states, including conditions associated with transfusion dependence seen in myeloid disorders or thalassemias (which can occur in later years with increased ability to absorb and store iron), TIBC levels are low, with proportional increases in iron saturation levels (UIBC).[11] It has been reported that UIBC and TIBC levels decreased significantly in patients with preeclampsia compared to the control group.[24]

PRINCIPLES OF THE PROCEDURE

The test has Endpoint measurement method. To saturate existing binding sites on the transferrin molecule in the sample, an alkaline pH reagent containing a known concentration of ferrous (Fe^{+2}) iron is added to the sample. In an alkaline environment, ferrous (Fe^{+2}) iron binds to transferrin and converts to ferric (Fe^{+3}) form. After transferrin is completely saturated with iron, the unbound Fe^{2+} in the reagent reacts with ferrozine reagent to form a colored compound. The result is obtained by photometrically measuring the absorbance increase due to the color intensity formed as a result of the reaction. There is an inverse relationship between the color intensity and the corresponding absorbance increase and UIBC: More color intensity indicates more occupation of transferrin by iron (lower UIBC). Less color intensity indicates that transferrin has more binding capacity (high UIBC). As a result, the increase in absorbance due to color intensity is measured in two points, at wavelengths of 570 nm and 600 nm, and the amount of this increase is inversely proportional to UIBC.

$$Fe(II) + Transferrin \xrightarrow{Alkaline\ Buffer} Transferrin - Fe(III) + Fe(II)(excess)$$

$$Fe(II)(excess) + 3\ FerroZine\ Fe(II) \rightarrow Fe(II) - (FerroZine)_3\ (colored\ complex)$$

REAGENTS

Kit Contents

R1 Tris Buffer (≥ 0,2 mol/L). pH : 8,45. Ferrous ammonium sulphate : (≥ 8,4 µmol/L). Hydroxylamine hydrochloride (≥ 0,1 mol/L). Nonionic surfactant

R2 Ferrozine (≤ 24,3 mmol/L). Preservative (< 0,1%)

Warnings and Precautions

IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger
EUH032 : Releases a very toxic gas if contacts with acid.
H317 : May cause allergic skin reaction.

Precaution
P280 :Use protective gloves / clothes / glasses / mask.
P264 :Wash your hands properly after using.
P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention
P302+P352 :Wash with plenty of water and soap if it contacts with skin.
P333+P313 :Seek medical help if it irritates your skin or develops rash.
P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal
P501 :Dispose the vials and contents according to the local regulations.

Reagent Handling
- Reagent cartridges should be kept in an upright position for at least 8 hours after receipt and before use to eliminate any air bubbles that may have formed inside.
- If the cartridge is dropped, it should be kept upright for 1 hours before use to allow the air bubbles to dissipate.
- Foam and air bubbles may form in the reagents; this may prevent accurate detection of the reagent level inside the cartridge, leading to insufficient reagent aspiration and potentially affecting the analysis results.

Reagent Storage [25]

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	+2/+8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	

Indications of Reagent Deterioration
When a calibration error occurs or the control value falls outside the accepted range, the reagents may be considered to have deteriorated. In this case, the test results are not valid and the samples should be reanalyzed. Recalibration may be required.

Alternative Result Units
Use the unit conversion table provided below for alternative result units.

Default Unit	Conversion Factor	Result Unit
µmol/L	5.59	µg/dL
µmol/L	0.0559	mg/L
µg/dL	0,179 [36]	µmol/L

SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

Sample Types
The recommended sample types for this test are listed below.

Sample Type	Collection Tube
Serum	Serum tubes
Plasma	Li-heparin plasma sample collection tubes

Follow the instructions provided with your sample collection tubes for use and handling.

Sample Conditions
- To obtain reliable results, serum should be free of fibrin, blood cells, or foreign particles. In samples obtained from individuals receiving anticoagulant or thrombolytic therapy, fibrin residues may be observed due to incomplete clotting.
- To reduce the risk of contamination between samples, a new pipette or pipette tip should be used for each procedure.
- Samples containing EDTA, oxalate, or citrate, or samples with hemolysis should not be used. Hemolyzed samples may cause interference. In addition, sodium fluoride/oxalate is not among the anticoagulants suitable for this test.[37]
- Liquid anticoagulants may cause dilution of the sample, leading to lower test results in some patient samples.
- To avoid low results that may be caused by variations throughout the day, samples should be collected in the morning. [35]

Preparation for Analysis
- When preparing sample tubes, the manufacturer's instructions should be followed; separation by standing alone is not sufficient.
- Samples should be free of air bubbles. Before analysis, bubbles should be removed using a stick, and a separate stick should be used for each sample.
- If the samples contain fibrin, red blood cells, or other particulate matter, centrifuge them again before testing to ensure reliable results. Clot formation must be complete before centrifugation.
- If samples do not appear homogeneous, they should be mixed by low-speed vortexing or by inverting the tube 10 times.
- Frozen samples must be completely thawed before the mixing process.
- After dissolution is complete, the samples must be thoroughly mixed until they are homogeneous.
- Samples should be visually inspected; if stratification or layering is observed, mixing should continue until a homogeneous appearance is achieved.
- Insufficient mixing can lead to inconsistent and unreliable results.

Sample Storage

Temperature	Maximum Storage Time
+2/+8°C	21 days [38.39]
+20/+25°C	7 days [38]
-20°C	1 year [38]

The information provided applies to serum and plasma samples. Repeated freeze–thaw cycles of samples should be avoided.

PROCEDURE

Materials Provided
UIBC Reagent Kit
UIBC Calibrator

Materials Required but Not Provided
Commercially available controls
Saline solution (0.85%–0.90% NaCl) for sample dilution

Assay Procedure
- If primary or aliquot tubes are used, ensure that a sufficient amount of sample is available.
- To prevent evaporation of the specimen, make sure that the tube volume is adequate before each test.
- Minimum Sample Volume Requirements:
  - Sample volume for a single test: 11 µL
  - This volume does not include dead space or the additional aspiration volume.

Sample Dilution Procedures
This method demonstrates measurement linearity up to 500 µg/dL. For concentrations with results above this value, dilution procedure should be applied.

Automatic Dilution Protocol
The system dilutes the sample at a 1:10 ratio and automatically calculates the concentration by multiplying the result by the dilution factor.

Manual Dilution Procedures
Dilute the sample with a 0.85%–0.90% NaCl solution. Enter the dilution factor on the relevant screen of the device. If the user does not enter the dilution factor, the result must be manually multiplied by the correct factor before it is reported. If the result of the diluted sample is below 25 µg/dL, which is the lower limit of the measurement range, the result is not reported, and the procedure is repeated with an appropriate dilution.

Calibration
The use of an UIBC Calibrator Liquid is required for this test.

UIBC Calibrator
Ref.No: A301S

Calibration *stability is 3 days*. Changes in the reagent lot number require

recalibration. Calibration is necessary if quality control results are not within acceptable limits. **For the UIBC Calibrator, the calibrator value must be entered as a *negative* number.**

Quality Control Procedures
Commercially available control materials with values assigned by this method may be used.

At least two levels of control should be run every 24 hours. Each laboratory should establish its own quality control procedures. If more stringent control monitoring is required, refer to the quality control procedures established for your laboratory.

LIMITATIONS OF THE PROCEDURE
Single-use plastic pipettes or glassware that will come into contact with the sample must be soaked in 1 N hydrochloric acid before use and then rinsed twice with distilled water.

EXPECTED VALUES

Each laboratory should investigate the transferability of expected values for its own patient population and, if necessary, establish its own reference range.

Reference Range [26]
Women: 135 - 392 µg/dL
Men: 125 - 345 µg/dL

SPECIFIC PERFORMANC CHARACTERISTICS

Precision

			Within-Run (Repeatability) [30.31]		Within-Laboratory (Total)* [30.31]	
Sample	n	Mean (µg/dL)	SD	%CV	SD	%CV
Level 1	80	132	4.21	3.18	5.62	4.25
Level 2	80	256	4.91	1.91	4.99	1.94

*: Includes within-run, between-run, and between-day variability.

Lower Measurement Limits
The lower measurement limits refer to the range between the lower limit of quantitation (LLoQ) and the upper limit of quantitation (ULoQ), within which the analyte concentration can be measured with the required medical and laboratory accuracy without dilution, concentration, or any pre-treatment.[27] The LoD and LoQ values have been verified using the CLSI EP17-A2:2012 protocol.[28]

	µg/dL
LoD**	12
LoQ***	25

**** :** The LoD represents the lowest concentration at which the analyte can be detected with 95% probability, based on ≥ 60 replicates of samples with low analyte levels.
*****:** When determining the LoQ value, a coefficient of variation (%CV) of ≤20% is used as the basis.

Measuring Interval
This method shows measurement linearity in the activities between 25-500 µg/dL. For samples with results above this value, the automatic dilution procedure should be applied. For additional information, please refer to the instrument's user manual. Linearity studies data have been verified by using CLSI EP06-A:2003 protocol.[28]

Interference
Endogenous interferant and analyte concentrations that have been used in the UIBC scanning tests has been determined according to "CLSI EP37-ED1:2018" and "CLSI EP07-ED3:2018" manuals.[32,33]

The total acceptable error rate, which is going to be used to detect whether the observed differential value obtained from UIBC interference scanning test is appropriate, is determined as ±10%.[34]

In UIBC test results, no significant interaction has been observed in the determined endogenous interferant and analyte concentrations or between interferants and analyte.

Interferant-Concentration	UIBC Target (µg/dL)	n	Observed Recovery %
Hemoglobin 270 mg/dL	230	3	108%
Hemoglobin 990 mg/dL	421	3	102%
Bilirubin 30 mg/dL	117	3	94%
	275	3	98%
Lipemia 1000 mg/dL	117	3	95%
	275	3	99%

*In calculating how many times the control and test samples (containing interferent), prepared as a serum pool, would be run repetitively, the within-run SD values previously determined for the relevant method and the total allowable error rate defined as the interference limit were used. In the calculations, a type 1 error (α error) rate of 5% and a type 2 error (β error) rate of 10% (90% power) were accepted.[33]

Gadolinium-based MRI contrast agents[40],[41] and deferasirox[42] may affect UIBC test results.

It should be noted that, in addition to endogenous interferents, various drugs and metabolites; anticoagulants (e.g., heparin, EDTA, citrate, oxalate) and preservatives (e.g., sodium fluoride, iodoacetate, hydrochloric acid); substances that may come into contact with samples during collection and handling (such as serum separation devices, sample collection containers and their contents, catheters, catheter flushing solutions, skin disinfectants, hand sanitizers and lotions, glassware detergents, powdered gloves, etc.); dietary substances known to affect certain tests (e.g., caffeine, beta-carotene, poppy seeds); or certain substances present in a sample that may cause interference due to foreign proteins (e.g., heterophilic antibodies), autoimmune responses (e.g., autoantibodies), or malignancy (e.g., paraproteins causing interference in phosphate tests and indirect ion-selective electrode methods) may lead to various interferences and erroneous evaluations for many different reasons.[29]

These performance characteristics were obtained using an autoanalyzer. Results may vary when different equipment or manual procedures are used.

Method Comparison [43]
As a result of the statistical evaluation of method comparison data, the table was constructed according to the Passing–Bablok regression method as follows:

Archem UIBC – Roche Cobas Integra 400 Plus

	Units	n	Correlation Coefficient	Intercept	Slpoe	Concentration Range
Serum	µg/dL	100	0.9921	13.3	0.90	55-493

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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 Limits
	Consult Instructions for Use
	Caution
	Number of Tests

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