DIAGNOSTICA PRODUCTS

Liquid Reagents – ready to use

UIBC

(Unsaturated Iron Binding Capacity)

Ferene, with ATCS*

2 Reagents

Diagnostic reagent for quantitative in vitro determination of unsaturated iron binding capacity (UIBC) in human serum or plasma on photometric systems.

Ref.No.	Kit Size	Content
DIA010351	50 ml	2x20 ml R1 + 1x10 ml R2
DIA010352	5 x 20 ml	4x20 ml R1 + 1x20 ml R2
DIA010353	5 x 25 ml	4x25 ml R1 + 1x25 ml R2

Additionally offered:

DIA040012	1 x 3 mL	**Diacal Auto** (Calibrator)
DIA030012	1 x 5 mL	**Diacon N** (Control Normal)
DIA030022	1 x 5 mL	**Diacon P**(Control Abnormal)

TEST PARAMETERS

Method: Colorimetric, endpoint, Decreasing reaction, Ferene
Wavelength: 600-620 nm, Hg 578 nm, 623 nm
Temperature: 37°C
Sample: Serum, heparin plasma
Linearity: up to 750 µg/dL(135 µmol/L)
Sensitivity: The lower limit of detection is 6 µg/dL (1µmol/L)

SUMMARY [1,2]

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 sum of UIBC and serum iron gives a value for the total iron binding capacity (TIBC). TIBC represents the maximum concentration of iron that serum proteins can bind. Serum UIBC levels vary in disorders of iron metabolism where iron capacities are often increased in iron deficiency and decreased in chronic inflammatory disorders or malignancies.

TEST PRINCIPLE

A known ferrous ion concentration incubated with serum binds specifically with transferrin at unsaturated iron binding sites.
Remaining unbound ferrous ions are measured with the ferene reaction. The difference between the amount of excess iron and the total amount added to the serum is equivalent to the quantity bound to transferring. This is the UIBC of the sample.

Fe^{2+} (known) + Transferrin → Transferrin(Fe^{2+}) + Fe^{2} (excess)

Fe^{2+} (excess) + 3 Ferene → Ferrous Ferene (blue complex)

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION	
Reagent 1:		
Buffer, pH 8.7	100	mmol/L
Ammonium iron (II) sulfate	13	µmol/L
Thiourea	120	mmol/L
Reagent 2:		
Ascorbic Acid	240	mmol/L
Ferene	6	mmol/L
Thiourea	125	mmol/L

REAGENT PREPARATION

Reagents are ready to use.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light!
Close immediately after use
Do not freeze the reagents!
Avoid contamination.
Storage: at 2 – 8 °C
Stability: up to the expiration date

SAMPLE STABILITY AND STORAGE

Separate serum/plasma at the latest 2 h after blood collection to minimize haemolysis.

Stability [3]:

at 20 - 25 °C	5 days
at 2 - 8 °C	1 month
at -20 °C	1 month

Discard contaminated specimens. Freeze only once!

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./ Cal.	Sample
Sample	-	-	75 µL
StdandardCalibrator	-	75 µL	-
Distilled Water	75 µL	-	-
Reagent 1	1000 µL	1000 µL	1000 µL
Mix, read absorbance A1 after 5 min. Then add:			
Reagent 2	250 µL	250 µL	250 µL
Mix, read absorbance A2 after exactly 5 min. ΔA = [(A2 – 0.81 A1) Sample or Cal.] -[(A2 – 0.81 A1) blank]			

The Factor 0.81 compensates the decrease of the absorbance by addition of reagent 2. The factor is calculated as follows: (sample + R1) / total volume.

CALCULATION

$$\text{UIBC [µg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Calib}} \times \text{Conc. Cal. [µg/dL]}$$

TIBC [µg/dL] = UIBC [µg/dL] + Iron [µg/dL]

Transferrin [µg/dL] = 0.7 x TIBC [µg/dL]

UNIT CONVERSION

µg/dL x 0.1791 = µmol/L

REFERENCE RANGE [4]*

Taking into account reference values for iron and transferrin the following reference range results for UIBC:
120 – 470 µg/dl (21 – 84 µmol/L).

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

The test has been developed to determine UIBC within a measuring range of 6 - 750 µg/dL (1 – 135 µmol/L).
A sample with a UIBC level exceeding the upper limit should be diluted 1+ 2 with 0.9% NaCl solution (9 g/L) and the result multiplied by 3.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 6 mg/dL(1 µmol/L).

PRECISION

Intra-assay n = 20	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	65.8	1.27	1.93
Sample 2	264	3.62	1.37
Sample 3	531	8.73	0.64
Inter-assay n = 20	**Mean [µg/dL]**	**SD [µg/dL]**	**CV [%]**
Sample 1	170	4.43	2.61
Sample 2	263	3.61	1.37
Sample 3	475	6.31	1.33

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SPECIFICITY/INTERFERENCES

No interference up to:

Ascorbate	30 mg/dL
Bilirubin	60 mg/dL
Hemoglobin	200 mg/dL
Triglyceride	2000 mg/dL
RF	350 IU/ml
Copper	15 mg/dL
Zinc	15 mg/dL

Strong hemolysis interferes as destroyed erythrocytes release iron.
For further information on interfering substances refer to Young DS [7].

METHOD COMPARISON

A comparison between Diagnostica UIBC Ferene (y) with values calculated from transferrin and iron measurement (x) using 98 samples gave following results:
y = 0.985 x – 6.558 µg/dL; r = 0.993.

CALIBRATION

The assay requires the use of an UIBC calibrator.
We recommend the the Diagnostica multi calibration serum **Diacal Auto**.
The assigned values of the calibrator have been made traceable to a measurement of transferrin and iron. Thereby, the transferrin value is traceable to ERM®-DA470k/IFCC and the iron value is traceable to NIST SRM 682.

QUALITY CONTROL

All control sera with Iron values determined by this method can be used.
We recommend the Diagnostica serum control **Diacon N**.
Each laboratory should establish corrective action in case of deviations in control recovery.

AUTOMATION

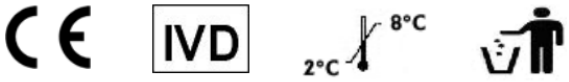
Special applications for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. Reagent 1: Danger.
   H318: Causes serious eye damage.
   P280: Wear protective gloves/protective clothing/eye protection/face protection.
   P314: Get medical advice/attention if you feel unwell.
   P305+ P351+ P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
2. Use only disposable material to avoid iron contamination. Rinse glass material with diluted HCl and copious dist. water.
3. Reagent 1 contains sodium azide (0.95 g/l) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
4. In very rare cases, samples of patients with gammopathy might give falsified results [8].
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
6. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.



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