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UIBC
Ferene

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

Reagents with ATCS*

REF	Kit Size	Configuration
D07320	5 x 100 mL	4 x 100 mL R1 + 1 x 100 mL R2
D07330	5 x 50 mL	4 x 50 mL R1 + 1 x 50 mL R2
D07340	5 x 25 mL	4 x 25 mL R1 + 1 x 25 mL R2
D07350	5 x 10 mL	4 x 10 mL R1 + 1 x 10 mL R2
D86911	5 x 50 mL	4 x 50 mL R1 + 2 x 25 mL R2
D0444917	5 x 62.5 mL	4 x 62.5 mL R1 + 1 x 62.5 mL R2
DA0844	5 x 50 mL	5 x 40 mL R1 + 4 x 10 mL R2
DT1044	4 x 62.5 mL	4 x 50 mL R1 + 4 x 12.5 mL R2
DK0741	5 x 50 mL	4 x 50 mL R1 + 1 x 50 mL R2
DE1844	2 x 62.5 mL	2 x 50 mL R1+ 2 x 12.5 mL R2

* Advanced Turbidity Clearing System; minimizes turbidity caused by lipemia.

Additionally available:

D98485	5 x 3 mL	Calibrator	Diacal Auto
D98485SV	1 x 3 mL	Calibrator	Diacal Auto
D98481	12 x 5 mL	Control normal	Diacon N
D14481	5 x 5 mL	Control normal	Diacon N
D98481SV	1 x 5 mL	Control normal	Diacon N

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method	Colorimetric, endpoint, increasing (without blank) / decreasing (blank reaction subtracted), Ferene.
Shelf life	18 months from production date
Storage	2 – 8 °C
Wavelength	600 - 620 nm, Hg 578 nm, 623 nm
Temperature	37°C
Sample	Serum, heparin plasma

INTENDED USE

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

DIAGNOSTIC SIGNIFICANCE [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 sample 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 transferrin. 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

MATERIAL REQUIRED BUT NOT PROVIDED

- NaCl solution (9 g/L).
- Clinical chemistry analyser.

REAGENT PREPARATION

Reagents are ready to use.

STORAGE AND STABILITY

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

WARNINGS AND PRECAUTIONS

1. Reagent 1: Danger

H318: Causes serious eye damage.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a poison center or doctor/physician.
Special labelling: Contains Dodecan-1-ol, ethoxylated and Alcohols, C9-11-iso, C10-rich, ethoxylated.

2. Reagent 2: --
   Special labelling: EUH210.
3. Use only disposable material to avoid iron contamination. Rinse glass material with diluted HCl and copious dist. water.
4. Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
5. In very rare cases, samples of patients with gammopathy might give falsified results [7].
6. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
7. For diagnostic purposes, the results should always be assessed with the patients' medical history, clinical examinations and other findings.
8. For professional use only!

SPECIMEN COLLECTION AND STORAGE

Serum, heparin plasma
Separate serum/plasma at the latest 2 h after blood collection to avoid hemolysis.

Stability [3]:

In serum	at 20 – 25 °C	5 days
	at 2 – 8 °C	1 month
	at - 20 °C	1 month
In plasma	at 2 – 8 °C	1 month
	at - 20 °C	1 month

Freeze only once! Discard contaminated specimens!

TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Calibrator	Sample
Sample	-	-	75 µL
Calibrator	-	75 µL	-
Dist. 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. This compensation is necessary as a high sample volume is used.

Automation

Special adaptations for automated analysers can be made on request.

INTERPRETATION OF RESULTS

Calculation

With calibrator:

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

TIBC [µg/dL] = UIBC [µg/dL] + Iron [µg/dL]
Transferrin [mg/dL] = 0.7 x TIBC [µg/dL]

Unit Conversion

UIBC [µg/dL] x 0.1791 = UIBC [µmol/L]

QUALITY CONTROL AND CALIBRATION

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

Calibration

The assay requires the use of an UIBC calibrator.
We recommend the the Dialab multi calibration serum **Diacal Auto**.

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 an UIBC level exceeding the upper limit should be diluted 1+ 2 with NaCl solution (9 g/L) and the result multiplied by 3.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 6 µg/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	1.64

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

SPECIFICITY/INTERFERENCES

no interference up to:

Ascorbate	30 mg/dL
Bilirubin	60 mg/dL
Hemoglobin	200 mg/dL
Triglycerides	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 [6].

METHOD COMPARISON

A comparison between Dialab 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.

TRACEABILITY

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.

EXPECTED VALUES [4, 5*]

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 define its own reference range for the relevant population to take into account all affecting factors.

LIMITATIONS

- Eventual UIBC, Ferene carry-over to reagents Carbon Dioxide (PEP-C), Protein Total in Urine/CSF (Pyrogallol red) and Triglycerides (GPO-PAP). The actual carry-over depends on the analyser.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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