Unsaturated Iron-Binding Capacity (UIBC) Assay Kit

METHOD: Ferene method

R1:1×60mL	R2:1×15mL
R1:2×60mL	R2:2×15mL
R1:1×40ML	R2:1×10mL
R1:1×20Ml	R2:1×5mL
R1:24×3.8mL	R2:6×3.8mL
R1:16×3.8mL	R2:4×3.8mL
R1：1×70mL	R2：1×21mL
R1:1×62mL	R2:1×20.5mL
R1:1×41mL	R2:1×12mL

INTENDED USE

This kit is used for *in vitro* quantitative determination of unsaturated iron-binding capacity in human serum or plasma.

ASSAY 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 blue complexs (600nm) was formed after the action of the chromogenic agent, and the unsaturated iron-binding force of the serum could be calculated by calculating the reduction iron ions in the buffer solution.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
Tris buffer	0.6 mol/L
Sulfocarbamide	0.12 mol/L
Ammonium ferrous sulfate	14 umol/L
Reagent 2 (R2)	
Ferene	6 mmol/L
Deoxidizer	30 mmol/L

Transferrin can be traced to the reference material ERM-DA470k/IFCC, iron to the standard material GBW09152.

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use and stable up to 12 months when stored at 2-8℃.
Calibrator, quality control is stable for 12 months when stored at 2~ 8 ℃.
The reagents should not be frozen and thawed.
Once opened please avoid contamination.

Do not mix reagents with different batch numbers.
Production and expiry date are stated on labels.

SAMPLE COLLECTION AND PREPARATION

Fresh serum or heparin lithium anticoagulant plasma.
The sample can be stable for 10 days at 2-8℃, and stable for 1 month at -20℃.
It is recommended that the samples should not be frozen and thawed more than 3 times.
If the concentration of UIBC is more than 140 μ mol/L, it is recommended to dilute it 2 times with normal saline and multiply the result by the corresponding dilution multiple.

ASSAY PROCEDURE

Test Conditions

Main Wavelength	600 nm	Sample (S)	15 μl
Sub Wavelength	700 nm	Reagent (R1)	200μl
Reaction Temp	37℃	Reagent (R2)	50μl
Colorimetric cup diameter	1cm	Assay mode	End-point

Test Procedure

Add the sample and reagents into colorimetric cup	
Sample（S）	15 μl
Reagent（R1）	200μl
Mix and then incubate for 180 seconds at 37℃	
Reagent（R2）	50μl
Mix and incubate for 300 seconds at37℃, Read rbsorbance A2, caculate∆A=A2-A1.	

Note: the above parameters are set on Hitachi 7180 analyzer as an example. The parameter settings are slightly different on diverse and analyzers, it's suggested to read and check the user manual of the analyzer first.

CALIBRATION

Gcell UIBC Calibrator (EGC-UIBC) is recommended.

QUALITY CONTROL

Using Gcell UIBC control (EGQ-UIBC) as daily quality control which can be purchased separately. Control values should fall within a specific target range. If these values fall outside the range, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

Normal human serum or plasma：21-84 μmol/L
It is recommended that each laboratory establishes its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

INTERFERENCE

The following analytes were tested up to the levels indicated and no interference found.

HB	up to 500mg/dl
Ascorbic acid	up to 50mg/dl
DB	up to 70mg/dl
Intralipid	up to 600mg/dl
Zn^{2+}	up to 3.0mmol/L
Cu^{2+}	up to 3.0mmol/L
Heparin Sodium	up to 120U/ml

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SENSITIVITY
The LOD of BSBE UIBC is 3.8 μmol/L.

LINEARITY
The BSBE UIBC linearity is up to 140 μmol/L.

PRECISION

Repeatability		
N=20	Level1	Level 2
Mean	33.28	61.90
SD	0.62	0.55
CV%	1.87	0.89
Total precision		
N=20	Level1	Level 2
S_T^2	0.78	1.04
S_T	0.88	1.02
$CV\%_T$	2.72	1.68

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
y = 1.0287x - 0.0737, R2 = 0.9946
120 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS
1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains preservatives. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Preservatives reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.
6. The HIV (HIV1, HIV2) antibody, hepatitis B surface antigen (HbsAg) and hepatitis C virus (HCV) antibody were detected by using human matrix serum. Both of them were negative, although the method was highly accurate. There is no guarantee that all infected donors will be found, so quality control should also be treated as infectious specimens.

REFERENCE
1.Dong Zhennan. Methodological Evaluation of unsaturated Iron Kit [J]. China Journal of Laboratory Medicine, 2005 28 (1): 102-104.
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3.Wick M, Pingerra W, Lehmann P. Clinical aspect and laboratory. Iorn metabolism, anemias. 5th ed. Wien, New York: Springer; 2003.

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