Iron Assay Kit (Fe)

Method: Ferrozine

Cat .No.	Size	Instrument
GB440E	R1: 4×40 ml R2: 2×20 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS441E	R1: 4×40 ml R2: 2×20 ml	For Hitachi917 & OlympusAU640/400/600
GX441E	R1: 1×80 ml R2: 1×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT441E	R1:4×40 ml R2:2×20 ml	For TOSHIBA

INTENDED USE

For the quantitative *in vitro* determination of Serum Iron in serum or plasma.

CLINICAL SIGNIFICANCE [1, 2]

Iron measurements are used in the diagnosis and treatment of diseases such as iron deficiency anaemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

ASSAY PRINCIPLE

Ferric iron is dissociated from its carrier protein, transferrin, in an acid medium and simultaneously reduced to the ferrous form. The ferrous iron is then complexed with the chromogen, a sensitive iron indicator, to produce a coloured chromophore which absorbs at 560 nm.

SAMPLE COLLECTION AND PREPARATION

Serum, heparinized plasma. Haemolysis and plasma treated with oxalate interfere with the test. Even minimal concentrations of EDTA in the sample lead to depressed results.

The samples stable for 7 days at 2-8℃, or for 4 days at 15-25℃.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Acetate Buffer	100 mmol/L, pH 4.2
Ferrozine	5 mmol/L
Deoxidizer and Surfactant	

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8°C.

ASSAY PROCEDURE

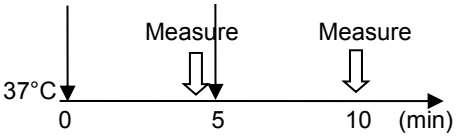
Test Procedure for Analyzers

Assay Mode: 2 Point End

Wave Length (main/sub): 570 nm/700 nm

Sample: 20 µl

R1: 200 µl R2: 50 µl



1. Mix 20 µl sample with 200 µl R1 and incubate at 37℃ for 5 minutes, then read initial absorbance A_1.
2. Add 50 µl R2 into cuvette, mix and incubate for 5 minutes at 37℃, Read final absorbance A_2.
3. Calculate the absorbance change $\Delta A=A_2-A_1$.

CALCULATION

$$\text{Concentration} = \frac{\Delta A_{sample}/\text{min}}{\Delta A_{calibrator}/\text{min}} \times \text{Calibrator value}$$

CALIBRATION

Recommend that this assay should be calibrated using Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, 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 VALUE	ug/dl	umol/L
Men	59-158	10.6-28.3
Women	37-145	6.6-26.0

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

UNIT CONVERSION

µg/dl × 0.179 = µmol/L

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 180 µmol/L. If the sample above this concentration should be diluted with 0.9% NaCl and repeat assay. Multiply the result by dilution factor.

PRECISION

The CV of the test should be less than 5%

Intra assay precision		
N=20	Level1	Level 2
Mean (µmol/L)	18.58	36.07
SD	0.12	0.34
CV	0.63%	0.95%
Inter assay precision		

Beijing Strong Biotechnologies, Inc.
Add:5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

Revised 01DEC11 version 1001

N=5	Level1	Level 2
Mean (μmol/L)	18.27	35.73
SD	0.25	0.39
CV	1.35%	1.09%

SENSITIVITY

The minimum detectable level that can be distinguished from zero has been determined as 1.11 μmol/L.

INTERFERENCE

The following analyze were tested up to the levels indicated and found not to interfere:

Hemoglobin: 250 mg/L
Intralipid: 500 mg/L
Bilirubin: 600 mg/L
Ascorbic Acid: 500 mg/L
Cu^{2+}: 50 μmol/L
Zn^{2+}: 80 μmol/L

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. The reagents contains Sodium Azide. 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. Sodium Azide 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 build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Ceriotti, F., and Ceriotti, G., Improved Direct Specific. Determination of Serum Iron. Clin. Chem. 26/2, 327-331 (1980).
2. Henry, R.J.: Clinical Chemistry Principles and Techniques, New York, Harper and Row (1968) pg.386.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use

EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
Address： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China
Tel：+86 10 61667168

EC REP :Lotus NL B.V.
Address： Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail：peter@lotusnl.com
Tel：+31645171879(English), +31626669008（Dutch）

Beijing Strong Biotechnologies, Inc.
Add:5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

Revised 01DEC11 version 1001