CE IVD

Fe Reagent Kit (Ferrozine Chromogenic Method)

Instructions for Use REF CC1034

PRODUCT NAME

Fe Reagent Kit (Ferrozine Chromogenic Method)

PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×10 mL	R1: 1×40 mL	R2: 1×20 mL
R1: 1×60 mL	R2: 1×30 mL	R1: 2×20 mL	R2: 2×10 mL
R1: 2×30 mL	R2: 2×15 mL	R1: 2×40 mL	R2: 2×20 mL
R1: 2×50 mL	R2: 1×50 mL	R1: 2×60 mL	R2: 1×60 mL
R1: 2×60 mL	R2: 2×30 mL	R1: 2×60 mL	R2: 3×20 mL
R1: 2×65 mL	R2: 1×65 mL	R1: 2×80 mL	R2: 1×80 mL
R1: 2×120 mL	R2: 2×60 mL	R1: 3×20 mL	R2: 3×10 mL
R1: 3×40 mL	R2: 3×20 mL	R1: 3×60 mL	R2: 3×30 mL
R1: 4×40 mL	R2: 4×20 mL	R1: 4×50 mL	R2: 2×50 mL
R1: 4×55 mL	R2: 2×55 mL	R1: 4×60 mL	R2: 2×60 mL
R1: 4×60 mL	R2: 4×30 mL	R1: 4×60 mL	R2: 6×20 mL
R1: 6×63 mL	R2: 6×31 mL	R1: 4×65 mL	R2: 2×65 mL
R1: 4×65 mL	R2: 2×65 mL	R1: 4×100 mL	R2: 2×100 mL
R1: 4×639 mL	R2: 4×294 mL	R1: 4×641 mL	R2: 4×278 mL
R1: 4×653 mL	R2: 4×283 mL	R1: 24×4.2 mL	R2: 24×2.1 mL
1×2000 mL（R1: 1×1800 mL R2: 1×200 mL）			
2×2000 mL（R1: 2×1800 mL R2: 2×200 mL）			
12×72 T（R1: 12×17.2 mL R2: 12×8.6 mL）			
Calibrator (optional): 1×1 mL			

INTENDED USE

This reagent kit is intended for the *in vitro* quantitative determination of ferrum concentration in human serum and plasma. Clinically, it is mainly used to aid in the diagnosis of anemia.
For professional and laboratory use only.

TEST PRINCIPLE

$$\text{Transferrin} + (Fe^{3+})_2 \xrightarrow{\text{Acetic acid}} \text{Transferrin} + 2Fe^{3+}$$

$$Fe^{3+} \xrightarrow{\text{Hydroxylamine}} Fe^{2+}$$

$$Fe^{2+} + \text{Ferrozine} \longrightarrow Fe_2 + \text{Ferrozine (purple)}$$

Within a certain range, the absorbance (A) is directly proportional to the concentration.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Hydroxylamine hydrochloride	2.0 g/L
	Thiourea	5.0 g/L
	Sodium acetate	18.0 g/L
Reagent 2	Ferrozine	2.0 g/L
Calibrator (optional)	Ferrous sulfate, aqueous matrix	25-40 μmol/L

The components in different batches of a multi-component kit are not interchangeable.
Calibrator traceability: Traceable to international Standard Reference Material (SRM) 909c.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Fasting is required prior to sample collection. Serum and heparin anticoagulated plasma should be separated as soon as possible after sample collection to avoid hemolysis. Once separated, the sample is stable for 7 days at 15-25°C and for 3 weeks at 2-8°C.

TEST PROCEDURE

1. Reagent preparation: The reagent is ready for use directly
2. Test conditions:

Wavelength	570 nm/700 nm	**Calibration Type**	Linearity
Sample/R1/R2	30/200/100 μL	**Time of Mixture of Serum and R1**	1-5 min
Method	Two-point end assay	**Reaction time after addition of R2**	5 min
Calibration Method	Two-point calibration	**Direction**	Upward

(Absorbance (A) read by the instrument=$A_{\text{Primary Wavelength}}$-$A_{\text{Secondary Wavelength}}$)
Operating procedures

Sample (calibrator)	30 μL
R1	200 μL
Mix well, incubate at 37°C for 1-5 min, and read the absorbance A_0	
R2	100 μL
Mix well, incubate at 37°C for 5 min, and read the absorbance A_1, $\Delta A=A_1-A_0$	

3. Calibration procedure: A calibrator from Getein is recommended, and a Randox calibration serum can also be used.
4. Quality control procedure: Use the quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sample probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth can lead to incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation

$$\text{Fe concentration (μmol/L)} = \text{Fe standard concentration} \times \frac{\triangle A_{\text{tested}}}{\triangle A_{\text{calibrated}}}$$

REFERENCE RANGE

Male: 11-30 μmol/L. Female: 9-27 μmol/L.

The reference range is established based on "National Standard Operating Procedure for Clinical Testing (2nd Edition) (1997)" and is for reference purpose only. It is recommended that each laboratory establish its own reference range.

RESULT INTERPRETATION

The concentration of ferrum in serum is extremely low; therefore, use cuvettes and reagents that are free from ferrum contamination.

LIMITATIONS

There is no interference with the measurement when hemoglobin ≤ 150 mg/dL, ascorbic acid ≤ 500 mg/dL, bilirubin ≤ 200 mg/dL and triglycerides ≤ 300 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reagent blank absorbance
   Reagent blank absorbance A_{570nm} ≤ 0.200.
3. Accuracy
   The relative deviation of test reference materials should not exceed ±20%.
4. Linear range
   4.1 Linear correlation coefficient
   Linear correlation coefficient (r) should be ≥ 0.990 in the range of [2, 179] μmol/L.
   4.1 Linear deviation
   Within the range of [2, 15] μmol/L, the linear absolute deviation should not exceed ±3 μmol/L; within the range of (15, 179] μmol/L, the linear relative deviation should not exceed ±10%.
5. Analytical sensitivity
   When testing a 35.8 μmol/L sample, the absorbance difference should be ≤ 0.140.
6. Precision
   6.1 Repeatability
   The coefficient of variation (CV) should not be greater than 6.0%.
   6.2 Between-run precision
   Between-run precision should not be greater than 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnostic use only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
2. Precautions for operation
   2.1 Treat the specimens as dangerous materials that may cause infection with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or touch the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Do not use frozen reagents whose quality may change.
   3.2 Do not use expired reagents whose test results may be inaccurate.
   3.3 Avoid adding reagents halfway during a test.
   3.4 Avoid direct sunlight during operation.
   3.5 Do not use the reagent if it displays any signs of turbidity.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically hazardous. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the calibration result.
   5.5 Do not mix reagents in different batches.

REFERENCE

Hong Shang, et al. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 265-269.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Fe Reagent Kit (Ferrozine Chromogenic Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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