



Fer Reagent Kit (Immunoturbidimetric Method)

Instructions for Use

REF CC1096

PRODUCT NAME

Fer Reagent Kit (Immunoturbidimetric Method)

PACKAGE SPECIFICATION

| | | | |
|--|-------------|--------------|--------------|
| R1: 1×20 mL | R2: 1×10 mL | R1: 3×40 mL | R2: 3×20 mL |
| R1: 1×40 mL | R2: 1×20 mL | R1: 4×40 mL | R2: 4×20 mL |
| R1: 2×30 mL | R2: 2×15 mL | R1: 4×50 mL | R2: 2×50 mL |
| R1: 2×40 mL | R2: 2×20 mL | R1: 4×55 mL | R2: 2×55 mL |
| R1: 2×50 mL | R2: 1×50 mL | R1: 4×60 mL | R2: 2×60 mL |
| R1: 2×60 mL | R2: 1×60 mL | R1: 4×60 mL | R2: 4×30 mL |
| R1: 2×60 mL | R2: 3×20 mL | R1: 4×60 mL | R2: 6×20 mL |
| R1: 2×65 mL | R2: 1×65 mL | R1: 4×65 mL | R2: 2×65 mL |
| R1: 2×80 mL | R2: 1×80 mL | R1: 4×65 mL | R2: 2×65 mL |
| R1: 2×120 mL | R2: 2×60 mL | R1: 4×100 mL | R2: 2×100 mL |
| R1: 3×20 mL | R2: 3×10 mL | R1: 4×64 mL | R2: 4×278 mL |
| 12×72 T (R1: 12×16.8 mL R2: 12×8.4 mL) | | | |
| Calibrator (optional): 4×1 mL | | | |
| Control (optional): 2×1 mL | | | |

INTENDED USE

This reagent kit is intended for the *in vitro* quantitative determination of ferritin concentration in human serum and plasma. Clinically, it is mainly used to aid in the diagnosis of conditions related to iron metabolism, such as hemochromatosis and iron deficiency anemia. For professional and laboratory use only.

TEST PRINCIPLE

Anti-human ferritin antibodies are added to the sample, where they specifically bind to the ferritin in the sample via an antigen-antibody reaction to form immune complex particles, resulting in increased turbidity. At a specific wavelength, the increase in turbidity correlates with the number of immune complex particles, enabling quantification of the ferritin concentration in the sample¹.

MAIN COMPONENTS

| Kit composition | Reagent components | Content |
|-----------------------|------------------------------|-------------------|
| Reagent 1 (R1) | Glycine buffer | 100 mmol/L |
| | Sodium chloride | 50 mmol/L |
| Reagent 2 (R2) | Glycine buffer | 100 mmol/L |
| | Sodium chloride | 50 mmol/L |
| | Anti-human ferritin antibody | 0.2 g/L |
| | Latex microspheres | 30 mL/L |
| Calibrator (optional) | Ferritin | 94.5-1089 ng/mL |
| Control (optional) | Ferritin | 101.7-434.5 ng/mL |

The components in different batches of a multi-component kit are not interchangeable. Calibrators and controls have batch-specific characteristics. Refer to the label for target values of each batch. The calibrator is traceable to a reference material.

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 30 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

- Fresh serum or sodium heparin anticoagulated plasma can be used.
- Transport and store samples at low temperatures. Refrigerate and centrifuge them immediately after collection. Sealed samples remain stable for 7 days at 15-25°C, for 7 days at 2-8°C and for 1 year at -20°C. Frozen samples should be thawed carefully and thoroughly mixed before analysis. Thawed samples can only be used once.
- Hemolysis or lipemia should be avoided.
- If the ferritin (Fer) concentration in the sample is greater than 500 ng/mL, dilute it 1:1 or 1:2 with purified water before measurement. Multiply the result by the dilution factor accordingly.

TEST PROCEDURE

- The dual reagent is ready for use directly.
- Test conditions:

| Primary/Secondary Wavelength | 570/800 nm | Sample (S) | 7 μ L |
|------------------------------|---------------------|-------------------------|-------------------------|
| Reagent 1 | 140 μ L | Reagent 2 | 70 μ L |
| Calibration Type | Nonlinearity | Calibration Method | Multi-point calibration |
| Method | Two-point end assay | Reaction Temperature | 37°C |
| Direction | Positive | Optical Path of Cuvette | 1 cm |

- Operating procedures:

| Sample | Blank tube (B) | Standard tube (S) | Test tube (T) |
|---|----------------|-------------------|---------------|
| Reagent 1 | 140 μ L | 140 μ L | 140 μ L |
| Purified water | 7 μ L | | |
| Calibrator | | 7 μ L | |
| Sample | | | 7 μ L |
| Mix well, incubate at 37°C for 300 s | | | |
| Reagent 2 | 70 μ L | 70 μ L | 70 μ L |
| Mix well, incubate at 37°C for 30 s, and read the absorbance A_1 . Incubate at 37°C for 270 s, read the absorbance A_2 , and calculate the change in absorbance ($\Delta A=A_2-A_1$). | | | |

- Calibration procedure: Calibrators for the kit are recommended. Carry out multi-point non-linear calibration using calibrators of varying concentrations and their corresponding absorbance changes. The automatic biochemistry analyzer then fits the values to a calibration curve. Under normal circumstances, calibration should be conducted at least once a week, or after maintenance, replacement of key components, or when quality control test results exceed the defined range.
- Quality control procedure: Use the control from Getein, and the 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:

- 5.1 Check whether the parameter settings and light source are correct.
 - 5.2 Check whether the cuvettes and sample probes are clean.
 - 5.3 Check whether water is contaminated, and bacterial growth can lead to incorrect results.
 - 5.4 Check reaction temperature.
 - 5.5 Check the expiration date of the kit.
6. Result calculation
- Construct a calibration curve using the absorbance changes (ΔA) corresponding to the concentration of the calibrator. Then, determine the Fer concentration in sample from this calibration curve using the sample's ΔA .

REFERENCE RANGE

Reference range can be determined by testing 200 samples: for men and women over 50 years old: 30-400 ng/mL; for women under the age of 50: 15-150 ng/mL.
It is recommended that each laboratory establish their own reference ranges, taking into account factors such as the patient's age, gender, diet and region.

RESULT INTERPRETATION

Test results will be reviewed by the professionals. These results may be affected by the age, gender, diet and region of the individual being tested. Under normal circumstances, if the result is within the reference range, it is considered normal; if it exceeds the reference range, a retest should be conducted. If the test results are inconsistent with, or even contradict, clinical symptoms, the cause should be analyzed and investigated.

LIMITATIONS

There is no interference with the measurement when bilirubin \leq 85 mg/dL, hemoglobin \leq 300 mg/dL, and triglyceride \leq 1000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
 - a) The reagent kit components should be complete. Both the inner and outer packaging should be intact, and labels should be visible and legible.
 - b) There should be no leakage in liquid reagents.
 - c) Reagent 1 in the kit is a colorless or slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a white emulsion, which may contain a small number of insoluble particles that do not affect determination.
2. Net Content
The volume of liquid reagents shall not be less than the labeled value.
3. Accuracy
When using national standard materials as the sample for testing, the relative deviation of the test results should not exceed $\pm 10\%$.
4. Limit of detection
The limit of detection should not be more than 10.0 ng/mL.
5. Linearity
Linear correlation coefficient (r) should be ≥ 0.9900 in the range of [10, 500] ng/mL.
6. Precision
 - 6.1 Repeatability
When repeatedly testing samples with concentrations of (40 \pm 10) ng/mL and (400 \pm 80) ng/mL, the coefficient of variation (CV) should not be greater than 10%.
 - 6.2 Between-run precision
When testing samples with concentrations of (40 \pm 10) ng/mL and (400 \pm 80) ng/mL using three different reagent kit lots, the between-run precision (CV) should not be greater than 15%.

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.
 - 2.3 Hemolysis should be avoided during the operation procedure.
















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 A calibration is required for each test, and when changing to a new reagent lot.
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 Do not use the reagent bottles for other purposes.
 - 5.4 Do not mix reagents in different batches.

REFERENCE


Shang Hong, wang Yusan, shen Ziyu. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2014.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Fer Reagent Kit(Immunoturbidimetric 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 |  | Catalogue number |
|  | Date of manufacture |  | Batch code |  | Temperature limit |
|  | <i>In vitro</i> diagnostic medical device |  | Keep away from sunlight |  | Biological risks |
|  | Consult <i>instructions for use</i> or consult electronic <i>instructions for use</i> |  | Do not use if package is damaged and consult <i>instructions for use</i> |  | Authorized representative |
|  | CE mark |  | This way up |  | Do not re-use |

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