This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Notification No. 13A2X00197218075

**Revised: January 2017 (8th edition)
*Revised: April 2008 (7th edition)

This package insert must be read carefully prior to use.

Iron assay kit
(Classification No.: 30379000)

Clinimate FE

General Precautions

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
4. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
5. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
6. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients
FE Coloring Solution 1:
L-Ascorbic acid
Surfactant
FE Coloring Solution 2:
Ferrozine sodium

Intended Use

Measurement of iron in serum

It has been reported that the serum iron level is influenced by iron intake, absorption of iron from the digestive tract, red cell hemoglobin production in the bone marrow, and erythrocyte destruction among other factors. It has also been reported to be influenced by damage to liver cells. Measurement of serum iron plays an important role in the diagnosis of diseases associated with abnormalities of such factors, especially iron-deficiency anemia, hemolytic diseases, hemorrhage, and liver disorders.

Assay Principle

1. Assay Principle

Iron is bound to transferrin in the sample. It is separated by the action of a surfactant under acid conditions, and is reduced from trivalent to bivalent by a reducing agent.

Bivalent iron binds to ferrozine to form a red-purple complex. The iron content is determined by measuring the absorbance of this red-purple color complex.

$$Fe^{3} + \xrightarrow[\text{Acidity}]{\text{Surfactant}} Fe^{2+}$$

$$Fe^{2+} + \text{Ferrozine} \longrightarrow \text{Complex (red-purple color)}$$

2. Features

1) Analytical results are hardly affected by interfering substances, because the self-sampling blank method is employed.
2) Instruments are not damaged because strong acids are not used.

Procedural Precautions *

1. Properties of Samples and Sampling Methods

1) Samples
Serum may be used.
2) Storage of samples[2)]
If the isolated serum sample cannot be tested on the same day, specimens should be stored as follows:
2–10°C: for tests within 1 week
≤ -20°C: for tests after more than 1 week
Bring samples to room temperature (15–30°C) before use.

2. Interfering substances

1) Assay results are not affected by bilirubin (up to 20 mg/dL).
2) Measurement of hemolyzed blood samples results in artifactual reduction of the serum iron level. Perform re-measurement by another test method if the results obtained are extremely low compared with those of other related variables.

3. Others

1) Always use Anaserum FE/UIBC Standard Solution for calibration.
2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Reagent (1): FE Coloring Solution 1 is ready to use.
Reagent (2): FE Coloring Solution 2 is ready to use.

2. Assay Procedure

This product is compatible with various types of automated analyzer. An example of the assay procedure is indicated below.

Sample 20 µL + Reagent (1) 300 µL → (37°C, 3 min) → Measurement (Absorbance I※)
Reagent (2) 50 µL → (37°C, 4.5 min) → Measurement (Absorbance II※)
→ Calculation of Concentration

※Absorbance I and II: The difference in absorbance between 700 nm and 570 nm.
Calibration material: Anaserum FE/UIBC Standard Solution (manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results **

1. Reference standard range[3)]
40–188 μg/dL

2. There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance

1. Sensitivity
1) Reagent blank: absorbance being equal to or lower than 0.03
2) Sensitivity: The absorbance is 0.22–0.32 per 1000 μg/dL of iron.

2. Accuracy: 90–110 % of the expected assay value

3. Within-run Reproducibility:
Coefficient of variation ≤ 5 %
(Test methods used for 1.–3. are in-house methods.)

4. Measurement Range[4)]**:** (On Hitachi 7170S automated analyzer)
6–1800 μg /dL

5. Correlation[4)]
Serum N=60 r=0.968 y=1.06x+1.44
Control method: Approved in vitro diagnostic (chemical assay)

6. Standard Material
SRM937（NIST）

Precautions for Use or Handling **

1. Precautions for Handling (to Ensure Safety)
1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
2) FE Coloring Solution 1 and FE Coloring Solution 2 are acidic (pH 2.9–3.1). If these solutions are accidentally ingested or come into contact with the eyes or skin, immediately implemet first-aid measures such as rinsing the area with water and seek medical treatment if necessary.

2. Precautions for use
1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) Do not replenish the reagents.
4) Do not perform the assay under direct sunlight

3. Precautions for Disposal
1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1 % for longer than 1 hour or autoclaved at 121 ºC for 20 minutes.
2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1 %.
3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.

4. Other precautions
Do not use the containers for other purposes.

Storage and Shelf Life **

Name		Storage temperature	Shelf life
Clinimate FE	FE Coloring Solution 1	2–10°C	1 year from the date of manufacture
	FE Coloring Solution 2	Room temperature	1 year from the date of manufacture

Packaging

Name			Package
Clinimate FE	(1)	FE Coloring Solution 1	4 × 100 mL
	(2)	FE Coloring Solution 2	4 × 50 mL

References **

1) Kitamura M. (author and editor): Clinical Chemical Analysis V, 91, Tokyo Kagaku Dojin, 1967.
2) Sasaki M. et al.: Sampling of constituents of the human body, 147, Kodansha, 1972.
3) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 594, Kanehara Shuppan, 2015.
4) In house data, SEKISUI MEDICAL CO., LTD.

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Manufacturer **

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