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

In Vitro Diagnostics
Marketing Notification No. 13A2X00197218076

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This package insert must be read carefully prior to use.

Unsaturated iron-binding capacity assay kit
(Classification No.: 44236000)

Pureauto S UIBC

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.
Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients
UIBC Buffer Solution 1:
Ammonium ferrous sulfate
2-Amino-2-hydroxymethyl-1,3-propanediol buffer solution
UIBC Coloring Solution 2:
Ferrozine sodium
L-Ascorbic acid

Intended Use

Measurement of unsaturated iron-binding capacity in serum

Unsaturated iron-binding capacity (UIBC) means the amount of iron that can bind to unsaturated (unbound) transferrin. Unlike serum iron, UIBC decreases in aplastic anemia and increases in iron deficiency anemia.

Assay Principle

1. Assay Principle
When a fixed excess of iron is added to serum, transferrin that is not bound to iron (unsaturated transferrin) binds to the added iron and forms saturated transferrin, while the excess added iron remains unbound. When ferrozine acts on the residual iron, a red-purple complex is formed. The UIBC is determined by measuring the absorbance of the red-purple dye.

Unsaturated transferrin + Iron (a fixed excess amount) ⟶ Saturated transferrin + Residual iron

Residual iron + Ferrozine ⟶ Complex (red-purple color)

2. Features
1) This product shows a high sensitivity and excellent reproducibility.
2) Liquid reagents, ready-to-use
3) Applicable to various automated analyzers

Procedural Precautions *

1. Properties of Samples and Sampling Methods
1) Samples
Serum may be used.
2) Storage of samples
The isolated serum should be tested on the same day.
Store samples at -20°C or lower.
Bring samples to room temperature (15–30°C) before use.

2. Interfering substances
1) Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), or ascorbic acid (up to 50 mg/dL).
2) Measurement of hemolyzed blood samples results in artifactual reduction of the UIBC 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): UIBC Buffer Solution 1 is ready to use.
Reagent(2): UIBC 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, 5 min) → Measurement (Absorbance I※)
Reagent (2) 75 µL → (37 °C, 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**[4)]
   Serum: Males, 172–256 (214 ± 42) μg/dL
   Female, 194–268 (231 ± 37) 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 0.20–0.30
   2) Sensitivity: The absorbance is 0.09–0.15 per 500 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**[5)]: (On Hitachi 7170S automated analyzer)
   20–800 μg/dL
5. **Correlation**[5)]
   Serum N=100 r=0.999 y=1.00x–2.8
   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) Sodium azide is added as an antiseptic agent in the UIBC Buffer Solution 1. Therefore, if the reagent comes in accidentally contact with eyes, mouth or skin, rinse immediately with ample water as first aid, and consult the doctor if required.

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.
5) Sodium azide has been added as an antiseptic agent in the UIBC Buffer Solution 1. It can react with lead or copper pipes to produce the highly explosive metal azide. Therefore, the reagent should be flushed with large amounts of water during disposal.

4. Other precautions

Do not use the containers for other purposes.

Storage and Shelf Life **

1. Storage temperature: 2–10 °C
2. Shelf life: 1 year from the date of manufacture
   (The expiration date is printed on the outer package.)

Packaging

Name			Package
Pureauto S UIBC	(1)	UIBC Buffer Solution 1	4 × 100 mL
	(2)	UIBC Coloring Solution 2	4 × 50mL

Constituent reagents are available in other configurations. For further details please contact SEKISUI MEDICAL CO., LTD.

References *

1) Horak E. et al.: A.J.C.P., 62, 133, 1974.
2) Ruutu R.: Clin Chim Acta, 61, 229, 1975.
3) Persijin J.P. et al.: Clin Chim Acta, 35, 91, 1971.
4) Karigome S: Jpn J Clin Med (Autumn extra edition) 40, 406, 1982.
5) In house data, SEKISUI MEDICAL CO., LTD.

Contact *

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Manufacturer **

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