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

In Vitro Diagnostics
Marketing Notification No. 13A2X00197218040

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*Revised: April 2008 (8th edition)

This package insert must be read carefully prior to use.

Complement component C4 assay kit
(Classification No.: 30243000)

Immunotesta C4

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
Buffer Solution 1: Phosphate Buffer Solution
Antiserum 2: Anti-human complement protein C_4 goat antiserum

Intended Use

Measurement of complement protein C4 in serum

Complement components are a group of proteins involved in defense against infections, immune responses, and inflammatory responses. There are two pathways for activation of complement. Complement protein C_4 closely reflects activation of the classical pathway by antigen-antibody complexes. It is a reliable indicator of immune responses, inflammation, etc.

Assay Principle

1. Assay Principle

Complement protein C_4 in samples undergoes an antigen-antibody reaction with anti-human complement protein C_4 goat antiserum (C_4 antiserum), resulting in turbidity. The C_4 content of the sample is determined by measuring the turbidity. This method is a two-point assay in which the values of the self-sampling blank are subtracted.

C_4+C_4 antiserum ⟶ Antigen-antibody precipitate

2. Features

1) Sample dilution is not necessary.
2) Assay results are not affected by normal turbidity, bilirubin, or hemoglobin.
3) Reagent preparation is not required.
4) Applicable to various automated analyzers.

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:
Store samples at -20°C or lower.
Bring samples to room temperature (15–30°C) before use.

2. Interfering substances

Assay results are not affected by bilirubin (up to 40 mg/dL) or hemoglobin (up to 1000 mg/dL).

3. Others

1) Always use GAM complement calibrator 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): Buffer Solution 1 is ready to use.
Reagent (2): Antiserum 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 5 μL + Reagent (1) 200 μL —(37 °C, 5 min)→ Measurement (Absorbance I※)
Reagent (2) 50 μL —(37 °C, 5 min)→ Measurement (Absorbance II※)
—→ Calculation of concentration

※Absorbance I and II: Absorbance at 600 nm
Calibration material: GAM complement calibrator (manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results

1. Reference standard range[3)]

12–37 mg/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 0.10
2) Sensitivity: The absorbance is 0.11–0.28 per 50 mg/dL of complement protein C_4.

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)
1–100 mg /dL

5. Correlation[4]
1) Serum N=60 r=0.973 y=0.71x+1.22
Control method: SRID method

6. Standard Material
IRMM（CRM470）

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 Buffer Solution 1 and Antiserum 2. 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 Buffer Solution 1 and Antiserum 2. 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
Immunotesta C4	Buffer Solution 1	2 × 40 mL
	Antiserum 2	2 × 10 mL

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

References * *

1) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 763, Kanehara Shuppan, 2015.
2) Medical Practice Editorial Board: Laboratory test guide revised in 2015, Bunkodo, 676, 2015.
3) Murakami C. et al.: Clinical report, 24, 4609, 1990.
4) In house data, SEKISUI MEDICAL CO., LTD.

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Manufacturer * *

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