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

In Vitro Diagnostics
Marketing Approval No. 20300AMZ00140000

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This package insert must be read carefully prior to use.

Class II General and Biochemical Test Series
(Classification No.: 80022002)
Calcium assay kit
(Classification No.: 30187002)

Clinimate CA

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. For the effects of an administered drug on the measured value, carefully read the Precautions for Use in the package insert of the drug, especially the section about the effects on laboratory test results. Please also read carefully the "2. Interfering Substances," in the "Procedural Precautions" section, as well as "2. Precautions for Assessment" in the "Assessment of Assay Results" section, of this package insert.
4. 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.
5. 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.
6. 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.
7. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients
Calcium Alkaline Solution 1
Calcium Coloring Solution 2:
o-Cresolphthalein complexone

Intended Use

Measurement of calcium in serum or urine

Calcium is mostly localized in the bones of the body, but it also exists in other tissues and the serum. It plays an important role in bone formation, blood coagulation, and neurotransmission.
Therefore, measurement of the blood level of calcium is considered to be important for the diagnosis of bone and endocrine diseases.

Assay Principle

1. Assay Principle

Calcium in the samples binds to o-cresolphthalein complexone to form a red-purple complex. The calcium content is determined by measuring the absorbance of this complex. (With this method, the influence of magnesium is eliminated by adding 8-hydroxyquinoline-5-sulfonate.)

Calcium + o-Cresolphthalein complexone
$\xrightarrow{\text{Alkaline}}$ Complex (red-purple color)

2. Features

1) This product specifically reacts with calcium.
2) The influence of magnesium is eliminated.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples
Serum and urine may be used.
2) Storage of samples[1)]
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
Bring samples to room temperature (15–30°C) before use.
Urine samples should be tested on the same day.

2. Interfering substances

1) Assay results are not affected by bilirubin (up to 20 mg/dL), hemoglobin (up to 500 mg/dL), or ascorbic acid (50 mg/dL).
2) When samples from patients who have dosed with gadolinium contrast medium are measured, false low results may be obtained.[2) 3)]

3. Others

1) Serum Multicalibrator (SEKISUI), Seronorm Multicalibrator, Seronorm Human or Anaserum CA 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): Calcium Alkaline Solution 1 is ready to use.
Reagent (2): Calcium 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 5 µL + Reagent (1) 200 µL $\xrightarrow[5\text{ min}]{37°C}$ Reagent (2) 200 µL $\xrightarrow[5\text{ min}]{37°C}$ Measurement (Absorbance※)
→ Calculation of concentration

※Absorbance: The difference in absorbance between 660 nm and 600 nm

Calibration material: Serum Multicalibrator (SEKISUI), Seronorm Multicalibrator, Seronorm Human or Anaserum CA Standard Solution (Manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results **

1. Reference standard range[4)]
In serum: 8.8–10.1 mg/dL (Within the JCCLS common standard)
In urine: 0.1–0.3 g/day

2. Precautions for Assessment
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 0.10–0.20
2) Sensitivity: The absorbance is 0.29–0.37 per 10 mg/dL of calcium.

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

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

4. Measurement Range[5)]: (On Hitachi 7170S automated analyzer)
0.2–20 mg/dL

5. Correlation[5)]
1) Serum N=65 r=0.997 y=0.98x + 0.11
Control method: Approved in vitro diagnostic (OCPC method)
2) Urine N=51 r=0.997 y=0.96x –0.17
Control method: Approved in vitro product (enzymatic method)

6. Standard Material
SRM915 (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) The Calcium Alkaline Solution 1 contains monoethanolamine. If it is accidentally ingested or comes into contact with the eyes or skin, immediately wash with water and seek medical treatment, if necessary.
3) Sodium azide is added as an antiseptic agent in the Calcium Coloring Solution 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) If atmospheric carbon dioxide is absorbed by the reagent, the sensitivity of the color change decreases due to a decrease of pH. Use this product promptly after opening, and perform calibration at regular intervals.
5) 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 121ºC 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 antisepticagent in the Calcium Coloring Solution 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 *

Name		Storage temperature	Shelf life
Clinimate CA	Calcium Alkaline Solution 1	Room temperature	2 years from the date of manufacture
	Calcium Coloring Solution 2	2–10°C	2 years from the date of manufacture

(The expiration date is printed on the outer package.)

Packaging

Name			Package
Clinimate CA	(1)	Calcium Alkaline Solution 1	4 × 100mL
	(2)	Calcium Coloring Solution 2	4 × 100mL

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

References **

1) Sasaki M. et al. Sampling of constituents of the human body. Tokyo: Kodansha; 1972. Japanese.
2) Hyunseok P. K. et al.: Clin. Chem, 50:4, 2004.
3) GE Healthcare Japan, OMNISCAN

INTRAVENOUS INJECTION SYRINGE 32% (1st ed.) [Instructions for Use]. 2020 Mar. Japanese.
4) Kanai M, editor. Kanai's manual of clinical laboratory medicine. 35th ed. Tokyo: Kanehara Shuppan; 2020. Japanese.
5) SEKISUI MEDICAL CO., LTD. In house data. Japanese.

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