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)
β-Lipoprotein assay kit
(Classification No.: 44378000)

Clinimate β-L

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
β-L Reactant Solution: Heparin sodium (derived from porcine intestinal mucosa)
Magnesium chloride

Intended Use

Measurement of β-lipoprotein in serum

Lipo-protein in samples is classified as α-lipoprotein, β-lipoprotein, preβ-lipoprotein, chylomicron, etc.
Measurement of these lipoproteins has been reported to be useful for the evaluation of lipid metabolism disorder and hyperlipidemia.

Assay Principle

1. Assay Principle

β-lipoprotein in samples forms an insoluble complex together with heparin in the presence of Mg^{2+}, resulting in the occurrence of turbidity. The amount of β-lipoprotein is determined by measuring the degree of turbidity.

$$\text{β-lipoprotein in sample} + \text{Heparin} \xrightarrow{Mg^{2+}} \text{Turbidity}$$

2. Features

1) Single liquid method without any need for reagent preparation.
2) This reagent is characterized by high sensitivity and good reproducibility.

Procedural Precautions

1. Properties of Samples and Sampling Methods

1) Samples
Serum may be used.
2) Storage of samples[2)]
The isolated serum should be tested on the same day.

2. Interfering substances

1) Assay results are not affected by bilirubin (up to 20 mg/dL) or ascorbic acid (up to 50 mg/dL).
2) Hemolysis of blood samples result in artifactual elevation of the β-lipoprotein level. Perform re-measurement by another test method if the results obtained are extremely high compared with those of other related variables.

3. Others

1) Use serum of known concentration as the calibration material.
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: β-L Reactant Solution is ready to use.

2. Assay Procedure

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

Sample 8 μL + Reagent 350 μL → (37°C, 7.5 min) → Measurement (Absorbance※) → Calculation of concentration

※ Absorbance: The difference in absorbance between 700 nm and 600 nm
Calibration material: Serum of known concentration
Reagent blank: Purified water or saline

Assessment of Assay Results

1. Reference standard range

220–650 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 0.01
2) Sensitivity: The absorbance is 0.19–0.30 per 600 mg/dL of β-lipoprotein.

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**[3]: (On Hitachi 7170S automated analyzer)
10–1200 mg/dL

5. **Correlation**[3]
Serum N=65 r=0.993 y=0.95x-4.01
Control method: Approved in vitro diagnostic (turbidimetric method)

6. **Standard Material**
Serum with known value (In-house reference standard)

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 β-L Reactant Solution. 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 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 is added as an antiseptic agent in the β-L Reactant Solution. 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 when disposing.

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
Clinimate β-L	β-L Reactant Solution	4×100 mL

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

References *

1) Kanai I and Kanai M. (author and editor): Kanai's manual of clinical laboratory medicine. 32nd ed. 548, Kanehara Shuppan, 2005.
2) Oda A et al.: Jpn J Clin Pathol (extra edition) 21, 82, 1975
3) In house data, SEKISUI MEDICAL CO., LTD.

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Manufacturer * *

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