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

In Vitro Diagnostics
Marketing Approval No. 20600AMZ01063000

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This package insert must be read carefully prior to use.

Lipoprotein (a) assay kit
(Classification No.: 41419000)

Lp (a) Latex "DAIICHI"

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
Latex Reagent: Anti-human lipoprotein (a) mouse monoclonal antibody-coated latex

Intended Use

Measurement of lipoprotein (a) in serum or plasma

Lipoprotein (a) is a lipoprotein that contains Apo (a) as its apoprotein. It is extremely similar to low-density lipoprotein (LDL) in both lipid composition and structure.
Lipoprotein (a) was discovered by Berg in 1963, but little importance was attached to it initially because the physiological or pathological significance was unclear. At present, Lipoprotein (a) is attracting attention as a lipid that plays a role in the progression of arteriosclerosis independently of other lipids.
In 1987, McLean et al. found that the primary structure of Apo (a) is partially homologous with the structure of plasminogen. Since then, Apo (a) has been studied actively as a key connection between lipids and blood coagulation factors.

Assay Principle

1. Assay Principle

In a sample, lipoprotein (a) (Lp (a)) reacts with anti-human Lp (a) mouse monoclonal antibody-sensitized latex beads to cause agglutination of the beads. The Lp (a) concentration is determined by measuring the change of turbidity due to this agglutination reaction.

Lp (a) in samples
+ Anti-human Lp (a) mouse monoclonal antibody- coated latex
⟶ Agglutination by antigen-antibody reaction

2. Features

1) The monoclonal antibody used has a high specificity.
2) This product is not affected by interfering substances.
3) Thanks to the high sensitivity of this assay, low concentrations can also be measured accurately.
4) Because sample dilution or preparation of reagents is not required, measurement can be performed conveniently and rapidly.

Procedural Precautions

1. Properties of Samples and Sampling Methods

1) Samples
Serum and plasma may be used.
2) Storage of samples
The isolated serum (plasma) should be tested on the same day.
Samples are stable for 2 weeks at 2–10°C. Freeze samples if storage for a longer period is required.
Refrigerated or frozen samples should be warmed to room temperature (15–30°C) before measurement and mixed gently to ensure complete homogeneity.

2. Interfering substances

Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), hemoglobin (up to 500 mg/dL), or Intralipos (up to 5%).

3. Others

1) Always use Lp (a) latex standard serum L, M, and H for calibration.
2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

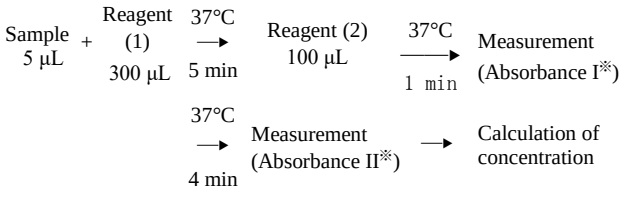
Dosage/Administration (Assay Procedure) *

1. Preparation of reagents

Reagent (1): Buffer Solution is ready to use.
Reagent (2): Latex Reagent is ready to use.
Before using this product, gently invert the Latex Reagent bottle to mix it thoroughly, and check that there are no bubbles.

2. Assay Procedure

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



※ Absorbance I and II: Absorbance at 600 nm
Calibration material: Lp (a) latex standard serum L, M, and H (Manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results

1. **Reference standard range**[4)]
   ≤ 30.0 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 0.02
   2) Sensitivity: The absorbance is 0.04–0.20 per 20.0 mg/dL of Lp (a).
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 7170 automated analyzer)
   1–100 mg/dL
5. **Correlatio**[4)]
   1)Serum N=50 r=0.992 y=1.08x–4.8
   Control method: enzyme immunoassay
   2) plasma N=50 r=0.997 y=1.06x+0.20
   Control method: enzyme immunoassay
6. **Standard Material**
   Purified lipoprotein (a) (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) Lp (a) latex standard serum L, M, and H contain components of human origin that have been shown to be negative for HBs antigens, HIV antibodies (AIDS virus antibodies), and HCV antibodies. However, these reagents (as well as the samples) should be considered potentially infectious and handled with great care.
3) Sodium azide is added as an antiseptic agent in the Buffer 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.
4) ProClin 300, which possesses skin-irritative potential, is added as an antiseptic agent in the Buffer Solution and Latex Reagent. Therefore, if the reagent comes in contact with skin or clothes, rinse immediately with ample water, and consult the doctor if skin irritation develops.

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 agentin the Buffer 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: 2 years from the date of manufacture
   (The expiration date is printed on the outer package.)

Packaging ＊＊

Name		Package
Lp (a) Latex "DAIICHI"	Buffer Solution	1 × 61mL
	Latex Reagent	1 × 20mL

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

References

1) Berg K.: Acta Pathol Microbiol Scand, 59, 369, 1963.
2) Eaton D. L. et al.: Proc Natl Acad Sci, USA 84, 3224, 1987.
3) Mclean J. W. et al.: Nature, 300, 132, 1987.
4) In house data, SEKISUI MEDICAL CO., LTD.

Contact

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Manufacturer ＊

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