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

In Vitro Diagnostics
Marketing Notification No. 13A2X00197218036

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This package insert must be read carefully prior to use.

Apolipoprotein A-1 assay kit
(Classification No.: 30256000)

Apo A-I Auto・N "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 : 2-Amino-2-hydroxymethyl-1, 3-propanediol buffer
Macrogol 4000
Antibody Solution: Anti-human apolipoprotein A-I goat polyclonal antibody

Intended Use

Measurement of apolipoprotein A-I in serum or plasma

Lipoprotein is composed of lipid and protein, and the protein part is called apolipoprotein.
Many kinds of apolipoprotein are available. Among them, apolipoprotein A-1 is the most abundant in the serum (plasma).
Apolipoprotein A-I is mostly noted on the granule surface of high density lipoprotein (HDL). It is known to play an important role in the solubilization of HDL and also has an activating effect on lecithin-cholesterol acyltransferase (LCAT).

Assay Principle

1. Assay Principle
Apolipoprotein A-I in samples causes an antigen-antibody reaction with anti-human apolipoprotein A-I goat polyclonal antibody, resulting in the occurrence of turbidity. The amount of apolipoprotein A-I is determined by measuring the degree of turbidity. This method is two-point assay in which the values of self-sample blank are subtracted.

Apolipoprotein A-I in samples
+ Anti-human apolipoprotein A-I goat polyclonal antibody
→ Measurement of turbidity caused by an antigen-antibody reaction

2. Features
1) The γ-globulin fraction of anti-human apolipoprotein A-I goat serum is used for the product having high specificity.
2) Due to the self-sample blank method, measurement can be performed rapidly and accurately.
3) Sample dilution is not required.
4) Reagent preparation is not required.

Procedural Precautions *

1. Properties of Samples and Sampling Methods
1) Samples
Serum and plasma may be used.
2) Storage of samples[1)]
If the isolated serum or plasma sample cannot be tested on the same day, specimens should be stored as follows:
2–10°C: for tests within 2 weeks
Bring samples to room temperature (15–30°C) before use.

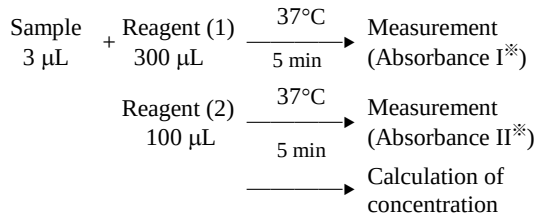
2. Interfering substances
1) Assay results are not affected by bilirubin (up to 40 mg/dL), hemoglobin (500 mg/dL), or Intralipos (up to 20%).
2) This reagent has been devised so that hyperlipidemia samples, especially chylomicron-abundant samples, can also be measured accurately. However, if the analytical result is extremely higher or lower than those of other lipid parameters, perform remeasurement by other methods.

3. Others
1) Calibration material
Use Apo Auto・N "DAIICHI" Calibrator (manufactured by SEKISUI MEDICAL CO., LTD.) as the one-point calibration material and Apo Auto・N Highcalib AB (manufactured by SEKISUI MEDICAL CO., LTD.) as the multi-point 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 (1): Buffer is ready to use.
Reagent (2): Antibody Solution 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.



※ Absorbance I and II: The difference in absorbance between 800 nm and 600 nm

Calibrator: Apo Auto・N "DAIICHI" Calibrator or Apo Auto・N Highcalib AB (manufactured by SEKISUI MEDICAL CO., LTD.).

Reagent blank: Purified water or saline

Assessment of Assay Results

1. Reference standard range

122–161 mg/dL[4)]

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 0.20

2) Sensitivity: 0.11–0.24 abs per 100 mg/dL of apolipoprotein A-I.

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[6)]: (On Hitachi 7170S automated analyzer)

1–200 mg/dL

5. Correlatio[6)]

1) Serum N=50 r=0.956 y=1.00x+1.7

Control method: Single immunodiffusion method

2) Plasma N=50 r=0.946 y=1.03x-3.5

Control method: Single immunodiffusion method

6. Standard Material

BCR393 (IRMM)

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) Apo Auto・N "DAIICHI" Calibrator and Apo Auto・N Highcalib AB contain human-derived components 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 and Antibody 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 Buffer and Antibody 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: 18 months from the date of manufacture (The expiration date is printed on the outer package.)

Packaging **

Name			Package
Apo A- I Auto・N "DAIICHI"	(1)	Buffer	1×45mL
	(2)	Antibody Solution	1×15mL

References *

1) Sakai Y. et al.: Anal. Biochem, 137, 1, 1984.

2) Itakura H: Fundamental and Clinical Medicine of Apoprotein, 13, Daiichi Chemical, 1985.

3) Akanuma Y et al.: J Jpn Atheroscl, 12, 1283, 1984.

4)Sakurabayashi I. et al.: Clinica Chimica Acta, 312, 87, 2001.

5) Nakamura H: Japan Medical Journal, 3775, 23, 1996.

6) In house data, SEKISUI MEDICAL CO., LTD.

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