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

In Vitro Diagnostics
Marketing Approval No.20400AMZ00177000

** Revised: January 2017 (8th edition)
* Revised: April 2008 (7th edition)

This package insert must be read carefully prior to use.

Leucine aminopeptidase assay kit
(Classification No.: 38546000)

Pureauto LAP

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
LAP Buffer Solution 1:
2-Amino-2-hydroxymethyl-1,3-propanediol buffer
LAP Substrate Solution 2:
L-Leucyl-*p*-nitroanilide･hydrochloride

Intended Use

Measurement of leucine aminopeptidase in serum

Leucine aminopeptidase is an enzyme that is extremely widely distributed in human tissues such as the intestinal mucosa, kidneys, muscles, liver, and pancreas. It hydrolyzes peptide bonds with N-terminal leucine.
Serum leucine aminopeptidase activity increases in hepatobiliary disease, etc.

Assay Principle

1. Assay Principle
When serum leucine aminopeptidase (LAP) acts on L-leucyl-*p*-nitroanilide as the substrate, *p*-nitroaniline (yellow) is released. LAP activity is determined by measuring the production velocity of *p*-nitroaniline.

L-Leucyl-*p*-nitroanilide･hydrochloride $\xrightarrow{\text{LAP}}$ L-Leucine + *p*-Nitroaniline (yellow)

2. Features
1) This product is based on the GSCC recommended method and modified so that it is applicable to automated analyzers.
2) Liquid reagents, ready-to-use.
3) The kit is based on the rate assay method, so coexisting substances have little effect.
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[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
≤ -20°C: for tests after more than 1 week
Bring samples to room temperature (15–30°C) before use.

2. Interfering substances
Assay results are not affected by bilirubin (up to 20 mg/dL) and hemoglobin (up to 400 mg/dL).

3. Others
1) For calibration, use the calibration factor obtained with 4NA "Daiichi" (manufactured by SEKISUI MEDICAL) for measuring calibration factor.
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): LAP Buffer Solution 1 is ready to use.
Reagent (2): LAP Substrate Solution 2 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 10 μL + Reagent (1) 260 μL $\xrightarrow[5\text{ min}]{37°C}$
Reagent (2) 130 μL $\xrightarrow[60\text{-}300\text{ sec}]{37°C}$ Measurement (Absorbance※)
→ Calculation of activity

※ Absorbance: The difference in absorbance between 505 nm and 405 nm
Calibration: Conversion factor
Reagent blank: Purified water or saline

Assessment of Assay Results

1. Reference standard range[3)]
30–70 U/L

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: change in absorbance being equal to or lower than 0.01/min
2) Sensitivity: The change of absorbance is 0.015–0.020/min per 100 IU/L of leucine aminopeptidase.

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[4]: (On Hitachi 7170S automated analyzer)
1–1500 U/L

5. Correlatio[4]
1) Serum N=86 r=0.999 y=1.06x+1.7
Control method: Approved in vitro diagnostic (L−leucyl-*p*-nitroanilide substrate method)

6. Standard Material
Purified *p*-nitroaniline (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 LAP Buffer Solution 1. 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 LAP Buffer Solution 1. 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
Pureauto LAP	(1)	LAP Buffer Solution 1	4 × 100 mL
	(2)	LAP Substrate Solution 2	4 × 100 mL

References * *

1) Sasaki M. et al.: Sampling of constituents of the human body, 223, Kodansha, 1972.
2) Kobayashi T, Omori S. J Clin Lab Inst Reag, 14, 929, 1991.
3) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 586, Kanehara Shuppan, 2015.
4) In house data, SEKISUI MEDICAL CO., LTD.

Contact *

SEKISUI MEDICAL CO., LTD.
international@sekisui.com

Manufacturer * *

SEKISUI MEDICAL CO., LTD.
1-3, Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan