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

In Vitro Diagnostics
Marketing Approval No. 21200AMZ00595000

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This package insert must be read carefully prior to use.

Amylase isozyme assay kit
(Classification No.: 38541012)

Pureauto S P-AMY-G2

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

P-AMY-G2 Antibody Solution 1:
Anti-human salivary amylase mouse monoclonal antibody
Sodium chloride
Magnesium chloride
Good's Buffer Solution

P-AMY-G2 Substrate Solution 2:
α-2-Chloro-4-nitrophenyl-galacto pyranosyl maltoside
Potassium thiocyanate
Good's Buffer Solution

Intended Use

Measurement of amylase isozymes in serum, plasma, or urine

In human body fluids, amylase has isozymes, which are produced in the pancreas (pancreatic amylase) or the salivary glands (salivary amylase).
Measurement of the total amylase level is commonly performed for diagnosis of pancreatic diseases, while measurement of amylase isozymes is considered promising as a more accurate indicator of acute pancreatitis.

Assay Principle

1. Assay Principle

Activity of α-Amylase produced by the salivary glands is inhibited by the anti-human salivary amylase mouse monoclonal antibody. When amylase produced in the pancreas acts on α-2-chloro-4-nitrophenyl-galactopyranosyl maltoside (Gal-G2-CNP), this substrate is decomposed to form 4-galactopyranosyl maltose (Gal-G2) and 2-chloro-4-nitrophenol (CNP). Amylase isozyme activity is determined by measuring the velocity of CNP production (yellow color).

α-Amylase (pancreatic amylase + salivary amylase)

Anti-human salivary amylase mouse monoclonal antibody
→
Pancreatic amylase + Inactive salivary amylase

Gal-G2-CNP —(Pancreatic amylase)→ Gal-G2 + CNP

2. Features
1) Liquid reagents, ready-to-use
2) Reproducibility is good.
3) Applicable to various automated analyzers.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples
Serum and plasma (heparin plasma, EDTA plasma, citrated plasma and NaF-EDTA plasma) may be used.

2) Storage of samples
If the isolated serum sample cannot be tested on the same day, specimens should be stored as follows[6]:
2–10°C: for tests within 3 weeks
≤ -20°C: for tests after more than 3 weeks
Bring samples to room temperature (15–30°C) before use.

2. Interfering substances

Assay results are not affected by free bilirubin (up to 40 mg/dL), conjugated bilirubin (up to 40 mg/dL), hemoglobin (up to 500 mg/dL), ascorbic acid (up to 50 mg/dL), or formazin turbidity (up to 5600 FTU).

3. Others

1) Always use Enzyme Calibrator Plus "Daiichi" for calibration.
2) Precautions for assay range
If the activity of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

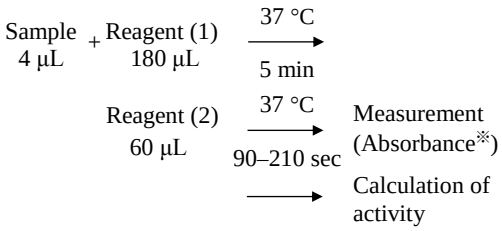
Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Reagent (1): P-AMY-G2 Antibody Solution (1) is ready to use.
Reagent (2): P-AMY-G2 Substrate 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.



※ Absorbance: The difference in absorbance between 546 nm and 405 nm.
Calibration material: Enzyme Calibrator Plus "Daiichi" (manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results ＊＊

1. Reference standard range[7)]
In blood: 15–50 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 0.10/min
2) Sensitivity: The change of absorbance is 0.017–0.027/min per 100 U/L of pancreatic amylase.

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[8)]**:** (On Hitachi 7600Ds automated analyzer)
1–1000 U /L

5. Correlation[8)]
1)Serum N=54 r=0.999 y=0.96x+2.6
Control method: Approved in vitro diagnostic (inhibition method)
2) Plasma N=156 r=0.999 y=0.96x+1.6
Control method: Approved in vitro diagnostic (antibody inhibition method)
3) Urine N=64 r=0.999 y=0.95x+5.1
Control method: Approved in vitro diagnostic (inhibition method)

6. Standard Material
Enzyme Calibrator Plus, the calibration material used for this product, is in line with the Japanese Standard for Certified Enzyme Reference Materials.

Precautions for Use or Handling ＊＊

1. Precautions for Handling (to Ensure Safety)
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. 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.

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 S P-AMY-G2	(1)	P-AMY-G2 Antibody Solution 1	2 × 50 mL
	(2)	P-AMY-G2 Substrate Solution 2	2 × 50 mL

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

References ＊＊

1) Jpn J Clin Med, 57 (1999 extra edition), 359–361, 1999.
2) Morishita Y. et al.: Clin Chem, 46, 928−933. 2000.
3) Suzuki H. et al.: J Jpn Soc Clin Labo Autom, 27, 229–232, 2002.
4) Noguchi M. et al.: J Clin Lab Inst Reag, 26, 135–144, 2003.
5) Noma K. et. al.: J Med Pharm Sci, 47, 109–113, 2002.
6) Sasaki M. et al.: Sampling of constituents of the human body, 181, Kodansha, 1972.
7) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 567, Kanehara Shuppan, 2015.
8) In house data, SEKISUI MEDICAL CO., LTD.

Contact

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Manufacturer ＊＊

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