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

In Vitro Diagnostics
Marketing Notification No.13A2X00197218096

** Revised: January 2017 (11th version)
* Revised: August 2011 (10th version)

This package insert must be read carefully prior to use.

γ-Glutamyltranspeptidase assay kit for blood tests
(Classification No.: 38507001)

Pureauto S GGT

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
GGT Reaction Solution 1:
Good's buffer
GGT Substrate Solution 2:
L-γ-glutamyl-3-carboxy-4-nitroanilide
Glycylglycine

Intended Use

Measurement of γ-glutamyltranspeptidase in serum or plasma

γ-GTP is an enzyme with an extremely wide distribution in human organs/tissues, including kidneys, pancreas, prostate, and liver. It hydrolyzes γ-glutamyl peptide and transfers γ-glutamyl groups. The blood level of γ-GTP activity is mainly increased in obstructive jaundice, liver cancer, and alcoholic liver disease, and is usually determined by measuring the velocity of reaction with a synthetic substrate.

Assay Principle

1. Assay Principle

γ -glutamyltranspeptidase (γ-GTP) in the sample transfers the γ-glutamyl group of L-γ-glutamyl-3-carboxy-4-nitroanilide (the substrate) to glycylglycine in the presence of glycylglycine. The γ-GTP acitivity is determined by measuring the velocity of production of 5-amino-2-nitrobenzoic acid, which is released at this time.

L-γ-Glutamyl-3-carboxy-4-nitroanilide + Glycylglycine

$$\xrightarrow{\gamma\text{-GTP}} \text{L-}\gamma\text{-glutamyl glycylglycine} + \text{5-amino-2-nitrobenzoic acid (yellow)}$$

2. Features

1) Final concentration of the principal ingredient matches with the final concentration stipulated in the JSCC Recommendation for Enzyme Activities.
2) 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 or plasma sample cannot be tested on the same day, they should be stored at 2–10°C or -20°C.[4)]
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), formazin turbidity (up to 5600 FTU), or ascorbic acid (up to 50 mg/dL).

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): GGT Reaction Solution 1 is ready to use.
Reagent (2): GGT 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.

Sample 10 μL + Reagent (1) 260 μL $\xrightarrow{37°C,\ 5\ \text{min}}$

Reagent (2) 130 μL $\xrightarrow{37°C,\ 60\text{–}300\ \text{sec}}$ Measurement (Absorbance ※)

$\longrightarrow$ Calculation of activity

※ Absorbance: The difference in absorbance between 660 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**[5)]
   Male: 13–64 U/L
   Female: 9–34 U/L (≤ 45 years);
   10–53 U/L (> 45 years)
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 0.002/min
   2) Sensitivity: The change of absorbance is 0.086–0.138/min per 500 IU/L of γ-GTP activity.
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**[6)]: (On Hitachi 7600Ds automated analyzer)
   3–2000 U/L
5. **Correlation**[6)]
   1) Serum N=100 r=0.999 y=1.00x+0.6
      Control method: using an already approved in vitro diagnostic product with method in line with the JSCC Recommendation for Enzyme Activities
   2) Plasma N=90 r=0.999 y=0.99x+2.3
      Control method: using an already approved in vitro diagnostic product with method in line with the JSCC Recommendation for Enzyme Activities
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, avoid freezing. Freezing can cause deterioration of the reagents, leading to inaccurate results. Therefore, do not use the product if it has 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 GGT	(1)	GGT Reaction Solution 1	4 × 250 mL
	(2)	GGT Substrate Solution 2	4 × 100 mL

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

References **

1) Persijn J. P. et al.: J Clin Chim Clin Biochem, 14, 421, 1976.
2) IFCC Section No.5. 1: Clin Chim Acta, 135, 315 F, 1983.
3) Kobayashi T. et al.: J Clin Lab Inst Reag, 14, 929, 1991.
4) Medical Practice Editorial Board: Laboratory test guide 2005–2006, 124, Bunkodo, 2015.
5) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 587, Kanehara Shuppan, 2015.
6) 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