

This package insert must be read carefully prior to use.

Amylase assay kit
(Classification No.: 38502002)

QUALIGENT 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

- AMY-G2 Buffer Solution 1
- AMY-G2 Substrate Solution 2:
 α -2-Chloro-4-nitrophenyl-galactopyranosyl maltoside

Intended Use

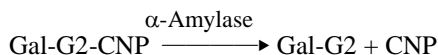
Measurement of amylase in serum, plasma or urine

Amylase is a digestive enzyme. It is found in the pancreatic fluid, saliva, blood, and urine. Because the serum amylase level increases rapidly in acute pancreatitis and other diseases, the measurement of amylase is important for the diagnosis of pancreatic disease.

Assay Principle

1. Assay Principle

When blood or urinary amylase (α -amylase) acts on α -2-chloro-4-nitrophenyl-galactopyranosyl maltoside (Gal-G2-CNP) as the substrate, it is decomposed to form 4-galactopyranosyl maltose (Gal-G2) and 2-chloro-4-nitrophenol (CNP). Amylase activity is determined by measuring the velocity of CNP production (yellow color).



2. Features

Reaction system based on simple measurement principles.

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, specimens should be stored as follows⁶⁾:

2–10°C: for tests within 3 weeks

≤ -20°C: for tests after more than 3 weeks

Urine samples should be tested on the same day.

Bring samples to room temperature (15–30°C) before use.

2. Interfering substances

- 1) Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), ascorbic acid (up to 50 mg/dL), or formazin turbidity (up to 3000 FTU).
- 2) On Hitachi 9000 series automated analyzers, hemolysis causes the negative impact to the measurement result. Therefore, perform re-measurement with another device or test method if the results obtained are extremely low compared with those of other related variables.

3. Others

- 1) Always use Enzyme Calibrator Plus “Daiichi” for calibration material.
- 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) **

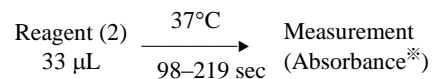
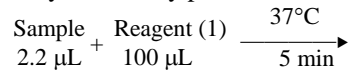
1. Preparation of reagents

Reagent (1): AMY-G2 Buffer Solution 1 is ready to use.

Reagent (2): AMY-G2 Substrate Solution 2 is ready to use

2. Assay Procedure

This product is compatible with Hitachi 9000 series and LABOSPECT series automated analyzers. Assay procedure is indicated below.



Measurement (Absorbance^{**})
—————> Calculation of activity

- ※ Absorbance: The difference in absorbance between 546 nm and 415 nm (on a Hitachi 9000 series automated analyzer)
- Calibration material: Enzyme Calibrator Plus “Daiichi” (Manufacturer’s assigned value)
- Reagent blank: Purified water or saline

Assessment of Assay Results *

1. Reference Criteria⁷⁾

In blood: 40–126 U/L

In urine: 87–665 U/L (random urine samples)

- 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 0.010/min.

2) Sensitivity: The change of absorbance is 0.017–0.027/min per 100 U/L of amylase.

- Accuracy:** 90–110 % of the expected assay value

3. Within-run reproducibility:

Coefficient of variation $\leq 5\%$

(Test methods used for 1. –3. are in-house methods.)

- Measurement Range⁸⁾:** (On Hitachi 9000 series automated analyzers)

5–2000 U/L

5. Correlation⁸⁾

1) Serum $N=54$ $r=0.999$ $y=0.97x+5.8$

Control method: Approved in vitro diagnostic (CNP G3 method)

2) Plasma $N=136$ $r=0.999$ $y=0.98x+0.7$

Control method: Approved in vitro diagnostic (CNP G5 method)

3) Urine $N=55$ $r=0.999$ $y=0.99x+17$

Control method: Approved in vitro diagnostic (CNP G3 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

- 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.
- Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
- Do not perform the assay under direct sunlight.

3. Precautions for Disposal

- 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 121°C for 20 minutes.
- 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%.

- The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
- 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.
- Do not take apart the reagent cartridge before use.

Storage and Shelf Life **

- Storage temperature: 2–10°C

- Shelf life: 1 year from the date of manufacture (The expiration date is printed on the outer package.)

Packaging * *

Name	Package		
QUALIGENT AMY-G2	Set (Cassette for Hitachi 9000 series)	AMY-G2 Buffer Solution 1 1 × 15.0 mL	×2
		AMY-G2 Substrate Solution 2 1 × 5.0 mL	
QUALIGENT AMY-G2	L set (Set for Hitachi LABOSPECT series)	AMY-G2 Buffer Solution 1 1 × 46.0 mL	×2
		AMY-G2 Substrate Solution 2 1 × 16.0 mL	

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

References

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- Morishita Y., et al.: Jpn J Clin Chem, 46, 928–933, 2000.
- Ikeda K. et al.: J Jpn Soc Clin Labo Autom, 27, 183–188, 2002.
- Suzuki H. et al.: J Jpn Soc Clin Labo Autom, 27, 229–232, 2002.
- Noguchi M. et al.: J Clin Lab Inst Reag, 26, 135–144, 2003.
- Sasaki M. et al.: Sampling of constituents of the human body, 181, Kodansha, 1972.
- Kosaka M. et al.: J Med Pharm Sci, 49, 503–507, 2003.
- In house data, SEKISUI MEDICAL CO., LTD.

Contact

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Manufacturer **

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