Bioway Chemistry Reagent Series

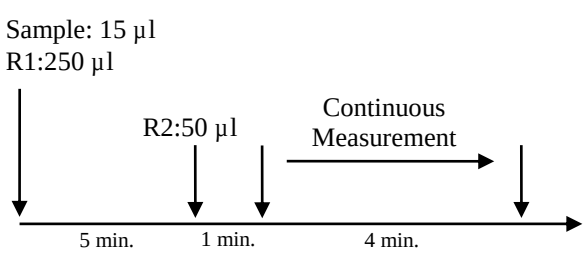
The Serum γ-GT Reagent Kit

Detection of Gamma Glutamyltransferase in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R029K11 ***The Serum γ-GT Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram



*Refer to Figure 1 and the package insert for detail

Table 1: Instrument Parameters*

Calibration method	2-point linear	Slope of reaction	Increase
Testing wavelength	Dλ : 405 nm Sλ : 505 nm	Sample volume	15 µl
Test method	Rate Method	R1 volume	250 µl
Reaction temperature	37℃	R2 volume	50 µl

INTENDED USE

***Bioway Chemistry Reagent Series* γ-GT Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of Gamma Glutamyltransferase in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Gamma Glutamyltransferase can be found in many tissues but especially rich in kidney, pancreas and liver. It is responsible for γ-glutamyl group transfering from a γ-glutamylpeptide to another peptide or an amino acid. Serum γ-GT can be elevated by liver diseases, viral cholestasis, liver metastasis or drug (alcohol, sedatives, anticonvulsants and tranquilizers) ingestion. It is also useful in diagnosing jaundice, cholangitis and cholecystitis.

TEST PRINCIPLES

The Kit utilizes enzymatic and kinetic reactions to measure the γ-GT activity (U/L) in human serum or plasma.

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

$$\xrightarrow{\gamma\text{-GT}}$$

L-γ-Glutamylglycylglycine + 5-amino-2-nitrobenzoate

A glutamyl group on L-γ-Glutamyl-3-carboxy-4-nitroanilide is transferred to glycylglycine by the catalysis of γ-GT and 5-amino-2-nitrobenzoate is formed proportional to the activity of γ-GT.

The process is quantified by measuring the absorbances at 405 nm in a kinetic fashion.

MATERIALS PROVIDED

Reagents:

R1	Tris buffer, pH7.7 Glycylglycine	100 mmol/L 100 mmol/L
R2	L-γ-Glutamyl-3-carboxy-4-nitroanilide Sodium azide	6 mmol/L 1 mmol/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. γ-GT control and calibrator set (commercially available)

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. The reagent is stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Reagents contain sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum preventing hemolysis.

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at 2~8℃ for 14 days.

TEST PROCEDURE (see Figure 1)

Reagent 1 and 2 are liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using commercially available calibrator set for optimal results.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 15 µl of sample and 250 µl of R1; mix well and incubate at 37℃ for 5 minutes.
2. Add 50µl of R2; mix well and incubate at 37℃ for 1 minute.
3. Take continuous optical density measurement for 4 minutes.
4. Calculate average Δ A /min

RESULT

The γ-GT activity in U/L can be obtained by the following calculation:

γ-GT (U/L) = $(\Delta A_{test} / min - \Delta A_{blank} / min) \times$ factor (F)

It is recommended for each laboratory to establish its own F factor. Please refer to instrument application if testing under different conditions.

EXPECTED VALUES

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Male : 11~50U/L (37℃)

Female : 7~32U/L (37℃)

It is recommended for each laboratory to establish its own expected values.

QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with γ-GT exceeding the maximum measurement range should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0 - 300 U/L (R≥0.990)

Accuracy: Bias proportion 90%~110%

Precision: Within Run: CV≤4%;
Run-to-Run: CV≤5%

Interference: no interference detected for: Unconjugated bilirubin (≤684umol/L), bilirubin (≤684umol/L), hemoglobin (≤500mg/dl), lipid (≤2500NTU) and ascorbic acid (≤50mg/dl)

Reagent Blank Absorbance: At 405nm wavelength and 10mmoptical diameter, O.D. ≤ 1.20.

REFERENCES

1. Szasz G. Clin. Chem., 15: 124-136 (1969).
2. Rosalki S. B. *et al.*, Clin. Chem., 20:1121-1124 (1974)
3. Persijn J. P. *et al.*, Clin. Chem. Clin. Biochem., 14:421-427 (1976)

Not Intended for Sale in the United States.

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