



## GGT Reagent Kit (GCANA substrate Method)

### Instructions for Use

REF CC1037

### PRODUCT NAME

GGT Reagent Kit (GCANA substrate Method)

### PACKAGE SPECIFICATION

|                                       |            |             |             |
|---------------------------------------|------------|-------------|-------------|
| R1:1×20 mL                            | R2:1×5 mL  | R1:1×30 mL  | R2:1×8 mL   |
| R1:1×40 mL                            | R2:1×10 mL | R1:1×60 mL  | R2:1×15 mL  |
| R1:2×30mL                             | R2:1×15 mL | R1:2×35 mL  | R2:1×20 mL  |
| R1:2×40 mL                            | R2:1×20 mL | R1:2×60 mL  | R2:2×15 mL  |
| R1:2×60 mL                            | R2:1×30 mL | R1:2×60 mL  | R2:1×35 mL  |
| R1:2×80 mL                            | R2:1×40 mL | R1:2×80 mL  | R2:2×20 mL  |
| R1:4×35 mL                            | R2:2×20 mL | R1:4×40 mL  | R2:2×20 mL  |
| R1:4×50 mL                            | R2:2×25 mL | R1:4×50 mL  | R2:3×20 mL  |
| R1:4×60 mL                            | R2:2×30 mL | R1:4×60 mL  | R2:2×35 mL  |
| R1:4×60 mL                            | R2:4×15 mL | R1:4×100 mL | R2:2×50 mL  |
| R1:4×120 mL                           | R2:2×60 mL | R1:4×653 mL | R2:4×146 mL |
| R1:6×66 mL                            | R2:6×16 mL |             |             |
| 12×60 T(R1: 12×16.8 mL R2: 12×4.2 mL) |            |             |             |

### INTENDED USE

This reagent kit is intended for the *in vitro* quantitative determination of gamma-glutamyl transferase activity in human serum and plasma. Clinically, it is mainly used for the auxiliary diagnosis of diseases related to the hepatobiliary system. For professional and laboratory use only.

### TEST PRINCIPLE

GluCANAs + Gly-Gly  $\xrightarrow{\gamma\text{-GT}}$  Glu-Gly-Gly + 5-Amino-2-nitrobenzoic acid  
The 5-amino-2-nitrobenzoic acid has a maximum absorption at a specific wavelength, and the rate at which it forms is directly proportional to the activity of  $\gamma\text{-GT}$  in sample. Therefore, the activity of  $\gamma\text{-GT}$  in sample can be determined by measuring the rate of increase in absorbance.

### MAIN COMPONENTS

| Kit composition | Reagent components                          | Content  |
|-----------------|---|----------|
| Reagent 1       | Gly-Gly                                     | 11.0 g/L |
| Reagent 2       | $\gamma$ -glutamyl-3-carboxy-4-nitroaniline | 4.0 g/L  |

The components in different batches of a multi-component kit are not interchangeable.

### STORAGE AND SHELF LIFE

The unopened reagents are stable for a shelf life of 18 months when stored away from direct sunlight at 2-8°C. Opened reagents are stable for 42 days when stored at 2-8°C. Refer to the label on the reagent kit for the manufacturing date and the expiry date.

### APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise

(China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc. models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

### SAMPLE REQUIREMENTS

Serum and heparin anticoagulated plasma should be separated as soon as possible after sample collection to avoid hemolysis. Once separated, the sample is stable for 7 days at 15-25°C, for 7 days at 2-8°C and for 1 year at -20°C.

### TEST PROCEDURE

- The dual reagent is ready for use directly.
- Test conditions:

| Primary/Secondary Wavelength | 405 nm/505 nm           | Calibration Type                   | Linearity |
|------------------------------|-------------------------|------------------------------------|-----------|
| Sample/R1/R2                 | 15/240/60 $\mu\text{L}$ | Time of Mixture of Serum and R1    | 3-5 min   |
| Method                       | Rate assay              | Reaction time after addition of R2 | 3 min     |
| Calibration Method           | Two-point calibration   | Direction                          | Upward    |

Operating procedures:  
Operation using two reagents

| Substances Added  | Blank Tube        | Test Tube         |
|---|-------------------|-------------------|
| Reagent 1   | 240 $\mu\text{L}$ | 240 $\mu\text{L}$ |
| Distilled Water   | 15 $\mu\text{L}$  | -                 |
| Sample  | -                 | 15 $\mu\text{L}$  |
| Mix well, incubate at 37°C for 3-5 min  |                   |                   |
| Reagent 2   | 60 $\mu\text{L}$  | 60 $\mu\text{L}$  |
| Mix well, incubate at 37°C for 60 s, continuously monitor the change of the absorbance for 1-3 min, and calculate $\Delta A/\text{min}$ |                   |                   |

- Calibration procedure: A calibrator from Randox is recommended.
- Quality control procedure: Use the quality control product from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
  - Check whether the parameter settings and light source are correct.
  - Check whether the cuvettes and sample probes are clean.
  - Check whether water is contaminated, and bacterial growth will cause incorrect results.
  - Check reaction temperature.
  - Check the expiration date of the kit.

### 5. Result calculation

$$\text{GGT (U/L)} = (\Delta A_{\text{measured}}/\text{min} - \Delta A_{\text{blank}}/\text{min}) \times K \quad (2213)$$

$$K = \frac{\text{Total Reaction Volume (mL)} \times 1000}{\text{Sample Volume (mL)} \times \text{Molar Extinction Coefficient} \times 1.0}$$

Note: 1000 is the conversion factor from U/mL to U/L; 1.0 refers to the optical path of the colorimetric cell. The molar extinction coefficient of 5-amino-2-nitrobenzoic acid at a wavelength of 405 nm is 9.49. The molar extinction coefficient of 5-amino-2-nitrobenzoic acid at a wavelength of 410 nm is 7.96.

### REFERENCE RANGE

|      | Male      | Female   |
|------|-----------|----------|
| 37°C | 11-50 U/L | 7-32 U/L |
| 30°C | 3-38 U/L  | 5-25 U/L |

Results measured at 37°C can be multiplied by the coefficient 0.77 if converted to the results at 30°C.  
The provided reference range is for reference only, and it is recommended that each laboratory establish its own reference range.

## RESULT INTERPRETATION

Hemolysis can interfere with the measurement, and it should be avoided during the operation.  
The storage duration of the sample can also affect the measurement results.

## LIMITATIONS

There is no interference with the measurement when hemoglobin is  $\leq 200$  mg/dL, ascorbic acid is  $\leq 50$  mg/dL, bilirubin is  $\leq 40$  mg/dL, and triglycerides is  $\leq 500$  mg/dL.

## PERFORMANCE CHARACTERISTICS

- Appearance  
Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination.
- Reagent blank  
2.1 Reagent blank absorbance  
Reagent blank absorbance  $A_{405nm} \leq 1.000$ .  
2.2 Rate of change in reagent blank absorbance  
At 37°C, a 405 nm wavelength, and the 1 cm optical path, when physiological saline is used as the sample added to the reagent test, the rate of change in reagent blank absorbance ( $\Delta A/min$ ) should not exceed 0.005.
- Accuracy  
The relative deviation should be within  $\pm 15\%$ .
- Linear range  
When testing serum samples, the linearity is within the range of [5,1200] U/L:  
a) The correlation coefficient ( $r$ ) should not be less than 0.990.  
b) Within the range of [5,30] U/L, the linear deviation should not exceed  $\pm 4$  U/L;  
Within the range of (30,1200] U/L, the linear deviation should not exceed  $\pm 10\%$ .
- Analytical sensitivity  
When testing 50 U/L GGT, the difference in the rate of absorbance change should be  $\leq 0.03$ .
- Precision  
6.1 Repeatability  
The coefficient of variation (CV) should not be greater than 5.0%.  
6.2 Between-run precision  
The relative range between batches should not be greater than 10%.

## PRECAUTIONS

- General precautions  
1.1 This product is for *in vitro* diagnostic use only.  
1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.  
1.3 Please use this product according to the user manual.
- Precautions for operation  
2.1 Treat the specimens as dangerous materials that may cause infection with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.  
2.2 If the reagents get into the eyes or mouth, or touch the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
- Precautions for use  
3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.  
3.2 Please do not use expired reagents whose test results may be inaccurate.  
3.3 Please avoid adding reagents halfway during a test.  
3.4 Please avoid direct sunlight during operation.  
3.5 Avoid using the reagent if it displays any signs of turbidity.
- Precautions for waste disposal  
Samples, waste liquids, etc. are potentially biologically hazardous. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
- Other precautions  
5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of
















- a sample to the amount of a reagent and the time of measurement.
- 5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
- 5.3 Please do not use the reagent bottles for other purposes.
- 5.4 Phenobarbital, phenytoin, pentobarbital, dichloroantipyrine, antipyrine, etc., may increase GGT levels. Heavy alcohol consumption can also lead to increased GGT levels.
- 5.5 A result calculated with the  $k$  value is not as reliable as that obtained using the calibration result.
- 5.6 Please do not mix reagents in different batches.

## REFERENCE


Shang Hong, et al. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 286-287.

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on GGT Reagent Kit (GCANA substrate Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

| Key to symbols used   |   |   |  |   |                           |
|---|---|---|--|---|---------------------------|
|  | Manufacturer  |  | Use-by date  |  | Catalogue number          |
|  | Date of manufacture   |  | Batch code   |  | Temperature limit         |
|  | <i>In vitro</i> diagnostic medical device   |  | Keep away from sunlight  |  | Biological risks          |
|  | Consult <i>instructions for use</i> or consult electronic <i>instructions for use</i> |  | Do not use if package is damaged and consult <i>instructions for use</i> |  | Authorized representative |
|  | CE mark   |  | This way up  |  | Do not re-use             |

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