PDM签审页

PDM版本：

PDM编码：

产品名称	出口_生化试剂_γ-谷氨酰转移酶试剂盒 GGT_说明书_英文		
库存编码	1017097	版本号	18.11.26
成品尺寸	210×297mm	单位	mm
印刷色	单色	允差	±2mm
材质	胶版纸		
备注			
设计			
审核			
批准			

DIRUI®

GGT

γ- GLUTAMYL TRANSFERASE REAGENT KIT（IFCC METHOD）

◆Product Name

γ-GLUTAMYL TRANSFERASE REAGENT KIT（IFCC METHOD）

◆Intended Use

This reagent is applied to the invitro quantitative measurement of the activity of γ-GT in human serum or plasma.
γ-GT exists in different human tissues. Serum γ-GT is mainly from liver and gall system. Therefore liver disease or damage may lead to the rise of γ-GT, which is often used in the diagnosis of obstructive jaundice, cholangitis, and cholecystitis etc. in clinical practices. Some drugs, such as alcohol, ataractic, anti- epilepsy etc., also can lead to the rise of γ-GT level.

◆Principle

The principle is based on the method recommended by IFCC. Catalyzed by GGT, L-γ- Glutamyl -3-carboxy-4-nitroaniline reacts with glycylglycine, generating 5 - amino-2 - nitrophenyl formate, leading to the rising of absorbancy at 405nm. The produced speed of 5 - amino -2 - nitrophenyl formate is in direct proportion to the activity of γ-GT of sample, which can be calculated by detecting the absorbency kinetics at 405nm.

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

↓ γ-GT

L-γ-Glutamylglycylglycine + 5 - amino -2 - nitrophenyl formate

◆Reagent Composition

Reagent 1	
Tris Buffer	100mmol/L
Sodium Chloride	5mmol/L
Glycylglycine	125mmol/L
Reagent 2	
Tris Buffer	100mmol/L
L-γ- Glutamyl -3-carboxy-4-nitroaniline	14.5mmol/L

Note: Ingredient in different lot kits cannot be exchanged.

◆Storage Conditions and Shelf Life

1. The reagent should be kept at temperature of 2℃~8℃ and sealed in dry place without sunshine. The shelf life is 12 months.
2. Under condition of 2℃~8℃, the open vial stability is 30 days.

◆Suitable Device

All semi-auto and auto-chemistry analyzers are suitable. All kinds of parameters of auto-chemistry analyzers are prepared for reference.

◆Sample Requirements

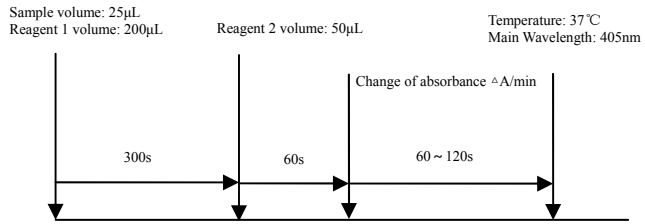
1. Sample should be serum or plasma.
2. Plasma sample should not be hemolyzed or polluted, and should adopt heparin or EDTA anticoagulant.
3. Sample can be stable for 7 days at 2~8℃. At room temperature, it can be saved for only 1 day.

◆Procedure

1. Reagent Preparation: Both reagent 1 and reagent 2 are liquid reagents and can be used directly.
2. Test conditions

Test mode	Rate assay	Reagent 1 volume	200 μL
Main Wavelength	405 ~420 nm	Reagent 2 volume	50 μL
Temperature	37℃	Sample volume	25 μL
Optical path	1.0 cm	Test time	60~120 s
Absorbance range	0~2A	Delay time	60 s

3. Testing procedure



4. Calibration

It is suggested to use supplementary calibrator as instructed. When lot number is changed or QC is invalid, calibration shall be conducted again.

5. QC

It is suggested to use QC products produced by Dirui. The laboratory shall establish its own QC area and limit. If QC value is out of control, correction measures shall be taken.

6. Calculation

$$\text{Sample Concentration(U/L)} = \frac{\text{Sample Tube } \triangle\text{A/min}}{\text{Calibration Tube } \triangle\text{A/min}} \times \text{Calibrator Concentration(U/L)}$$

◆Reference Range

At 37℃
Male: ≤50U/L（0.83μkat/L）
Female: ≤30U/L（0.50μkat/L）
The reference range applied is the expected value for this method, which is for reference only. It is recommended for all laboratories to do relevant tests to validate such range or establish their own reference range.

◆Explanation of Results

1. Sample should be diluted by 0.9% physiological saline or reduce the sample volume if its ΔA/min＞0.39A, and multiply diluting times or adjust the factor to calculate the result.
2. γ-GT activity determination is only one of the indicators of clinical diagnosis for patients, and clinicians also conduct a comprehensive diagnosis including body, history diagnosis, as well as other items and diagnostic methods.

◆Limit

1. The accuracy of results relies on the control of calibration, testing temperature and time.
2. When jaundice is ＞1368μmol/L, hemoglobin is ＞0.5 g/L, triglyceride is ＞43mmol/L, ascorbic acid is ＞5.7mmol/L, the test result will be affected.

◆Specifications

1. Linearity: up to 450U/L
2. Blank absorbance: A≤0.800
Blank absorbance change rate: |△A|/5min≤0.010
3. Limit of detection: test normal saline 20 times repeatedly, and the minimum test limit is determined as 0.31U/L by average +2 times SD.
4. Precision: test two samples with different concentration on the same test system within 20 work days.

QC serum	Precision of the same lot number n=20			Precision between days n=20		
	$\overline{X}$ (U/L)	SD	CV%	$\overline{X}$ (U/L)	SD	CV%
Sample 1	49.0	0	0.0%	48.4	1.14	2.35%
Sample 2	151.3	1.07	0.71%	149.5	2.61	1.74%

5. Method comparison: after 200 samples are clinical tested and compared with approved market reagent (x), the relevance between our reagent (y) and approved market reagent (x) is: y=0.9037x+2.1951，r=0.975.

◆Standardization Traceability

The constant value of calibrator can be traced to the international reference ERM-AD452.

◆Matters Need Attention

1. Cautions for Operation

1.1 The product is only for in vitro diagnosis.

1.2 Do not add additive during the test. Avoid direct sunlight in the process of operation.

1.3 Volume of reagent and sample can be changed proportionally in accordance with the requirements of instrument.

1.4 The delay period of most sample can not be observed.

1.5 The reagent cannot be used if it is turbid or water blank absorbance value at 405 nm is less than 0.800A.

1.6 Unit Conversion: $U/L \times 16.67 \times 10^{-3} = \mu kat/L$.

2. Cautions for safety

2.1 Consider the product as dangerous materials that may cause HIV, HBV, HCV and other infections. To avoid the risk, use disposable single-use gloves.

2.2 Avoid contact with skin, clothes, and eyes. Once in contact with skin or clothes, rinse the contact part with plenty of water, and go to see a doctor.

2.3 The samples and waste liquid have potential infectious risk, and the user should manage them according to the laboratory safety operation rule, local laws and regulations.

◆Reference

1. Bergmeyer:Methods of Enzymatic Analysis,Third Edition,Vol Ⅲ: 357~364.

2. Young DS. Effects of Drugs on Clinical Laboratory Tests. Third Edition. 1990; 3:183~185.

3. NCCLS . Interference Testing in Clinical Chemistry;Approved Guideline, 2005.

◆Date of Approval and Revision: 11/2018

◆Packaging Specification

No.	Specifications		Type
232010602006	R1:4×50mL	R2:1×50mL	Dirui CS-400/600/800/1200/1300/1600/6400 Package
232010602001	R1:4×80mL	R2:4×20mL	Dirui CS-240/300 Package
232010602010	R1:2×60mL	R2:2×15mL	Dirui CS-T Series Package
232010602011	R1:4×40mL	R2:4×10mL	Dirui CS-T Series Package
232010602015	R1:4×150mL	R2:1×150mL	Dirui CS-1600/6400 Package

◆P.S.：CS Series Auto-Chemistry analyzer parameters

Model	CS-240	CS-300	CS-400	CS-600	CS-1200	T240	T300	CS-6400	CS-1600	CS-1300
Item	GGT	GGT	GGT	GGT	GGT	GGT	GGT	GGT	GGT	GGT
Unit	U/L	U/L	U/L	U/L	U/L	U/L	U/L	U/L	U/L	U/L
Method	Rate A	Rate A	Rate A	Rate A	Rate A	Rate A	Rate A	Rate A	Rate A	Rate A
Time	20	20	10	10	10	13	10	9	12	9
Photometric point	19~26	19~26	21~31	23~38	21~31	28~37	28~40	19~27	16~22	21~32
Main wavelength	405	405	405	405	405	405	405	405	405	405
Sub wavelength	505	505	505	505	505	505	505	505	505	505
Reagent R1/T1	200	200	200	200	200	200	200	200	200	200
R2/T2	50	50	0	50	0	50	50	50	50	0
R3/T3	——	——	50	——	50	——	——	——	——	50
R4/T4	——	——	0	——	0	——	——	——	——	0
Normal volume of serum sample	25	25	25	25	25	25	25	25	25	25
Absorbance limit	3	3	3	3	3	3	3	3	3	3
Reaction type	Positive reaction	Positive reaction	Positive reaction	Positive reaction	Positive reaction	Positive reaction	Positive reaction	Positive reaction	Positive reaction	Positive reaction
Prozone check	-3.3 lower limit	-3.3 lower limit	-3.3 lower limit	-3.3 lower limit	-3.3 lower limit	-3.3 lower limit	-3.3 lower limit	-3.3 lower limit	-3.3 lower limit	-3.3 lower limit
Calibration method	2-point linearity	2-point linearity	2-point linearity	2-point linearity	2-point linearity	2-point linearity	2-point linearity	2-point linearity	2-point linearity	2-point linearity
Deflection check	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3
Discreteness check	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sensitivity check	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005
Blank horizontal check	-3.3~3.3	-3.3~3.3	-3.3~3.3	-3.3~3.3	-3.3~3.3	-3.3~3.3	-3.3~3.3	-3.3~3.3	-3.3~3.3	-3.3~3.3
Linearity range	0.3~450	0.3~450	0.3~450	0.3~450	0.3~450	0.3~450	0.3~450	0.3~450	0.3~450	0.3~450

Notes on symbols and marks

LOT	Batch code		Expiry date	REF	Catalogue Number
	Manufactured by	IVD	In Vitro Diagnostic Use	EC REP	Authorised Representative
	Please read package insert		Store at	CE	European In Vitro Diagnostic Medical Device Directive 98/79/EC(IVDD)

DIRUI®

DIRUI Industrial Co.,Ltd.
95 Yunhe Street, New & High Tech. Development Zone
Changchun, Jilin 130012 P.R. China
Tel :+86(431)85100409
Fax:+86(431)85172581

E-mail:dirui@dirui.com.cn
Http://www.dirui.com.cn

CE EC REP
IVD **EMERGO EUROPE** Prinsessegracht 20
2514 AP The Hague The Netherlands