產品型號: BC-0018
V2.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑 γ -麩胺醯轉移酶試劑(GGT)-colorimetric test

效能：

用於臨床實驗體外定量分析人體血清或血漿中 γ-麩胺醯轉移酶的活性。

臨床意義：

γ-麩胺醯轉移酶(GGT)組織分布以腎臟最多，對酒精性中毒的判定具有相當的價值。血清 γ-麩胺醯轉移酶檢測對肝膽疾病，如膽道阻塞、原發性膽汁性肝硬化、慢性肝炎、肝的惡性腫瘤、腎功能衰竭等病症的診斷具有重要的價值。

方法學原理：

$$\text{L-γ-glutamyl-p-nitroanilide + glycylglycine} \xrightarrow{\text{GGT}} \text{γ-glutamyl glycylglycine + p-nitroaniline}$$

試劑：

1. 產品規格:
   詳見外盒包裝標示。
2. 成份與濃度：

	成份	濃度
R_1:	Tris buffer	110 mmol/L
	Glycylglycine	100 mmol/L
R_2:	L-γ-glutamyl-p-nitroanilide	25 mmol/L

保存溫度：

2-8℃避光保存，請勿冰凍。

檢體：

新鮮血清或加 EDTA 抗凝的血漿。

操作步驟：

1. 測定主波長：405 nm　　測定副波長：660nm
   溫度：37℃　　比色杯光徑：1.0 cm
2. 本試劑盒爲液態雙試劑，可直接上機使用。

加入物	空白	標準	檢體
R_1 ml	0.8	0.8	0.8
去離子水 ml	0.05	---	---
標準液 ml	---	0.05	---
檢體 ml	---	---	0.05
R_2 ml	0.2	0.2	0.2

分別混勻，37℃保溫 5 分鐘，以去離子水調"零"點，分別在 405nm 及 660nm 處檢測各管吸光值 A，$A=A_{405}-A_{660}$。

結果計算

$$GGT\ (U/L) = \frac{(A_2 - A_1) \times Vt \times 1000}{Lp \times \varepsilon \times Vs}$$

$$= (A_2 - A_1) / \min \times 2210$$

Vt: 反應總體積 1.05ml, Vs: 檢體體積 0.05ml
ε: 對硝基苯胺的毫摩爾吸光係數 9.5
1000: 將 U/ml 轉換完成 U/L, Lp:光徑（1.0cm）

參考值：

男 11-50 U/L
女 7-32 U/L

注意事項：

1. **本試劑請用專用標準品(calibrator)，不另外提供質控血清(control)，建議質控血清爲 Bio-Rad Lyphochek control。**
2. **建議各實驗室建立獨立之品管系統，並定義專屬之參考值範圍。**
3. **本檢驗試劑限由醫師或醫檢師臨床使用。**
4. **當檢體的 γ-麩胺醯轉移酶活性大於 800 U/L 時，應將檢體用生理食鹽水稀釋後再分析，結果乘以稀釋倍數。**
5. **爲保證結果的準確性，必須在檢體加入後 30 分鐘內檢測吸光值，且檢體若有溶血或乳糜血的現象，會干擾此試劑的測定。**
6. **若試劑變混濁或空白吸光值大於 1.0，勿用。**
7. **以上操作步驟適用於手工操作及一般半自動及全自動生化分析儀。**
8. **本品操作時需穿戴手套及必要之防護措施，若不慎沾上，應用水或肥皂水清洗。(詳細溶液物化性請洽詢經銷商索取物質安全資料表)**
9. **用畢應按醫療事業廢棄物處理。(詳細溶液物化性請洽詢經銷商索取物質安全資料表)**
10. **有效期限見試劑盒上標籤所示。**
11. **經專業人員建議，試劑與檢體用量可根據所用分析儀的要求按比例調整，其吸光值不變，不影響監測結果。**
12. **試劑特性及參數設定請參見第四頁。**

台塑生醫科技股份有限公司
台北市敦化北路 201 號前棟五樓
TEL：+886-2-2712-2211 #7822
製造廠：台塑生醫宜蘭廠
Website: http://www. fbc.com.tw/
FAX：+886-2-2717-8381
廠址：宜蘭縣礁溪鄉龍潭村龍泉路 3 號

产品型号: BC-0018
V2.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑 γ -麸胺酰转移酶试剂(GGT)-colorimetric test

效能：

用于临床实验体外定量分析人体血清或血浆中 γ-麸胺酰转移酶的活性。

临床意义：

γ-麸胺酰转移酶(GGT)组织分布以肾脏最多，对酒精性中毒的判定具有相当的价值。血清 γ-麸胺酰转移酶检测对肝胆疾病，如胆道阻塞、原发性胆汁性肝硬化、慢性肝炎、肝的恶性肿瘤、肾功能衰竭等病症的诊断具有重要的价值。

方法学原理：

$$\text{L-γ-glutamyl-p-nitroanilide + glycylglycine} \xrightarrow{\text{GGT}} \text{γ-glutamyl glycylglycine + p-nitroaniline}$$

试剂：

1. 产品规格:
   详见外盒包装标示。
2. 成份与浓度：

	成份	浓度
R_1:	Tris buffer	110 mmol/L
	Glycylglycine	100 mmol/L
R_2:	L-γ-glutamyl-p-nitroanilide	25 mmol/L

保存温度：

2-8℃避光保存，请勿冰冻。

检体：

新鲜血清或加 EDTA 抗凝的血浆。

操作步骤：

1. 测定主波长：405 nm　　测定副波长：660nm
   温度：37℃　　比色杯光径：1.0 cm
2. 本试剂盒为液态双试剂，可直接上机使用。

加入物	空白	标准	检体
R_1 ml	0.8	0.8	0.8
去离子水 ml	0.05	---	---
标准液 ml	---	0.05	---
检体 ml	---	---	0.05
R_2 ml	0.2	0.2	0.2

分别混匀，37℃保温 5 分钟，以去离子水调"零"点，分别在 405nm 及 660nm 处检测各管吸光值 A，$A=A_{405}-A_{660}$。

结果计算

$$GGT\ (U/L) = \frac{(A_2 - A_1) \times Vt \times 1000}{Lp \times \varepsilon \times Vs}$$

$$= (A_2 - A_1) / \min \times 2210$$

Vt: 反应总体积 1.05ml, Vs: 检体体积 0.05ml
ε: 对硝基苯胺的毫摩尔吸光系数 9.5
1000: 将 U/ml 转换完成 U/L, Lp:光径（1.0cm）

参考值：

男 11-50 U/L
女 7-32 U/L

注意事项：

1. **本试剂请用专用标准品(calibrator)，不另外提供质控血清(control)，建议质控血清为 Bio-Rad Lyphochek control。**
2. **建议各实验室建立独立之品管系统，并定义专属之参考值范围。**
3. **本检验试剂限由医师或医检师临床使用。**
4. **当检体的 γ-麸胺酰转移酶活性大于 800 U/L 时，应将检体用生理食盐水稀释后再分析，结果乘以稀释倍数。**
5. **为保证结果的准确性，必须在检体加入后 30 分钟内检测吸光值，且检体若有溶血或乳糜血的现象，会干扰此试剂的测定。**
6. **若试剂变混浊或空白吸光值大于 1.0，勿用。**
7. **以上操作步骤适用于手工操作及一般半自动及全自动生化分析仪。**
8. **本品操作时需穿戴手套及必要之防护措施，若不慎沾上，应用水或肥皂水清洗。(详细溶液物化性请洽询经销商索取物质安全数据表)**
9. **用毕应按医疗事业废弃物处理。(详细溶液物化性请洽询经销商索取物质安全数据表)**
10. **有效期限见试剂盒上标签所示。**
11. **经专业人员建议，试剂与检体用量可根据所用分析仪的要求按比例调整，其吸光值不变，不影响监测结果。**
12. **试剂特性及参数设定请参见第四页。**

台塑生医科技股份有限公司
台北市敦化北路 201 号前栋五楼
TEL：+886-2-2712-2211 #7822
制造厂：台塑生医宜兰厂
Website: http://www. fbc.com.tw/
FAX：+886-2-2717-8381
厂址：宜兰县礁溪乡龙潭村龙泉路 3 号

IVD For *In Vitro* Diagnostic

MeDiPro γ-GLUTAMYL TRANSFERASE TEST (GGT) - colorimetric test

INTENDED USE

For the quantitative determination of γ-glutamyl transferase activity in serum or plasma.

CLINICAL SIGNIFICANCE

γ-glutamyl transferase (GGT) is a membrane-localized enzymes that catalyzes the transfer of a γ-glutamyl group from a γ-glutamylpeptide to another peptide or amino acid. Kidney, pancreas and liver are rich in γ-GT. Serum γ-GT is generally elevated as a result of liver disease. Cholestasis caused by alcohol or drug ingestion, mechanical or viral cholestasis, liver metastases will increase the activity of γ-GT. In bone disorders which alkaline phosphatase is elevated but γ-GT is normal; and in skeletal muscle disorder which the AST is elevated but γ-GT is normal.

PRINCIPLE

L-γ-glutamyl-p-nitroanilide + glycylglycine $\xrightarrow{\gamma\text{-GT}}$ γ-glutamyl glycylglycine + p-nitroaniline

REAGENT

1. Package: please see the reagent box label shown.
2. Components:

	Component	Conc.
R_1:	Tris buffer	110 mmol/L
	glycylglycine	100 mmol/L
R_2:	L-γ-glutamyl-p-nitroanilide	25 mmol/L

STORE TEMPERATURE

The standard is stable up to the end of the indicated expiration date. If stored at **2 – 8 °C**., reagent should be protected from light and contamination should be avoided. **Do not freeze the reagent!**

SPECIMEN COLLECTION AND PREPARATION

Serum or lithium heparized plasma is the choice. EDTA and citrate do not interfere with analysis. Serum GGT values are stable at room temperature or 4℃ for at least 7 days and are stable for at least 2 months when frozen.

PROCEDURES

1. Main wavelength：405nm
   Sub. wavelength：660nm
   Reaction Temperature：37℃
   Optical path length：1.0 cm
2. This kit contains two reagents, ready to use.

	Blank	Control	Specimen
R_1 (ml)	0.8	0.8	0.8
ddH_2O (ml)	0.05	---	---
control (ml)	---	0.05	---
Specimen(ml)	---	---	0.05
R2(ml)	0.2	0.2	0.2

Mix, incubate at 37℃ for 5 min, and read the absorbance against reagent blank. $A = A_{405} - A_{660}$

CALCULATION

$$GGT\ (U/L) = \frac{(A_2 - A_1)/min \times Vt \times 1000}{Lp \times \varepsilon \times Vs} = (A_2 - A_1)/min \times 2210$$

Vt: Reaction total volume 1.05 ml, Vs: sample volume 0.05 ml
ε: p-nitroaniline molar absorptivity 9.5,
1000: transfer U/ml to U/L, Lp: Optical path length（cm）

REFERENCE RANGE

Sex	Conc.（U/L）
Male	11-50 U/L
Female	7-32 U/L

WARNINGS AND PRECAUTIONS

1. **This kit offers an optional calibrator, which is sold individually. Bio-Rad Lyphochek control is recommended to use as serum control.**
2. **Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.**
3. **This kit is for professionals and *in vitro* diagnostic use only.**
4. **To ensure the accuracy of result, the absorbance should be measured within 30 minutes after sample addition. Hemolysis and lipemia might interfere with the test result.**
5. **The test is developed to determine γ-glutamyl transferase concentrations up to 800U/L. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.**
6. **Do not use if reagent turbid or blank OD higher than 1.0.**
7. **The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.**
8. **Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.**
9. **Waste management please refers to the local legal requirements.**
10. **Please refer to the manufacturer's safety data sheet and the product labeling for information on potentially hazardous components. (MSDS could be obtained from local dealer.)**
11. **According to the technical suggestion, the volume of reagent and specimen could be adjusted in a ratio for full-automatic biochemical analysis instrument use. It won't affect the absorbance and the result.**
12. **Validity please see the reagent box label shown.**

FORMOSA BIOMEDICAL TECHNOLOGY CORP.
F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: http://www. fbc.com.tw/
TEL: +886-2-2712-2211 #7822 FAX: +886-2-2717-8381
Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan

Product number: BC-0018
V2.0

IVD For *In Vitro* Diagnostic

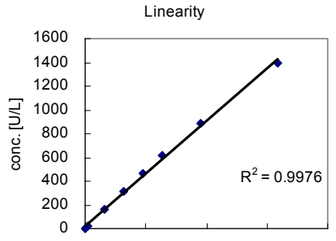
MeDiPro γ-GLUTAMYL TRANSFERASE TEST (GGT) - colorimetric test

REAGENT CHARACTERS

1. Precision (Within run)

N=15	Mean[U/L]	SD [U/L]	CV[%]
Sample1	35	0.85	2.46
Sample2	191	0.82	0.43
Sample3	197	0.84	0.43

2. Linearity



This kit has a good linearity up to 1200U/L.

3. Interference

Interference	Influence effect
Hemoglobulin	No interference was observed by hemoglobulin up to 150mg/dL
Ascorbic acid	No interference was observed by ascorbic acid up to 50mg/dL
Bilirubin (free form)	No interference was observed by bilirubin up to 40mg/dL
Bilirubin (conjugate form)	No interference was observed by bilirubin up to 40mg/dL
Intrafat	No interference was observed by intrafat up to 0.4%

4. Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

1. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37℃, Part 6. Clin. Chem. Lab. Med. 2002, 40: 631.
2. New IFCC reference procedures for the determination of catalytic activity concentrations of five enzymes in serum: preliminary upper reference limits obtained in hospitalized subjects. Clinica Chimica. Acta. 2003, 327: 69.

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[GGT]
ASSAY CODE	[Rate A]: [19]-[34]
SAMPLE VOLUME	[10]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH (nm)	[660][405]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[GGT]
ASSAY CODE	[Rate A]: [30]-[50]
SAMPLE VOLUME	[15]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH(nm)	[660][405]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0018M	MeDiPro γ-GLUTAMYL TRANSFERASE TEST	R1 6×20ml R2 3×10ml
BC-0018A	MeDiPro γ-GLUTAMYL TRANSFERASE TEST	R1 4×60ml R2 2×30ml
BC-0018B	MeDiPro γ-GLUTAMYL TRANSFERASE TEST	R1 4×100ml R2 2×50ml
BC-0018C	MeDiPro γ-GLUTAMYL TRANSFERASE TEST	R1 2×300ml
BC-0018D	MeDiPro γ-GLUTAMYL TRANSFERASE TEST	R1 2×500ml
BC-0018G	MeDiPro γ-GLUTAMYL TRANSFERASE TEST	R2 2×200ml

FORMOSA BIOMEDICAL TECHNOLOGY CORP.
F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: http://www. fbc.com.tw/
TEL: +886-2-2712-2211 #7822 FAX: +886-2-2717-8381
Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan