產品型號: BC-0027
V2.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑三酸甘油脂試劑（TG）- Enzymatic method

效能：
用於臨床實驗體外定量分析人體血清或血漿中三酸甘油脂的含量。

臨床意義：
高三酸甘油脂血症有原發的和繼發的兩類。原發的有遺傳因素，如家族性高三酸甘油脂血症與家族性混合型高三酸甘油脂血症等。繼發的見於糖尿病、甲狀腺機能不足，腎病綜合症、肥胖症等病症。三酸甘油脂降低見於吸收不良綜合症、甲狀腺亢進、重症肝損害等病症。

方法學原理：

$$\text{Triglyceride} + 3H_2O \xrightarrow{\text{Lipase}} \text{glycerol} + 3\ \text{fatty acid}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{GK}} \text{glycerol–3-phosphate} + \text{ADP}$$

$$\text{Glycerol–3-phosphate} + O_2 \xrightarrow{\text{GPOD}} \text{dihydroxyacetone phosphate} + H_2O_2$$

$$H_2O_2 + \text{4-AA} + \text{4-chlorophenol} \xrightarrow{\text{peroxidase}} \text{quinoneimine} + H_2O(\text{ red })$$

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
Buffer (pH6.5±0.25)	30 mmol/L
ATP	3 mmol/L
4-chlorophenol	0.8 mmol/L
NaOH	20 mmol/L
GK	400 U/L
4-AA	0.6 mmol/L
GPOD	7000 U/L
Peroxidase	1500 U/L
Lipase	200000 U/L

保存溫度：
2-8℃避光保存，請勿冰凍。

檢體：
空腹 12 小時後採血，儘快分離血清，避免溶血。血清、肝素或 EDTA 抗凝血漿可用。

操作步驟：
1. 測定主波長：505 nm　　測定副波長：660nm
   溫度：37℃　　比色杯光徑：1.0 cm
2. 本試劑盒爲液態單試劑，可直接上機使用。

加入物（ml）	空白管	標準管	檢體管
檢體	——	——	0.01
標準液	——	0.01	——
去離子水	0.01	——	——
試劑	1.0	1.0	1.0

各管立即搖勻後，於 37℃中放置 10 分鐘，在 505nm 處，以空白管調"零"點，分別檢測各管的吸光值。

結果計算
三酸甘油脂（mg/dL）

$$= \frac{A_{\text{檢體}}}{A_{\text{標準}}} \times \text{三酸甘油脂標準液濃度（mg/dL）}$$

參考值：
36-165 mg/dL (0.41-1.86 mmol/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. **本試劑線性可達 1800 mg/dL，當檢體的三酸甘油脂濃度大於 1800 mg/dL 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。檢體若有黃疸或乳糜血的現象，會干擾此試劑的測定。**

6. **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。**

7． **本品操作時請穿戴手套及必要之防護措施，操作中若不慎沾上，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)**

8． **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)**

9. **有效期限見試劑盒上標籤所示。**

10． **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。**

11． **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-0027
V2.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑三酸甘油脂试剂（TG）- Enzymatic method

效能：
用于临床实验体外定量分析人体血清或血浆中三酸甘油脂的含量。

临床意义：
高三酸甘油脂血症有原发的和继发的两类。原发的有遗传因素，如家族性高三酸甘油脂血症与家族性混合型高三酸甘油脂血症等。继发的见于糖尿病、甲状腺机能不足，肾病综合症、肥胖症等病症。三酸甘油脂降低见于吸收不良综合症、甲状腺亢进、重症肝损害等病症。

方法学原理：

$$\text{Triglyceride} + 3H_2O \xrightarrow{\text{Lipase}} \text{glycerol} + 3\ \text{fatty acid}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{GK}} \text{glycerol–3-phosphate} + \text{ADP}$$

$$\text{Glycerol–3-phosphate} + O_2 \xrightarrow{\text{GPOD}} \text{dihydroxyacetone phosphate} + H_2O_2$$

$$H_2O_2 + \text{4-AA} + \text{4-chlorophenol} \xrightarrow{\text{peroxidase}} \text{quinoneimine} + H_2O(\text{ red })$$

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
Buffer (pH6.5±0.25)	30 mmol/L
ATP	3 mmol/L
4-chlorophenol	0.8 mmol/L
NaOH	20 mmol/L
GK	400 U/L
4-AA	0.6 mmol/L
GPOD	7000 U/L
Peroxidase	1500 U/L
Lipase	200000 U/L

保存温度：
2-8℃避光保存，请勿冰冻。

检体：
空腹 12 小时后采血，尽快分离血清，避免溶血。血清、肝素或 EDTA 抗凝血浆可用。

操作步骤：
1. 测定主波长：505 nm　　测定副波长：660nm
   温度：37℃　　比色杯光径：1.0 cm
2. 本试剂盒为液态单试剂，可直接上机使用。

加入物（ml）	空白管	标准管	检体管
检体	——	——	0.01
标准液	——	0.01	——
去离子水	0.01	——	——
试剂	1.0	1.0	1.0

各管立即摇匀后，于 37℃中放置 10 分钟，在 505nm 处，以空白管调"零"点，分别检测各管的吸光值。

结果计算
三酸甘油脂（mg/dL）

$$= \frac{A_{\text{检体}}}{A_{\text{标准}}} \times \text{三酸甘油脂标准液浓度（mg/dL）}$$

参考值：
36-165 mg/dL (0.41-1.86 mmol/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． **本试剂线性可达 1800 mg/dL，当检体的三酸甘油脂浓度大于 1800 mg/dL 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。检体若有黄疸或乳糜血的现象，会干扰此试剂的测定。**

6． **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。**

7． **本品操作时请穿戴手套及必要之防护措施，操作中若不慎沾上，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)**

8． **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)**

9． **有效期限见试剂盒上标签所示。**

10． **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。**

11． **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 TRIGLYCERIDE TEST (TG) - Enzymatic method

INTENDED USE

For the quantitative determination of triglycerides in serum or plasma.

CLINICAL SIGNIFICANCE

Triglycerides (TG) circulate in blood associated with proteins in the form of lipoproteins. Elevated level of triglycerides in plasma was reported as a possible indicator of atherosclerosis. Diseases such as nephrotic syndrome, glycogen storage disease, biliary cirrhosis and others resulting from derangements in lipid metabolism also show increased triglyceride levels in serum.

PRINCIPLE

Lipase
Triglyceride + $3H_2O$ ⟶ glycerol + 3 fatty acid

GK
Glycerol + ATP ⟶ glycerol–3-phosphate + ADP

GPOD
Glycerol–3-phosphate + O_2 ⟶ dihydroxyacetone phosphate + H_2O_2

peroxidase
H_2O_2 + 4-AA + 4-chlorophenol ⟶ quinoneimine +H_2O (Red)

REAGENT

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

Component	Conc.
Buffer pH6.5±0.25	30 mmol/L
ATP	3 mmol/L
4-chlorophenol	0.8 mmol/L
NaOH	20 mmol/L
Glycerol kinase	400 U/L
4-AA	0.6 mmol/L
GPOD	7000 U/L
Peroxidase	1500 U/L
Lipase	200000 U/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

Fresh serum and plasma are the choices. Blood specimen should be drawn after the patient has fasted for at least 12 hours. All tubes and collection materials should be free of glycerol. Prolonged storage of samples at room temperature should be avoided in order to minimize possible degradation of triglyceride by endogenous lipase or by lipase secreted from contaminated bacteria.

PROCEDURES

1. Main wavelength：505 nm
   Sub. wavelength：660nm
   Reaction Temperature：37℃
   Optical path length：1.0 cm
2. This kit contains single reagent, ready to use.

	Blank	Control	Specimen
Specimen (ml)	——	——	0.01
Control (ml)	——	0.01	——
ddH_2O (ml)	0.01	——	——
R1 (ml)	1.0	1.0	1.0

Mix, incubate at 37℃ for 10 min, and read the absorbance against reagent blank. $A = A_{505}-A_{660}$

CALCULATION

With standard or calibrator

$$TG(mg/dL) = \frac{A_{sample}}{A_{std./cali.}} \times \text{conc. Std./cali.（mg/dL）}$$

REFERENCE RANGE

36-165 mg/dL (0.41-1.86 mmol/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. Bilirubin and lipemia might be interfere the result.**
5. **The test is developed to determine triglycerides concentrations up to 1800U/L. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.**
6. **The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.**
7. **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.**
8. **Waste management please refers to the local legal requirements.**

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-0027
V2.0

IVD For *In Vitro* Diagnostic

MeDiPro TRIGLYCERIDE TEST (TG) - Enzymatic method

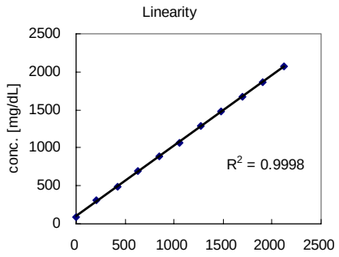
9. **Please refer to the manufacturer's safety data sheet and the product labeling for information on potentially hazardous components. (MSDS could be obtained from local dealer.)**
10. **According to the technical suggestion, the volume of reagent and specimen could be adjusted in a ratio for full-automatic biochemical analysis instrument use. It won't affect the absorbance and the result.**
11. **Validity please see the reagent box label shown.**

REAGENT CHARACTERS

1. Precision (Within run)

N=15	Mean[mg/dL]	SD [mg/dL]	CV[%]
Sample1	201	1.62	0.80
Sample2	87	1.19	1.36
Sample3	94	1.01	1.08

2. Linearity



This kit has a good linearity up to 2000mg/dL.

3. Interference

Interference	Influence effect
Hemoglobulin	No interference was observed by hemoglobulin up to 50mg/dL
Ascorbic acid	No interference was observed by ascorbic acid up to 40mg/dL
Bilirubin (free form)	Not suitable when jaundice occur
Bilirubin (conjugate form)	Not suitable when jaundice occur

4. Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

1. Klotzsch SG, McNamara JR. Triglyceride measurements: a review of methods and interferences. Clin. Chem. 1990. 36: 1605.
2. McGowan M, Artiss J, Strandbergh DR, et al. A peroxidase-coupled method for the colorimetric determination of serum triglyceride. Clin. Chem. 1983. 29: 538

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[TG]
ASSAY CODE	[1 POINT]: [34]-[0]
SAMPLE VOLUME	[2]
R1 VOLUME	[200]
R2 VOLUME	[0]
WAVELENGTH (nm)	[660][505]
CALIB. METHOD	[Linear]

Hitachi 7150 / 717 Applications

TEST	[TG]
ASSAY CODE	[1 POINT]: [50]-[0]
SAMPLE VOLUME	[3]
R1 VOLUME	[300]
R2 VOLUME	[0]
WAVELENGTH (nm)	[660][505]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0027M	MeDiPro TRIGLYCERIDE TEST	R1 6×20ml
BC-0027A	MeDiPro TRIGLYCERIDE TEST	R1 4×60ml
BC-0027B	MeDiPro TRIGLYCERIDE TEST	R1 4×100ml
BC-0027C	MeDiPro TRIGLYCERIDE TEST	R1 4×300ml
BC-0027D	MeDiPro TRIGLYCERIDE TEST	R1 4×500ml

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F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: http://www. fbc.com.tw/
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