TRIGLYCERIDES
Multi-Purpose (MPR) Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL801T	10 x 18 ml	TRIGLYCERIDES	2 - 8°C
	1 x 10 ml	TRIGLYCERIDES -Standard	
GL821T	4 x 250 ml	TRIGLYCERIDES	2 - 8°C
	1 x 10 ml	TRIGLYCERIDES -Standard	
GL841T	6 x 60 ml	TRIGLYCERIDES	2 - 8°C
	1 x 10 ml	TRIGLYCERIDES -Standard	

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Triglycerides in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: [5]

Triglycerides are esters of glycerol with 3 long chain fatty acids. They are partly synthesised in the liver and partly ingested in the diet. While triglycerides are most often requested as a screen for disorders and lipid metabolism they are also elevated in diabetes, nephrosis and liver obstruction.

PRINCIPLE OF THE TEST: [2, 3]

This procedure involves the conversion of triglycerides by lipoprotein lipase (LPL) to form glycerol. Glycerol then in the presence of glycerol kinase (GK), ATP and glycerol oxidase (GPO) produces hydrogen peroxide. The hydrogen peroxide in the presence of aminophenazone (4-AA) and the sensitive chromogen 4-chlorophenal and perioxidase produces a red quinine dye that amount of which is directly proportional to the triglyceride concentration in the sample.

$$\text{Triglycerides} + H_2O \xrightarrow{LPL} \text{Glycerol} + \text{fatty acids}$$

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

$$\text{Glycerol-3-phosphate} + O_2 \xrightarrow{GPO} \text{Dihydroxyacetone phosphate} + H_2O_2$$

$$2H_2O_2 + \text{4-AA} + \text{4-Chlorophenol} \xrightarrow{POD} \text{Red Quinone} + 4H_2O$$

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Pale beige liquid.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety Precautions:
Product is not hazardous under EU specification. Contains Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:
Instrument applications are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent	PIPES Buffer pH 7.0	43.6 mmol/l
	4 Chlorophenol	5.45 mmol/l
	LPL	≥1500 U/l
	POD	≥500 U/l
	Glycero-3-phos.Oxidase	≥3000 U/l
	Glycerokinase	≥500 U/l
	4-Amino-Antipyrine	0.3 mmol/l
	ATP	1.65 mmol/l
	Mg^{2+}	4.66 mmol/l
	PRESERVATIVES & DETERGENTS	---
Standard	Triglycerides	2.2 mmol/l

REAGENT PREPARATION AND STABILITY:

Reagent is ready to use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, components are stable until expiry date stated on the label.

TYPE OF SPECIMEN: [5]

Use serum or EDTA/heparin plasma as specimen.
It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Plasma/serum should be separated from cells within 2 hours after collection.
Stability: From 5 to 7 days at 2-8°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
General Chemistry Calibrator	GL983	Photometer	N/A
General Chemistry Control Level 1	GL922	General Laboratory Equipment	N/A
General Chemistry Control Level 2	GL932	Saline solution 0.9 g/l NaCl	N/A

Assay procedure:
Wavelength: λ: 505 nm
Temperature: 37°C
Optical path: 1 cm light path.

	Blank	**Standard (STD)**	**Sample**
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	10 µl
Standard (STD)	----	10 µl	----
Gently mix and Incubate at 37°C for 5 minutes. Read Optical Density (OD) against the reagent blank.			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory's Q.C. Programme.

CALCULATION:

$$\text{Concentration of Triglycerides} = \frac{OD_{Sample}}{OD_{Calibrator}} \times \text{Concentration of Calibrator}$$

*Photometer must be blanked with the reagent blank.

N.B: Free Glycerol represents approximately 10 mg/dl (0.11 mmol/l) in normal individuals[4]. Subtract this value from the Triglycerides concentration obtained to correct for free glycerol.

(Conversion Factor: Qty in mmol/l = Qty in mg/dl x 0.0113).

EXPECTED VALUES:

NCEP-ATP II Classification of Serum Triglycerides Concentration [5]

	mg/dl	mmol/l
Normal	<200	< 2.26
Borderline High	200 to 400	2.26 to 4.52
High	400 to 1000	4.52 to 11.3
Very High	>1000	> 11.3

Each laboratory should establish its own reference range. Triglycerides results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
Linear up to 9.8mmol/L (867 mg/dl).
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Interfering substances:
Bilirubin (mixed isomers): 11% interference up to 150µmol/l Bilirubin
Haemolysis: Less than 10% interference up to 5 g/l Haemoglobin.

Sensitivity:
The Lowest Detectable Level was estimated at 0.06mmol/l (5.31 mg/dl)

Precision:

Within Run N = 20	Mean *(mmol/l)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(mmol/l)*	*SD*	*% CV*
Level 1	1.71	0.05	3.08	Level 1	1.70	0.05	2.74
Level 2	2.86	0.07	2.43	Level 2	2.80	0.06	2.22

Method Comparison:
Using 50 samples, a comparison, between this Triglycerides test (y) and another commercially available test (x), gave the following results:

y = 1.093x – 0.083	r =0.999	Sample range: 0.69 to 8.36 mmol/l

BIBLIOGRAPHY:

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SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard
CE	CE Mark - Device comply with the Directives 98/79/EC		
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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Revision : 09 Issued on: 26 July 2021