ACCUCARE®

Triglycerides

Enzymatic colorimetric test – GPO PAP

Quantitative determination of Triglycerides in serum/plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
TGLSLR 25	1 X 25 mL
TGLSLR 125	5 X 25 mL
TGLSLR 100	2 X 50 mL
TGLSLR 200	4 X 50 mL

CLINICAL SIGNIFICANCE

Triglycerides are fats that provide energy for the cell. Like cholesterol, they are delivered to the body's cells by lipoproteins in the blood. A diet with a lot of saturated fats or carbohydrates will raise the triglycerides levels. The increases in serum triglycerides are relatively non-specific. For example liver dysfunction resulting from hepatitis, extra hepatic biliary obstruction or cirrhosis, diabetes mellitus is associated with the increase . Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

Colorimetric enzymatic test using glycerol-3-phosphate-oxidase (GPO PAP)

PRINCIPLE

Triglycerides are determined after enzymatic hydrolysis with lipases. The quinonemine indicator is formed from hydrogen peroxide, 4-aminophenazone, and 4-chlorophenol under the catalytic influence of peroxidase.

REAGENT

Reagent I : Triglycerides reagent
Triglycerides Standard : 200 mg/dl (2.25 mmol/L)

REAGENT PREPARATION

The Reagent is ready to use.

REAGENT STORAGE AND STABILITY

The Reagent is stable till expiry when stored at 2 - 8°C.
Store protected from light.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum, heparin plasma or EDTA plasma
Stability: 7 days at 4 – 8°C
1 Year at –20°C
Discard contaminated specimens! Freeze only once!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28°C, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	505 nm
Reaction Type	End Point
Cuvette	1 cm light path
Reaction Temperature	37°C
Measurement	Against Reagent Blank
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation	5 minutes
Blank Absorbance limit	<0.300
Low Normal at 37°C	40 mg/dl (0.45 mmol/L)
High Normal at 37°C	165 mg/dl (1.86 mmol/L)
Linearity at 37°C	1300 mg/dl (14.68 mmol/L)

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	Blank	Standard	Test
Reagent 1	1000µL	1000µL	1000µL
Standard	--	10µL	--
Sample	--	--	10µL

- Mix well, incubate for 5 mins. at 37°C (or 10 mins. at 20 - 25° C). Measure absorbance of Sample (AT) and Standard (AS) against reagent blank at 505 nm.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 1300 mg/dL.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

$$\text{Triglycerides mg/dL} = \frac{\text{Abs.of Sample (AT)}}{\text{Abs.of Standard (AS)}} \times \text{Standard Value (200mg/dL)}$$

CALIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of **Trigyceride standard** have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS).

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Norm	100.45	3.06	3.05%
Path	224.74	6.35	2.83%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm	101.20	2.67	2.64%
Path	225.32	4.15	1.84%

LINEARITY

The method is linear upto a concentration of 1300 mg/dL. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Triglycerides is 2 mg/dL.

Art No.: IFU/BC/TGL
Effective Date: 20/09/2019
Revision No.: 01

METHOD COMPARISON

A comparison of Accucare Triglycerides with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9900$

REFERENCE VALUES

Male	40 - 160 mg/dL (0.45 - 1.81 mmol/L)
Female	35 - 135 mg/dL (0.40 - 1.53 mmol/L)

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 18 mg/dl.
- Hemoglobin: No interference found upto 150 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Buccolo G., David M., Clin. Chem, 19, (1973), 476

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
Tel.: +91 22 2554 2109 /1558
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