

Ana-Chek® TRIGLYCERIDES

METHOD – GPO-POD
PRODUCT CODE – LT01

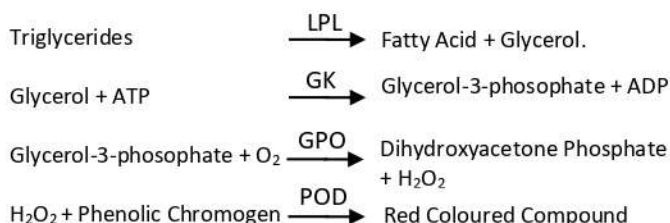


INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Triglycerides in serum / plasma using GPO-POD method.

SUMMARY AND PRINCIPLE

Measurement of Triglycerides is important in the diagnosis and management of hyperlipidaemias. Elevated levels of Triglycerides are associated with coronary artery, liver and renal diseases. Ana-Chek® Triglyceride is a single reagent set for determination of Triglycerides based on enzymatic method using Lipoprotein lipase, Glycerol kinase, Glycerol phosphate oxidase and Peroxidase.



KIT COMPONENTS

Reagent 1: Triglycerides Reagent
Reagent 2: Triglycerides Standard (200 mg/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Ana-Chek® Triglyceride is a single ready to use reagent. The reagent kit should be stored at 2-8 °C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.300 O.D. against D/W at 546 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Triglycerides	Reagent Volume	1000 µl
Reaction Type	End Point	Sample Volume	10 µl
Primary Wavelength	546 nm	Incubation Time	10 Min
Flow Cell Temp.	37 °C	Incubation Temperature	37 °C
Blank setting	Reagent	Standard Conc.	200 mg/dL
Blank abs. limit	< 0.300	Linearity	1600 mg/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Fasting blood is preferred for Triglyceride assay. Heparinised or EDTA-Plasma can be used. Anticoagulants such as Oxalate and sodium fluoride should not

be used. Triglycerides in the serum is stable for 4 days when stored at 2-8 °C and 3 months when stored at -20 °C.

COMPONENTS OF REAGENT

Component	Concentration
Buffer, pH 6.8	50 mmol/l
Lipase	>2000 IU/L
Glycerol Kinase	>300 IU/L
Glycerol Phosphate Oxidase	>1000 IU/L
Peroxidase	>500 IU/L
ATP	1 mmol/l
Chromogen	2 mmol/l
Stabilizers, inactive ingredients and surface-active agents.	-

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 µl	1000 µl	1000 µl
Standard	NA	10 µl	NA
Sample	NA	NA	10 µl
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 10 mins at 37°C.			
Aspirate reaction mixture into flow cell and measure the absorbance.			
The final colour is stable for 2 hours if not directly exposed to light.			

CALCULATION

$$\text{Triglycerides (mg/dL)} = \frac{\text{Abs. of sample} \times 200}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

Upto 160 mg/dL

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 11 - 1600 mg/dL. If the Triglycerides value exceeds linearity limit (above 1600 mg/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Triglycerides value of the specimen.

Interference: There is no significant interference in samples containing upto 20 mg/dL of Bilirubin and 500 mg/dL of haemoglobin.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	103.9	1.29	1.2	111.3	2.5	2.2
High Value Serum	184.4	1.17	0.6	191.2	1.55	0.8

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Triglycerides. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Discard the working reagent if its absorbance exceeds 0.300 at 546 nm against distilled water.
2. If Triglycerides value exceeds 1600 mg/dL then dilute the specimen suitably with normal saline & repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain the correct Triglycerides value.
3. Glycerol contamination in glassware leads to erroneous results.
4. Applying hand lotion may contain glycerine.
5. It is important that the Standard is brought to room temperature prior to use or else the results obtained could be erroneous.

BIBLIOGRAPHY

1. Foosati P., *et al.* Clin.Chem 28, 2077 (1982).
2. Henry, J.B., Clinical Diagnosis and management by laboratory Methods, 18th ed., W.B. Saunders, Philadelphia, 1991, p.204-211.
3. Tietz, N.W., Clinical Guide to laboratory Tests, 2nd ed., W.B. Saunders, Philadelphia, 1994, p. 1073-1091.
4. Young D.S., Effects of Drugs on Clinical Laboratory Tests, 3rd ed., AACC Press. Washington D.C., 1990, p.3-340-346.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE