BIOLABO
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TRIGLYCERIDES GPO Method

Reagent for quantitative determination of triglycerides (**TRI**) in human serum and plasma

REF LP80519	**R1** 2 x 50 mL	**R2** 1 x 5 mL
REF LP80619	**R1** 4 x100 mL	**R2** 1 x 5 mL

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CE

IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (1)

The measurement of the concentration in blood triglycerides is important for the diagnosis and the follow-up of hyperlipidemia. Its increase can be of genetic origin or secondary to other metabolic disorders such as: diabetes mellitus, hyper and hypothyroidisms, hepatic diseases, acute and chronic pancreatitis, nephrosis. A rise in triglycerides also represents an atherogenic risk factor. It is responsible for the opalescence, or even the cloudiness of the serum. Corticoids and oestrogen/progestin treatments can also aggravate hypertriglyceridemia.

PRINCIPLE (4) (5)

Fossati and Prencipe method associated with Trinder reaction.
Reaction scheme is as follows:

$$\text{Triglycerides} \xrightarrow{\text{Lipase}} \text{Glycerol} + \text{free fatty acids}$$

$$\text{Glycerol} + \text{ATP} \underset{}{\overset{\text{GK}}{\rightleftharpoons}} \text{Glycerol 3 Phosphate} + \text{ADP}$$

$$\text{Glycerol 3 Phosphate} + O_2 \xrightarrow{\text{GPO}} \text{DihydroxyacetonePhosphate} + H_2O_2$$

$$H_2O_2 + \text{4-Chlorophenol} + \text{PAP} \xrightarrow{\text{POD}} \text{Quinoneimine (pink)} + H_2O$$

The absorbance of the coloured complex (quinoneimine), proportional to the amount of triglycerides in the specimen, is measured at 500 nm.

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use (do not pipette with mouth).

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

REAGENTS PREPARATION

Ready for use

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer

REAGENTS

R1	**REAGENT**	REAG **TRI**	
PIPES		100	mmol/L
Magnesium chloride		9.8	mmol/L
Chloro-4-phenol		3.5	mmol/L
Lipase		≥ 1000	IU/L
Peroxydase (POD)		≥ 1700	IU/L
Glycerol 3 phosphate oxidase (GPO)		≥ 2000	IU/L
Glycerol Kinase (GK)		≥ 1000	IU/L
4 - Amino – antipyrine (PAP)		0.5	mmol/L
Adenosine triphosphate Na (ATP)		1.3	mmol/L
Clearing Agent		1.5	mmol/L
R2	**ETALON**	STD	
Triglycerides		2	g/L

According to 1272/2008 regulation, this reagent is not classified as dangerous

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, and used as described, reagents are stable:

Unopened:

- Until expiry date stated on the label of the kit.

Once opened:

- Transfer requested quantity, well recap vials and store at 2-8°C
- Working reagent (vial R1) is stable 3 months when free contamination.
- Discard working reagent if cloudy, in case of lost of sensitivity or if reagent blank > 0.400 at 505nm.

SPECIMEN COLLECTION AND HANDLING (2)

Serum or plasma (Heparin or EDTA) fasting ≥ 12 hours.

Separate from cells within 2 hours.

Do not use oxalate, fluoride or citrate.

Triglycerides are stable in specimen for:

- 5-7 days at 2-8°C.
- 3 months at –20°C.
- Many years at –70°C.

Avoid repeated freezing and thawing.

LIMITS (3)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

CALIBRATION (7)

- REF 95015 BIOLABO Multicalibrator traceable to SRM 909b

Or

- Standard (vial R2)

The calibration frequency depends on proper instrument functions and on the preservation of reagent.

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with | H2O Demineralized water | Biological hazard

QUALITY CONTROL

- REF 95010 BIOLABO EXATROL-N Level 1
- or REF 95516 Lipids Control serum Level 1
- REF 95011 BIOLABO EXATROL-P Level 2
- or REF 95526 Lipids Control serum Level 2
- External quality control program

It is recommended to control in the following cases:

- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:

1. Repeat the test with the same control
2. If control is still out of range, prepare a fresh control serum and repeat the test
3. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test
4. If control is still out of range, calibrate with a new vial of reagent
5. If control is still out of range, please contact BIOLABO technical support or your local Agent

EXPECTED VALUES (6)

Triglycerides	mg/dL	[mmol/L]
Reference range	35 -160	[0.40-1.82]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES at 37°C on KENZA 240TX (1) (2)

Linearity Range: between 10 and 1000 mg/dL

Detection limit: approx. 6 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	54.6	136	261.8
S.D. mg/dL	0.9	1.6	3.0
C.V. %	1.6	1.2	1.1

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	56.6	139.2	259.2
S.D. mg/dL	1.6	2.1	4.6
C.V. %	2.9	1.5	1.8

Comparison studies with commercially available liquid reagent:
Realised on human specimens (n=103) between 21.9 and 526.3 mg/L
y = 1.0139 x – 2.4376 r = 0.9977

Analytical sensitivity: approx. 0.00018 abs for 1 mg/dL

Interferences:

Total bilirubin	Negative interference from 238 µmol/L
Direct bilirubin	Negative interference from 90 µmol/L
Ascorbic acid	Negative interference from 304 mg/dL
Glucose	No interference up to 1064 mg/dL
Haemoglobin	Positive interference from 333 µmol/L
Free glycerol (1) (2)	Overestimation of approx. 10 mg/dL (0,11 mmol/L) due to endogen glycerol

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 2 months

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

PROCEDURE

Detailed Kenza 240TX procedure is available on request

Wavelength: 505 nm
Temperature: 37°C
Let stand reagent and specimens at room temperature.

	Automated analyzer	Manual procedure
Reagent	300 µL	1000 µL
Standard, Controls, Specimen	3 µL	10 µL

Mix. Let stands for 5 minutes at 37°C (10 minutes at room temperature). Record absorbance at 505 nm against reagent blank.

Reaction is stable for 1 hour.

Notes:

1- Performances and stability data's have been validated on KENZA 240TX and KENZA 450TX.

2-With Manual Procedure on Spectrophotometer and on other automated analyzers, performances and stability should be validated by user.

4- Applications proposal are available on request

CALCULATION

Calculate the result as follows:

$$\text{Result} = \frac{\text{Abs (Assay)}}{\text{Abs (Standard)}} \times \text{Standard concentration}$$

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 809-857.*
(2) *Clinical Guide to Laboratory Test, 4thEd., N.W. TIETZ (2006) p. 1074-1077.*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-573 to 3-589*
(4) *Fossati P., Prencipe L., Clin. Chem. (1982), 28, p.2077-2080.*
(5) *Trinder P. Ann. Clin. Biochem. (1969), 6, p.27-29.*
(6) *TIETZ N.W. Text book of clinical chemistry, 2nd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1994)p. 1030-1058 et p. 1073-1080.*
(7) *SRM: Standard Reference Material ®*