

TRIGLYCERIDES SYSTEM PACK

(GPO/POD METHOD)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 ,
Beaconnic chem 200, Beaconnic B200, Beaconnic analyzer 120,
Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA232	Triglycerides System Pack	5x40 ml

INTENDED USE

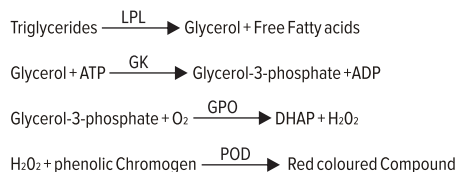
Diagnostic reagent for quantitative *in vitro* determination of Triglycerides in human serum, plasma.

CLINICAL SIGNIFICANCE

Triglycerides are a family of lipids absorbed from the diet and produced endogenously from carbohydrates. Measurement of triglycerides is important in the diagnosis and management of hyperlipidemias. These diseases can be genetic or secondary to other disorders including nephrosis, diabetes mellitus and endocrine disturbances. Elevation of triglycerides has been identified as a risk factor for atherosclerotic disease.

PRINCIPLE

The series of reactions involved in the assay system is as follows;



Triglycerides are enzymatically hydrolyzed by lipase to free acids and glycerol. The glycerol is phosphorylated by adenosine triphosphate (ATP) with glycerol kinase (GK) to produce glycerol-3-phosphate and adenosine diphosphate (ADP). Glycerol-3-phosphate is oxidized to dihydroxy-acetone phosphate (ADP) by glycerol phosphate oxidase producing hydrogen peroxide (H₂O₂).

In a Trinder type color reaction catalyzed by peroxidase, the H₂O₂ reacts with 4- aminoantipyrine (4AAP).

REAGENT COMPOSITION

Reagent 1: Triglycerides Enzyme Reagent

Pipes buffer	>45 mmol/L
4-Chlorophenol	>3 mmol/L
ATP	>1.5 mmol/L
Glycerolkinase	<1000 U/L
Peroxidase	>2000 U/L
Lipoproteinlipase	>2500 U/L
Glycerol-3-phosphate-Oxidase	>1000 U/L
4-Aminoantipyrine	>0.25 mmol/L

REAGENT PREPARATION

Reagents are liquid, ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2 - +8°C.

On board stability: Min. 30 days if refrigerated (+8 - +14°) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use unheamolyse serum, plasma (EDTA, Heparin).

It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability

2 days	at +20 - +25°C
7 days	at +4 - +8°C
at least 1 year	at -20°C

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagents performance.

EXPECTED VALUES

Normal : 60 to 170 mg/dl

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon System. Data obtained in your laboratory may differ from these values.

Limit of quantification:	4.00 mg/dl
Linearity:	1000 mg/dl
Measuring range:	4.00 - 1000 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	125	1.66	1.33
Sample 2	286	2.05	0.72
Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	174	1.51	0.86

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COMPARISON

A comparison between Triglycerides System Pack (y) and commercially available test (x) using 20 samples gave following results:

$$y = 1.018x + 1.137$$

$$r = 0.999$$

INTERFERENCES

Following substances do not interfere:

Haemoglobin upto 10 g/l, bilirubin up to 40 mg/dl. Interference by N-acetylcysteine (NAC), acetoaminophen and metazole causes falsely low results. To carry out the test, blood withdrawal should be performed prior to administration of drugs.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person. Reagents of the kit are not classified as dangerous. MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Test Name	TRIGLYCERIDES
Full Name	TRIGLYCERIDES
PRI Wave	505 nm
SEC Wave	630 nm
Assay/Point	1 POINT END
Start	-
End	34
Decimal	2
Unit	mg/dl
Linearity Range Low	4
Linearity Range High	1000
Sample Volume	2 µl
Reagent 1 (R1) Volume	200 µl
Reagent 1 (R2) Volume	-
Substrate Depleted/Abs.limit	-
Linearity	1000 mg/dl
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator value sheet

NOTE

The program is made as per the in house testing, it can be modified as per requirements.

Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

REFERENCES

1. Rifai N, Bachorik PS, Alberts JJ. Lipids, lipoproteins and apolipoproteins. In: Burtis CA, Ashwood ER, editors Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 809-61.
2. Cole, TG, Klotzsch SG, McNamara J. Measurement of triglyceride concentration. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 1997. p. 155-26.
3. Recommendation of the Second Joint Task Force of European and other - Societies on Coronary Prevention. Prevention of coronary heart disease in clinical practice. Eur Heart J 1998;19: 1434-503.
4. Tietz Textbook of Clinical Chemistry and Molecular diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E; 5th edition, WB Saunders Company 2012.

Symbols Used On Labels



Catalogue
Number



Manufacturer



See Instruction
for Use



Lot Number



Content



Storage Temperature



Expiry Date



In Vitro Diagnostics

BEA/24/TRI/SB/IFU Ver -02
09/05/2024

