TRIGLYCERIDES SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

BEACON

Code	Product Name	Pack Size
UNI32	Triglycerides System Pack	4 x 50 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 $\xrightarrow{LPL}$ Glycerol + Free Fatty acids

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

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

H_2O_2 + phenolic Chromogen $\xrightarrow{POD}$ Red coloured Compound

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 (H_2O_2).
In a Trinder type color reaction catalyzed by peroxidase, the H_2O_2 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 (2-10°) 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 reagent performance

EXPECTED VALUES

Normal : 60 to 170 mg/dl

It is recommended that each laboratory verify this range or derives referance 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

COMPARISON

A comparision 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 metamizole 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 handles by entitled and professionally educated person.
Reagents of the kit are not classified as dangerous.

WASTE MENAGEMENT

Please refer to local legal requirements.

Parameter for Unicorn 480, Bonavera Chem 480 &

Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

TEST NAME	TRIGLCERIDES
FULL NAME	TRIGLCERIDES
PRI WAVE	505 nm
SEC WAVE	630 nm
ASSAY/POINT	1 POINT END
START	-
END	33
DECIMAL	0
UNIT	mg/dl
LINEARITY RANGE LOW	4
LINEARITY RANGE HIGH	1000
SAMPLE VOLUME	2 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSATRATE DEPLETED	-
LINEARITY	1000 mg/dl
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator value sheet.
SAMPLE VOLUME	2 µ l

NOTE

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

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

IVD JAS-ANZ BSCIC ISO 9001 : 2015 BSCIC ISO 13485:2016

SYMBOLS USED ON LABELS

REF Catalogue Number | Manufacturer | See Instruction for Use

LOT Lot Number | CONT Content | Storage Temperature

Expiry Date | IVD In Vitro Diagnostics

BEA/24/TRI/UN/IFU-00 DATE :16/07/2022