TRIGLYCERIDES

Diagnostic reagent for determination of Triglycerides concentration.

Liquid, Monoeagent, Store at 2°C - 8°C, For in Vitro Diagnostic Use, Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack No
A2310	5X100 ml	T2310	5294 Tests	BY2311	4545 Tests	K2310	3415 Tests
A2311	5X50 ml	T2311	1471 Tests	N2310	758 Tests	K2311	2439 Tests
A2312	5X25 ml	S2310	2182 Tests	N2311	424 Tests	L2310	5000 Tests
M2310	2273 Tests	S2311	1364 Tests	R2310	1364 Tests	L2311	2667 Tests
M2311	1364 Tests	BY2310	6364 Tests	R2311	455 Tests	DM2310	780 Tests

INTENDED USE

The test is applied for quantitative determination of Triglycerides concentration in serum or EDTA plasma.

TEST PRINCIPLE

Triglycerides are hydrolized by lipoproteinlipase to produce glycerol and free fatty acids. The glycerol participates in a series of coupled enzymatic reactions, in which glycerol kinase / glycerol phosphate oxidase are involved and H2O2 is generated. The H2O2 reacts with p-chlorophenol and 4-aminoantipyrine in the presence of peroxidase to form a quinoneimine dye. The intensity of color formed is proportional to the triglycerides concentration and can be measured photometrically between 480 and 520 nm.

TEST PARAMETERS

Method : Colorimetric, Endpoint, Increasing Reaction, GPO – PAP
Wavelenght : 510 nm (allowed 480 ÷ 520 nm)
Temperature : 20-25°C or 37°C
Sample : Serum, heparinized or EDTA
Plasma Stability: several days at 2-8°C
Linearity : up to 1000 mg/dl (11,4 mmol/L)

REAGENTS COMPOSITION

Composition: 4-chlorophenol 2.7 mM, 4-AAP 0.3 mM, ATP 2 mM, GK >1000 U/l, POD >1000 U/l, LPL > 2000
U/l, GPO > 5000 U/l, Good's buffer pH 7.20 50 mM, surfactants
The components of the kit are stable until expiration date on the label at 2-8°C. Keep away from direct light sources.

REAGENT PREPARATION

Reagent ready to use.

REAGENT STABILITY AND STORAGE

The reagent is stable up to the expiration date on the label. Store reagent at 2-8°C, protected from light. Avoid contamination of the opened reagents.
Stability: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: ≥ 60 days at 2-8°C.
Warning! Reagent is slightly photosensitive. Avoid prolungate exposure to strong light sources.

SAMPLES

Specimens should not be obtained for triglyceride determination unless the patient has been fasting for 10 to 14 h.
Either serum or EDTA plasma can be used to determine triglycerides. When EDTA plasma is used, the plasma value is converted to the equivalent serum value by multiplying the plasma value by 1.03.
Store specimens at 4°C before analysis. Specimens can be stored at 4°C for 3 days, frozen at -20°C for two weeks, or frozen at -70°C for longer periods.
Lipemic specimens may require warming to 37°C and vigorous mixing before analysis, especially if they have been frozen.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Serum/plasma sample:
triglycerides mg/dl = Ax/As x 200 (standard value)
LDL=Cholesterol-(HDL + Triglyserid/5)

Unit Conversion

mg/dl x 0.0114 = mmol/L

REFERENCE INTERVALS (NORMAL VALUES) (Based on rules CLSI C28-P Document)*

Desirable: < 200 mg/dl (2.26 mmol/l)

* It is recommended that each laboratory establish its own normal range.

QUALITY CONTROL AND CALIBRATION

All control sera with triglycerides values determined by this method can be used. We recommend :

A3910 ARCON N
Assayed Control Serum Normal

A3920 ARCON P
Assayed Control Serum Abnormal

Calibration: This assay requires the use of a Triglycerides Standard or a Triglycerides Calibrator. We recommend
A2310S Standard (conc. 200 mg/dl)
A39050 Arcal Auto Calibrator

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low Linearity:10 mg/dL

High Linearity: The assay is linear up to 1000 mg/dl (11.4 mmol/L). Above this concentration, dilute the sample with physiological NaCl (150 mmol/L) and reassay multiplying the result by the dilution factor.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run)(intra-assay):

Mean conc.	SD	CV%	n
108.74 mg/dL	1.82 mg/dl	1.70%	10
189.09 mg/dL	1.50 mg/dl	0.80%	10

Reproducibility (run to run)(inter-assay):

Mean conc.	SD	CV%	n
115.46 mg/dL	3.75 mg/dl	3.30%	10
198.16 mg/dL	3.80 mg/dl	1.90%	10

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 1 mg/dl.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Methods comparison: A comparison between Archem TRIGLYCERIDES FL and a commercially available product gave the following results:
Triglycerides Archem = x
Triglycerides competitor = y
n = 147
y = 1.079x - 3.907 mg/dl $r^2 = 0.99$

Interferences: No interference was observed by the presence of:
Hemoglobin ≤ 500 mg/dl
Bilirubin ≤ 12 mg/dl

NOTES

1. For *in vitro* diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human&animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles can not be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTION AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.

Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV% : Coefficient of Variation Percentage
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
QC : Quality Control

REFERENCES

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number


Expiration date


Storage temperature interval


Read the directions


Biological risk

CE

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