Automation

TRIGLYCERIDES

IVD

REF	Σ	Reagenti
101296650	6x50 ml Manual : 150 test	R1:6x50 ml R3:1x4 ml

AUTOMATION

Hitachi 704 …….. 857 test
Hitachi 717, 902, 911, 912 …….. 1.200 test

1.0 SUMMARY

Triglycerides are a family of lipids, adsorbed by organism or endogenously synthesized from liver carboidrates and introduced into organism carried by VLDL proteins. Triglycerides quantification is important for iperlipidemia diagnosys and treatment. This disease can be of genetic origin or generated by other diseases as nefrosys , diabetes mellito and endocrine disease. Triglycerides high level has been identificated as arteriosclerosis risk factor. There are some methods for triglycerides determination, principally based upon glycerol preventive hidrolisys and its measurement. This method is high specificity, characteristic of Trinder enzymatic methods, associated to an high stability of reagent. Liproteinlipases (LPL) utilized in this formulation have an high hidrolisys capacity to all triglycerides in serum.

2.0 PRINCIPLE

Triglycerides are determined after enzymatic hydrolysis with LPL. The indicator is a quinoneimine formed from hydrogen-peroxide, 4-aminophenazone and 4-chlorophenol under the catalytic influence of peroxidase.

3.0 SPECIMEN

Serum not hemolized. Is possible to use plasma .If no bacteric contamination exist, sample is stable 1 week at room temp. and 1 months at 2-8 °C.

4.0 REFERENCE VALUES

Men:.....60-195 mg/dl/l)
Women:.....40-140 mg/dl l)
Each laboratory should establish appropriate reference intervals related to its population.

5.0 REAGENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.
101296 Reagent 1 single reagent : 6 x 50 ml (liquid)
Composition: p-chlorophenol 2.7 mM, 4-AAP 0.3 mM, ATP 2 mM, GK >1000 U/L, POD >2500 U/L, LPL >1000 U/L, GPO > 5000 U/L, Good buffer pH 7.20 50 mM, preservative and stabilizers.
Standard : glicerol solution, see value on the label.
Store all components at 2-8°C.

6.0 PREPARATION AND STABILITY OF REAGENTS

Use reagent ready to use.Stability: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: 60 days at 2-8°C.

7.0 MATERIALS REQUIRED BUT NOT PROVIDED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

8.0 PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.

9.0 QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available :
101265 PRECISE NORMAL with normal or close to normal control values.
101267 PRECISE PATH with pathological control values.
If required, a multiparametric, human based calibratori s available :
101031 BIOCAL HUMAN

10.0 PROCEDURE MANUAL

Wavelenght: 520 (490-550) nm
Temperature: 37°C
Reading: against water
Reaction: endpoint

	BLANK	STANDARD	SAMPLE
Reagent	2000 uL	2000 uL	2000 uL
Standard	-	20 uL	-
Sample	-	-	20 uL

Mix, incubate at 37°C for 5 minutes (8 min. at roo m temp). Read absorbances of standard (As) and samples (Ax) against reagent blank. The color is stable up to 30 min. avoid light.

10.1 PROCEDURE AUTOMATION (hitachi 911-912) programmation

PROGRAM

TEST: TRIG APP. CODE: 301 - 400 (choose in this interval)
WAVELENGHTS: 700 - 505
ASSAY: 1POINT TIME: 10 POINT: 31 - 0
SAMPLE VOL: NOMINAL 3
DECREASE 2
INCREASE 8
R1 VOLUME: 250
R2 VOLUME: 0
R3 VOLUME: 0
R4 VOLUME: 0
ABS LIMIT: 10000 - INC
ABS LIMIT: 10000 - INC
PROZONE LIMIT: 0 - LOWER
CALIB METHOD: LINEAR (POINT: 2 - SPAN: 2 - WEIGHT: 0)
SD LIMIT: 0.250
DUPLICATE LIMIT: 5% 10 Abs
SENSITIVITY LIMIT:
EXPECTED VALUE: 10 - 190
CLASS 1 TECHNICAL RANGE: 0 - 1000

11.0 CALCULATION OF RESULTS

serum/plasma sample:
Triglycerides mg/dl = Ax/As x standard value

12.0 TEST PERFORMANCES

12.1 Linearity Reaction is linear up to 1000 mg/Dl
12.2 Sensitivity/limit of detection (LOD). the limit of detection is 1 mg/dl.
12.3 Interferences. no interference was observed by the presence of:
hemoglobin 500 mg/dl
bilirubin 15 mg/dl
lipids 850 mg/dl
12.4 Precision :

intra-assay (n=10)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	101.50	1.84	1.80
Sample 2	176.20	2.74	1.60

Inter-assay (n=10)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	100.99	2.11	2.10
Sample 2	176.51	2.23	1.30

12.5 Methods comparison
a comparison between MEDIA and a commercially available product gave the following results:
TRIGLYCERIDES MEDIA = x, TRIGLYCERIDES competitor = y
n = 100, y = 0.979x + 1.71 mg/dl r = 0.995

13.0 WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.
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 sheet.

14.0 REFERENCES

Bucolo G., David M. - Clin. Chem. 19,476 (1973)
McGowan M.W., Artiss J.D., Standbergh D.R., Zak B. - Clin. Chem. 29, 538 (1983).

SYMBOLS – 98/79/EC DIRECTIVE

SCADENZA/EXPIRY
LOTTO / LOT
CAT N.

CE MARK
DIAGN. IN VITRO
TEMPERATURE
TAGLIO/SIZE

MANUFACTURER
MEDIA DIAGNOSTICI SRL
Via Costiera 31 D/E– 47100 FORLI (FO)
TEL 0543 782.786
FAX 0543 782.787
Email: info@mediagnostic.biz
WEB: www.mediagnostic.biz

TG-MR-650_CE_UK_2.04_20042011 Rev. 2.03 20 november 2009

CE

MeDia Diagnostici

If You need to be sure !