TRIGLYCERIDES FL

TR F100 CH	2 x 50 ml
TR F400 CH	4 x 100 ml
TR 100F CH	4 x 250 ml

INTENDED USE

Reagent for quantitative in vitro determination of triglycerides in biological fluids.

SUMMARY OF TEST

In human nutrition, triglycerides are the most prevalent glycerol esters encountered. They constitute 95% of tissue storage fat and are the predominant form of glycerol ester found in plasma. The fatty acid residues found in mono-, di-, or triglycerides vary considerably and usually include combinations of the long-chain fatty acids. Triglycerides undergo digestion in the duodenum and proximal ileum: through the action of lipases and bile acids, they are hydrolyzed into glycerol and fatty acids.

PRINCIPLE OF THE METHOD

Triglycerides are hydrolized by lipoproteinlipase to pro-duce 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. H₂O₂ reacts with TOPS 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 at 546 nm.

KIT COMPONENTS

For in vitro diagnostic use only. The components of the kit are stable until expiration date on the label at 2-8°C.

Keep away from direct light sources.

TRIG R1 F100: 2 x 50 ml (liquid) blue cap F400: 4 x 100 ml (liquid) blue cap 100F: 4 x 250 ml (liquid) blue cap

Composition: Good's buffer pH 6.80, ATP 2 mM, GK > 300 U/I, POD > 1000 U/I, LPL > 1000 U/I, GPO > 2000 U/I, TOPS 3 mM, 4-AAP 0.3 mM, , surfactants and stabilizers.

glycerol equivalent to 200 mg/dl - 5 ml Standard:

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

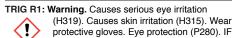
Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Use reagent ready to use.

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

PRECAUTIONS



ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

Standard: It is not classified as hazardous.

N-acetylcysteine (NAC), metamizole and acetaminophen may cause interference in the Trinder reaction.(1,2) To avoid interference, the blood withdrawal should be performed before drug administration.

SPECIMEN

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 are stable 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

Wavelenght: 546 nm (allowed 510 nm) Lightpath: 1 cm 37°C Temperature: dispense: blank standard sample reagent 1 ml 1 ml 1 ml water 10 µl standard -10 µl sample 10 µl --

TEST PROCEDURE

Mix incubate at 37°C for 5 minutes

Read absorbances of standard (As) and samples (Ax) against reagent blank.

RESULTS CALCULATION

serum/plasma sample:

triglycerides mg/dl = Ax/As x 200 (standard value)

EXPECTED VALUES			
desirable:	< 200 ma/dl	(2 26 mmol/l)	

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available

QUANTINORM CHEMA

with normal or close to normal control values

QUANTIPATH CHEMA

with pathological control values. If required, a multiparametric, human based calibrator is available:

AUTOCAL H

Please contact Customer Care for further information

TEST PERFORMANCE

Linearity

the method is linear up to 1000 mg/dl. If the value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10

Sensitivity/limit of detection (LOD)

the limit of detection is 0.69 mg/dl.

Interferences

no interrerence was	s observed by the presence of:
hemoglobin	≤ 150 mg/dl
bilirubin	≤ 18 mg/dl

Precision

k

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	109.61	1.02	0.93
sample 2	214.62	1.10	0.51
inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	108.64	3.31	3.05
sample 2	210.25	6.54	3.11

Methods comparison

a comparison between Chema TRIGLYCERIDES FL and a commercially available product gave the following results:

Triglycerides Chema = x

Triglycerides competitor = y n = 96

y = 0.9993 x - 0.614 mg/dl $r^2 = 0.995$

WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.

REFERENCES

1) N-acetylcysteine interference of Trinder-based assays. Genzen JR, Hunsaker JJ, Nelson LS, Faine BA, Krasowski MD. Clin Biochem. 2016 Jan;49(1-2):100-4 2) Drug interference in Trinder reaction.

Wiewiorka O, Čermáková Z, Dastych M. Euromedlab 2017. ISSN 1437-4431

3) Trinder P. - J. Clin. Path. 22, 158 (1969);

4) Fossati P. and Prencipe L. - Clin. Chem. 28/10, 2077-2080 (1982);

5) McGowan M. W., Artiss J. D., Strandbergh D. R. and Zak B. - Clin. Chem. 29/3, 538-542 (1983);

6) Spain M. A. and Wu A. H. B. - Clin. Chem. 32/3, 518-521 (1986):

7) Shephard M. D. S. and Whiting M. J. - Clin. Chem. 36/2,

325-329 (1990); 8) Klotzsch S. G. and McNamara J. R. - Clin. Chem. 36/9,

1605-1613 (1990); 9) Tietz Textbook of Clinical Chemistry, Second Edition,

Burtis-Ashwood (1994); 10) H.U.Bergmeyer Ed. 3, "Methods of enzymatic analysis" vol. VIII, 12.

MANUFACTURER

	Diagnostica npania 2/4
	Monsano (AN) - ITALY - EU
	+39 0731 605064
fax	+39 0731 605672
e-mail:	mail@chema.com
website:	: http://www.chema.com

SYMBOLS

IVD	in vitro diagnostic medical device
LOT	batch code
REF	catalogue number
X	temperature limit
\square	use by date
\triangle	caution
ī	consult instructions for use