TECO DIAGNOSTICS
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TRIGLYCERIDE REAGENT
TC MATRIX-240/480

INTENDED USE
The triglyceride test is used for the quantitative determination of triglyceride in human serum or plasma.

SUMMARY AND PRINCIPLE[1, 2, 3, 4, 5]
Triglycerides are hydrolyzed by lipoprotein lipase 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. H2O2 reacts with p-chlorophenol and 4-aminoantipyrine in the presence of peroxidase to form a quinoneimine dye. The intensity of formed color is proportional to the triglycerides concentration and can be measured photometrically between 480 and 520 nm.

REAGENTS
Each kit contains:
Reagent:

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

REAGENT PREPARATION
Reagents are ready for use.

PRECAUTIONS
IVD: For in Vitro Diagnostic use only. Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

REAGENT STORAGE AND STABILITY[6]
Reagents are stable at 2-8°C until the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 60 days at 2-8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SPECIMEN STORAGE
Serum and plasma are collected according to the standard procedures.
Serum and plasma are stable for:
2 days at 20-25°C, 7 days at 2-8°C, 1 year at -20°C

Unit Conversion:
mg/dL x 0.0113 = mmol/L

INTERFERING SUBSTANCES [1, 2, 3, 12]
No significant interactions were observed for hemoglobin, conjugated bilirubin, up to the interferent concentration given in the table.

Interfering Substance and Concentration	Triglycerides Target (U/L)	N	Observed Recovery %
Hemoglobin ≤540 mg/dL	135.6	3	110
Bilirubin ≤4.11 mg/dL	171.4	3	94

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances. These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

CALIBRATION
Calibration stability is 30 days. Calibration stability depends on the application characteristics and cooling capacity of the autoanalyzer used.

At least two level controls must be run once in every 24 hours. Each laboratory should determine its own quality control scheme and procedures. If quality control results are not within acceptable limits, calibration is required

Note: Refer to the TC Matrix manual for further instructions on calibrating the instrument

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
Arcal Auto Calibrator
At least two levels of control material.

PROCEDURE
Settings for TC-Matrix 240/480

Test Name:	Triglyceride	R1:	200
Full Name:	Triglyceride	R2:	0
Pri. Wave:	505 nm	Sample volume:	2
Sec. Wave:	700 nm	Calibration Type:	2 Point Linear
Assay/ Point:	1-point End	K Value:	/
Start - End:	1 - 21	Point:	2
Decimal place:	1	Blank Type:	Reagent
Unit:	mg/dL	Point 0 (Blank) Con.:	0.0
Linearity Range:	2 - 1000	Point 1 (CAL) Con.:	Standard/
Correlation Factor:	1.0000 - 0.0000		Calibrator

REFERENCE INTERVAL (NORMAL VALUES) [7]
Desired < 150 mg/dL

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

Reference interval has been verified by using CLSI EP28- A3c protocol.

PERFORMANCE CHARACTERISTICS
Limit of Detection (LoD): The limit of the test detection is 5 mg/dL.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) ≤20%]:[8] 10 mg/dL

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

Precision[9]**:**

Repeatability (Within Run)

Mean Concentration (mg/dL)	SD	CV%	n
97.32	1.37	1.41	40
185.23	3.12	1.68	40

Reproducibility (Day- to- Day)

Mean Concentration (mg/dL)	SD	CV%	n
89.85	1.67	1.85	84
219.28	6.03	2.75	84

±10% CV% differences can be observed between devices.
Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison[10, 11]:
Correlation with a comparative method is r= 0.99
According to Passing-Bablok Fit:
Slope: 0.9973
Intercept: 0.981481

Linearity: The method is linear up to 1000 mg/dL.
For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

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Manufactured by:

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