TRIGLYCERIDES

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

2°C – 8°C

REF 1419-0068 **Packaging:** 6 x 30 mL (R1) + 6 x 4 mL (R2)

Σ 900

INTENDED USE
Reagents for In Vitro quantitative automated measurement of the concentration of Triglycerides in samples of human serum or plasma from the general patient population. Measurements of Triglycerides are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid in screening, risk assessment, diagnosis and management of complications and comorbidities associated with hypertriglyceridemia.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

CLINICAL SIGNIFICANCE
Triglyceride levels increase in hyperlipoproteinemia type I, IIb, III and V, in familial lipoprotein lipase deficiency, in lipoprotein lipase cofactor (Apo C-II) deficiency, in familial dys-β-lipoproteinemia, familial combined hyperlipidemia, viral hepatitis, alcoholism, alcoholic cirrhosis, biliary cirrhosis, nephrotic syndrome, essential hypertension, diabetes mellitus, glycogen storage disease type I, III and VI, thalassemia major, Down's syndrome and various other endocrine diseases. Low triglyceride levels are observed in hypolipoproteinemia and a-β-lipoproteinemia, in hyperthyroidism, hyperparathyroidism, lactosuria, malnutrition, malabsorption syndrome, intestinal lymphangiectasia, and end-stage liver parenchyma disease.

METHOD PRINCIPLE
The enzymatic GPO-POD method is applied. The determination is based on the following reactions:

$$\text{Triglycerides} + H_2O \xrightarrow{LPL} \text{Glycerol} + \text{Fatty acids}$$

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

$$\text{3- Phosphoglycerol} + O_2 \xrightarrow{GPO} \text{Phosphodihydroxyacetone} + H_2O_2$$

$$2H_2O_2 + \text{TOOS} + \text{4- Aminoantipyrine} \xrightarrow{POD} \text{Quinoneimine} + H_2O$$

LPL = Lipoprotein Lipase
GPO = 3-Phosphoglycerol Oxidase
GK = Glycerol Kinase
POD = Peroxidase

The absorbance at 550/590 nm is proportional to the concentration of triglycerides in the sample.

METHOD LIMITATIONS
Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

REAGENT COMPOSITION

Reagent 1 (R1)	Reagent 2 (R2)
Tris buffer (pH: 6.8): 240 mM Peroxidase: > 5000 U/L Glycerokinase: > 1000 U/L Lipoprotein Lipase: > 15000 U/L ATP: 4.5 mM	4- Aminoantipyrine: < 15 mM GPO: > 55000 U/L Non reacting ingredients, preservative

⚠ **WARNINGS – PRECAUTIONS**
- The reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- This reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**
R1 and R2 reagents ready-to-use. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**
The reagents should not be used:
- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When they appear turbid or there is visible microbial infection.

⚠ **SHELF LIFE**
Unopened, the reagent is stable at 2 – 8°C up to the expiry date stated on the label. After opening it remains stable for 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum or EDTA plasma may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Patients must fast for at least 12 hours prior to sampling. Do not use hemolyzed, contaminated or turbid sample specimens. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. Multiply plasma results by 1.03 to get the equivalent triglycerides concentration for serum. Triglycerides are stable for 7 days at 2 - 8°C and 1 year at -20°C. Lipemic samples may require warming at 37°C and intense mixing before analysis, especially if they have been frozen. Do not freeze thawed samples.

CALIBRATION Diatron offers MECION MEDI-CAL (code 1578-0891) traceable to SRM 1951a (NIST) for serum calibration. Calibrate the assay every 2 weeks when used on Diatron Pictus® P700 or P500 analyzers. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

QUALITY CONTROL Diatron offers MEDICON Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT
- Triglycerides calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Serum or plasma: Suspicious: > 150 mg/dl Increased: > 200 mg/dl
Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

⚠ **WASTE DISPOSAL**
This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS
The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.
Linearity 1000 mg/dL
Lowest detection limit: 3.0 mg/dL
The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.
Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run). let accompanying the insert. The results taken in your laboratory may differ from these values.

Pictus® P700 and P500	
Mean (mg/dL)	**%CV**
105.0	1.30
229.0	1.20
Mean (mg/dL)	**TOTAL %CV**
105.0	4.60
229.0	2.40

INTERFERENCES - Criterion: recovery within ±10% from target value

	(Insignificant up to)
Hemoglobin	500 g/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbic acid	0.8 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and analyzer, and another, commercially available product. The results were as follows:
Y = 0.980X + 3.776 R=0.9965 N=142 Sample range = 39.1 – 482 mg/dL

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SYMBOLS

Manufacturer	IVD *In vitro* diagnostic medical device
Temperature Limit	REF Catalogue Number
Caution	Σ Contains sufficient for <n> tests

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