GGT

GAMMA GLUTAMYL-TRANSFERASE

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

2°C – 8°C REF 1419-0100 **Packaging:** 6 x 16 mL (R1) + 6 x 4 mL (R2) Σ 600

INTENDED USE
Reagents for In Vitro quantitative automated determination of Gamma-Glutamyl Transferase - GGT (EC 2.3.2.2) in samples of human serum or plasma from the general patient population. Measurements of GGT are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for diagnosis and management of liver disorders.

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
L-Gamma Glutamyl Transferase (γ-GT) is a liver enzyme catalyzing the transfer of amino acids from one peptide to another. γ-GT is present in all body cells except those in muscle. The enzyme present in serum appears to originate from the hepatobiliary system. Elevated levels in serum may indicate an abnormality in liver caused by congestive heart failure, cholestasis, cirrhosis, necrosis of the liver, liver tumors, hepatitis, and intrahepatic or post hepatic biliary obstruction. It is more sensitive than alkaline phosphatase in detecting obstructive jaundice, cholangitis, and cholecystitis and its rise occurs earlier and persists longer. γ-GT is also increased in acute or chronic pancreatitis, infectious hepatitis, fatty liver, in patients receiving anticonvulsant drugs such as phenytoin and phenobarbital. γ-GT testing also plays a role in the detection of alcoholism, alcoholic liver damage and in monitoring alcohol abstinence. γ-GT is a useful indicator for pancreatic or liver cancer, because its levels reflect the extent of the disease and the response to the treatment.

METHOD PRINCIPLE
The IFCC method is applied. The kinetic determination of γ-GT according to IFCC is based on the following reactions:

L-γ-glutamyl-3-carboxy 4-nitroanilide + Gly-G $\xrightarrow{\gamma\text{-GT}}$ Glutamyl-Glycyl-Glycine + 5-amino2-nitrobenzoate

γ-GT: Gamma Glutamyl-Transferase Gly-Gly: Glycyl-Glycine

The rate of increase of absorbance at 405/505 nm is proportional to the γ-GT activity in the sample.

METHOD LIMITATIONS
Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". 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 8.2):	160 mM	L-γ-glutamyl-3-carboxy 4-nitroanilide: 20 mM
Glycyl-Glycine:	200 mM	Non-reactive ingredients, preservatives.
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WARNINGS – PRECAUTIONS
- This 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.
- 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!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

PREPARATION
Reagents R1 and R2 are liquid and ready-to-use when placed in their corresponding positions on the analyzer. 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.
- After prolonged exposure to sunlight or high temperature.

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 2 months when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

SAMPLE Serum, or Li-heparin plasma may be used as specimen. Plasma samples may exhibit slightly lower values. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. GGT remains stable in serum or plasma for 1 month at 2 - 8°C and 12 months at –20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to IFCC method, for calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 1 month. Calibration should be repeated when a new lot of reagent is used, 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
- GGT calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Serum, plasma: 10 – 49 U/L (men) 7 – 32 U/L (women)
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 Up to 1200 U/L
Lowest detection limit 6.2 U/L
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).

Pictus® P700 and P500	
Level (U/L)	**%CV**
33.4	3.40
178.0	2.50
Level (U/L)	**TOTAL %CV**
33.4	3.60
178.0	2.90

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

	(Insignificant up to)
Triglycerides	3000 mg/dL
Bilirubin	20 mg/dL
Ascorbate	3 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer, and another commercially available product. The results were as follows:
Y = 1.037X + 0.230 R=0.9990 N=80 Sample range=9.8–944U/L

BIBLIOGRAPHY

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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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