diatron

GGT

For use on Diatron Pictus® series analyzers
Method: IFCC
Product code: 1419-0102, 1419-0100
Package: 6 x 32 ml (R1) + 6 x 8 ml (R2), 6 x 16 ml (R1) + 6 x 4 ml (R2)
Store at: 2° – 8°C
For *in vitro* use only

INTENDED USE
Ready to use reagents for the quantitative determination of L-Gamma Glutamyl Transferase (γ-glutamyltranspeptidase) in human serum or plasma specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE[1,2]
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 posthepatic 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 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".
The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION
Reagent 1 (R1):
Tris buffer (pH 8.2): 160 mM
Glycyl-Glycine: 200 mM
Non reactive ingredients, preservatives.
Reagent 2 (R2):
L-γ-glutamyl-3-carboxy 4-nitroanilide: 20 mM
Non reactive ingredients, preservatives.

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.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT 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 Pictus® series 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 56 days when stored in the cooled reagent tray of the Pictus® series analyzers.

SAMPLE[3,5]
Fresh, non hemolysed serum or plasma with 1 mg/ml EDTA. Fluoride, oxalate and citrate reduce the enzyme activity about 10 – 15%. Heparin produces turbidity in the reaction mixture. γ-GT in samples is stable for a month when stored at 2 – 8°C. Avoid repeated freezing and thawing.

CALIBRATION
Diatron provides MEDI-CAL (1578-0891) for calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 28 days. 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 provides the 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 SUPPLIED WITH THE KIT
- γ-GT calibrator
- Quality control materials
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment.

REFERENCE INTERVALS[4]
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® series 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.

	Pictus® P400	Pictus® P700/P500
Linearity	Up to 1200 U/L	Up to 1200 U/L
Lowest detection limit	4.9 U/L	3.9 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® P400			Pictus® P700/P500		
	Level (U/L)	Within Run CV%	Total CV%	Level (U/L)	Within Run CV%	Total CV%
	55.5	3.08	3.97	52.9	2.39	3.47
	148	2.16	2.65	155	1.99	2.51

Interferences: Criterion: recovery within ±20% from target value

	Pictus® P400	Pictus® P700/P500
Lipemia	Insignificant up to 1000 mg/dL Intralipid®	Insignificant up to 1000 mg/dL Intralipid®
Haemoglobin	Insignificant up to 500 mg/dL	Insignificant up to 180 mg/dL
Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 3 mg/dL

Correlation: A comparison was performed between this reagent on a Pictus® series analyzer, and another, commercially available, product on a BECKMAN COULTER AU-series system. The results were as follows:

Pictus® P400			
Y = 0.957X + 6.759	R=0.9990	N=60	Sample range = 12.6 – 275 U/L
Pictus® P700/P500			
Y = 1.037X + 0.230	R=0.9990	N=80	Sample range = 9.8 – 944 U/L

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Thomas L. Gamma glutamyltransferase (Γ-GT). In Thomas L ed. Clinical laboratory diagnostics. Use and assessment of clinical laboratory results. Frankfurt/Main: TH-Books Verlagsgesellschaft, 1998:80-86
3. Ehret W, Heil W, Schmitt Y, Topfer G, Wisser H, Zawta B, et al. Use of anticoagulants in Diagnostics. Laboratory investigations and stability of blood, plasma and serum samples. WHO/DIL/LAB/99.1 Rev.2:32pp
4. Schumann G, Klauke R. New IFCC reference procedures for the determination of catalytic activity concentrations of five enzymes in serum: preliminary upper reference limits obtained in hospitalized subjects. Clin Chim Acta 2003;327:69-79.
5. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.
6. Szasz, G. A kinetic photometric method for serum γ-glutamyltranspeptidase. Clin Chem. 1969: 15; 124 – 136.

SYMBOLS
Temperature Limits (L/H)
Manufacturer
Read the Instructions
Catalog Number (ISO 15223 / rev. EN980)
Batch Code (ISO 15223 / rev. EN980)
For in vitro use (ISO 15223 / rev. EN980)
Date of Expiry (ISO 15223 / rev. EN980)

CE IVD

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