ALT/GPT

ALANINE AMINOTRANSFERASE

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

2°C – 8°C

REF 1419-0080 **Packaging:** 6 x 18 mL (R1) + 6 x 4.5mL (R2) Σ 672

REF 1419-0082 **Packaging:** 6 x 36 mL (R1) + 6 x 9 mL (R2) Σ 1350

INTENDED USE

Reagents for In Vitro quantitative automated measurement of the activity of Alanine Aminotransferase - ALT/GPT (EC 2.6.1.2) in samples of human serum or plasma from the general patient population. Measurements of ALT are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid in the evaluation of liver health and the screening for, detection, differential diagnosis, severity assessment and monitoring of hepatic diseases.

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

Alanine aminotransferase (ALT/GPT) is an enzyme that catalyzes the reversible transfer of an amino group from alanine to a-ketoglutarate. Elevated ALT/GPT levels do not always signify a health problem. Fluctuation of ALT levels over the course of the day is normal and ALT levels can also increase in response to strenuous physical exercise. Elevated levels of ALT can be observed in liver cell necrosis or injury of any cause, severe shock, heart failure, acute anoxia, extensive wounds or burns, cirrhosis, obstructive jaundice, myositis, myocarditis, muscular dystrophy, occasionally in hemolytic disease, chronic alcohol abuse, or use of drugs such as penicillin, salicylic or opiates.

METHOD PRINCIPLE

The Modified IFCC without pyridoxal phosphate is applied. The determination of ALT/GPT is based on the following reactions:

L-alanine + α-ketoglutarate $\xrightarrow{ALT}$ pyruvate + L-glutamate

Pyruvate + NADH + H^+ $\xrightarrow{LDH}$ L-Lactate + NAD^+

ALT: Alanine Aminotransferase LDH: Lactate Dehydrogenase

The rate of absorbance change at 340/650 nm is proportional to the ALT/GPT 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 7.4):	125 mM	NADH:	1.4 mM
D-LDH:	< 3500 U/L	α-ketoglutarate:	75 mM
L-Alanine:	624 mM	Non-reactive ingredients, preservative.	
Non-reactive ingredients, preservative.			

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 the corresponding positions of 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 reagents are stable at 2 – 8°C up to the expiry date stated on the label. After opening, they remain stable for 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or analyzers.

SAMPLE Serum or Li-heparin plasma can be used as specimen. 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, separate serum or plasma from blood cells and store properly if analysis cannot take place right after sample separation. ALT/SPT is not stable in serum and plasma samples at room temperature, when stored at 2 – 8°C, or when stored at –20°C, so testing should be done as soon as possible after centrifugation and separation.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to Medicon Master Lot for calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 2 weeks. 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

- ALT/GPT calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum, plasma: 5 – 35 U/L (men) 5 – 31 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 500 U/L

Lowest detection limit 2.8 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**
50.0	4.0
128.0	2.8
Level (U/L)	**TOTAL %CV**
50.0	4.2
128.0	3.4

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

	(Insignificant up to)
Triglycerides	2400 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	40 mg/dL
Conj. Bilirubin	40 mg/dL
Ascorbate	3 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 = 0.982X + 2.074 R=0.9925 N=106 Sample range = 6.3 – 216 U/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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