diatron

Lipase

With Calibrators

For use on Diatron Pictus® series analyzers

Method:	**Methyl-rezorufin**
Product code:	**1419-0307**
Package:	**6x9ml (R1) + 6x5.4ml (R2)**
	Lyophilized Calibrator 6x1ml
Store at:	**2° – 8°C**

For *in vitro* use only

INTENDED USE

Reagents for the quantitative determination of lipase in human serum, plasma or urine specifically for use with Diatron Pictus® series analyzers. For *in vitro* diagnostic use only.

CLINICAL SIGNIFICANCE [1,2,3]

Lipase appears increased in case of pancreatitis and values remain high longer than the values of amylase. Lipase values appear high in cases of chronic dysfunction of the pancreas, and in cases of primary biliary cirrhosis, chronic kidney failure and in patients on dialysis.

METHOD PRINCIPLE

In an alkaline medium, 1,2-o-dilauryl-rak-glycero-3-glutaric acid-(6'-methylrezorufine) is converted by lipase to 1,2-o-dilauryl-rak-glycerol and an unstable intermediate, which spontaneously breaks up to form glutaric acid and methylrezorufine, that absorbs light at 590 nm. The rate of absorbance change over time is proportional to the activity of lipase 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 R1	
Buffer (pH 8,0)	50 mM
Cholipase:	≥1 mg/ml
Sodium Deoxycholate:	1,8 mM
Calcium Chloride	12mM
Reagent R2	
Buffer pH 4,0	12mM
1,2-o-dilauryl-rak-glycero-3-glutaric acid-(6'-methylrezorufine) ester	0,27mM
Taurodeoxycholic acid	9,0 mM
Non reactive components and 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.
- The 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 MEDICON HELLAS (manufacturer) upon request.

REAGENT PREPARATION

Lipase reagents are ready-to-use when placed in the corresponding position on the analyzer. The vials bear barcode for automatic recognition by Pictus® series analyzers Reconstitute each calibrator vial with 1 mL deionized water.

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.
- 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. Once opened, it remains stable for 14 days when stored in the reagent tray of the Pictus® P700/P500 analyzer. The reconstituted calibrator remains stable for 15 days at 2 – 8°C.

SAMPLE

Non-hemolyzed serum or plasma with fluoride or iodoacetate. Serum specimens remain stable for 8 hours at 25°C and 72 hours at 4°C. Plasma specimens are stable for 24 hours at room temperature. Serum should be separated from blood as soon as possible.

CALIBRATION

Recalibrate the assay every 7 days when used on Pictus® P700/P500. 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 provides the Clinical Chemistry Control Level 1 & 2 (code 1578-0901-12 & 1578-0902-12 respectively) for serum quality. 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

- Diatron Pictus® P400/P700/P500
- Quality control materials.
- Common laboratory equipment.

REFERENCE INTERVALS[5]

Serum, plasma: < 60 U/L

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.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following values are representative of the reagent performance on Diatron Pictus® analyzers. The results taken in your laboratory may differ from these values.

	Pictus® P700/P500
Linearity	up to 200 U/L
Lowest detection limit	1.2 U/L

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/P500		
Level (IU/ml)	Within Run CV%	Total CV%
48	2.45	5.71
160	3.09	6.55

Interferences: Criterion: recovery within ±10% from target value

	Pictus® P700/P500
Lipemia	No interference up to 1000 mg/dL Intralipid®
Heamoglobin	No interference up to 500 mg/dL
Non conj. Bilirubin	No interference up to 20 mg/dL
Ascorbate	No interference 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 SIEMENS ADVIA 2400 analyzer. The results were as follows:

Serum: Y=1,0715X-7,7879 R=0,9906 N=113 Sample range = 7,5-158,9 U/L

BIBLIOGRAPHY

1. Thomas L ed. Labor und Diagnose, 4th ed. Marburg: Die Medizinische Verlagsgesellschaft, 1992.
2. Kjellman NIM, Johansson SGO, Roth A. Clinical Allergy 1976;6: 51-59.
3. Dati F, Ringel KP. Reference values tor serum IgE in healthy non-atopic children and adults. Clin Chem 1982;28:1556.
4. Ringel KP, Dati F, Buchhoiz E. IgE-Normalwerte bei Kindern. Laboratoriumsbiatter 1982;32:26-34.

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)

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