DIAZYME LABORATORIES

LIPASE ASSAY

Dual Vial Liquid Stable

Diazyme's Lipase Assay is a cost effective dual vial stable liquid method which utilizes industry standard 6' Methylresorufin ester for consistent reliable performance. The test has a ten-fold reduction in interference from triglycerides and cholesterol in comparison to older 1, 2 diglyceride method for improved accuracy. Determination of lipase is used for diagnosis and treatment of diseases of the pancreas such as acute and chronic pancreatitis and obstruction of the pancreatic duct.

DIAZYME LIPASE ASSAY ADVANTAGES

- Fast test results (under 10 minutes) for a rapid turnaround time
- Liquid stable reagent, calibrator and controls are offered separately for added convenience
- User friendly instrument specific packaging options available
- A wide range of instrument parameters are offered for facilitating and simplifying implementation

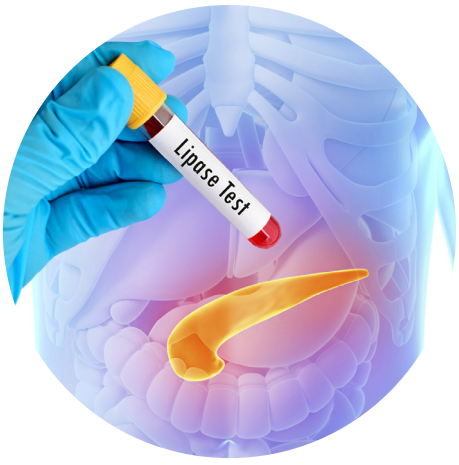
REGULATORY STATUS

510(k) Exempt

CE

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Hitachi
- **Beckman**
  - AU Series



LIPASE ASSAY
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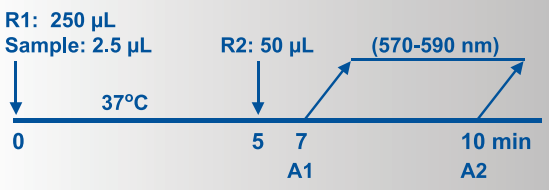
ASSAY SPECIFICATIONS

Method	Kinetic assay monitoring at 580 nm of the enzymatic cleavage of a synthetic substrate (6' Methylresorufin)
Sample Type & Volume	• Serum • Plasma Sample Volume 2.5 µL
Method Correlation	N = 101 y-intercept = 3.9443 Slope = 0.50054 R^2 = 0.99732 -Excellent correlation to Roche's 6' Methylresorufin method
Linear Range	Up to 250 U/L
LOD	5 U/L
Calibration Levels	2-Point Calibration
Reagent On-Board Stability	Opened: 90 days when stored at 2-8°C

*Lipase Assay Procedure**



Analyzer Dependent

Parameter questions for Lipase Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

ASSAY PRECISION

Intra-Assay Precision was determined on 20 replicates of each control (3 levels - L1/L2/L3).

Intra-Assay Precision:

n=20	Average U/L	SD	CV%
L1	11.80	2.63	22.27%
L2	119.20	4.14	3.47%
L3	215.35	6.11	2.84%

Inter-Assay Precision was determined in accordance with NCCLS Document EP5-T (3 levels - L1/L2/L3).

Inter-Assay Precision:

	Mean	Within run		Run to run		Total	
	U/L	SD	CV%	SD	CV%	SD	CV%
L1	11.65	2.55	21.88%	1.17	10.00%	2.80	24.06%
L2	119.55	4.13	3.45%	5.43	4.54%	6.82	5.71%
L3	215.03	5.97	2.78%	10.79	5.02%	12.33	5.73%

ASSAY INTERFERENCE

Triglycerides give a negative interference on lipase determination (-6%) from a 300 mg/dL concentration. The test is not affected by hemoglobin up to 150 mg/dL and bilirubin concentration up to 20 mg/dL.

ASSAY REFERENCE RANGE

Lipase in normal subjects (U/L methylresorufin at 37 °C): ≤ 38 U/L

The study has been done on 237 healthy patients (116 males and 121 females); all of them have been previously tested for pancreatic amylase and found normal. The obtained data was processed with non parametric method. The upper limit of the normal range, calculated at 97.5% percentile, is 37.8 U/L with a 90% confidence range between 35.0 and 43.4 U/L; 95% of the tested population showed lipase values ≤ 37.8 U/L. Slight differences could be observed on a different population. It is recommended that each laboratory establish its own expected range characteristic for the local population.

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