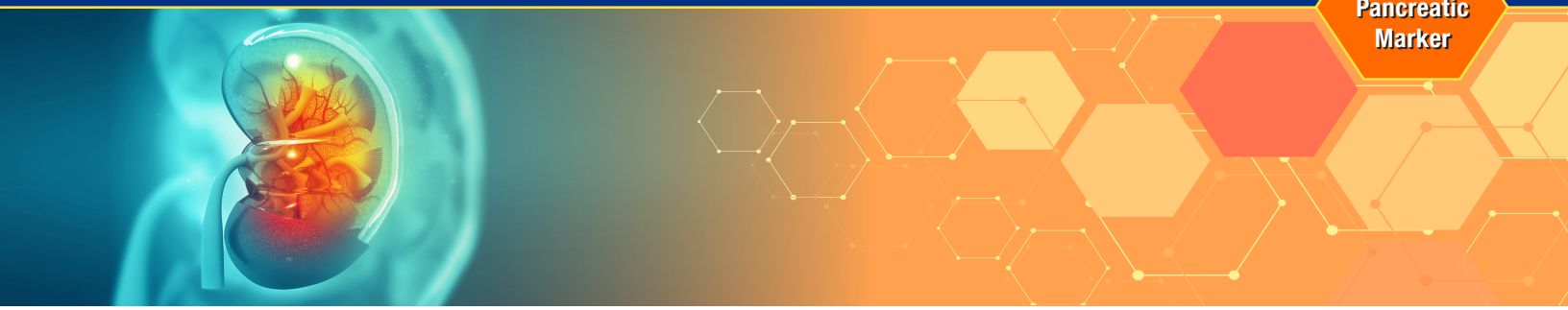
LIPASE ASSAY

Renal and Pancreatic Marker



Lipase enzymes are produced in the pancreas and also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. 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's Lipase Assay is a cost effective dual vial stable liquid method which utilizes industry standard 6' Methylresorufin ester for consistent reliable performance.

DIAZYME LIPASE ASSAY ADVANTAGES

- Enzymatic assay for accurate determination of Lipase in patient samples
- Fast test results (10 minutes) for a rapid turnaround time
- Liquid stable reagent, calibrator and controls are offered separately for added convenience
- Wide range of instrument parameters are offered for simplifying implementation

REGULATORY STATUS

510(k) Exempt; EU: CE IVD

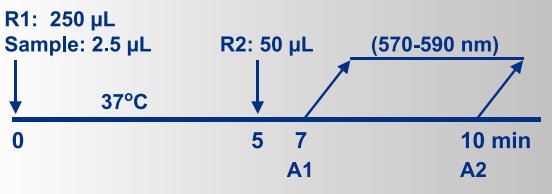
LIPASE ASSAY

Dual Vial
Liquid Stable

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
Linearity	Up to 250 U/L
LOD	5 U/L
Calibration Levels	2-Point Calibration
Reagant 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 (U/L)	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 (U/L)	CV (%)	SD (U/L)	CV (%)	SD (U/L)	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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