

PANCREATIC ELASTASE ASSAY



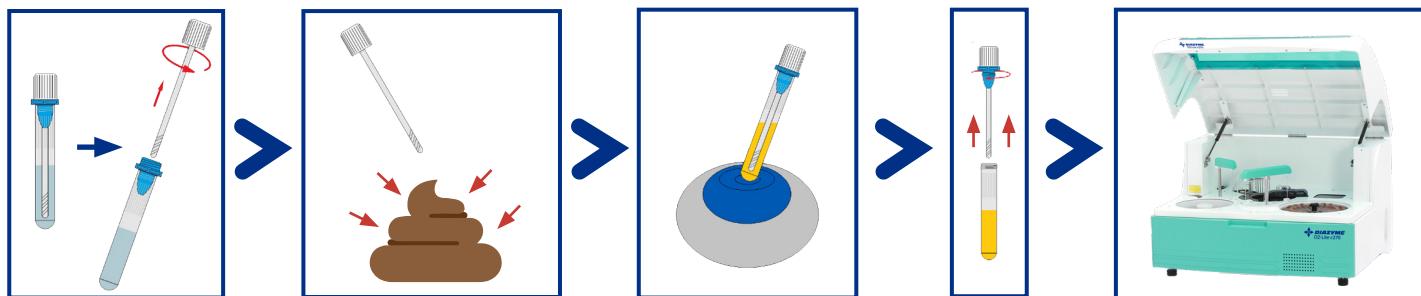
Diazyme's Pancreatic Elastase Assay is a particle-enhanced immunoturbidimetric assay. Pancreatic Elastase in the sample binds to specific anti-Pancreatic Elastase antibodies, which is coated on latex particles, and causes agglutination. This agglutination is detected as an absorbance change, with the magnitude of the change directly related to the quantity of Pancreatic Elastase in the sample. The actual concentration is then determined by the interpolation from a calibration curve prepared from calibrators of known concentration.

DIAZYME PANCREATIC ELASTASE ASSAY ADVANTAGES

- Particle-enhanced immunoturbidimetric method
- Used for the quantitative measurement of human fecal Pancreatic Elastase in human fecal specimens
- Liquid stable reagent kit, calibrator and control sets offered separately
- Fast test results (10 minutes) for a rapid turnaround time
- Wide range of instrument parameters available for simplifying implementation

REGULATORY STATUS

510(k) Exempt



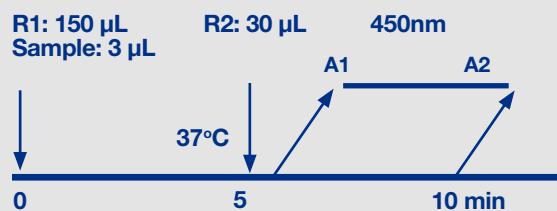
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Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Particle Enhanced Immunoturbidimetric
Sample Type & Volume	Stool extracts Sample Volume 3 μ L
Patient Sample Comparison with ELISA	Positive Agreement: 88% Negative Agreement: 94% Total Agreement: 91%
Linearity	18.4 to 438.3 μ g/g
LOQ	11.8 μ g/g
Calibration Levels	6-Point Calibration
Reagent On-Board Stability	30 days on-board stability (when stored at 2-8°C)

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***Analyzer Dependent**

For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

ASSAY PRECISION

The precision of the Pancreatic Elastase Assay was evaluated on an AU5800 analyzer. Three samples containing 83.4, 161.1, and 360.6 μ g/g Pancreatic Elastase were tested with 5 replicates with one run per day for 5 days for a total of 25 replicates per sample. Results are summarized below:

Sample	Mean (μ g/g)	n	Within Run		Between Day		Total	
			SD	CV(%)	SD	CV(%)	SD	CV(%)
1	83.4	25	1.79	2.2	3.76	4.5	4.59	5.5
2	161.1	25	3.05	1.9	5.21	3.6	6.61	4.1
3	360.6	25	3.14	0.9	2.89	2.9	4.52	1.3

REFERENCE RANGE

Level	Range (μ g/g)
Insufficiency	<100
Slight to moderate insufficiency	100 - 200
Normal	>200

Note each laboratory is recommended to establish a range of normal values for the population in their region.

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