

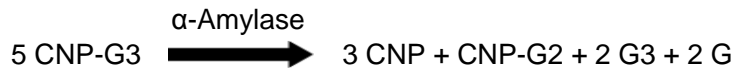
Amylase

Intended Use

For **IN VITRO** quantitative determination of **Amylase** in serum using manual or automated applications.

Method Principle

α -Amylase hydrolyzes the 2-chloro-p-nitrophenyl- α -D-maltotrioside (CNP-G3) to release 2-chloro-p-nitrophenol and form 2-chloro-p-nitrophenyl- α -D-maltoside (CNP-G2), maltotriose (G3) and glucose (G). The rate of formation of the 2-chloro-p-nitrophenol can be detected spectrophotometrically at 405 nm to give a measurement of α -Amylase activity in the sample.



Method Performance Characteristics

Sensitivity: 0.00026 – 0.00031 absorbance units per U/L.

Linear Range: 0 – 2000 U/L.

Precision: Within-run and day-to-day precision is summarized below.

Amylase	Within-Run Precision		Day-to-Day Precision	
	SD	CV	SD	CV
U/L	U/L	%	U/L	%
105	2.34	2.21	2.46	2.35
257	4.91	1.90	4.98	1.94
448	7.48	1.65	11.70	2.61

Correlation

A comparison of the Catachem Amylase method using an automated analyzer and a reference method based on the CNP-G3 substrate oxidation was conducted on a human sample population. The following regression statistics were observed.

Correlation Data	
Parameter	Data Observed
N	48
Range	10-255 U/L
Regression	$Y = 0.994x + 1.44$
Correlation	$r = 0.994$