

Note :

The expected values of α - Amylase is dependent on the substrate used in the formulation. Result cannot be compared with kits based on formulation using other substrates.

Expected range varies from population to population. It is therefore recommended that each laboratory should establish its own normal range. For diagnostic purposes, the α - Amylase results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

Performance Characteristics**Linearity**

With AutoPure α - Amylase, the assay is linear upto 2000 IU/l (33.4 μ kat/l). Determine samples with higher concentrations via the rerun function. On instruments without rerun function, manually dilute samples with higher concentrations using 0.9% NaCl or distilled / deionized water (e.g. 1 + 4). Multiply the result by the appropriate dilution factor (e.g. 5).

Interference

Avoid contamination of reagent, samples and glassware by saliva or sweat because they have a high α - Amylase content. Do not pipette by mouth.

There is no significant interference in samples containing upto 60 mg/dl of bilirubin, 500 mg/dl of haemoglobin and 100 mg/dl of ascorbic acid.

Precision

Reproducibility was determined using quality control sera as shown below :

n = 10

Quality Control Material	Within run			Between run		
	Mean IU/l	SD IU/l	%CV	Mean IU/l	SD IU/l	%CV
Low Control Serum	76	1.15	1.5	76	2.00	2.4
High Control Serum	194	3.06	1.6	193	2.60	0.9

Co-Relation Studies

A comparison of the α - Amylase determination using AutoPure α - Amylase and Infinite α - Amylase reagent gave the following co-relation (IU/l) :

Linear Regression

$$y = -5.647 + 1.100x$$

$$r = 0.9990$$






$$S_{y.x} = 8.07$$

No. of samples measured : 95

The sample concentrations measured were between 30 and 600 IU/l.

References

1. Tietz, N.W. ed. **Clinical Guide to Laboratory Tests**, 3rd ed. Philadelphia, Pa : WB Saunders Company, 1995 : 46-51.
2. Winn - Deen, E.S., David, H., Siglet E. and Chavzer, R. **Clin. Chem.** 34/10, 2005 - 2008 (1988).
3. Junge, W. et al., **Clin. Biochem.** 22, 109 (1989).
4. In-house test data. **Accurex Biomedical Pvt. Ltd.** 2002.

IVD	In Vitro Diagnostic Use		Date of Manufacturing
	Consult Instructions for use		Use by (YYYY-MM-DD)
REF	Catalogue Number		Temperature Limitation
LOT	Batch Code		Manufacturer



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 α - AMYLASE

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