

TECO DIAGNOSTICS

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α - AMYLASE LIQUID REAGENT (KINETIC METHOD) For TC MATRIX

INTENDED USE

For the quantitative determination of α -amylase activity in serum, plasma or urine on TC Matrix analyzers.

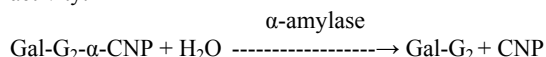
SUMMARY AND EXPLANATION OF THE TEST

The determination of amylase activity in serum, plasma and urine is most commonly performed for the diagnosis of acute pancreatitis. In acute pancreatitis, amylase levels are elevated for longer periods of time in urine than in serum. Therefore, determining the ratio of the amylase and creatinine clearances is important in following the course of the pancreatitis.

Substrate

Galactose-Glucose-Glucose-Chloronitrophenol(Gal-G₂- α -CNP) is hydrolyzed by α -amylase to G₂ and CNP stoichiometrically. The rate of CNP formation due to substrate hydrolysis by α -amylase is proportionally correlated with α -amylase activity which is measured by following the rate of absorbance increase at 405 nm.

The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 405 nanometers. This change in absorbance is directly proportional to the activity of α -amylase in the sample and is used by the TC Matrix System to calculate and express α -amylase activity.



REAGENT CONTENTS:

Each kit contains: Two Amylase reagent 1 (2 x 20 ml)
Two Amylase reagent 2 (2 x 4 ml)

Instruction Insert.

REAGENT PREPARATION

No preparation is required.

REAGENT COMPOSITION

Gal-G₂- α -CNP: 0.3 mmol/L

CaCl₂: 10 mmol/L

Phosphate buffer: 50 mmol/L

Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY

α -Amylase Reagent stored unopened at 2°C to 8°C is stable until the expiration date showed on the bottle label. Once opened, Teco α -Amylase Reagent is stable for 30 days, unless the expiration date is exceeded.

DO NOT FREEZE.

REAGENT DETERIORATION

The reagent should be discarded if:

1. Turbidity has occurred; turbidity may be a sign of contamination.
2. The mixed reagent has an absorbance of 0.70 or greater when measured against water at 405 nm.

SPECIMEN COLLECTION AND HANDLING

1. The test can be performed on serum, plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and allow clotting. The serum is then separated from the clot. A maximum limit of two hours from the time of collection is recommended.
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum and plasma should be stored at 2°C to 8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.
3. It is recommended that urine assays be performed within 2 hours of collection. Due to the instability of amylase in acidic urine; the pH of the specimen should be adjusted to the alkaline range and stored at 4°C. For timed specimens, the collection container should be kept in the refrigerator or on ice during the timed period.
4. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.

CALIBRATION

Calibration is not required.

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

At least two levels of control material.

LIMITATIONS

1. The anticoagulants Potassium Oxalate, Sodium Fluoride, Sodium Citrate and EDTA were found to be incompatible with this method.
2. The anticoagulants Ammonium Heparin, Sodium Heparin and Lithium Heparin were found to be compatible with this method.

INTERFERENCE

1. Samples showing evidence of hemolysis should not be used.
2. Lipemic samples >3+ should be ultra-centrifuged and the analysis performed on the infranate.
3. Pyruvate at a level of 2 mg/dL may cause decreased results.
4. On this method, refer to the work of Young for a review of drug and comprehensive list of substances effect on α -Amylase level.

EXPECTED VALUE

Serum or Plasma: 12.5 – 62.5 IU/L or 0.21 - 1.04 μ kat/L

Urine: 0.5 – 8.5 IU/L or 0.01 - 0.14 μ kat/L

PRECAUTIONS:

1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

PROCEDURES

TEST NAME:	AMYL	R1:	200
TEST NO.		R2:	40
FULL NAME:	α -amylase	SAMPLE VOLUME:	6
REFERENCE NO.:		R1 BLANK:	/
ANALY. TYPE:	Kinetic	MIX REAG. BLANK:	0 - 1.5
PRI. WAVE :	405nm	CONCENTRATION:	/
SECON. WAVE:	546 nm	LINEARITY LIMIT:	0 - 1996
TREND:	Ascending	SUBSTRATE LIMIT:	/
REACT. TIME:	1 - 8	FACTOR:	4824
INCUBATE TIME:	20	PROZONE CHECK:	/
UNIT:	IU/L	Q1: / Q2: / Q3: / Q4: /	
PRECISION:	Integer	PC: / ABS.: /	

PERFORMANCE CHARACTERISTICS

Analytical Range: 2.5-400 IU/L

For α -amylase analyte by α -Amylase Reagent on TC Matrix System, this method has been demonstrated to be linear from 2.5-400 IU/L

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter α -Amylase Reagent was used to compare with α -Amylase Reagent. The results of this study in yield a correlation coefficient of 0.98 with a regression equation of $y=0.98X-1.8$

Precision: Within Run precision for α -Amylase Reagent Set was determined following a modification of NCCLS EP5-A. Two commercial human serum were assayed on TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	78	381
Standard Deviation (mg/dl)	3.4	10.5
Coefficient of Variation (%)	3.8	3.3

Run-Day precision for α -Amylase Reagent was determined following a modification of NCCLS EP5-A. Two commercial human serum were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	79	379
Standard Deviation (mg/dl)	3.2	10.9
Coefficient of Variation (%)	3.6	2.9

REFERENCES:

1. Richterich R. 1969. Clinical chemistry. Theory and Practice, A.P. New York.
2. Caraway W.T. 1959. Am. Clin. 32:97.
3. Tietz, N.W., "Speciman Collection and Processing; Sources of Biological Variation," Textbook of Clinical Chemistry, 2nd Edition, W.B. Saunders, Philadelphia, PA (1994)
4. National Committee for Clinical Laboratory Standards. Approved Guideline, NCCLS publication C28-A, Villanova, PA (1994).
5. Henry, J. B., ed., Clinical Diagnostics and Management by Laboratory Methods, 18th Edition, W.B. Saunders, Philadelphia.

6. Tietz, N.W., ed., Clinical Guide to Laboratory Tests, 2nd Edition, W.B. Saunders, Philadelphia, PA (1990)
7. National Committee for Clinical Laboratory Standards, Method Comparison and Bias Estimation Using Patient Samples; Tentative Guideline, NCCLS Publication EP9-T, Villanova, PA (1993)
8. National Committee for Clinical Laboratory Standards, Precision Performance of Clinical Chemistry Devices; Tentative Guideline, 2nd Edition, NCCLS publication EP5-T2, Villanova, PA (1992)
9. National Committee for Clinical Laboratory Standards, National Evaluation Protocols for Interference Testing, Evaluation Protocol Number 7, Vol. 4, No. June 1984.
10. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 3rd Ed., AACC Press, Washington DC, 1990, 3-104 thru 3-106.

A532-200TM: 10/10

Manufactured by:



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