TECO DIAGNOSTICS
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α – AMYLASE LIQUID REAGENT (KINETIC METHOD) TC MATRIX-160

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-G_2-α-CNP) is hydrolyzed by α-amylase to G_2 and CNP stochiometrically. 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 a-amylase in the sample and is used by the TC Matrix System to calculate and express α-amylase activity.

$$\text{Gal-}G_2\text{-}\alpha\text{-CNP} + H_2O \xrightarrow{\text{A-amylase}} \text{Gal-}G_2 + \text{CNP}$$

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
Gal- G_2-α-CNP: 0.3 mmol/L
$CaCL_2$: 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 2ºC to 8ºC is stable until the expiration date shown on the bottle label. Once opened, a-Amylase Reagent is stable for 30 days or until the expiration date on the label, whichever occurs first.
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*.
   *__NOTE:__ The mixing reagent can be prepared by mixing five (5) volumes of R1 with one (1) volume of R2 in a disposable container. *Example:* 1 Ml R1 + 0.2 Ml R2.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum or plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and it is allowed to clot. 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 2ºC to 8ºC. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15ºC to -20ºC. 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 4ºC. 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
1. Calibrator required: TECO MULTI Calibrator.
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

Note: Refer to the TC Matrix manual for further instructions on calibrating the instrument

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 μkat/L
Urine: 0.5 – 8.5 IU/L or 0.01 – 0.14 μkat/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 the USA NIH Biosafety in Microbiological and Biomedical Laboratories manual and in accordance with national or local regulations related to the safety precautions of such materials.
3. Each laboratory should perform quality control testing to ensure the results are reliable before testing the specimens.

PROCEDURES

Test Name:	Amylase	R1:	150
Full Name:	Amylase	R2:	0
Pri. Wave:	405 nm	Sample volume:	2.0
Sec. Wave:	700 nm	Calibration Type:	2 point linear
Assay/ Point:	Kinetic	K Value:	/
Start - End:	2 - 7	Point:	2
Decimal place:	0	Blank Type:	Water
Unit:	U/L	Point 0 (Blank) Con.:	0.0
Linearity Range:	3.000 - 2500.00	Point 1 (STD) Con.:	Standard/
Correlation Factor:	1.0000 - 0.0000		Calibrator

PERFORMANCE CHARACTERISTICS

Analytical Range: 3-2500 IU/L

For a-amylase analysis by α-Amylase Reagent on TC Matrix System, this method has been demonstrated to be linear from 3-2500 IU/L

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter a-Amylase reagent was used to compare with α-Amylase reagent. The results of this study 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 samples were assayed on TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (IU/L)	78	381
Standard Deviation (IU/L)	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 samples were assayed on TC Matrix System five times per day for five days for the total of 25 values.

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

REFERENCES

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Manufactured by:

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