DXC (AMY7) AMYLASE

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PURPOSE

To provide instructions for the quantitative determination of amylase on the DXC 600/800.

PRINCIPLE

AMY7 reagent, in conjunction with UniCel® DxC 600/800 System(s) is intended for the quantitative determination of total Amylase activity in human serum, plasma or urine.

BACKGROUND

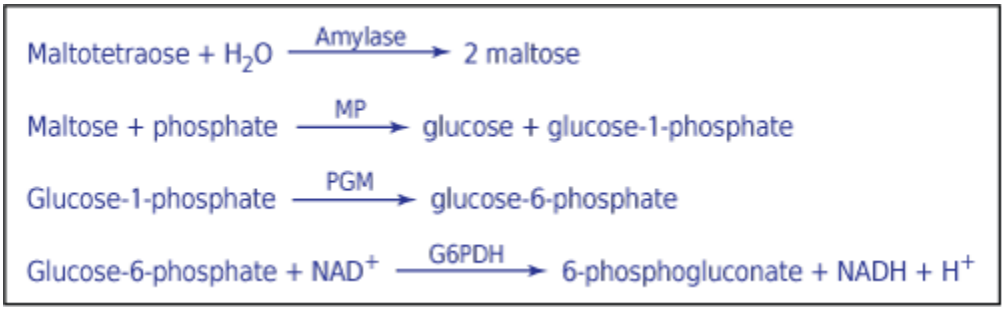
Clinical Significance

Amylase measurements are used primarily in the diagnosis and treatment of pancreatitis.

Methodology

AMY7 reagent is used to measure amylase activity by an enzymatic rate method.[1] In the reaction, amylase cleaves 4,6-ethylidene(G1)-4-nitrophenyl(G7)-α-(1→4)-D-maltoheptaoside (Ethyledene Protected Substrate = EPS) and subsequent hydrolysis of all the degradation products to p-nitrophenol with the aid of α -glucosidase. The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 30 parts reagent. The system monitors the change in absorbance at 410 nanometers. This change in absorbance is directly proportional to the activity of AMY7 in the sample and is used by the System to calculate and express the total AMY7 activity. Use of this product will result in assay values which are compatible with the methods recommended by the International Federation of Clinical Chemistry (IFCC).[2]

Chemical Reaction



RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol

J-F-CH0820	DXC 800 Controls
M-F-CH0820	Chemistry Controls
J-F-CH0826	DXC 800 Calibrators
M-F-CH0826	Chemistry Calibrators
M-F-CH1940	DXC 600 (AMR) Analytical Measurement Range
J-F-CH1940	DXC 800 (AMR) Analytical Measurement Range
R-W-CH0815	DXC Reagent Lot to Lot Correlations
R-F-CH0814	Lot-to-Lot Correlation

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Freshly collected urine may also be used for testing. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or 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. For timed specimens, the collection container should be kept in the refrigerator or on ice during the timed period. No preservative is required.

Sample Type	Volume	Sample stability
Plasma Serum Urine Fluid	0.5mL	• Separate serum from cells within 2 hours. • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 months. • Urine: Analyze within 2 hours or keep on ice; no preservative required

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two AMY Reagent Cartridges (2 x 200 tests) Kit #A71607

Volume per Test	
Sample Volume	7 µL
Ordac Sample Volume	3 µL
Total Reagent Volume	210 µL
Cartridge Volumes	A 175 µL B 35 µL C – –

Reactive Ingredients	
α-glucosidase (microorganism)	9700U/L
4,6-ethylidene(G1)-4-nitrophenyl (G7)-α-(1→4)-D-maltoheptaoside (Ethyledene Protected Substrate=EPS)	11mmol/L
Sodium Chloride Calcium Chloride Magnesium Chloride Also non-reactive chemicals necessary for optimal system performance -	87mmol/L 0.08 mmol/L 12.6 mmol/L

NOTICE
Avoid all contact with reagent. Sweat and saliva contain α-amylase. It is recommended that gloves be worn when handling the reagent cartridges. Use caution when recapping reagent cartridges. Reagent Mixture and Starter Reagent caps must not be interchanged or reagent contamination will occur.

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by ensuring that quality control results are within your facility`s acceptance criteria.

NOTE: New lots of reagent require lot to lot correlation studies. Refer to Related Documents section for related work instructions/forms.

Reagent Storage and Stability

AMY7 reagent when stored unopened at +2°C to +8°C will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 21 days at +2°C to +8°C. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

CALIBRATION

Calibrator Required

Calibration is not required.

Traceability

AMY7 assay is traceable to IFCC primary reference method.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system.

2. Program controls for analysis.

3. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

ANTICOAGULANT TEST RESULTS

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Acceptable Anticoagulants[a]

1. The following anticoagulants were assessed by Deming regression analysis with 52 paired human serum and plasma samples. Values of serum (X) ranging from 8.0 to 1203.3 U/L were compared with the values for plasma (Y) yielding the following results.

Anticoagulant	Level tested for in vitro interference	Deming regression analysis
Lithium Heparin	14 Units/mL	Y = 0.996X + 1.21, r = 1.000
Sodium Heparin	14 Units/mL	Y = 1.000X + 0.85, r = 1.000

PERFORMANCE CHARACTERISTICS

Reference Ranges	
Serum/Plasma	25-125 U/L
Peritoneal fluid	No normals established
Pleural fluid	No normals established
Urine timed	0 - 14 U/hour
Urine random	0 – 500 U/L

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

Sample type	Conventional units
Serum/Plasma/Urine	5 – 2000 U/L
Serum/Plasma/Urine (ORDAC)[d]	1000 – 2000 U/L

Samples with activities exceeding the high end of the analytical range should be rerun with ORDAC enabled or diluted with saline and reanalyzed.

Reporting Results outside of the Analytical Range

Lower limit of range	Serum/Plasma/urine 5 U/L	Results below 5, report as <5 U/L
Upper limit of range	Serum/Plasma 2000 U/L	Results > 2000 U/L should be diluted, with saline and reanalyzed. The maximum allowable dilution is X5. Results >10000 U/L are reported as >10000 U/L.
Upper limit of range	Urine 202000 U/L	Results > 2000 U/l should be diluted, with saline and reanalyzed. Start with a dilution of X51. The maximum allowable dilution is X101. Results >202,000 are reported as >202,000 U/L.

LIMITATIONS

None identified.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level tested	Observed effect
Bilirubin (unconjugated)	Bovine	30 mg/dL	NSI[a]
Bilirubin (Total)	Porcine	5.7 mg/dL DBIL 15 mg/dL TBIL INDEX of 10	≤8.6 U/L or 7%
Hemoglobin	RBC hemolysate	250 mg/dL INDEX of 6	NSI (see note 2 below)
Lipemia	Intralipid[b] Human	500 mg/dL INDEX of 10	NSI
Ascorbic Acid	NA[c]	200 mg/dL	NSI
Glucose	NA	2000 mg/dL	NSI

2. Samples showing evidence of hemolysis may cause decreased results.

3. For interferences in urine samples, refer to Reference (10), for other interferences caused by drugs, disease and preanalytical variables refer to References (10, 11, 12).

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

REFERENCES

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DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
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