BECKMAN COULTER CE 2797

AU/DxC AU
Instructions For Use

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Alpha Amylase
a-Amylase

REF OSR6182 4 x 40mL R1, 4 x 10mL R2

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED PURPOSE

Alpha(α)-Amylase reagent is an in vitro diagnostic medical device intended to be used by healthcare professionals for the quantitative kinetic measurement of α-amylase in human serum, plasma and urine using the automated Beckman Coulter AU/DxC AU analyzer.

Measurement of α-amylase is intended to be used as an aid in the diagnosis of pancreatic disorders.

SUMMARY AND EXPLANATION

Reference[1,2,3]

Amylases are a group of hydrolases that split complex carbohydrates composed of alpha-D-glucose units linked through carbon atoms 1 and 4 located on adjacent glucose residues. In the body, amylase is present in a number of organs and tissues. The greatest concentration is present in the pancreas, where the enzyme is synthesised by the acinar cells and then secreted into the intestinal tract by way of the pancreatic duct system. The salivary glands also secrete a potent amylase to initiate hydrolysis of starches while the food is still in the mouth and oesophagus.

Diseases resulting in elevation of plasma alpha-amylase include: acute pancreatitis, parotitis, alcoholism, renal insufficiency and diseases such as viral hepatitis, AIDS, abdominal typhoid, sarcoidosis and trauma to the upper abdomen. There is also a detectable increase in amylase after an ERCP procedure.

In acute pancreatitis, amylase increases 5-6 hours after the onset of symptoms and remains elevated for 2-5 days. The increase in plasma activity does not reflect disease severity and conversely, extensive destruction of the pancreas may not cause a significant increase in the plasma concentration of pancreatic alpha-amylase.

Alpha amylase is excreted by glomerular filtration and then 50% of it is reabsorbed by the tubules. This reabsorption is significantly reduced in transient tubular damage, after burns, in the presence of diabetic ketoacidosis and acute pancreatitis as well as proteinuria resulting in an increase of alpha-amylase clearance. The measurement of alpha amylase in urine is indicated in the investigation of hyperamylasemia associated with macroamylasemia or renal insufficiency. Hypoamylasemia has been observed in advanced cystic fibrosis, severe liver disease and pancreatectomy. Also due to the decreased concentration of the salivary fraction hypoamylasemia has been found in obese subjects.

METHODOLOGY

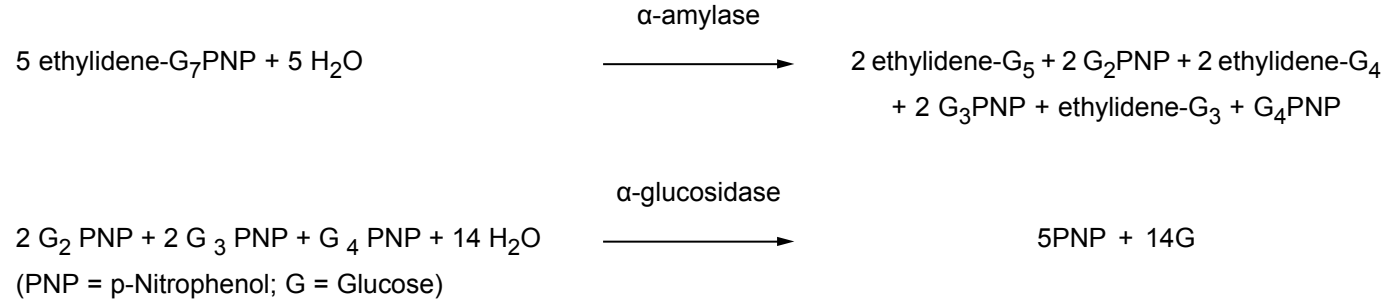
Reference[4]

Method based on the recommendations of the “International Federation of Clinical Chemistry” (IFCC).

The α-amylase colour test employs 4,6-ethylidene(G_7)-p-nitrophenyl(G_1)-α-D-maltoheptaoside (ethylidene-G_7PNP) as substrate. This substrate reacts with α-amylase and the fragments with α-glucosidase to give a 100% release of p-Nitrophenol (PNP). The increase of absorbance at 410 nm is directly proportional to the α-amylase activity in the sample.

CHEMICAL REACTION SCHEME

Reference[4]



(PNP = p-Nitrophenol; G = Glucose)

SPECIMEN

TYPE OF SPECIMEN

Serum, urine or Na/Li- heparinized plasma.

Plasma using EDTA, oxalate and citrate should be avoided.[1,5]

Urine: Timed or random sample.[1] Adjust pH to approximately 7.0 before storage.[5]

SPECIMEN STORAGE AND STABILITY

Stable in serum and plasma for 7 days when stored at 4…25°C.[6]

Stable in urine for 10 days when stored at 4…8°C and 2 days when stored at 10…25°C.[6]

Specimen storage and stability information provides guidance to the laboratory. Based on specific needs, each laboratory may establish alternative storage and stability information according to good laboratory practice or from alternative reference documentation.

REAGENTS

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.
Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

ACTIVE INGREDIENTS

Final concentration of active ingredients:

HEPES buffer (pH 7.15)	50 mmol/L
Sodium chloride	70 mmol/L
Calcium chloride	1 mmol/L
4,6-ethylidene-G_7PNP	> 1.4 mmol/L

α-Glucosidase	≥ 4.8 kU/L
Preservatives	

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Alpha-Amylase R1

WARNING



H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before use.
	5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone < 0.05%

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

REAGENT PREPARATION

The reagent is ready for use and can be placed directly on board the instrument.

Care should be taken when handling this reagent to avoid contamination with skin and body fluids.

REAGENT STORAGE AND STABILITY

Closed vial shelf life per stability study: 18 months.

The reagents are stable, unopened, up to the stated expiry date when stored at 2…8°C.

Opened bottles of reagent are stable for 90 days when stored in the refrigerated compartment of the analyzer.

INDICATIONS OF DETERIORATION

Visible signs of microbial growth, gross turbidity, precipitate, or change in color may indicate degradation and warrant discontinuance of use.

CALIBRATION

CALIBRATION INFORMATION

The test is run in MB-mode. To provide a robust approach to generate the analyzer specific MB factor it is recommended that 5 separate calibration events should be used. A fresh vial of calibrator, utilising System Calibrator Cat No. 66300 for serum application and Urine Calibrator Cat no B64606, in the AB calibration mode, should be used for each of these runs. When calculating the mean factor from the separate runs the data should be examined for obvious outliers which should be repeated and replaced. For the AU5800 and DxC 6000 AU this procedure needs to be performed for each ring. Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice.

Re-establishment of the analyzer specific MB factor is recommended when a critical part of the analyzer is replaced.

Reagent blank measurement is recommended when changing to a new lot of reagent.

DxC 500 AU and DxC 500i CALIBRATION INFORMATION ONLY

For DxC 500 AU and DxC 500i, a baseline MB factor is hardcoded in the instrument software and requires adjustment using a **Calculated Manufacturer Factor** to ensure optimal calibrator and control target recovery as follows:

With the **Manufacturer Factor A** set to 1.0, prepare 3 fresh vials of System Calibrator Cat No. 66300 for serum application and Urine Calibrator Cat no B64606, and run as samples in duplicate. For each individual vial, calculate the mean result. Calculate the **Overall Mean** for the 3 vials and examine the data for outliers which should be repeated and replaced. Calculate the **Manufacturer Factor:**

$$\textbf{Calculated Manufacturer Factor} = \frac{\textbf{Calibrator Set Point per product Insert}}{\textbf{Overall Mean}}$$

Enter the **Calculated Manufacturer Factor** in the **Manufacturer Factor A** field of the **Customer Configurable Options** section of the **Test Configuration** menu. Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice.

Re-establishment of the analyzer specific MB factor is recommended when a critical part of the analyzer is replaced.

Reagent blank measurement is recommended when changing to a new lot of reagent.

TRACEABILITY

The B64606 calibrator values are traceable to a manual IFCC reference method.

The 66300 calibrator values are traceable to a manual IFCC reference method.

QUALITY CONTROL

Controls Cat. No. ODC0003 and ODC0004 or other control materials with values determined by this Beckman Coulter system may be used for the serum application.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration/blanking is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU/DxC AU analyzer Instructions For Use (IFU) for analyzer-specific assay instructions for the sample type as listed in the Intended Purpose statement.

CALCULATIONS

The Beckman Coulter analyzers automatically compute the α-amylase activity of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

Reference[7]

Reference Range	U/L	µkat/L	U/g creatinine
Serum/Plasma	28 - 100	0.46 - 1.66	
Urine Male	≤ 490	8.16	280
Urine Female	≤ 450	7.50	380

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

PROCEDURAL NOTES

INTERFERENCES

Results of serum studies conducted to evaluate the susceptibility of the method to interference were as follows:

Icterus:	Interference less than 3% or 9.5 U/L up to 40 mg/dL or 684 µmol/L bilirubin
Haemolysis:	Interference less than 10% or 9.5 U/L up to 5 g/L haemoglobin
Lipemia:	Interference less than 3% or 9.5 U/L up to 1,000 mg/dL Intralipid

Results of urine studies conducted to evaluate the susceptibility of the method to interference were as follows:

Ascorbate:	Interference less than 5% up to 50 mg/dL ascorbate
Icterus:	Interference less than 10% up to 40 mg/dL or 684 µmol/L bilirubin
Haemolysis:	Interference less than 5% up to 5 g/L haemoglobin

Further information on interfering substances is available.[8]

PERFORMANCE CHARACTERISTICS

PERFORMANCE CHARACTERISTICS

Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

ANALYTICAL MEASURING RANGE/LINEARITY

ANALYTICAL MEASURING RANGE	Enzyme activity range U/L	Enzyme activity range µkat/L
Serum Plasma	10 - 1,500	0.2 - 25.0
Urine	10 - 4,800	0.2 - 80.0

SENSITIVITY

The Limit of Detection (LoD) and the Limit of Quantitation (LoQ) were determined in accordance with the CLSI EP17-A2 guideline.[9]

Correctly operating AU/DxC AU systems should exhibit the following LoD/LoQ:

LoD/LoQ	≤ 10 U/L

LoD is defined as the lowest concentration that can be detected with a probability of 95%.

LoQ is the lowest level of measurand which can be quantitatively determined with a within-laboratory CV of ≤ 20%, established as per EP17-A2.

METHODS COMPARISON

Patient serum samples were evaluated in method comparison studies.

Results of Deming regression analysis were as follows:

DxC 700 AU versus AU680

Regression Equation	r	n	Range
y = 0.988x +0.851	1.000	134	13.3 - 1371.4 U/L

Patient Urine samples were evaluated in method comparison studies.

Results of Deming regression analysis were as follows:

DxC 700 AU versus AU680

Regression Equation	r	n	Range
y = 0.993x -2.743	1.000	121	44 - 4537 U/L

PRECISION

Correctly operating AU/DxC AU systems should exhibit the following precision values:

TYPE OF IMPRECISION	% CV Serum	% CV Urine
Repeatability (Within-run)	≤ 3	≤ 5
Within Laboratory (Total)	≤ 5	≤ 10

Estimates of precision, based on CLSI recommendations[10] are consistent with typical performance.

The following data was obtained on a representative analyzer using 3 serum pools analyzed over 20 days:

AU5800

n=80	Repeatability (Within-run)		Within Laboratory (Total)	
Mean U/L	**SD**	**CV%**	**SD**	**CV%**
54.58	0.66	1.2	0.88	1.6
149.23	2.13	1.4	2.47	1.7
1422.63	13.71	1.0	19.41	1.4

The following data was obtained on a representative analyzer using 3 urine pools analyzed over 20 days.

AU5800

n = 80	Repeatability (Within-run)		Within Laboratory (Total)	
Mean U/L	**SD**	**CV%**	**SD**	**CV%**
44.37	0.64	1.4	0.74	1.7
601.88	4.38	0.7	6.70	1.1
3878.07	43.60	1.1	60.22	1.6

ADDITIONAL INFORMATION

Setting Sheet Footnotes
User defined
* Values set for working in U/L. To work in SI units (µkat/L) divide by 60.
§ For use in AB mode only, refer to IFU for further instruction.

Notice to User

Any serious incident that has occurred in relation to this device should be reported to Beckman Coulter and the competent authority of the Member State in which the user and/or patient is established.

Refer to the Beckman Coulter Chemistry Systems Reagent Guide (BLGUIDE) for specific chemistry information for the AU/DxC AU clinical chemistry systems and guidance on symbols used on all AU/DxC AU product labelling.

REVISION HISTORY

Updated GHS Hazard Information

Add DxC 6000 AU instrument to IFU

Updated Additional Information section

Preceding version revision history

Updated REAGENTS section

Updated Performance Characteristics section

Updated References section

REFERENCES

1. Lorentz K. Alpha-Amylase. In: Thomas L, hrsg. Labor und Diagnose. Indikation und Bewertung von Laborbefunden für die Medizinische Diagnostik. Frankfurt/Main: TH-Books Verlagsgesellschaft, 2005:51-56.

2. Tietz NW, ed. Clinical guide to laboratory tests, 3rd ed. Philadelphia: WB Saunders Company,1995:47pp.

3. Moss DW, Henderson RA. Clinical Enzymology. In: Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry. Philadelphia:WB Saunders Company, 1999; 689-692.

4. Lorentz K. Approved recommendation on IFCC methods for the measurement of catalytic concentration of enzymes. Part 9. IFCC method for alpha-amylase (1,4-alpha-D-glucan 4-glucanohydrolase, EC 3.2.1.1). International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Committee on enzymes. Clin Chem Lab Med 1998;36(3):185-203.

5. Moss DW, Henderson RA, Kachmar JF. Enzymes. In: Tietz NW, ed. Fundamentals of clinical chemistry. Philadelphia:WB Saunders Company, 1987:393-396.

6. Ehret W, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B, et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. WHO/DIL/LAB/99.1 Rev.2:22, 46pp.

7. Junge W, Wortmann W, Wilke B, Waldenstrom J, Weittenhiller A, Finke J, Klein G, Development and evaluation of assays for the determination of total and pancreatic amylase at 37°C according to the principle recommended by the IFCC. Clin Biochem 2001;34:607-615.

8. AACC Effects on Clinical Laboratory Tests: Drugs, Disease, Herbs and Natural Products https://clinfx.wiley.com/aaccweb/aacc/

9. Clinical and Laboratory Standards Institute: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second edition. CLSI document EP17-A2, Wayne PA 2012.

10. Clinical and Laboratory Standards Institute. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition. CLSI document EP05-A3, Wayne PA 2014.

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