

# ALPHA AMYLASE

## α-AMYLASE

### IFCC - EPS G7 SUBSTRATE

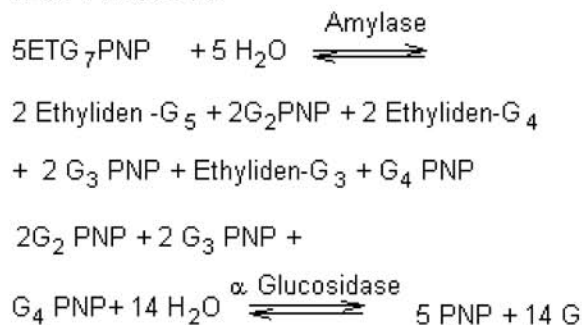
Liquid. Dual reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2030	5x100ML	T2030	3474 Tests	R2030	2885 Tests	L2031	2000 Tests
A2031	5x50ML	T2031	1795 Tests	R2031	840 Tests	K2030	6364 Tests
A2032	5x25ML	BY2030	7670 Tests	S2030	3077 Tests	K2031	4545 Tests
A2033	5x10ML	BY2031	5114 Tests	S2031	1477 Tests	M2030	2512 Tests
N2030	800 Tests	DM2030	962 Tests	L2030	3750 Tests	M2031	1675 Tests
N2031	400 Tests						

### INTENDED USE

The test is applied for quantitative determination of Alpha Amylase concentration in human serum and plasma. α-Amylase (1,4-α-D-Glucan glucono hydrolase, EC 3.2.1.1) is an enzyme of the digestive tract. It hydrolyzes dietary starch and glycogen to form maltose by splitting their chains at alternate hemiacetal linkages. The enzyme is normally secreted into the digestive tract from the parotid glands and the pancreas. In diseases affecting these glands, and particularly when the pancreatic duct is obstructed, the amount of enzyme in serum is increased.

### TEST PRINCIPLE



The method uses benzylidene blocked p-nitrophenyl maltoheptaoside as substrate. Two indicator enzymes, glucoamylase to cleave the amylase reaction products, and l-glucosidase to release the p-nitrophenol, are also employed in the method. The terminal glucose of the substrate is chemically blocked preventing cleavage by the indicator enzymes.

### TEST PARAMETERS

Method : Kinetic, Increasing Reaction  
Wavelength : 405 nm  
Temperature : 37°C

Sample : Serum, Heparinized Plasma, Urine  
Linearity : 3 U/L - 1500 U/L (for Sample start)

### REAGENTS COMPOSITION

Components	Final Concentration
Calcium Acetat	≤ 7,2 mmol/L
NaOH	≤ 36 mmol/L
Potassium Thiocyanate	≤1080 mmol/L
2-Chloro 4 Nitrophenyl-α-maltotrioside	≤ 2.72 mmol/L

### REAGENTS PREPARATION

Mix 4 volumes of R1 and a volume of R2. This working reagent is stable when stored at 20-25°C, for 10 days and stable for 30 days when stored at 2-8°C.

Working reagents are stable at 2°C - 8°C in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

### REAGENTS STABILITY AND STORAGE

Store unopened and opened reagents at 2°C - 8°C. Note expiration date on the label. Close immediately after use. Avoid contamination of the opened reagents.

Once opened vials are stable minimum 15 days at 2°C - 8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

## SAMPLE

Serum and plasma are collected by standard procedures.

Amylase in serum is stable for 7 days at 20 - 25°C, 7 days at 2-8°C and 1 year at - 20°C.

## TEST PROCEDURE

### Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

### Substrate Start

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

## CALCULATION

To calculate the amylase activity, use the following formula:

Serum:  $U/l = 3180 \times \Delta A_{405} \text{ nm/min}$

Urine:  $U/l = 6255 \times \Delta A_{405} \text{ nm/min}$

## REFERENCE INTERVALS (NORMAL VALUES) (Based on rules CLSI C28-P Document)\* (37°C)

Serum/Plasma < 95 U/L  
Urine < 490 U/L

\* It is recommended that each laboratory establish its own normal range.

## QUALITY CONTROL AND CALIBRATION

All control sera with Amylase values determined by this method and employing comparable substrate concentrations may be used. We recommend:

"ARCON N", Assayed Control Serum Normal  
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal  
Cat.No. A3920

Maximum allowable absorbance of the Reagent measured at 405 nm against water as reference is 0.15.

The use of a  $\alpha$ -Amylase Calibrator (for automated Systems) is optional. We recommend:  
A39050 ARCAL AUTO

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

\*Calibration Stability: It is strongly depend of

application to auto analyzers and auto analyzers specification. Calibration stability is 15 days in general.

\*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

## PERFORMANCE CHARACTERISTICS

**Low Linearity:** 3 U/L

**High Linearity:** The method is linear up to a concentration of 1500U/l. If concentration exceeds 1500U/l, dilute 1+4 with 0.9% NaCl solution and re-assay. Multiply the result by 5. Linearity may considerably vary depending on the instrument used.

### Precision Studies (Based on CLSI EP5 Doc.):

#### Repeatability (within run)(intra-assay)

Mean concentration	CV	n
180 U/L	2.13 %	20
1260 U/L	1.07 %	20

#### Reproducibility (run to run)(inter-assay):

Mean concentration	CV	n
159 U/L	2.85 %	20
1110 U/L	1.0 %	20

### Sensitivity (LOD) (Based on CLSI EP17 document): 10 U/L

**Trueness:** Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

## NOTE

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.



## PRECAUTIONS AND WASTE DISPOSAL

Avoid hemolysis as it may decrease results. Avoid contamination of reagent, samples and glassware by saliva or sweat because they have high amylase content. Do not do mouth pipette. Do not use EDTA, Citrate or oxalate as anticoagulant because of amylase activity inhibition.

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

R36/38 : Irritating to eyes and skin.

S20/21 : When using, do not eat, drink or smoke.

S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S28 : After contact with skin wash immediately with plenty of water.

S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

S45 : In case of accident or if you feel unwell, seek medical advice immediately.

S56 : Dispose of this material and its container at hazardous or special waste collection point.

S57 : Use appropriate container to avoid environmental contamination.

S61 : Avoid release in environment. Refer to special instructions/safety data sheets.

Please consult local regulations for a correct waste disposal.

## ABBREVIATIONS

CLSI	: Clinical and Laboratory Standards Institute
CV%	: Coefficient of Variation Percentage
EP	: Evaluation Protocols
ET-G7PNP	: 4,6-Ethyliden-4-Nitrophenylmaltoheptaosid
G	: Glucose
GLP	: Good Laboratory Practice
IU	: International Unit
mA	: miliabsorbance
mL	: milliliter
NCCLS	: National Committee for Clinical Laboratory Standards
PNP	: p-Nitrophenol
QC	: Quality Control

## REFERENCES

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## SYMBOLS

<b>IVD</b>	Only for in vitro diagnostic use
<b>LOT</b>	Lot of manufacturing
<b>R1</b>	Reagent 1
<b>R2</b>	Reagent 2
<b>CONC</b>	Concentration
<b>INGRED</b>	Reagent Ingredients
<b>REF</b>	Reference Number (Catalog Number)
<b>SN</b>	Serial Number



Expiration date



Storage temperature interval



Read the directions



Biological risk



**Archem Diagnostics Industry LTD. ŞTİ.**  
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