AMYLASE EPS FL

EA F080 CH	4 x 20 ml
EA F245 CH	12 x 20 ml

INTENDED USE

Reagent for quantitative in vitro determination of amylase in biological fluids.

SUMMARY OF TEST

Assays of amylase activity in serum and urine are largely of use in the diagnosis of diseases of the pancreas and in the investigation of pancreatic function.

PRINCIPLE OF THE METHOD

The enzyme α-amylase (EC 3.2.1.1, 1,4 α-D-glucose glucanohydrolase) hydrolizes the EPS to release several different fragments. The fragments so formed are completely hydrolyzed to 4-nitrophenol and glucose by α-glucosidase.
The 4-nitrophenol formed is detected spectrophotometrically at 405 nm to give a measurement of α-amylase activity in the sample.
The present method has been made according to IFCC.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.
DO NOT PIPETTE BY MOUTH!

AMY EPS R1 F080: 4 x 16 ml (liquid) blue cap
F245: 12 x 16 ml (liquid) blue cap

AMY EPS R2 F080: 1 x 16 ml (liquid) red cap
F245: 3 x 16 ml (liquid) red cap

Composition in the test: Hepes buffer 50 mM pH 7.10, NaCl 70 mM, calcium acetate 1.0 mM, EPS-G7 5.0 mM, α-glucosidase 6 kU/l.

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Serum as starter procedure:
Add 4 ml of reagent R2 to a vial of reagent R1.
Stability of working reagent: 60 days at 2-8°C, away from light sources.

Reagent as starter procedure:
use separate reagents ready to use.
Stability: up to expiration date on labels at 2-8°C;
Stability since first opening of vials: preferably within 60 days at 2-8°C.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Serum, plasma (heparinate only). Urine.
Amylase is stable in serum and plasma sample up to 2 months at 2-8°C.

TEST PROCEDURE (sample as starter)

Wavelenght:	405 nm
Ligthpath:	1 cm
Temperature:	37°C
dispense in cuvette working reagent:	1.5 ml
preincubate at 37°C for 5 minutes.	
add sample:	50 µl
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the ΔA/min.	

TEST PROCEDURE (reagent as starter)

Wavelenght:	405 nm
Ligthpath:	1 cm
Temperature:	37°C
dispense in cuvette reagent R1:	1.2 ml
add sample:	50 µl
incubate at 37°C for 5 minutes.	
dispense in cuvette reagent R2:	300 µl
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the ΔA/min.	

RESULTS CALCULATION

Perform calculation in units per litre, multiplying the ΔA/min by the factor as it is indicated.

Calculation in U/l: ΔA/min x 3480

Calculation in µkat/l: U/l x 0.0167 = µkat/l

EXPECTED VALUES

Serum - plasma: 28 - 100 U/l (0.47 - 1.67 µkat/l)
Random urine: ≤ 460 U/l (≤ 7.68 µkat/l)

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
QUANTINORM CHEMA
with normal or close to normal control values
QUANTIPATH CHEMA
with pathological control values.
If required, a multiparametric, human based calibrator is available:
AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity
the method is linear up to 1500 U/l.
If a ΔA/min of 0.500 is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)
the limit of detection is 6 U/l.

Interferences
no interference was observed by the presence of:

hemoglobin	≤ 200 mg/dl
bilirubin	≤ 48 mg/dl
lipids	interfer in low values

Precision

intra-assay (n=10)	mean (U/l)	SD (U/l)	CV%
sample 1	77.90	0.74	0.90
sample 2	194.80	1.99	1.00

inter-assay (n=20)	mean (U/l)	SD (U/l)	CV%
sample 1	75.77	1.90	2.50
sample 2	194.15	2.39	1.20

Methods comparison
a comparison between Chema Amylase FL and a commercially available product gave the following results:

Amylase Chema = x
Amylase competitor = y
n = 108

$y = 1.067x + 5.21$ U/l $r^2 = 0.99$

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Clin.Chem. 33, 1158-1162 (1987)
Lab.Med. 12 110-113 (1989)
Clin.Chem.Lab.Med. 1998; 36(3):185-203
Junge W, Waldenström J, Bouman A et al. Evaluation of the Assays for Total and Pancreatic α-Amylase based on 100% Cleavage of Et-G7-PNP at 6 European Clinical Centres (Poster Medlab 97). Basel, Switzerland: 12th IFCC European Congress of Clinical Chemistry, 17–22 August1997.

MANUFACTURER

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

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