AMYLASE FL

AM F060 CH	6 x 10 ml
AM F120 CH	12 x 10 ml
AM 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 2-chloro-4-nitrophenyl-α-D-maltotrioside (CNPG3) to release 2-chloro-4-nitrophenol and form 2-chloro-4-nitrophenyl-α-D-maltoside (CNPG2), maltotriose (G3) and glucose (G). The rate of formation of the 2-chloro-4-nitrophenol can be detected spectrophotometrically at 405 nm to give a measurement of α-amylase activity in the sample.

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 R1 **F060: 6 x 10 ml (liquid) blue cap**
F120: 12 x 10 ml (liquid) blue cap
F245: 12 x 20 ml (liquid) blue cap

Composition: CNP-G3 2.3 mM, NaCl 350 mM, calcium acetate 6 mM, potassium thiocyanate 600 mM, Good's buffer pH 6.0 100 mM, stabilizers and non-reactive components.

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

Use reagent 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).
Amylase is stable in serum and plasma sample up to 2 months at 2-8°C.

TEST PROCEDURE

Wavelenght:	405 nm
Ligthpath:	1 cm
Temperature:	37°C
dispense in cuvette working reagent:	1 ml
preincubate at 37°C for 5 minutes.	
add sample:	25 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 3178

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

EXPECTED VALUES

Serum - plasma: < 96 U/l (< 1.60 µkat/l)
Urine: < 480 U/l (< 8.00 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 informations.

TEST PERFORMANCE

Linearity
the method is linear up to 2000 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 0.91 U/l.

Interferences
no interference was observed by the presence of:

hemoglobin	≤ 500 mg/dl
bilirubin	≤ 50 mg/dl
lipids	≤ 1200 mg/dl

Precision

intra-assay (n=10)	mean (U/l)	SD (U/l)	CV%
sample 1	67.89	0.97	1.42
sample 2	171.67	2.61	1.52

inter-assay (n=21)	mean (U/l)	SD (U/l)	CV%
sample 1	67.81	1.93	2.85
sample 2	175.16	4.92	2.81

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

Amylase Chema = x
Amylase competitor = y
n = 181

$y = 1.071x - 0.54$ U/l $r^2 = 0.997$

WASTE DISPOSAL

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

REFERENCES

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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

CE