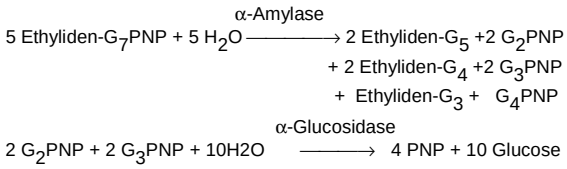
AMYLASE

IFCC (EPS)

Cat.No	Package Size	
107 016	7 x 10 ml	2 x 7 ml
107 000	5 x 20 ml	1 x 20 ml
107 001	2 x 100 ml	2 x 20 ml
107 002 Hit I	4 x 50 ml	2 x 20 ml
107 008 Hit II	2 x 80 ml	2 x 16 ml
107 006 AU	4 x 70 ml	3 x 20 ml

METHOD / REACTION PRINCIPLE:
Kinetic measurement /colorimetric test according to IFCC recommendation with substrate EPS (4,6 - Ethyliden-p-nitrophenyl-maltoheptaosid.



(PNP=p-Nitrophenol)

REAGENTS (concentrations in the test):

R1:	Good's Buffer	(pH 7,1)	0,1 mol/l
	NaCl		50 mmol/l
	$MgCl_2$		10 mmol/l
	α-Glucosidase		≥ 2 kU/L
R2:	Good's Buffer	(pH 7,1)	0,1 mol/l
	EPS-G7		1,6 mmol/l

The sealed reagents are stable up to the indicated expiry date if stored at 2 - 8°C.

NOTE:
-Do not pipette by mouth. Avoid contact of the reagent with skin, as saliva and sweat contain a-amylase.
-Reagents contain < 0.95 % sodium azide as a preservative. Avoid swallowing as well as contact with skin or mucuous membranes.
p-Nitrophenol is formed by the reaction. This is dangerous to health when being inhaled or swallowed at skin contact. In case of skin contact immediately wash off with plenty of water

SAMPLE MATERIAL:
Serum, Heparin- and EDTA- plasma, urine

Stability :
Serum: No significant activity decrease within 5 days.
Urine:: 10 days at + 4°C
2 days at +25°C

REFERENCE VALUES (37°C)

Serum/plasma	Spontaneous urine	Collected urine
28-100 U/L	<450 U/L	<410 u/24h
0,5-1.67 µkat/l	<7,5 µkat/l	<6.9 µkat/l/24h

ASSAY PROCEDURES:

Reagent Start :
R1 and R2 are ready for use.

Sample Start :
Mix 5 parts R1 + 1 part R2 .
Stability of reaction mixture is 3 weeks at 2 - 8°C

Wavelength : Hg 405 nm
Light path: 1 cm
Temperature: 37°C
Measure against water (increasing absorbance)
Pipette into cuvettes:

Start with R2	**Serum**	**Urine**
R1 (Buffer Rgt)	1000 µl	1000 µl
Sample	20 µl	10 µl
R2 (Starter Rgt)	200 µl	200 µl

Start with sample		
	Serum	**Urine**
Reaction Mixture	1000 µl	1000 µl
Sample	20 µl	10 µl

Mix and incubate for 2 min at 37°C. Determine average ΔA /min from the absorbance difference after 3 min.

CALCULATION with Factor:

Start with R2
Serum/plasma: U/L = 6157 x ΔA /min
µKat/L = 102,7 x ΔA /min

Urine: U/ L= 12218 x ΔA /min
µKat/L = 203,7 x ΔA /min

Start with sample
Serum/plasma: U/L = 5148 x ΔA /min
µKat/L = 86 x ΔA /min

Urine: U/L = 10198 x ΔA /min
µKat/L = 170 x ΔA /min

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CALIBRATORS & CONTROLS

For the calibration of automated analyzers Greiner Multicalibrator is recommended, for quality control use Greiner normal and abnormal control, Unitrol I and Unitrol II

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PERFORMANCE DATA (37°C)

-Linearity

The linearity limit is defined by a maximum ΔA /min = 0.35. This means, for reagent start, = 2100 U/L for the serum procedure, and = 4250 U/L for the urine procedure.
At higher activities mix 0.1ml sample with 1.0 ml NaCl solution 0.9%, and repeat assay, multiply result by 11.

- Sensitivity

The low detection limit is equal to 1.5 U/L.

- Precision

Within-run reproducibility

Within series n = 11	Mean value [U/L]	Standard-deviation [U/L]	CV [%]
Sample 1	77,7	1,009	1,298
Sample 2	196	1,834	0,935
Sample 3	72,1	1,700	2,36

Between-run reproducibility

Day to day n = 11	Mean value [U/L]	Standard-deviation [U/L]	CV [%]
Sample 1	79,5	0,934	1,176
Sample 2	195	0,674	0,345
Sample 3	72,5	0,934	1,288

- Correlation

A comparative study has been performed between Greiner method and another commercial reagent on 27 human serum samples. The parameters of linear regression are as follows:

Linear regression: y = 1.007x + 2.480 U/L
Correlation coefficient r = 1.000

INTERFERENCES

- Ascorbic Acid: no interference up to 100 mg/dl
- Bilirubin: no interference up to 40 mg/dl
- Hemoglobin interferes even at low levels
- Triglycerides: no interference up to 1500 mg/dl

BIBLIOGRAPHY

1. Lorentz K. α-Amylase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft;1998.p.192-202.
2. Moss DW, Henderson AR. Digestive enzymes of pancreatic origin. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company;1999.p.689-98.
3. Kruse-Jarres JD, Kaiser C, Hafkenscheid JC, Hohenwallner W, Stein W., Bohner J et al. Evaluation of a new alpha-amylase assay using 4,6-ethylidene-(G7)-1-4-nitrophenyl-(G1)-alpha,D-maltoheptaoside as substrate. J Clin Chem Biochem 1989;27:103-13.
4. Hohenwallner W, Stein W, Hafkenscheid JC, Kruse-Jarres JD, Kaiser C, Hubbuch A et al. Reference ranges for alpha-amylase in serum and urine with 4,6-ethylidene-(G7)-1-4-nitrophenyl-(G1)-alpha,D-maltoheptaoside as substrate. J Clin Chem Clin Biochem 1989;27:97-101.

SYMBOLS USED

For *in vitro* diagnostic medical use

Batch Code


Use by


Temperature limitation