α-Amylase Assay Kit (AMY)

Method: Enzymatic

Cat .No.	Size	Instrument
GB500Y	R1: 2×50 ml R2: 2×19 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS501Y	R1: 2×50 ml R2: 2×19 ml	For Hitachi 917 & OlympusAU640/400/600
GT500Y	R1: 2×50 ml R2: 2×19 ml	For TOSHIBA 40

INTENDED USE

For the quantitative determination of amylase activity, using manual or automated procedures, in human serum samples.

CLINICAL SIGNIFICANCE

The determination of amylase activity in serum and urine is most commonly performed for the diagnosis of acute pancreatitis. In acute pancreatitis, amylase levels are elevated for longer periods of time in urine than in serum. Therefore, determining the ratio of the amylase and creatinine clearances is important in following the course of the pancreatitis.

ASSAY PRINCIPLE

The method uses ethylidene blocked pnitrop-henyl-maltoheptaoside (EPS-G7) as substrate. Amylase hydrolyzes EPS-G7 to Et-Gx and Gy-pNP. Gy-pNP is further hydrolyzed by a coupled enzyme, α-glucosidase to glucose and pNP which is quantitated colorimetrically at 405 nm. The amount of pNP formed is directly proportional to the amylase activity in the sample.

$$\text{Et-G7-pNP} \xrightarrow{\alpha\text{-Amylase}} \text{Et-Gx + Gy-pNP}$$

$$\text{Gy-pNP} \xrightarrow{\alpha\text{-glucosidase}} \text{glucose + pNP-glucoside}$$

$$\text{pNP-glucoside} \xrightarrow{\alpha\text{-glucosidase}} \text{glucose + pNP}$$

G = glucose
x and y = 2-5 and x + y =7
pNP = p-nitrophenol

SAMPLE COLLECTION AND PREPARATION

Serum: Use fresh patient serum free from haemolysis.
Amylase is stable for 3 hours at 2-8°C.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Hepes buffer	50 mmol/L
NaCl	50 mmol/L
$MgCl_2$	510 mmol/L
α-glucosidase	4 KU/L
Reagent 2 (R2)	
Hepes buffer	
EPS-G7	1.6 mmol/L

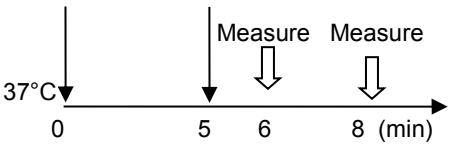
STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8 °C.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 917)
Assay Mode: Rate, 25-30
Wave Length (main/sub): 405 nm/700 nm

Sample: 7μl
R1: 250 μl R2: 90 μl



1. Mix 7 μl sample with 250 μl R1 and incubate at 37°C for 5 minutes.
2. Add 90 μl R2 into cuvette, mix and incubate for 1 minute at 37°C
3. Read initial absorbance and start timer simultaneously, read again after 1, 2 and 3 minutes.
4. Calculate absorbance change per minute (ΔA/min).

CALCULATION

$$\text{Concentration} = \frac{\Delta A_{sample}\ /\text{min}}{\Delta A_{calibrator}\ /\text{min}} \times \text{Calibrator value}$$

CALIBRATION

Recommend Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiray date of kit and contents.

REFERENCE VALUE

Serum: 25-104 U/L
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 3500 U/L. If the Sample above this concentration should be diluted 1:1 with 0.9% NaCl and repeat assay. Multiply the result by 2.

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CE Revised 01DEC11 version 1101

PRECISION

The CV of the test should be CV≤5%

Intra assay precision		
N=15	Level1	Level 2
Mean (U/L)	95.77	304.23
SD	0.567	0.686
CV	0.59%	0.55%
Inter assay precision		
N=5	Level1	Level 2
Mean (U/L)	97.59	318.43
SD	0.929	3.434
CV	0.95%	1.08%

SENSITIVITY

The minimum detectable level has been determined as 6.4 U/L.

INTERFERENCE

The following analyze were tested up to the levels indicated and found not to interfere:

Hemoglobin: 500 mg/dl
Intralipid: 900 mg/dl
Bilirubin: 100 mg/dl
Ascorbic Acid: 100 mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

$y = 1.0001x-0.6885$, $R^2=0.9998$;

113 patient samples were analyzed .

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. The reagents contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Tietz, N. W. (Ed): Textbook of Clinical Chemistry., Philadelphia, W. B. Saunders Co., pp. 725-734(1986)
2. Klaus Lorentz. Clinical Chemistry, 46(5)644-649(2000)
3. Davidson, et al. Clin Chem. 38: 976-977(1992)
4. Junge, et al. Clin Biochem. 22: 109(1989)
5. Tietz, et al. Clin. Chem. 34: 2096-102(1988)

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
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