CE IVD

AMY Reagent Kit (EPS Substrate Method)

Instructions for Use REF CC1007

PRODUCT NAME

AMY Reagent Kit (EPS Substrate Method)

PACKAGE SPECIFICATION

R1:1×20 mL	R2:1×5 mL	R1:1×30 mL	R2:1×8 mL
R1:1×40 mL	R2:1×10 mL	R1:1×60 mL	R2:1×15 mL
R1:2×30 mL	R2:1×15 mL	R1:2×35 mL	R2:1×20 mL
R1:2×40 mL	R2:1×20 mL	R1:2×60 mL	R2:2×15 mL
R1:2×60 mL	R2:1×30 mL	R1:2×60 mL	R2:1×35 mL
R1:2×80 mL	R2:1×40 mL	R1:2×80 mL	R2:2×20 mL
R1:4×35 mL	R2:2×20 mL	R1:4×40 mL	R2:2×20 mL
R1:4×50 mL	R2:2×25 mL	R1:4×50 mL	R2:3×20 mL
R1:4×60 mL	R2:2×30 mL	R1:4×60 mL	R2:2×35 mL
R1:4×60 mL	R2:4×15 mL	R1:4×100 mL	R2:2×50 mL
R1:4×120 mL	R2:2×60 mL	R1:6×66 mL	R2:6×16 mL
750 T (R1:1 x 80 mL R2:1 x 18 mL)		300 T (R1: 1 x 33 mL R2: 1 x 9 mL)	
2 x 160 T (R1: 2 x 44 mL R2: 2 x 11 mL)		6 x 60 T (R1: 6 x 16.8 mL R2: 6 x 4.2 mL)	

INTENDED USE

Used for the *in vitro* quantitative determination of amylase activity in human serum, plasma or urine.
It is mainly used clinically as an aid in the diagnosis of pancreatic diseases. For professional and laboratory use only.

TEST PRINCIPLE

The rate of pNP production was measured at specific wavelengths and AMY viability was calculated.

$$5EPS + 5H_2O \xrightarrow{\alpha\text{-Amylase}} \text{ethyliden-}G_3 + \text{pNP-}G_4^+$$

$$\text{2ethyliden-}G_2 + \text{2pNP-}G_3 + \text{2ethyliden-}G_5 + \text{2pNP-}G_2$$
$$\text{pNP-}G_4 + \text{2pNP-}G_3 + \text{2pNP-}G_2 + 14H_2O \xrightarrow{\alpha\text{-Glucosidase}} 5pNP+14G$$

MAIN COMPONENTS

Kit composition	Reagent Components	Concentration
Reagent 1	4-(2-Hydroxyethyl)-1-piperazine-ethanesulfonic acid	2 mol/L
	α-Glucosidase	8 KU/L
	sodium chloride	1.5 g/L
	calcium chloride	1.0 g/L
Reagent 2	4,6-Ethylidene-p-nitrophenyl-alpha-D-malt heptoside	6 g/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. Serum and plasma anticoagulated with heparin should be separated in time after blood collection to avoid hemolysis.
2. The test results for serum and plasma will not change within 7 days at 15-25°C, 1 month at 2-8°C and 12 months at −20°C. The test results for urine will not change within 2 days at 15-25 °C and 10 days at 2-8°C.

TEST PROCEDURE

1. Reagents preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary / secondary wavelength	415nm/505 nm	**Calibration type**	Linearity
Sample/R1/R2	6/240/60 μL	**Time of mixture of serum + R1**	3 min
Method	Rate method	**Reaction time after addition of R2**	3 min
Calibration method	Two-point calibration	**Direction of reaction**	Upward

Operating Procedure:
Dual Reagent Operation

Substances added	Blank tubes	Test tubes
Reagent R1	240 μL	240 μL
Distilled water	6 μL	-
the root cause and symptoms of a disease	-	6 μL
Mix well, incubate at 37°C for 3 min		
Reagent R2	60 μL	60 μL
Mix well, incubate at 37°C for 60-90s, continuously monitor the absorbance change of each tube at the measurement wavelength for 1-3min, and calculate △A/min of each tube.		

3. Calibration procedure: A Randox calibration serum is recommended.
4. Quality control procedure: Select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation:
   AMY viability (U/L) = $(\Delta A_{assay}/\text{min}-\Delta A_{blank}/\text{min}) \times 8100$

REFERENCE RANGE

Serum/plasma: ≤220 U/L
Urine: ≤1200 U/L
The above reference range is only a guideline. Each laboratory should establish its own reference range.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation. The time period between sample collection and tests may also affect the measurement results.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 200 mg/dL, ascorbic acid ≤ 50 mg/dL, bilirubin ≤ 100 mg/dL, and triglycerides ≤ 1000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless or slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a colorless or slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reagent blanks
   2.1 Reagent blank absorbance
   Reagent blank absorbance A_{415nm} ≤ 0.350.
   2.2 Rate of change in absorbance of reagent blanks
   Reagent blank absorbance change rate $|\Delta A_{415nm}|$ /min≤0.002.
3. Accuracy
   The relative deviation should not fall outside the range of ± 10.0%.
4. Linear range
   For serum sample testing within the reagent linear range of [5, 1500] U/L (37°C):
   a) The linear correlation coefficient (r) should not be less than 0.990;
   b) The deviation from linearity should not fall outside the range of ± 5 U/L for testing within the linear range of [5, 50] U/L;
   the deviation from linearity should not fall outside the range of ± 10% for testing within the linear range of (50, 1500] U/L.
5. Analytical sensitivity
   When a sample has a concentration of 1 U/L, its absorbance difference should be ≤ 0.00056.
6. Precision
   6.1 Repeatability
   The repeatability (coefficient of variation, CV) should be ≤ 5.0%.
   6.2 Between-run precision
   The between-run precision should be ≤ 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 Reagents from different manufacturers used to test the same sample may produce different results, which should be considered in conjunction with clinical findings.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 Do not use the reagents with visible signs of turbidity or the absorbance of the reagent blank is higher than 0.500.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong et al. National clinical testing operation procedures (4th ed.). People's Health Publishing House.2015:289-290.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on AMY Reagent Kit (EPS Substrate Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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DN: C=VN, CN=CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM, L=Huyện Đông Anh, O=CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM, ST=Hà Nội, UID=MST:0106416199