JOINT RESEARCH CENTRE
Directorate F – Health, Consumers and Reference Materials

CERTIFICATE OF ANALYSIS

ERM®-AD456/IFCC

ENZYME IN SOLUTION		
Catalytic activity concentration		
	Certified value [2]	Uncertainty [3]
Alpha–amylase [1]	274 U/L 4.58 µkat/L	7 U/L 0.12 µkat/L

1) Catalytic activity concentration of alpha-amylase in the reconstituted material, as obtained by the IFCC primary reference measurement procedure for the catalytic activity concentration of alpha-amylase at 37°C.

2) Certified values are values that fulfil the highest standards of accuracy. The given values represent the unweighted mean value of the means of accepted sets of data, each set being obtained in a different laboratory. The certified values and their uncertainties are traceable to the International System of Units (SI). Values were converted from U/L into µkat/L by multiplication with the factor $f = 0.01667$.

3) The uncertainty of the certified value is the expanded uncertainty with a coverage factor $k = 2$ corresponding to a level of confidence of about 95 % estimated in accordance with ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement (GUM:1995), ISO, 2008.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used after reconstitution is 5 µL.

Geel, September 2019

Signed:

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DESCRIPTION OF THE MATERIAL

The starting material was human pancreatic alpha-amylase purified from human tissue. The enzyme was diluted in a buffered solution containing human serum albumin. The certified reference material is available in glass vials containing lyophilised powder from 1.0 mL of the alpha-amylase solution.

ANALYTICAL METHODS USED FOR CERTIFICATION

The IFCC primary reference measurement procedure (PRMP) for the catalytic activity concentration of alpha-amylase at 37 °C was used for the characterisation (Schumann *et al.*, Clin. Chem. Lab. Med. 44 (2006) 1146-1155 and Schumann *et al.*, Clin. Chem. Lab. Med. 48 (2010) 615-621). An automated version of this PRMP was used for the stability and homogeneity measurements.

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SAFETY INFORMATION

The usual laboratory safety measures apply. The human pancreatic alpha-amylase and the human serum albumin used in the production of the material have been tested and found negative for Hepatitis B surface antigen, HIV 1 and 2, and Hepatitis C antibodies. However, the product must be handled with adequate care as any material of human origin. It is intended for *in vitro* analysis only.

INSTRUCTIONS FOR USE AND INTENDED USE

The main purpose of the material is to assess method performance of the PRMP for the catalytic activity concentration of alpha-amylase at 37 °C from the IFCC. In addition the material can also be used as trueness control or external quality control material for routine measurement systems if commutability has been proven for the assay concerned.

It is not recommended to use this material and its certified value for calibration. If used nevertheless, the uncertainty of the certified value shall be taken into account in the estimation of the measurement uncertainty. When the material is used as a calibrant in a routine measurement procedure the commutability should be verified for the assay concerned.

Reconstitution of the material

To make it ready for use, the material has to be reconstituted according to the following procedure:

1. Remove the vial from the freezer and let equilibrate to room temperature (20-25 °C).
2. Tap the vertically positioned vial gently to ensure that the lyophilised material is at the bottom of the vial. Remove the screw cap.
3. Weigh the vial together with the rubber stopper and record the weight to the nearest 0.1 mg (i.e. m_1).
4. Carefully lift the rubber stopper, avoiding the loss of lyophilised material.
5. Reconstitute with (1.00 ± 0.01) mL distilled water (20-22 °C) and carefully close the vial again with the rubber stopper.
6. Weigh the vial after adding the water and record the weight to the nearest 0.1 mg (i.e. m_2). Calculate the mass of the water added during the reconstitution (m_{H2O}) by subtracting m_1 from m_2. Use this m_{H2O} to calculate volume of the added water (v_{H2O}) taking into account the temperature dependent density.
7. The catalytic concentration of alpha-amylase in the solution, corrected for the reconstitution volume, can be obtained by multiplying the certified value with $v_{intended}/v_{H2O}$ with $v_{intended}$ the volume intended to be added (1.0000 mL)
8. Dissolve the lyophilised material by gently swirling and carefully invert the vial at least five times. Allow to stand at room temperature for 10 minutes.
9. It is recommended to store the vials cold (2-8 °C) if not measured directly. Carefully invert the vial five times just before starting the measurements.
10. The catalytic activity concentration of amylase must be measured within 4 hours following the reconstitution.

STORAGE

The materials should be stored at (-20 ± 5) °C in the dark. After reconstitution, the material must be used within four hours.

However, the European Commission cannot be held responsible for changes that happen during storage of the material at the customer's premises, especially of opened samples.

LEGAL NOTICE

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NOTE

A detailed certification report is available at https://crm.jrc.ec.europa.eu/.

A paper copy is obtainable from the Joint Research Centre, Directorate F – Health, Consumers and Reference Materials on request.

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