JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements

CERTIFICATE OF ANALYSIS

ERM®- AD457/IFCC

ASPARTATE TRANSAMINASE (AST)

also called aspartate aminotransferase (ASAT)

	Certified value [2]	Uncertainty [3]
Catalytic activity concentration in reconstituted material [1]	1.74 µkat/L 104.6 U/L	0.05 µkat/L 2.7 U/L

1) The certified values express the catalytic activity concentration of AST as defined by the IFCC reference procedure for the determination of AST at 37 °C (see page 2 Section "Analytical method used for characterisation") in the sample after gravimetrically controlled reconstitution with 2.00 g of distilled water.

2) Unweighted mean value of the means of 12 accepted sets of data, each set being obtained in a different laboratory. The certified value and its uncertainty are traceable to the International System of Units (SI). The catalytic activity concentration in µkat/L can be converted into U/L by multiplying with the factor f = 60.

3) The certified uncertainties are the expanded uncertainties estimated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM). They are expressed with a coverage factor k = 2, corresponding to a level of confidence of about 95 %.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of reconstituted sample to be used is 14 µL.

NOTE

European Reference Material ERM®-AD457/IFCC was produced and certified under the responsibility of the Institute for Reference Materials and Measurements of the European Commission's Joint Research Centre according to the principles laid down in the technical guidelines of the European Reference Materials® co-operation agreement between BAM-IRMM-LGC. Information on these guidelines is available on the internet (http://www.erm-crm.org).

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INFORMATION ONLY

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DESCRIPTION OF THE SAMPLE

The certified reference material is a lyophilised powder from 1.0 mL of recombinant AST from *E. coli* in a pH 7.5 buffer containing bovine serum albumin, pyridoxal-phosphate, saccharose and antibiotics. It is filled in a glass vial equipped with a rubber stopper and an aluminium cap allowing direct reconstitution by injection through the septum. The vial is under slight underpressure of Argon (800 mbar).

ANALYTICAL METHOD USED FOR CERTIFICATION

IFCC reference procedure for the measurement of catalytic activity concentrations of enzymes at 37 °C. Part 5. Reference Procedure for the measurement of catalytic activity concentration of aspartate aminotransferase.

G. Schumann, R. Bonora, F. Ceriotti, G. Férard, C. A. Ferrero, P. F. H. Franck, F.-J. Gella, W. Hoelzel, P. J. Jørgensen, T. Kanno, A. Kessner, R. Klauke, N. Kristiansen, J.-M. Lessinger, T. P. J. Linsinger, H. Misaki, M. Panteghini, J. Pauwels, F. Schiele, H. Schimmel, G. Weidemann, L. Siekmann, Clin Chem Lab Med 40 (2002) 725-733.
See also the corrigendum published by Schumann *et al*. Clin Chem Lab Med 2010;48:615–21.

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* Measurements within the scope of accreditation according to ISO/IEC 17025; DKD-K-20602.

SAFETY INFORMATION

The usual laboratory safety precautions apply.

INSTRUCTIONS FOR USE AND INTENDED USE

The material is primarily intended to be used to control the performance of the IFCC reference procedure for the determination of AST at 37 °C. When the material is used as a calibrant in a particular measurement procedure the commutability should be verified for the assay concerned.

To prepare the material for use, the entire content of the vial must be reconstituted with 2 g of distilled water. The reconstitution procedure is gravimetrically controlled, according to the following procedure.

Reconstitution procedure:

1. Check that the room temperature stays between 20 and 25 °C.
2. Take the vial out of the freezer and allow to reach room temperature.
3. Tap the vertically positioned vial gently to ensure that the lyophilised material is at the bottom of the vial.
4. Weigh the vial with its contents to the nearest 0.1 mg. Record the mass m_1.
5. Take an injection needle (e.g. 0.55 x 25 mm). Insert it through the septum and leave it in to create a venting of the vial. Leave some space to introduce a second injection needle in the same stopper.
6. Take a syringe of 2 mL (e.g. single-use insulin syringe), with another injection needle (e.g. 0.9 x 40 mm).
7. Using the syringe, reconstitute by slow injection of (2.00 ± 0.02) mL distilled water through the stopper.
8. Remove syringe and needles.
9. Weigh the vial after adding the water. Record the mass m_2.

10. Calculate the mass of water added in g (m_3) :

$$m_3 = m_2 - m_1$$

and calculate the correction factor (f) which will be applied to the catalytic activity concentration of AST (b_E) determined in the reconstituted material :

$$f = (b_E \times m_3)/2.00$$

11. Invert the vial several times and mix content by gentle swirling. Allow to stand at room temperature for 20 min. Swirl the vial again and then allow to stand for 10 min. Total reconstitution time is approximately 30 min.

The procedure for sampling is left to the discretion of the laboratory (either open the vial with a crimp tool and use calibrated pipettes or aspirate the reconstituted material through the stopper using a clean syringe and injection needle).

STORAGE

Unopened vials should be stored at - 20 °C ± 5 °C. After reconstitution, the material should be used within 6 hours, as it was verified that changes to the certified concentration observed during that period at ambient temperature are not significant. It is advisable to cover the vial with the original seal and to store it at 2 to 8 °C if the reconstituted material must be stored for 6 hours before use.

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 technical report is available on www.erm-crm.org. A paper copy can be obtained from the Joint Research Centre, Institute for Reference Materials and Measurements on request.

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