

JOINT RESEARCH CENTRE  
Institute for Reference Materials and Measurements

# CERTIFICATE OF ANALYSIS

ERM<sup>®</sup>-AD453k/IFCC

ENZYME IN BUFFER		
	Catalytic activity concentration <sup>1)</sup>	
	Certified value <sup>2)</sup>	Uncertainty <sup>3)</sup>
Lactate dehydrogenase isoenzyme 1 (LD1)	330 U/L 5.50 µkat/L	7 U/L 0.12 µkat/L
<p>1) Catalytic activity concentration of lactate dehydrogenase isoenzyme 1 (LD1) in the reconstituted material, as obtained by the IFCC primary reference measurement procedure for the measurement of catalytic activity concentration of lactate dehydrogenase at 37 °C.</p> <p>2) Certified values are values that fulfil the highest standards of accuracy and represent the unweighted mean value of the means of 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). Values were converted from U/L into µkat/L by multiplication with the factor <math>f = 0.01667</math>.</p> <p>3) The uncertainty is the expanded uncertainty of the certified value with a coverage factor <math>k = 2</math> 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.</p>		

This certificate is valid for one year after purchase.

Sales date:


The minimum amount of reconstituted sample to be used is 13 µL.

## NOTE

European Reference Material ERM<sup>®</sup>-AD453k/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<sup>®</sup> co-operation agreement between BAM-IRMM-LGC. Information on these guidelines is available on the internet (<http://www.erm-crm.org>).

Accepted as an ERM<sup>®</sup>, Geel, June 2016

Signed: \_\_\_\_\_



Prof. Dr. Hendrik Emons  
European Commission  
Joint Research Centre  
Institute for Reference Materials and Measurements  
Retieseweg 111, B-2440 Geel, Belgium

## DESCRIPTION OF THE MATERIAL

The starting material was a recombinant form of human LD1 expressed in *E. coli*. It was purified and lyophilised from a buffer (pH 7.5) containing among others bovine serum albumin and polysaccharides. The certified reference material (CRM) is available in glass vials containing lyophilised powder from 1 mL of LD solution.

## ANALYTICAL METHODS USED FOR CERTIFICATION

The IFCC primary reference measurement procedure for the measurement of the catalytic activity concentration of LD at 37 °C was used for the characterisation (Schumann *et al.*, Clin. Chem. Lab. Med. 40 (2002) 643-648 and Schumann *et al.*, Clin. Chem. Lab. Med. 48 (2010) 615-621). A Beckman Coulter UniCel® DxC 800 Synchron Clinical System with LD-IFCC reagent cartridges was used for stability and homogeneity measurements.

## PARTICIPANTS

- Affiliated Hospital of Nantong University, Reference Laboratory, Nantong, CN\*
- Asahi Kasei Pharma Corporation, Tokyo, JP
- Beckman Coulter, Inc., Clare, IE
- Beijing Aerospace General Hospital, Reference Laboratory, Beijing, CN\*
- Biosystems, S.A., Barcelona, ES
- European Commission, Joint Research Centre, Institute for Reference Materials and Measurements, Geel, BE
- INSTAND e.V., Düsseldorf, DE\*
- LabWest HagaZiekenhuis, Klinisch Chemisch en Hematologisch Laboratorium, Den Haag, NL
- Servizio Di Medicina Di Laboratorio Diagnostica e Ricerca, Ospedale San Raffaele, Milano, IT
- Sichuan Maker Biotechnology Co., Ltd., Reference System Department, Chengdu, CN\*
- Stiftung für Pathobiochemie und Molekulare Diagnostik, Referenzinstitut für Bioanalytik, Kalibrierlaboratorium II, Medizinische Hochschule Hannover, Institut für Klinische Chemie, Hannover, DE\*
- Universitat Autònoma de Barcelona, Departament de Bioquímica i Biologia Molecular, Unitat de Bioquímica de Medicina, Barcelona, ES\*
- Università degli Studi di Milano, Laboratorio Analisi Chimico-Cliniche, Centro Interdipartimentale di Ricerca sulla Riferibilità Metrologica in Medicina di Laboratorio (CIRME), Milano, IT\*

\* Measurements within the scope of accreditation to ISO/IEC 17025.

## SAFETY INFORMATION

For *in vitro* use only.

## INSTRUCTIONS FOR USE AND INTENDED USE

The main purpose of the material is to control the performance of the IFCC primary reference measurement procedure for the measurement of catalytic activity concentration of LD at 37 °C. When the material is used as a calibrant in a routine measurement procedure the commutability should be verified for the assay concerned.

To prepare ERM-AD453k/IFCC for use, the lyophilised material shall be reconstituted according to the following procedure:

- 1) Remove vial from 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.
- 3) Carefully open vial, avoiding the loss of lyophilised material.
- 4) Weigh the vial with its content to the nearest 0.1 mg.
- 5) Reconstitute with  $(1.00 \pm 0.01)$  mL distilled water (20-22 °C) slowly added to the sides of the vial.
- 6) Weigh the vial after adding the water and record the weight.
- 7) Carefully close the vial.
- 8) Allow to stand at room temperature for ten minutes.
- 9) Slowly swirl the vial to dissolve the lyophilised material completely.

- 10) Keep the vial cold (2-8 °C) until use.
- 11) Calculate the volume of water at 20 °C from the mass of water added taking into account the temperature dependent density.
- 12) The catalytic activity concentration of LD must be measured within four hours\* following the reconstitution.

\*The catalytic activity concentration of LD is not guaranteed afterwards.

## **STORAGE**

Unopened vials of the material should be stored at  $(-20 \pm 5)^\circ\text{C}$  in the dark. After reconstitution, the material must be kept cold (2 - 8 °C) and 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 technical report is available at [www.irmm.jrc.be](http://www.irmm.jrc.be). A paper copy is obtainable from the Joint Research Centre, Institute for Reference Materials and Measurements on request.