EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements

CERTIFIED REFERENCE MATERIAL
BCR® – 647

CERTIFICATE OF ANALYSIS

HUMAN ADENOSINE DEAMINASE (ADA 1) FROM HUMAN ERYTHROCYTES			
	Enzymatic Activity		Number of accepted sets of data p
	Certified value [1] [µkat/L]	Uncertainty [2] [µkat/L]	
Human Adenosine Deaminase (ADA 1)	2.55	0.09	5

1) This value is the unweighted mean of p accepted (unweighted) mean values, independently obtained by 5 laboratories. The catalytic concentration of the enzyme was measured at 37 °C following the method described by Bota *et al* (see overleaf). Values were converted from U/L into µkat/L by multiplication with 0.01667. The certified value is traceable to the analytical method described by Bota et al.
2) The uncertainty is taken as the half width of the 95% confidence interval of the mean of means .

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 50 µL.

NOTE

This material has been certified by BCR (Community Bureau of Reference, the former reference materials programme of the European Commission). The certificate has been revised under the responsibility of IRMM.

Brussels, November 2000
Latest revision: November 2007

Signed:

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DESCRIPTION OF THE SAMPLE

Each sample is in lyophilised form and equivalent to about 1 mL of solution of purified adenosine deaminase (ADA 1) from human erythrocytes. The preparation has been stabilised by incorporation in a matrix of 50 mmol/L Tris/HCl buffer pH = 7.4 and human serum albumin 30 g/L.
No contamination, as assessed by measurement of their catalytic activity, has been detected for the following enzymes : acid phosphatase, acetylcholinesterase, glutamate dehydrogenase, glucose-6-phosphate dehydrogenase and adenosine deaminase isoenzyme 2. L-lactate dehydrogenase, alanine aminotransferase and aspartate aminotransferase were found in trace amounts 0.39 %, 0.01 % and 0.09 %, respectively (% of total adenosine deaminase catalytic activity).
The material is kept under dry nitrogen in rubber stoppered vials. The residual moisture mass fraction of the sample had a value of (0.74 ± 0.21 %). The intended use of the material is to validate, to calibrate or to assess the performance of adenosine deaminase catalytic concentration measurement procedures. The user must assure that the transfer procedure is adequate.

ANALYTICAL METHOD USED FOR CERTIFICATION

Using adenosine as substrate and glutamate dehydrogenase as auxiliary enzyme measurements are performed at 37 °C (Bota A, Gella FJ, Canalias F. Optimization of adenosine deaminase assay by response surface methodology. Clin Chim Acta 2000;290:145-57).

PARTICIPANTS

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SAFETY INFORMATION

This serum material was produced from blood from healthy blood donors. Each portion of serum was tested negative for Anti-HIV-1&2, Anti-HCV and Anti-HTLV-I&II. However, the material is of human origin and should be handled with adequate care. For in vitro analysis only.

INSTRUCTIONS FOR USE

It is not recommended that a portion of the lyophilised material contained in an ampoule be used. The entire content of the ampoule must be reconstituted.
To make it ready for use, the material has to be reconstituted according to the procedure described in Chapter 9 of the certification report. The commutability of the material with routine in vitro diagnostic devices has not been assessed. If the material is used for the calibration of in vitro diagnostic devices the commutability has to be assessed by the user.

STORAGE

Upon arrival at the laboratory the material shall be stored at - 20°C.
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 technical report on the production of BCR®-647 is available on the internet (http://www.irmm.jrc.be). A paper copy can be obtained from IRMM on request.

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