



CERTIFIED REFERENCE MATERIAL BCR[®] – 694

CERTIFICATE OF ANALYSIS

RECOMBINANT HUMAN PANCREATIC LIPASE			
	Enzymatic activity		Number of accepted sets of data p
	Certified value ¹⁾ [μ kat/L]	Uncertainty ²⁾ [μ kat/L]	
Human Pancreatic Lipase	17.4	1.0	4

1) This value is the unweighted mean of p accepted (unweighted) mean values, independently obtained by 4 laboratories, following a titrimetric standard operating procedure at 37 °C, specified in detail in the report. Values were converted from U/L into μ kat/L by multiplication with 0.01667. The certified value is traceable to the Titrimetric standard operating procedure at 37 °C (see overleaf).

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 100 μ L.

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 2002
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 recombinant pancreatic lipase from V79-rHPL cell line. The preparation has been stabilised by incorporation in a matrix of Tris 20 mmol/l, pH = 7.6 and BSA 40 g/l. No contamination, as assessed by measurement of their catalytic activity, has been detected by the following enzymes: ALP, ALT, α -Amylase, AST, esterase, GGT and LDH. The material is kept under dry nitrogen in neutral clear glass ampoules, sealed by fusion. The residual water mass fraction of the sample had a mean value of 0.114 %. It is not recommended that a portion of the lyophilised material contained in an ampoule be used.

ANALYTICAL METHOD USED FOR CERTIFICATION

Titrimetric standardized operating procedure at 37 °C (details specified in the report).

PARTICIPANTS

- Aristotle University of Thessaloniki, School of Chemistry, Laboratory of Biochemistry (GR)
- Association Pharmaceutique Belge, Service de Contrôle des Médicaments, Bruxelles (BE)
- Laboratoire de Bioénergétique et Ingénierie des Protéines, CNRS, Marseille (FR)
- Université Louis Pasteur Strasbourg I, Faculté de Pharmacie, Laboratoire de Biochimie Appliquée, Illkirch (FR)
- Zentrallaboratorium, Friedrich-Ebert Krankenhaus Neumunster, Neumunster (DE)

SAFETY INFORMATION

The recombinant enzyme material was prepared from V79-rHPL cell line. V79 (Chinese Hamster Fibroblasts) have been stably transfected with human pancreatic lipase cDNA under the control of CMV promoter. However, the product must be handled as any material of human origin. It is intended for in vitro analysis only and usual laboratory safety precautions apply.

INSTRUCTIONS FOR USE

To make it ready for use, the material has to be reconstituted according to the procedure described in section 12 of the certification report. The intended use of the material is: a) to ensure the transferability of results obtained with procedures having the same analytical specificity; b) to assign values to secondary materials and c) to calibrate the colorimetric routine procedure, described in the 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.

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NOTE

A technical report on the production of BCR[®]-694 is available on the internet (<http://www.irmm.jrc.be>). A paper copy can be obtained from IRMM on request.