

Certified Reference Material
(Code 416-57191)



JAB
RMP 00010

Enzyme Calibrator

(AST, ALT, ALP, CK, ChE, LD, γ -GT, AMY)

Certificate

Lot No. EF762

The Enzyme Calibrator is the Certified Reference Material (CRM) for the AST, ALT, ALP, CK, ChE, LD, γ -GT and AMY assays and is manufactured under a quality system that conforms with ISO 17034 : 2016. The Enzyme Calibrator can be used with the AST, ALT, ALP, CK, ChE, LD, γ -GT and AMY assays for calibration, Quality Control (QC) and validation of analytical instruments.

【Scope】

For the AST, ALT, ALP, CK, ChE, LD, γ -GT and AMY assays, the Enzyme Calibrator is used for the purpose of standardizing values assigned by the JSCC method to the values calculated by routine methods and is used as the calibration material in the clinical laboratory. Use this material strictly according to the package insert provided herein.

【Certified value and uncertainty】

The certified value and uncertainty of the Enzyme Calibrator are as follows.

Measuring Temperature : 37°C

Enzyme	Origin	Isozyme	Method for determining the assigned values	Certified Value (U/L)	Expanded Uncertainty* (U/L)
AST	Recombinant (Human liver)	S type	Manufacturer's standing measurement procedure**	144	5
ALT	Recombinant (Human liver)	S type	Manufacturer's standing measurement procedure**	162	5
ALP	Recombinant (Human liver)	Liver type	Manufacturer's standing measurement procedure**	426	18
CK	Recombinant (Human skeletal muscle)	MM type	Manufacturer's standing measurement procedure**	453	14
ChE	Human plasma	pseudo	Manufacturer's standing measurement procedure**	491	15
LD	Recombinant (Human I type gene)	I type	Manufacturer's standing measurement procedure**	412	13
γ -GT	Recombinant (Human liver)	II type	Manufacturer's standing measurement procedure**	148	6
AMY	Recombinant (Human pancreas) and Human saliva	P type, S type	Manufacturer's standing measurement procedure**	298	9

* Uncertainty is represented as a total level of confidence based on the expanded uncertainty (coverage factor $k=2$), including homogeneity and experimental error.

** Measurement procedure using by our JSCC transferable products.

【Method for certified value determination】

The certified value of the Enzyme Calibrator was determined by using the "Reference Standard-JSCC Enzyme (JCCLS CRM-001)" and "Reference Standard-ChE (JSSLS CRM-002)" as JCCLS certified reference material and following our manufacturer's standing measurement procedure.

【Traceability】

The certified values for AST, ALT, ALP, CK, ChE, LD, γ -GT and AMY are determined by the above mentioned method, therefore these certified values are traceable to the JSCC Consensus method.

【Expiration date】 2021.10

【Preparation and precautions】

Preparation, Precautions and Storage conditions are described in the package insert.

【Certificate date and certification body】

Date 2020. Dec. 18

【Prohibition of duplicating certificate】

Any part of this certificate should not be duplicated without prior approval.

T. Kurosawa

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