

ENZYME REVIEW TEAM

“Environment scan” presentation

Prof Mauro Panteghini
University of Milan

Key points

- What is the current status of entries in the JCTLM Database with respect to the existing standardized measurands in the field of ENZYMES. What are the missing materials, and methods and calibration services providers for standardized measurands?
- Are there any key measurands for which Reference Measurement System Components exist that are not yet covered by JCTLM in your Review Team area?
- What are the new standardization projects underway in your field that could lead to JCTLM Database entries in the future?
- Can you provide a contact list for reference material producers, developers of measurement procedures, providers of reference measurement services to be targeted/contacted by JCTLM with regard to the missing, and new nominations?

Point #1

- **What is the current status of entries in the JCTLM Database with respect to the existing standardized measurands in the field of ENZYMES.**
- **What are the missing materials, and methods and calibration services providers for standardized measurands?**

JCTLM database

IFCC reference methods for enzymes

Enzyme	Reference
ALP	<i>Clin Chem Lab Med</i> 2011 ;49:1439-46
ALT	<i>Clin Chem Lab Med</i> 2002 ;40:718-24
Amylase	<i>Clin Chem Lab Med</i> 2006 ;44:1146-55
AST	<i>Clin Chem Lab Med</i> 2002 ;40:725-33
CK	<i>Clin Chem Lab Med</i> 2002 ;40:635-42
GGT	<i>Clin Chem Lab Med</i> 2002 ;40:734-38
LDH	<i>Clin Chem Lab Med</i> 2002 ;40:743-48

JCTLM database

Enzyme reference measurement service providers



Accurate results
for patient care

CIRME (Centro di Ricerca per la Riferibilita' Metrologica in Medicina di Laboratorio - Universita' di Milano), Italy –
Contact person: Prof. M Panteghini

RfB-DGKL (Reference Institute of the German Society of Clinical Chemistry and Laboratory Medicine), Germany –
Contact person: Prof. G Schumann

Instand e.V., Germany – Contact person: Dr. P Kaiser

NCCL (National Center for Clinical Laboratories), China – Contact person: Prof. Wenxiang Chen

Beijing Aerospace General Hospital Reference Laboratory, China – Contact person: Dr. Baorong Chen

LREC (Clinical Enzymology Reference Laboratory - Universitat Autònoma de Barcelona), Spain – Contact person: Dr. F Canalias

SCCL (Shanghai Center for Clinical Laboratory), China – Contact person: Dr. Yuan Lu

CLNU (Center of Laboratory Medicine, Affiliated Hospital of Nantong University), China – Contact person: Dr. Huimin Wang

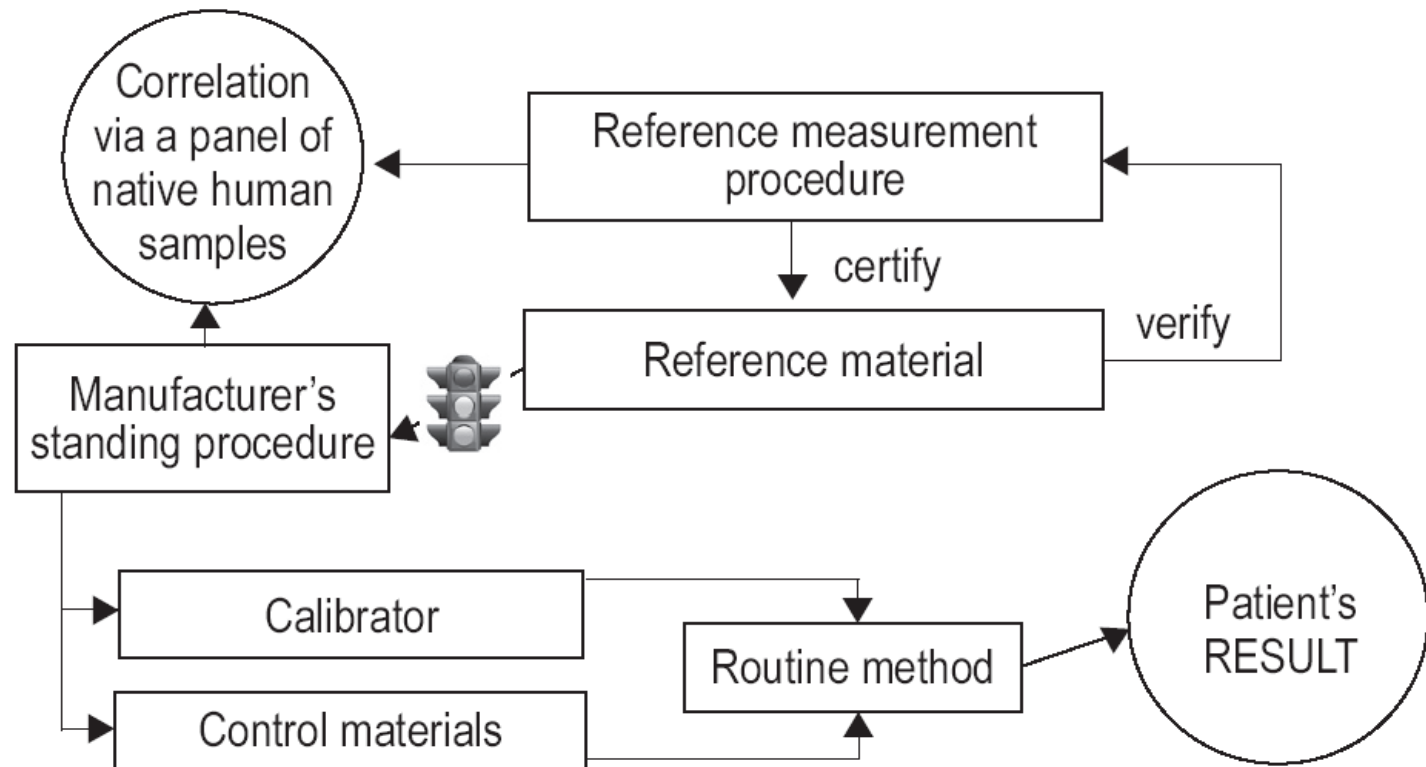
Maccura, China – Contact person: Dr. Lei Lv

JCTLM database

Enzymes reference materials

AST	ERM-AD457/IFCC
ALT	Missing
γGT	ERM-AD452/IFCC
LDH	Missing
CK	ERM-AD455/IFCC (no longer available)
Amylase	IRMM/IFCC-456
ALP	Missing

It should be noted that **the lack of ERMs is not a major issue for the implementation of enzyme measurement standardization**, as manufacturers may better approach it by splitting a panel of native clinical samples with an accredited reference laboratory performing RMP and then calibrate their commercial systems in accordance with correlation results obtained using the RMP-assigned values of clinical samples



Point #2/3

- **Are there any key enzymes for which Reference Measurement System Components exist that are not yet covered by JCTLM?**
- **What are the new standardization projects underway in the field of enzymes that could lead to JCTLM Database entries in the future?**

The JRC released three new Certified Reference Materials (CRMs) applicable for in-vitro diagnostics to monitor the function and state of heart, liver and soft tissues.

CERTIFICATE OF ANALYSIS

ERM[®]-AD454k/IFCC

ENZYME IN BUFFER		
	Catalytic activity concentration ¹⁾	
	Certified value ²⁾	Uncertainty ³⁾
Alanine aminotransferase (ALT)	103.8 U/L 1.73 µkat/L	2.6 U/L 0.05 µkat/L

1) Catalytic activity concentration of alanine aminotransferase (ALT) in the reconstituted material, as obtained by the IFCC primary reference measurement procedure for the measurement of catalytic activity concentration of alanine aminotransferase at 37 °C.

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 $f = 0.01667$.

3) The uncertainty is the expanded uncertainty of the certified value with a coverage factor $k = 2$ 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.

CERTIFICATE OF ANALYSIS

ERM[®]-AD455k/IFCC

ENZYME IN BUFFER		
	Catalytic activity concentration ¹⁾	
	Certified value ²⁾	Uncertainty ³⁾
Creatine kinase isoenzyme MM (CK-MM)	314 U/L 5.23 µkat/L	6 U/L 0.10 µkat/L

1) Catalytic activity concentration of creatine kinase isoenzyme MM (CK-MM) in the reconstituted material, as obtained by the IFCC primary reference measurement procedure for the measurement of the catalytic activity concentration of creatine kinase at 37 °C.

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 $f = 0.01667$.

3) The uncertainty is the expanded uncertainty of the certified value with a coverage factor $k = 2$ 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.

CERTIFICATE OF ANALYSIS

ERM[®]-AD453k/IFCC

ENZYME IN BUFFER		
	Catalytic activity concentration ¹⁾	
	Certified value ²⁾	Uncertainty ³⁾
Lactate dehydrogenase isoenzyme 1 (LD1)	330 U/L 5.50 µkat/L	7 U/L 0.12 µkat/L

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.

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 $f = 0.01667$.

3) The uncertainty is the expanded uncertainty of the certified value with a coverage factor $k = 2$ 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.



IFCC

International Federation
of Clinical Chemistry
and Laboratory Medicine

Scientific Division

*Committee on Reference Systems
for Enzymes (C-RSE)*

Reference measurement procedure for pancreatic lipase

- C-RSE is working on a concept for the development of a RMP for lipase.
- C-RSE is in favour of spectrophotometry as the measurement principle for the RMP for lipase.

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Letter to the Editor

Yoshiaki Iizuka, Keita Yamashita, Shin-Ichi Sakasegawa, Toshiro Hanada, Wataru Tani, Hiroshi Adachi, Riichi Haga, Mari Yamaguchi, Wataru Kurotani, Mitsuo Sekiguchi, Susumu Osawa, Shigemi Hosogaya, Dongchon Kang and Shigeru Ueda*

Improvement and evaluation of a 1,2-dioleoylglycerol method for measuring pancreatic lipase catalytic activity in serum

Commutability study of amylase candidate reference materials for ERM-AD456/IFCC



Purpose

The aim is to develop a CRM for the calibration of field assays for pancreatic amylase and total amylase

Suggested reading

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Clin Chem Lab Med 2016; aop

Mini Review

CIRME



UNIVERSITÀ DEGLI STUDI
DI MILANO

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Progress and impact of enzyme measurement standardization

standardization

