



STANDARDIZATION IN CLINICAL ENZYMOLOGY – RESULTS OF A SURVEY PERFORMED IN 2008 IN BIG HOSPITAL LABORATORIES IN POLAND

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Abstract

The survey was performed in December 2008 in 21 big hospital laboratories in Poland. The purpose of this survey was to estimate how the IFCC standardization in clinical enzymology is recognized and followed in medical laboratories. Each participant received a short questionnaire in an electronic version consisting of 5 questions dealing with the main features for the Reference Procedures for measurement of catalytic activity concentrations of CK, LDH, GGTP, AST and ALT. Measurement temperature for all enzyme assays in question was 37°C and wavelength was 340 nm for LDH, ALT, AST and CK in all but one lab. Most of laboratories (80%) performed GGTP assay according to the reference procedure. Surprisingly, the methods used for the LDH measurement were discordant with the IFCC reference procedure in respect to reaction principle in 50% of laboratories. On the other hand, methods for measurements of catalytic activity concentration of ALT and AST were incompatible with the IFCC reference procedures in respect to reaction mixture composition in 55% of laboratories.

INTRODUCTION

Standardization in clinical enzymology means obtaining comparable results measuring enzyme activities in human samples, independent of the laboratory where the assay is carried out. In 2002 Clinical Chemistry and Laboratory Medicine has published a series of seven papers on reference procedures for the measurement of catalytic activity concentrations of enzymes: creatine kinase, lactate dehydrogenase, alanine aminotransferase, aspartate aminotransferase and gamma-glutamylotranspeptidase. The measurement conditions for catalytic activity concentrations of enzymes were switched from 30°C to 37°C. IFCC has proposed primary reference methods for enzyme assays and manufacturers of diagnostic systems should demonstrate the traceability of their measurement results to these procedures with the use of certified reference materials (1).

The purpose of this survey was to estimate how the IFCC standardization in clinical enzymology is recognized and followed in big medical laboratories.

METHODS

The survey was performed in December 2008 in 21 big hospital laboratories in Poland. Among those were: 4 University Hospital laboratories, 7 medical laboratories in big regional hospitals, 7 medical laboratories from Specialistic Medical Centers, 3 Military Hospital laboratories. All the laboratories used the automatic diagnostic systems of different manufacturers. Each participant received a short questionnaire in an electronic version consisting of 5 questions dealing with the main features for the reference procedures for measurement of catalytic activity concentrations. Participants were requested to reply questions concerning the following enzyme assays: CK (measurement conditions: temperature, wavelength), LDH (reaction principle, measurement conditions: temperature, wavelength), ALT and AST (reaction mixture, measurement conditions) and gamma-GTP (measurement conditions: temperature, wavelength). Each laboratory was informed individually about the results of the Survey. The

final results of the Survey were presented in January 2009 during the Meeting of the College of Laboratory Medicine in Poland.

RESULTS

95% of laboratories took active part in the survey. Measurement temperature for all enzyme assays in question was 37°C and wavelength was 340 nm for LDH, ALT and AST (2,3,4). All but one lab measured CK at 340 nm (5). Most of laboratories (80%) performed GGTP assay according to the reference procedure at 410 nm, however in 4 of them the wavelength of 405 nm or 400 nm was used (6).

The methods used for the LDH measurement were discordant with the IFCC reference procedure in respect to reaction principle (L-lactate + NAD⁺ → pyruvate + NADH + H⁺) in 50% of laboratories (2).

On the other hand, assays for the measurement of catalytic activity concentration of ALT and AST were incompatible with the IFCC reference procedures in respect to reaction mixture composition (addition of pyridoxal-5'-phosphate 0,1 mmol/L) in 55% of laboratories (3,4).

COMMENTS

IFCC Committee on Reference Systems for Enzymes emphasize that European legislation requires all manufacturers of in vitro diagnostics systems to demonstrate the traceability of their results to recognized standards or procedures (1). However, the compliance with the law is not always a case. Surprisingly, this refers particularly to the Reference Procedures for the measurement of catalytic concentrations of LDH and alanine/aspartate aminotransferases that are most frequently performed measurements as an efficient screening for several diseases.

Table 1. Frequency of compatible and incompatible answers – lab survey on standardization of measurements of catalytic concentrations of enzymes.

Enzyme assay	Positive answers (following the IFCC reference procedures)	Negative answers (incompatible with IFCC reference procedures)
Creatine Kinase	19 (95%)	1 (5%)
Gamma-Glutamyl transpeptidase	16 (80%)	4 (20%)
Lactate dehydrogenase	10 (50%)	10 (50%)
Alanine aminotransferase/ Aspartate aminotransferase	9 (45%)	11 (55%)

The authors of this Survey had no intention to compare between different IVD systems manufacturers otherwise the names of major producers/distributors would appear in the body of the text. Evaluating the questionnaire we also took into account an individual laboratory's preference for an automatised analytical system.

In conclusion, it seems that the introduction of standardized procedures for enzyme assays for some in vitro diagnostics manufacturers is somewhat a complicated task and much more time is needed until the full compliance with the IFCC guidelines will be accomplished.

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