Accuracy evaluation of high- and low-density lipoprotein cholesterol assays in clinical laboratories by comparison with isotope dilution mass spectrometry

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Background: Accurate and precise measurement of blood cholesterol, including high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol, is essential for generating the correct burden and trends of dyslipidemia. We evaluated the performance of five HDL/LDL cholesterol assays currently used in Korea with field method to assess the traceability of current HDL/LDL cholesterol in vitro diagnostic products to commutable frozen serum (CFS) reference materials.

Methods: The commonly used HDL/LDL assays were categorized as five groups according to the combination of instrument and reagent. There were 2 open and 3 closed systems as follows: Toshiba-Kyowa, Hitachi-Sekisui, Siemens ADVIA, Roche Cobas or Modular, and Beckman Coulter AU series. Five levels of CFS pools were prepared according to CLSI 37-A, and sent to 13 laboratories at both refrigerated and frozen state with quadruplicate measurements. Each group comprised of 2 or 3 laboratories. Target reference values were measured at National Medical Reference Laboratory of Korea Centers for Disease Control and Prevention in CDC reference method (β-quantification) using a gas chromatography–isotope dilution mass spectrometry procedure.

Results: The target values of 5 materials were 35.0 ~ 55.2 mg/dL for HDL and 81.7 ~ 155.2 mg/dL for LDL cholesterol. The mean absolute bias of HDL cholesterol in each group was ranged from 1.5 mg/dL to 3.5 mg/dL with mean relative bias of 3.2 ~ 8.0%. The LDL cholesterol values of one reference material with the highest triglyceride value (330 mg/dL), due to one dyslipidemic patient included, were significantly overestimated (mean, 20.4

mg/dL) in all assays, regardless of temperature conditions. The degree of difference was greater in Beckman and Roche assays (33.5 and 23.5 mg/dL).

Conclusions: HDL cholesterol values of 5 routine assays showed some positive bias compared with those of reference measurement procedure, but the degree of bias was acceptable except the Hitachi-Sekisui assay by National Cholesterol Education Program criteria. Current direct LDL cholesterol assays could not provide the accurate measurements in patients with hypertriglyceridemia at both refrigerated and frozen state, but the degree of overestimation was quite different depending on the instrument and/or reagent.