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SYMPOSIUM

Use of Serial Patient Hemoglobin A1c Differences to Determine Long-Term Imprecision of Immunoassay and High-Performance Liquid Chromatography Analyzers

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Abstract

Background:

The quality of the HbA1c assay is inversely proportional to the variation of the assay. Most published measures of HbA1c variation are limited by the data collection period, the statistical treatment of outliers, and even the noncommutability of the products used to generate the variation measurements. We have used an alternate approach to derive HbA1c variation, using serial patient data.

Methods:

HbA1c measurements of outpatient blood sample pairs drawn within 30 days of each other were made on three different immunoassay systems: the Roche INTEGRA® 700, the Roche INTEGRA® 400, and the Dade Dimension® RxL; and two high-performance liquid chromatography assays: the Tosoh G7 and the Tosoh 2.2+. The standard deviation of duplicates was calculated for the following time intervals: 1 to 3 days, 4 to 6 days, 7 to 9 days, . . . , 28 to 30 days. These intra-individual variations were then plotted; extrapolation to time zero yields the long term total random error which consists of both analytic and pre-analytic error. Data collection periods were usually 2 years.

Results:

At the mean HbA1cs of 7.08%, 7.14%, 7.20%, 6.96%, and 7.51% for populations tested on the Roche INTEGRA 700, Roche INTEGRA 400, Dade Dimension RxL, Tosoh 2.2+, and Tosoh G7, respectively, the total analytic imprecisions (coefficient of variation) were 2.56%, 2.29%, 2.25%, 1.66%, and 1.14%, respectively.

Conclusion:

Assessment of the HbA1c long term total imprecisions shows that while the three immunoassay systems are acceptable, the Tosoh HbA1c analyzers demonstrate superior analytic performance.

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Abbreviations: (CAP) College of American Pathologists , (CV) coefficient of variation, (HbA1c) Hemoglobin A1c, (HPLC) high-performance liquid chromatography, (NACB) National Academy of Clinical Biochemistry, (NGSP) National Glycohemoglobin Standardization Program, (SDD) standard deviation of duplicates

Keywords: hemoglobin A1c, long-term analytic variation

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