Use of patient glycohemoglobin data to derive intralaboratory long term random error of multiple Bio-Rad Variant II's

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Estimates of imprecision are usually based on the repeated analysis of reference samples. These estimates are dependent on the reference sample's characteristics and where it enters the analytical stream. We have used a novel, independent approach for deriving the long term imprecision of glycohemoglobin in which intra-individual glycohemoglobin variations are plotted against the time between sampling. Extrapolation to zero time will yield the long term random error.

Glycohemoglobin measurements of pairs of outpatient blood samples drawn between 0 and 30 days were made on any one of 3 different Bio-Rad (Hercules, CA) Variant II cation exchange HPLC analyzers operated in a large reference laboratory. The standard deviation of duplicates was calculated for the following time intervals: 0 to 3 days, 4 to 6 days, 7 to 9 days, . . ., 28 to 30 days. The standard deviations of duplicates were then regressed against time with extrapolation to zero time representing the long term random error. Over the data collection period, Nov 7, 2002 to October 27, 2004, 150,048 glycohemoglobins were measured, with roughly one third run on each analyzer. 3478 pairs of intrapatient glycohemoglobins were measured with the between sampling time varying from 0 to 30 days. With removal of any duplicate differences exceeding 3.5 s, the total random error at zero time is 0.262% (See Figure). At a mean glycohemoglobin of 7.16%, the coefficient of variation is 3.7%. This variation is remarkably low, given that the glycohemoglobins were measured over two years on any one of three Variants and the within-analyzer CV usually documented between 3.0 to 4.0% by the repeated analysis of reference samples. We recommend that our approach for deriving long term random error be extended to all glycohemoglobin analyzers. Unlike reference sample statistics, the patient-derived random error should allow easy comparison among different analytical systems.