COLLEGE of AMERICAN PATHOLOGISTS

2016 GH5-B
PARTICIPANT SUMMARY

Evaluation Criteria

Analyte	Target Value	Evaluation Limit
Hemoglobin A_{1c}	Accuracy-Based	±6%

In the event a result is not graded, a numeric code will appear next to your result. A definition of the code will appear on the first page of your evaluation. Please see "Actions Laboratories Should Take when a PT Result is Not Graded" on page 14.

The quantitative data tables provided in the Participant Summary report include the mean, SD, median, %CV and the lowest and highest values reported for each peer group. The low and high values are not the limits of acceptability. The acceptable limits are located on your participant evaluation report.

To provide a timely evaluation of your results, statistics presented in this Participant Summary reflect participant data received by the due date.

Discussion

GH-06, GH-07, GH-08, GH-09, and GH-10 samples were prepared from pooled whole blood obtained from healthy or diabetic individuals. The target values were determined from the means of all results from seven National Glycohemoglobin Standardization Program (NGSP) Secondary Reference Laboratories (SRLs). Each laboratory analyzed each sample in triplicate on two separate days. These NGSP Network Laboratories use methods that are calibrated and traceable to the method used in the Diabetes Control and Complications Trial (DCCT). Comparison to the NGSP Network allows both manufacturers and clinical laboratories to trace their glycated hemoglobin results to the DCCT. The target HbA_{1c} values for the survey are as follows: GH-06, 5.27%; GH-07, 10.59%; GH-08, 6.2%; GH-09, 12.23% and GH-10, 7.51%.

Commencing in 2015, all laboratories that are accredited by the Laboratory Accreditation Program are required to perform 15 challenges annually for HbA_{1c}. Therefore, the College of American Pathologists is offering three HbA_{1c} challenges, each with five samples, per year. These are named GH5-A, GH5-B and GH5-C. Laboratories that wish to continue to perform six samples annually will receive two shipments, each with three samples. These will retain the prior terminology, namely GH2-A and GH2-B. Samples GH-01, GH-02, GH-03, GH-11, GH-12 and GH-13 will be analyzed by all participants and the data will be combined.

The Survey uses an accuracy based evaluation against the NGSP reference method targets with an acceptable limit equal to ± 6% of the target value. Because the PT samples are prepared from human whole blood, the bias observed for the PT samples is expected to reliably reflect the bias that exists for patient samples analyzed with the same method. The percentage is a mathematical fraction, not the HbA_{1c} reporting unit. For example, the acceptable range for GH-08, which has a HbA_{1c} value of 6.2%, would be HbA_{1c} values between 5.8 and 6.6%.

For the five specimens, the pass rates vary considerably depending on the HbA_{1c} method (data for all methods $n \geq 10$ are summarized in Table 1). While the overall pass rate ranged from 92.3 to 97.8%, depending on the target value, the lowest pass rate was 63.6%. Nevertheless, some methods were able to achieve 100% (or close to 100%) pass rates for all five samples.

Table 1

Specimen	NGSP Target (% HbA_{1c})	Acceptable Range	Pass rate % (Low/High)	Cumulative Pass Rate %
GH-06	5.27	4.9 - 5.6	81.8/100.0	97.5
GH-07	10.59	9.9 - 11.3	72.7/100.0	95.2
GH-08	6.20	5.8 - 6.6	81.8/100.0	97.5
GH-09	12.23	11.4 - 13.0	71.8/100.0	92.3
GH-10	7.51	7.0 - 8.0	63.6/100.0	97.8

Pass rates listed are for methods with a peer group $n \geq 10$.

Examination of the HbA_{1c} results obtained by participants in the Survey reveals that in general the mean values measured by the participants did not differ markedly from the values determined by the NGSP Secondary Reference Laboratories. Only one of the means for the laboratory analyzers differed from the target value by more than 0.5% HbA_{1c}. (A change of 0.5% HbA_{1c} is considered by many to be a clinically significant difference.) The method-specific HbA_{1c} means for GH-10 (HbA_{1c} target value 7.51%) exhibited the least variation, ranging from 7.29% to 7.74% HbA_{1c} (these are differences of -2.9 and +3.1%, respectively, from the target value). The method-specific means for GH-06 (HbA_{1c} target value 5.27%) ranged from 5.06% to 5.39% HbA_{1c} (differences of -4.0 and +2.3%, respectively, from the target value). GH-07 (HbA_{1c} target value 10.59%) had method-specific means ranging from 10.2% to 10.87% HbA_{1c} (differences of –3.7 and +2.6%, respectively, from the target value). GH-08 (HbA_{1c} target value 6.2%) had method-specific means ranging from 5.94% to 6.37% HbA_{1c} (differences of

–4.2 and +2.7%, respectively, from the target value). GH-09 (HbA_{1c} target value 12.23%) had method-specific means ranging from 11.64% to 12.58% HbA_{1c} (differences of –4.8 and +2.9%, respectively, from the target value). Tosoh G8 Automated HPLC had the lowest CVs (≤1.6%) for all five samples. Sebia Capillarys 2/Minicap Flex Piercing had CVs ≤1.7% for four samples and Beckman UniCel DxC Synchron had CVs ≤1.8% for three samples. By contrast, Abbott Architect i System had CVs ≥4.9% for all five samples. Guidelines from The National Academy of Clinical Biochemistry and the American Diabetes Association recommend an inter-laboratory CV <3.5% (Clin Chem 2011; 57:e1-e47 and Diabetes Care 2011; 34:e61-99). Most methods were able to achieve this criterion. However, Beckman AU Systems had CVs >4% for three samples. Bio-Rad Variant II had the highest mean value for three samples.

In addition to the tables, the data obtained for each method (with a peer group $n \geq 10$) are also presented in the style of box-and-whisker plots (Fig. 1). Each method is listed individually, with the number of participants using that method in parentheses after the name of the method. The individual lines extend from the minimum to maximum difference, expressed as a percentage from the target value (the percentage is a mathematical fraction). The thicker line indicates the distribution of the middle 90% of values. The grey shaded area represents the evaluation limit, i.e., ± 6% from the target. The diamond is the median for the particular method. Outliers were excluded. The presentation allows rapid visualization of bias [how far the diamond (median) is from zero], imprecision (length of the line) and the number of laboratories that failed (those that lie outside the shaded area) for each method. This new feature provides additional detailed information that should be useful to individual laboratories to assess their method and compare it to both their peers and to other methods.

Manufacturers of methods that have the means furthest from the reference value and those with the largest imprecision are encouraged to improve their performance, especially those methods that consistently exhibit large bias and/or large CVs. This is particularly important in the clinically relevant HbA_{1c} ranges (~5.5% to 8%).

David B. Sacks, MB, ChB
Chemistry Resource Committee

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