COLLEGE of AMERICAN PATHOLOGISTS

2014 GH2-A
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 9.~~

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

Discussion

GH2-01, GH2-02, and GH2-03 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: GH2-01, 6.49%; GH2-02, 6.97% and GH2-03, 9.65%.

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 analyed with the same method. The percentage is a mathematical fraction, not the HbA_{1c} reporting unit. For example, the acceptable range for GH2-01, which has a HbA_{1c} value of 6.5%, would be HbA_{1c} values between 6.1 and 6.9%.

For the three 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 88.8 to 94.2%, depending on the target value, the lowest pass rate was 57%. Nevertheless, some methods

were able to achieve 100% (or close to 100%) pass rates for all three samples.

Table 1

Specimen	NGSP Target (%HbA_{1c})	Acceptable Range	Pass Rate % (Low/High)	Cumulative Pass Rate %
GH2-01	6.49	6.1-6.9	57.0/100	88.8
GH2-02	6.97	6.5-7.4	60.7/100	89.1
GH2-03	9.65	9.0-10.3	74.5/100	94.2

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. None of the means for the laboratory analyzers differed from the target value by more than 0.43% 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 GH2-03 (HbA_{1c} target value 9.7%) exhibited the least variation, ranging from 9.39% to 10.06% HbA_{1c} (these are differences of -2.7 and +4.3%, respectively, from the target value). The method-specific means for GH2-01 (HbA_{1c} target value 6.5%) ranged from 6.28% to 6.88% HbA_{1c} (differences of -3.2 and +6.0%, respectively, from the target value). GH2-02 (HbA_{1c} target value 7.0%) had method-specific means ranging from 6.77% to 7.4% HbA_{1c} (differences of -2.9 and +6.2%, respectively, from the target value). Sebia Capillarys 2 Flex Piercing had the lowest CVs (<1.5%) for all three samples. Abbott Architect i System was the only method that had a CV >5% and this was for one sample.

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 difference for the particular method. Outliers were excluded. The presentation allows rapid visualization of the direction of the bias [how far the diamond (median) is from zero], imprecision (length of the line) and a general estimate of 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%).

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