July 27, 2015

Changes to Whole Blood Glucose Programs

Dear Participant:

American Proficiency Institute is making a change to Whole Blood Glucose programs for 2016 in response to recent clarifications from the Centers for Medicare and Medicaid Services (CMS) to all PT providers.

CLIA regulations state that laboratories are not to test proficiency samples during the PT Event with more than one instrument unless that is how they test patient specimens. CMS clarified that this restriction also applies to analytes categorized as waived under CLIA. As a result of this directive, in 2016 participants will not be able to test and report whole blood glucose from more than one meter during the PT testing period. However, results from additional meters may be obtained and reported after the PT due date.

We understand the concerns you might have in regard to this change and have worked to minimize its effect on your efforts to ensure laboratory quality. We have created special Verification programs that will allow you to report results for additional meters after the PT due date. One of these programs has been added to your 2016 renewal at no extra charge. With this program you may continue to report results for up to 20 meters, without having to purchase additional testing material.

The program will work as follows:

- When you receive your Whole Blood Glucose proficiency samples you will be instructed to test the samples on one of your meters, and submit those results as part of the proficiency event.
- After testing the samples you will refrigerate them until the Verification testing period begins, after the PT due date.
- When the Verification testing period begins, you will test the samples on your remaining meters, and submit your results online.
- Your evaluation for these results will be available online at the same time as the evaluations for proficiency programs.

Please feel free to call Technical Support at 800-333-0958 if you have any questions.