

Dear Laboratory Director,

This notice is to alert you that the College of American Pathologists' (CAP) Laboratory Accreditation Program (LAP) will **no longer require enrollment and participation in proficiency testing (PT) for *waived* whole blood glucose on glucose meters (ie, WB2/WBG) and waived whole blood Prottime/INR (ie, WP10) beginning with the 2017 PT program year. Laboratories will be required to perform alternative performance assessment for these analytes.**

The Centers for Medicare and Medicaid Services (CMS) states that laboratories are not permitted to test the same PT samples on multiple instruments unless that is how the laboratory tests a patient specimen and laboratory procedures are written to reflect that process. In August 2015, CMS clarified that this interpretation extended to all analytes (not just those listed in Subpart I of the CLIA regulations), including waived methods.

Because laboratories can only perform PT on one (of dozens in many cases) meter, it is unlikely that requiring PT for *waived* whole blood glucose and *waived* Prottime/INR will allow you or LAP to identify performance issues. Many PT providers offer a secondary product for quality assurance (ie, CAP's Quality Cross Check) that allows for reporting of multiple instruments. Laboratories may choose to enroll in one of these products to meet alternative performance assessment requirements; though LAP does not require or monitor these quality assurance products.

To summarize, the CAP LAP will no longer require laboratories to enroll and participate in PT for *waived* whole blood glucose on glucose meters and waived whole blood Prottime/INR. LAP will require alternative performance assessment per LAP checklist requirement COM.01500.

If you have questions regarding this change, please contact a PT Compliance representative at 1-800-323-4040 ext. 6052 or 1-847-832-7000 ext. 6052. To learn more about CAP Quality Crosscheck products, please [visit the CAP online store](#) (please note, the whole blood glucose Quality Cross Check product will not be available until the 2017 ordering information is posted) or contact CAP Customer Service at 1-800-323-4040 (Option 1).

Thank you for your ongoing support of the CAP's Laboratory Accreditation Program.

