

CMS Clarification for Multiple Instrument Testing

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. In July 2015 CMS clarified to all PT providers that in addition to analytes regulated by CLIA (those listed in Subpart I of the CLIA regulations), **this restriction also applies to non-regulated analytes and to analytes categorized as waived under CLIA.**

With this clarification, CMS has indicated that laboratories may test proficiency samples with multiple instruments/methods after the PT due date. API offers Verification programs for this purpose. These programs offer the convenience of using proficiency samples to verify secondary instruments and methods, while remaining compliant with CLIA regulations. Verification samples are shipped along with samples for proficiency testing. Laboratories are directed to test and submit results for these samples online after the PT due date. Verification evaluations are available online, at the same time as the evaluations for proficiency programs.

In addition to the Verification programs described above, API has two different options for testing blood glucose meters in compliance with CLIA regulations. Whole Blood Glucose proficiency programs allow reporting of only one set of PT results. However, they contain enough sample volume and, if stored properly, are stable through the verification testing period to allow testing more meters after the PT due date. One Verification program allows reporting of results for up to 20 meters on the PT samples, after the due date, without having to purchase additional testing material. Another Verification program includes an additional set of samples to report 20 meters per sample set purchased.

If you have further questions about multiple instrument testing, please contact Technical Support at 800-333-0958 or TechSupport@api-pt.com.