

CMS Clarification on Secondary Instrument Reporting on Non-regulated Analytes and Waived Methods

Q: Are laboratories allowed to test the same analyte with two different instruments in the same PT event, if the samples for each instrument are targeted differently and the lab indicates which instrument is primary for PT purposes? By way of example, samples for Prothrombin Time in the main lab (Module A) and Prothrombin Time in the surgery department on a CoaguChek (Module B) would not be compatible with the other department's instrument; is enrolling in both programs allowed? The PT score would be based only on the primary instrument.

CMS response: When a laboratory enrolls in two different modules for two unique instruments (because the samples in either module are not compatible for both instruments), the laboratory would be allowed to test both PT modules, as long as they designate the primary instrument for PT purposes. The laboratory should have robust policies and procedures in place to ensure that any communication or discussion across sites/locations does not occur.

Q: Some laboratories own multiple instruments of the same model (e.g., i-STAT) and may perform regulated sodium, chloride, etc. in the main lab, and pH, pO₂, and pCO₂ in respiratory therapy. These analytes are all contained in the same proficiency sample. Due to stability issues, the samples must be tested soon after opening the vial and cannot be shared between the two areas. Therefore, each department needs their own set of samples. Are they allowed to test these identical samples and rely on "robust policies and procedures" to prevent intra-laboratory communication?

CMS response: Laboratories are not permitted to test PT samples on multiple instruments unless that is how the laboratory tests patient specimens and laboratory procedures are written to reflect that process. In the situation described above, robust policies and procedures to prevent any communication or comparison would not be sufficient. The laboratory would be allowed to test the identical PT samples on more than one instrument only if the laboratory tests their patient specimens in this manner.

Q: It is clear that the directive on multiple instruments applies to the analytes listed in Subpart I of the CLIA regulations. Does it also apply to non-scored analytes (those not included in Subpart I), if laboratories choose to use PT to perform the accuracy checks required by §493.1236(c)(1)?

CMS response: Yes, it applies to analytes not listed in Subpart I of the CLIA regulations.

Q: Does the rule on multiple instruments also apply to waived methods like whole blood glucose meters?

CMS response: Yes, it applies to analytes categorized as waived complexity under CLIA.