

Responses for the competency assessment questions posed to Sarah Bennett, Medical Technologist at CMS Division of Laboratory Services (CLIA) at the VA POCC on June 19, 2015:

**Question #1:** May I combine for competency purposes, all tests performed simultaneously on the same testing platform (e.g., iStat)?

**Response #1:** As long as there are no unique aspects, problems or procedures associated with any test on the testing platform, all tests performed simultaneously on the same testing platform may be combined. However, any test with unique aspects, problems or procedures within the same testing platform should be assessed separately to ensure that staff maintain their competency to report test results promptly, accurately and proficiently.

Example #1 for the iStat: If one syringe is used to load 2 different cartridges (e.g., G3+, EC4+) the portion of the competency assessment that is the same between the cartridges can be done once; however, any aspects with the test (i.e., evaluating results, reporting results) must be taken into account on the competency assessment.

Example #2 for the iStat: If using different cartridges with overlapping analytes the policy on competency assessment is the same as Example #1 above. Any unique aspects of a test cartridge must be taken into account (e.g., sample type, limitations for testing)

**Question #2:** Does CLIA allow for "simulated" test performance? For instance, if there are large numbers of employees performing a test?

Response #2: CA measures how accurately the testing personnel can perform the test, so each employee must perform his/her test. In addition, the CLIA regulations require direct observation for certain parts of the competency assessment. A simulation is not the same as direct observation of performing a test or performing maintenance. For accredited facilities, I would suggest checking with their requirements. I will bring this up at Central Office so that we can have a discussion about simulated tests for competency assessment.

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