

CLIA CORNER

State Hygienic Laboratory at The University of Iowa

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Method Correlations

There are many reasons a laboratory may have duplicate instruments and methodologies. A few examples include:

- Back-up method for when the main instrument is not functioning;
- The laboratory's test volume is too high for only one instrument;
- The laboratory performs the same testing with both an automated and manual kit method;
- Multiple instruments are kept in different departments of the facility; and
- The laboratory has multiple molecular platforms to give providers the option for a panel that includes several targets or an option with fewer of the same targets.



VS.



D5775 §493.1281 Standard: Comparison of test results

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

Who and What?

The laboratory must perform and document comparison testing between different or identical models of an instrument from the same manufacturer and between instruments from different manufacturers. This includes those test systems that perform the same target or analyte but are not necessarily back-up systems for one another, e.g., molecular platforms that provide testing for the same targets, but in a different testing configuration or for different diagnostic reasoning. It includes both qualitative and quantitative testing as well as automated and non-automated systems. Examples include: Clostridium difficile testing on an automated, molecular stool panel and a manual lateral flow test kit; or, chemistry testing performed on the laboratory's main chemistry analyzer and a non-waived point of care analyzer.

When?

The regulation specifies that comparison activities must be performed twice a year. Many laboratories choose to perform these activities every 6 months, however, they can be performed at lesser or greater intervals, according to the laboratory's written policy.

How?

CLIA does not specify the number of specimens to be used in a comparison study or the target thresholds for acceptability. It is up to the laboratory to determine the type and number of specimens to be used for comparison activities. In addition, the laboratory must have a written policy/procedure outlining these details and written criteria for acceptable differences in test values between the testing platforms/methods.

Examples of materials that may be used for comparison testing include:

- Proficiency testing (PT) samples.
 - ⇒ These may only be used for instruments/methods utilized under the same CLIA number. **NEVER send PT samples to another laboratory with another CLIA number, even if it is within the same organization. This is considered PT Referral. Please see [CMS Memo S&C: 18-07-CLIA](#) and the [CLIA Brochure - Proficiency Testing and PT Referral – September 2017 \(PDF\)](#) for more information.**
 - ⇒ Perform PT on the main instrument/method and submit the results; save and store the leftover PT samples as instructed in the PT manufacturer instructions. After the graded PT results are released, run the saved PT samples on the alternate instrument(s)/ method(s). Evaluate the results for acceptability according to the laboratory's written criteria.
- Split samples or “blind” testing of materials with known values.
- If the laboratory performs calibration verification as specified in §493.1255(b) of the regulations, it may use the calibration verification to meet the requirements for comparison testing between multiple test systems, provided the 3 levels of materials used for calibration verification meet the laboratory's criteria for acceptable differences in test values.



Remembering to perform comparison activities throughout the year can be challenging. It may be beneficial for the laboratory to use an annual calendar as a visual reminder to list which tests need comparison activities and when they need to be performed. Electronic calendar appointments and reminders may also be helpful.

CLIA Personnel Files

One of the areas of the laboratory all CLIA surveyors review is personnel. It is recommended that the laboratory have the initial hire date and/or the initial training beginning and completion dates for each testing personnel. The initial training beginning and completion dates are especially helpful for testing personnel who are not trained immediately after hire or for those who have not performed testing previously but are trained to do so over a long period of time. It is helpful to write those dates directly on the outside of the personnel files or keep them in a spreadsheet for quick reference. This info, in addition to the laboratory's policy for performing competency assessments, helps surveyors determine when the first two competencies must be performed for new testing personnel.

Within the personnel file, the following should be included:

- Documentation of education (diploma and/or transcripts)
- State license and/or certification, if required
- Documentation of experience, as applicable
- Initial training for each test system
- Two competency assessments from within the first year of hire/training, as applicable
- Annual competency assessments



Documentation of Education, State Licensure, and/or Certification

For non-waived laboratories, personnel must meet specific educational requirements. Those requirements can be found in Subpart M of the [State Operations Manual: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services](#). Within Subpart M, the personnel requirements are broken into three sections: Laboratories Performing Provider-Performed Microscopy (PPM) Procedures; Laboratories Performing Moderate Complexity Testing; and Laboratories Performing High Complexity Testing. Personnel in laboratories performing multiple complexities of testing must meet the requirements for the highest complexity of testing they perform in the laboratory. CLIA attempts to qualify personnel under Subpart M according to the highest level of academic achievement that the individual has obtained, as it applies to CLIA testing.



For additional information about required education, licensure, and certification documentation, please refer to the CMS [Survey and Certification Memo 16-18-CLIA: Personnel Policies for Individuals Directing or Performing Non-waived Tests](#). For state specific requirements, contact your local [State Agency](#) office.

Documentation of Experience

For some CLIA roles, surveyors must also ensure or verify that an individual's clinical laboratory training/experience or supervisory experience has been appropriate for the laboratory testing performed. Please refer to Subpart M of the [State Operations Manual: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services](#) for more information about the training/experience requirements for each CLIA role.

The type of experience required under the CLIA regulations must be clinical in nature. This means personnel must have performed, directed, or supervised (depending on the CLIA role) testing on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring a patient's condition. Patient or medically oriented experience, such as ordering and interpreting tests and applying the results of those tests in diagnosing and treating a patient's illness, does not meet the requirement for laboratory training or experience. Documentation of an individual's training/experience may be presented in a variety of formats; however, curricula vitae (CVs) and resumes are not acceptable as the only evidence. For more specific information about acceptable training/experience documentation, contact your local [State Agency](#) office.



Documentation of Training

Each individual must have documentation of training applicable to the types and complexity of testing they perform prior to analyzing patient specimens. The individual must be able to demonstrate that they have the skills required for proper performance of preanalytic, analytic, and postanalytic phases of testing, including proper specimen handling prior to testing, proper test performance according to the laboratory's policies and manufacturer's instructions, and proper reporting of patient test results in accordance with the laboratory's policies.



If you would like your name added to our CLIA Corner Google Group,
send an email to:

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Documentation of Competency Assessment

Competency assessments are required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant (CC), technical consultant (TC), technical supervisor (TS), general supervisor (GS) and testing personnel (TP).

The laboratory must have policies and procedures to assess competency based on the position responsibilities listed in Subpart M for the following positions: CC, TC, TS, and GS. These competency assessments must be performed at a frequency determined by the laboratory. Individuals fulfilling these positions and who also perform testing on patient specimens are required to have competencies performed based upon the six criteria for testing personnel, in addition to, competencies based on their regulatory/supervisory responsibilities.

Testing personnel competency assessments must be performed:

- At least semiannually during the first year of employment;
- Annually thereafter;
- With changes in test methodology or instrumentation; and
- With the addition of new test systems.

They may be performed throughout the entire year by coordinating them with routine laboratory practices and procedures. For additional information about requirements for performing competency assessments, please refer to the [CLIA Brochure - What Do I Need to Do to Assess Personnel Competency? – November 2012 \(PDF\)](#).



CLIA Corner

Q & A



Q: The GeneXpert MVP (vaginal panel) instructions for use (IFU) states the following in the limitations section: *“The Xpert Xpress MVP test performance has been evaluated in patients 18 years of age and older (including pregnant women).”* To satisfy the CLIA requirements, what do I need to do to validate for patients under 18?

A: Performing testing on patients under 18 is considered testing outside the manufacturer’s instructions and intended use, which makes the test a modified FDA categorized high complexity test. The laboratory must establish the performance specifications of accuracy, precision, analytical specificity, and analytical sensitivity using specimens obtained from individuals under the age of 18.

Q: If a laboratory performs testing on two different analyzers for the same analyte, but the analyte is a measured value on one instrument and a calculated value on the other instrument, is there a requirement to do an annual method comparison study? Example: hemoglobin as a measured analyte on a hematology analyzer, and a calculated analyte on a blood gas analyzer.

A: Comparison testing is not required for measured vs. calculated analytes. However, comparisons are required for two or more non-waived test systems for which analytes are all measured.