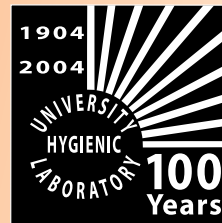


CLIA Corner

The University of Iowa Hygienic Laboratory

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In This Issue...

Answers to Questions on the Following Topics:

- *MLT qualifications as general supervisor*
- *Validation of a new test kit*
- *Affirm VP test system QC*
- *Fungal/yeast culture PT requirements*

Q: Our hospital is looking to hire a new laboratory manager/supervisor. Does a medical laboratory technician (MLT) with an associate's degree qualify for the laboratory manager position?

The personnel regulations for general supervisor and testing personnel did not change in 2003. MLTs with an associate's degree does qualify as a general supervisor as long as they have at least two (2) years of laboratory experience in high complexity testing. They do NOT qualify as a technical supervisor or technical consultant (minimum requirement is a bachelor's degree in chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution along with the appropriate number of years of experience depending on the specialty or subspecialty).

Q: Our laboratory wants to perform urine drug screens using a test kit that the Food and Drug Administration (FDA) has approved and classified as moderate complexity. What do we need to do prior to testing patient specimens?

For all moderate and high complexity test systems or instruments that have been approved by FDA, the laboratory must complete the following prior to testing patient specimens and reporting test results:

1. Verify the manufacturer's performance specifics, including accuracy, precision, reportable range and reference ranges (normal values).
2. Develop a written procedure, including frequency of testing control materials. (Package inserts and/or operator manuals may be used as written procedures, but the laboratory must include specifics for its laboratory, i.e. reporting patient results.)
3. Train testing personnel.
4. Document all of the above.
5. Ensure that the laboratory director reviews and approves the verification process and procedure prior to testing and reporting patient results.

For a brochure to help you with this process, go to www.cms.hhs.gov/clia, click on brochures and select CLIA Brochure #2, Verification of Performance Specifications.

Q: What quality control (QC) is required for the Affirm VP test system?

Each day of patient testing, the laboratory must run a negative and positive control material. However, since this test system is eligible for the equivalent quality control (EQC) procedures, the laboratory may opt to reduce the QC testing frequency by completing the evaluation process for one of the options.

For the quality control material, if the laboratory is using a tri-level QC swab that contains Gardnerella, Trichomonas and Candida all impregnated on one swab, then the lab must test this tri-level QC swab and also a negative control.

If the laboratory uses three (3) separate QC organisms or single swabs (i.e. one for Gardnerella, one for Trichomonas and one for Candida) instead of a tri-level QC swab, then the lab is not required to run a separate negative control. Each individual organism swab serves as the negative control for the other two organisms being tested.

For a brochure to help you with this EQC evaluation process, go to www.cms.hhs.gov/clia, click on CLIA Brochures and select Brochure #4, Equivalent Quality Control Procedures.

Q: Our laboratory performs fungal/yeast cultures. For positive yeast cultures, we report as either “Candida albicans (germ tube positive)” or “yeast, not C. albicans.” For all other positive fungal cultures, we report “fungal element isolated, would refer for further identification.” Do we need to enroll in a proficiency testing (PT) module for both yeast and other fungal elements?

Because the laboratory is only qualitatively determining the presence or absence of a fungus and not identifying the fungus to the genus and/or species level, the laboratory needs to only enroll in a PT module for yeast identification. The module must offer five (5) specimens for yeast identification. In addition, the laboratory must verify the accuracy of fungal cultures with “no growth” at least twice annually.

However, if the laboratory begins identifying fungus to a genus and/or species level, then they would be required to enroll in a PT module that contains both yeast identification and fungal cultures.

Contact Information:

If you want to be added to our e-mailing list, need a change of address, or have a question or topic suggestion for the CLIA Corner you can contact either Kristi Rotzoll at krotzoll@uhl.uiowa.edu or Nancy Grove at ngrove@uhl.uiowa.edu.