CLIA Corner

The University of Iowa Hygienic Laboratory

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In This Issue...

Happy New Year!! For this edition of the CLIA Corner we are answering a few of the most frequently asked CLIA questions.

Q: **If a laboratory changes from a nonwaived Influenza test kit to a different manufacturer's test kit, does the laboratory need to perform patient correlations?**

A: Anytime a laboratory brings a new, unmodified, FDA-approved, moderate or high complexity test system, including test kits for rapid strep screen, influenza, mono, etc., into the laboratory, the laboratory is required to verify the performance specifications prior to reporting patient test results. The laboratory must demonstrate that it can obtain performance specification comparable to those established by the manufacturer for the following characteristics:

- **Accuracy**: The laboratory is responsible for verifying that the method produces correct results. This can be accomplished by testing reference materials, comparing results of the test performed by the laboratory against the results of a reference method, or comparing split-sample results with results obtained from a method that is shown to provide clinically valid results. For qualitative methods, the laboratory must verify that a method will identify the presence and absence of the analyte.

- **Precision**: The laboratory is responsible for verifying the precision of each test system by assessing day-to-day, run-to-run, and within-run variation, as well as operator variance. Precision checks may be accomplished by repeat testing of known patient samples over time, testing quality control material in duplicate and over time, or repeat testing of calibration materials over time.

- **Reportable Range**: The laboratory is responsible for verifying the reportable range of patient test results for each test system. Verification of the reportable range may be accomplished by assaying low and high calibration materials or control materials or evaluating known samples of abnormal high and low values.

- **Reference Range**: The laboratory is responsible for verifying that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. If the manufacturer has not provided reference ranges appropriate for the laboratory's patient population, then it is the laboratory's responsibility to establish an appropriate reference range.

Please remember when the laboratory is verifying performance specifications, the testing should be performed among all operators on different days. When a new piece of equipment has been installed by the manufacturer, the manufacturer can assist the laboratory in verifying performance specifications.

*When a temporary replacement (loaner) instrument is received that is identical (i.e. same make and model, and method for the same analyte) to the instrument that is being replaced, the laboratory must verify comparable performance by comparing, at a minimum, results of two or more levels of controls **and** either previously tested proficiency samples or previously testing patient samples.*

Q: How often does the laboratory need to perform alarm checks on the blood bank refrigerator?

A: §493.1271 D5555 Standard: Immunohematology
(c) Blood and blood products storage. Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected.

(c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period.

(c)(2) Inspections of the alarm system must be documented

Because the regulations for inspecting the alarm system do not define "regularly inspected," the laboratory must establish and follow a procedure/policy that states the frequency that alarm checks will be performed on the blood bank refrigerator. When the laboratory is establishing the frequency, it should check with the blood center that supplies blood and blood products to ensure compliance with the center's storage requirements. The Iowa CLIA surveyors interpret "regularly inspected" as checking the alarm system more than once per year.

In order to perform the alarm checks properly, the laboratory must follow a procedure that includes using ice and warm water baths to activate the refrigerator alarm system at the low- and high- temperature settings, and the freezer at the high setting. Switching the electronic sensors "on" and "off" is not an adequate inspection of the alarm system. The alarm system inspection must also include checking the recording chart for deviations and remote response (e.g. nursing station). The entire procedure must be documented.

Q: D-Dimers are performed on our laboratory's chemistry analyzer. How often do controls need to be performed?

A: §493.1269 D5545 Standard: Hematology
(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each eight (8) hours of operation and each time a reagent is changes.

D-Dimers are classified as a coagulation test. Therefore, even though the analyte is being performed on a chemistry analyzer, controls will have to be performed each eight (8) hours that a patient is being tested and with a change of reagents.

New Year Reminder

It's enrollment time for proficiency testing. Be sure your laboratory is enrolled for all regulated analytes/tests and subspecialties (e.g. bacteriology, virology, etc.) it performs. Don't forget that nonregulated analytes must be verified for accuracy twice each year. To determine the regulated analytes, specialties and subspecialties, go to www.cms.hhs.gov/clia, click on Appendix C, Interpretative Guidelines. At downloads, click on the selection that includes Subpart I.