

WHAT HAPPENS DURING A LABORATORY INSPECTION?

Federal, state and voluntary agencies require onsite inspections by their staff. Inspectors examine various aspects of the laboratory operation, including:

• QUALITY ASSURANCE PROGRAM

Since it is impossible for inspectors to directly view all details of a laboratory's operation, they want to be sure the laboratory has clear, planned and systematic quality assurance policies and procedures. The inspectors also check to see that these are, in fact, being followed by the laboratory personnel.

• OPERATING PROCEDURE MANUAL

This document describes the methods, materials, and other information necessary to perform each test offered by the laboratory. The inspectors observe and talk with the lab staff to verify the procedures are being followed as set forth in the manual.

• PERSONNEL RECORDS

Inspectors check to make sure the personnel records contain documentation that the staff involved in laboratory testing have the appropriate educational background, experience, competency and training necessary to produce quality test results.

• QUALITY CONTROL (QC) DATA

Each time a test is performed, the laboratory technician runs QC material of known concentration. The QC results indicate if the test meets the laboratory's analytical standards for precision and accuracy. The inspectors review whether the laboratory has been running sufficient QC and monitoring QC data in a manner to produce accurate results.

• PROFICIENCY TESTING (PT)

Certain agencies offer PT surveys for specific analytes. A proficiency sample containing a known amount of the compound to be measured is carefully prepared and shipped, according to exacting standards, to all laboratories participating in the survey. Each laboratory analyzes the sample using routine patient specimen procedures and reports its results back to the agency. The agency compiles the results and sends a report to the participating laboratories so they can see how they compare to other laboratories testing for the same analyte. The results are also sent to CLIA and all licensing and accrediting agencies. They may also be reviewed during the inspection process.

• ALTERNATIVE PROFICIENCY TESTING

Because of the expense of developing quality proficiency samples and administering the process, PT programs are available only for tests that are commonly performed. If PT is not available, other methods are used to check accuracy, such as split-sample comparison with other laboratories or methods. Spiked recovery studies are also used, wherein a specimen is split into several parts and each is spiked with a different, known amount of the analyte to be measured. These specimens are tested to see if the method is accurately measuring the increase due to the added spike material.

• WORKFLOW ASSESSMENT

Weaknesses in a quality assurance program can be determined by performing a workflow assessment, where a single specimen and test order are monitored from the beginning (pre-analytic) to the end (post-analytic). Inspectors check to see that the laboratory routinely performs this process and responds appropriately to any problems:

- o **Pre-analytic** (was the specimen collected, shipped, received and processed properly and was the test order entered into the computer system correctly?)
- o **Analytic** (was the test performed according to procedures, was the instrument functioning properly, and were the results reviewed before reporting?)
- o **Post-analytic** (were the results reported and archived appropriately and was the specimen stored properly for potential retest if necessary?)

ON THE HORIZON

Clinical laboratories and the agencies that monitor them have been continually "raising the bar" on accuracy, reliability and timeliness of patient test results. Until recently, the focus has been on the technical components of laboratory testing as described above. New initiatives are being developed along the lines of Total Quality Management Systems and ISO 9000 standards that have been so successful in manufacturing environments. These focus on procedures that permeate all departments of the company – not just the laboratory – to consistently provide the highest standards for patient care.

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QUALITY IN THE CLINICAL LABORATORY



Your doctor has recommended laboratory testing for you. You have your blood drawn or collect your urine sample. The specimen is sent to the laboratory and in a week or so you return to your doctor to discuss the test results. You assume the test results are accurate. ***But are they?***

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