

## 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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Advances in medical sciences over the past 50 years have brought a tremendous growth in laboratory tests and clinical laboratories. Concerns over the quality of the clinical laboratory's product -- test results -- have been a driving force behind increased regulation and quality improvement programs. Several agencies have been created to help improve the quality of laboratory testing.

### WHO CERTIFIES LABORATORIES?

In response to public furor about one or more deaths attributed to false-negative Pap smear readings, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988. This expanded earlier regulations to include all laboratories, regardless of size or location (including physician office laboratories) that test human specimens collected in the United States and its territories. This means that they must be certified by CLIA. Laboratories performing tests of moderate or high complexity must be inspected for compliance with CLIA regulations and are issued a Certificate of Compliance. Laboratories performing only very simple tests (such as the urine dipstick) are issued a Certificate of Waiver and are not

routinely inspected. Forensic and research laboratories are exempt from these regulations but they must not provide test results for patient care.

### WHO LICENSES LABORATORIES?

Many states have their own licensing agencies that monitor and inspect laboratories. Some states require out-of-state laboratories that perform testing on specimens collected in their states to hold a license issued by them. New York State requires any laboratory that tests specimens collected in New York to be licensed and inspected by its own agency, and this is considered the most rigorous state licensing program available.

### WHAT ARE VOLUNTARY ACCREDITING AGENCIES?

In addition to mandatory federal (CLIA) certification and state licensing, voluntary accreditation is also available. COLA, the College of American Pathologists (CAP), and the Joint Commission of Healthcare Organizations (JCAHO) were originally created to serve different types of clinical laboratories. Today they share similar scopes and objectives. These agencies currently accredit a laboratory only if 70% or more of its test menu falls within the agency's area of expertise.

### WHAT IS THEIR AREA OF EXPERTISE?

The voluntary agencies are most comfortable with tests that use FDA approved kits (as opposed to tests developed in-house), have external proficiency testing (as opposed to less objective methods of measuring accuracy), and are accepted by a majority of the conventional medical community (as opposed to innovative tests that are not yet considered "mainstream"). This makes the inspection and accreditation process substantially simpler and reduces liability for these agencies.

### WHAT TYPES OF LABORATORIES DO THEY NOT ACCREDIT?

Conventional laboratories can offer up to 30% of these innovative types of tests and still be accredited by these agencies. Laboratories specializing in innovative tests (including many of those offered in functional/integrative medicine) are required to hold federal certification and many have state licenses, but none are currently accredited by the voluntary agencies. This is because these agencies do not feel competent to monitor the quality of these tests.

### DOES THIS MEAN ANYTHING ABOUT QUALITY OF THESE LABORATORIES?

The decision by voluntary agencies not to accredit these laboratories does not mean they are not high quality. Many tests that today are generally accepted as routine by conventional medicine were once outside the area of expertise of traditionally trained laboratory professionals. Realizing the contribution innovative tests make to medicine, these agencies are working to find ways to assist innovative laboratories with quality assurance programs while not incurring the burden and liability of accrediting tests they and their inspectors are not familiar with.

### DO CERTIFICATION, LICENSURE AND ACCREDITATION ASSURE QUALITY?

There is no doubt that quality has improved as a result of monitoring by external agencies. Yet laboratory errors still occur in certified, licensed, and accredited laboratories. Each agency responds by improving its own standards for monitoring. For example, most recently errors were detected at a CLIA certified, state licensed laboratory that was also accredited by voluntary agencies. The errors resulted in potentially several hundred inaccurate HIV test results. The agencies quickly responded by making significant alterations in their inspection programs to improve their own monitoring processes.