College of Applied Medical Sciences

Department of Environmental Health

Quality Control

Lecture 7

GENERAL MEASURES

The quality control measures that are essential for reliable and reproducible test results are as follows.

1. Clean, well-lighted, temperature-controlled laboratories, with adequate space for work, both technical and clerical, and storage including both shelf and refrigerated .
2. Proper equipment, instruments, and glassware, all of which meet specifications and are of sufficient quantity and quality for the types and volume of testing performed; records of dates of purchase, repair, maintenance of equipment and instruments, and daily calibration checks .
3. Satisfactory cleaning methods for reusable glassware .
4. Proper test procedures adapted to the laboratory facilities and the qualifications of the personnel performing tests .
5. Current techniques available for reference .

   The procedures should be reviewed annually and the review results documented .

   A copy of a discontinued procedure must be maintained for 2 years thereafter, recording initial date of use and retirement date

6. Careful and precise measurements of specimens and reagents

7. Periodic reading of tests to maintain uniform reading levels by all laboratory personnel

8. Control of reagents

Chemicals and distilled water should be of high quality, and solutions should be prepared according to the directions specified for each technique .

Adequate evaluation of new lots of reagents for standard reactivity must be done before they are placed in routine use .

There should be proper preparation, labeling, and storage of reagents. Substandard, deteriorated, or outdated reagents should be discarded .

Documentation of steps in the preparation of new lots of reagents and control serums, and maintenance of evaluation records of each lot must be done. Reagents should be dated when prepared or opened and placed in service .

9. Maintenance of reference serum samples with established reactivity patterns for each test performed. Include these each time serologic testing is performed to provide a stable baseline and day-to-day consistency.

10. Acceptable test specimens and identification. Ensure acceptability by correct collection and labeling, prompt transmission to the laboratory, and proper storage conditions and processing methods .

All specimens must be accompanied by a requisition form that includes patient identification, name of physician or authorized person ordering the tests, and the tests or assays requested

The disposition of all unacceptable specimens should be documented in the patient=s report or the laboratory=s quality improvement records .

Specimen requisitions must be retained for at least two years

At a minimum, serum and body fluid specimens should be retained for 24 hours, and stained slides for direct microscopic examination should be retained for 7 days

11. Provision of daily worksheets designed for recording the specimen numbers, results of all tests performed, control results, lot numbers of reagents, reagent titers, room temperature, and the worker's initials. As tests are read, record the results of all controls and specimens, not just the interpretation or final report. These records should be retained for a minimum of 2 years.

12. Monitoring of all testing records and report forms. All records of testing should be identified with the specimen's laboratory accession number.

. Reports should be easy to read and results correctly reported

. Copies or files of reported results should be retained in a manner that permits prompt retrieval of information

. The laboratory must have a procedure for the immediate notification of a physician or other responsible clinical personnel of a reactive test result .

. The laboratory must have defined turnaround times for each of its tests and a policy for notifying the requester when testing is delayed for those tests considered as essential by clinical and laboratory personnel

. Laboratories using a computerized laboratory information system are responsible for:

the data produced in their laboratory, including data entry, storage and retrieval; the computer=s facility and maintenance; computer procedure manuals, and systems security

. The laboratory must have a system in operation to detect clerical and analytical errors, and to verify highly unusual results that could affect patient management. One common method is review of results by an experienced person.

. Patient test results and reports, and instrument printouts (when applicable) must be retained for at least two years

13. Participation in a recognized proficiency testing study in which the participating laboratory is provided a means of periodically detecting problems by comparing its results with those of a reference laboratory

. Proficiency testing samples must be integrated within the routine laboratory workload, and analyzed by personnel who routinely perform the tests

. For tests where proficiency testing is not available, performance must be checked with reference material or by split sample analysis with other laboratories or clinical validation by chart review or other suitable documented means

. Proficiency testing records must be retained for at least 2 years

14. Attendance of qualified laboratory personnel at basic and refresher training courses to obtain current information and instruction in new or modified test procedures. A functional in-service continuing education program to meet the needs of the laboratory personnel should be available.