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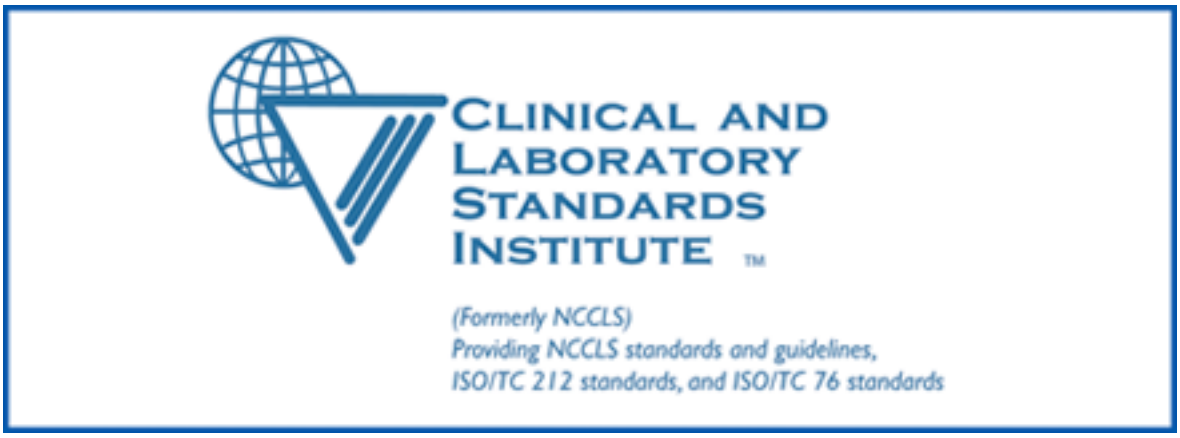
Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline



This document provides guidance to users of *in vitro* diagnostic (IVD) devices outside the clinical laboratory, to ensure reliable results comparable to those obtained within the clinical laboratory.

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Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline

Abstract

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This guideline provides users of *in vitro* diagnostic (IVD) devices outside the clinical laboratory with information and suggestions for good laboratory practice and for producing reliable test results regardless of where the test is performed.

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Foreword

As a result of pressures from outside and within, the healthcare community is re-evaluating how to best deliver services to society in a complex healthcare system. Part of this examination concerns the delivery of laboratory services to patients.

Medical conditions, physical location of the patient, and treatment regimens often require laboratory results to be obtained quickly, so appropriate medical care can be administered without delay. Laboratory medicine professionals have been challenged by the increasing demands for faster turnaround of results, but at the same time are faced with limitations in providing these services, imposed in part by cost constraints.

With the introduction of portable devices capable of producing results within minutes, point-of-care testing (POCT) (also referred to as near-patient testing or bedside testing), is evolving as one way to meet these demands. Because of the enormous consequences of unreliable test results, it is vital that results continue to be reliable and of high quality as these tests are transferred from the clinical laboratory to the point of care.

One of the challenges facing the healthcare community is acceptance of the idea that laboratory testing, traditionally performed by and under the supervision of trained laboratory personnel, will, in many instances, be performed by personnel not trained in clinical laboratory practice. It is the responsibility of the manufacturer to provide test systems capable of delivering reliable results when used properly by the testing personnel. Once the decision to offer POCT has been made, professionals in laboratory medicine should be involved to support and assess the results of these services.

POCT has been, and will continue to be implemented in a wide range of locations. It is up to each hospital, nursing home, ambulance company, insurance company, home healthcare delivery network, etc., to assess its POCT needs. This document provides information on how to proceed in assessing those needs and in the evaluation and implementation of POCT.

It is the intent of the Subcommittee on Point-of-Care Testing that this guideline provide useful information to those wishing to perform POCT. The guideline was written under the assumption that its primary users will be nonlaboratory healthcare personnel. Therefore, we have attempted to provide definitions, procedures, and recommendations that are both educational and practical. In addition, the format is designed to be user-friendly and easy to follow.

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Chairholder, Subcommittee on
Point-of-Care Testing

Key Words

Calibration, point-of-care testing, quality assurance, quality control, safety

Foreword (Continued)

Acronyms

POCT - Point-of-care testing
POL - Physician's office laboratory
IVD - *In vitro* diagnostic
CLIA - Clinical Laboratory Improvement Amendments
QC - Quality control
QA - Quality assurance
LIS - Laboratory information system
HIS - Hospital information system

POINT-OF-CARE *IN VITRO* DIAGNOSTIC (IVD) TESTING; APPROVED GUIDELINE

1 INTRODUCTION

Advances in technology and the implementation of micro-techniques and portable instruments have made it possible to move laboratory testing closer to the patient. Point-of-care testing (POCT), also known as bedside testing or near-patient testing, is intended to provide more rapid test results than can be achieved in central or satellite laboratory settings. This is particularly important in critical care areas such as the intensive care unit, emergency rooms, burn units, emergency transport vehicles, and operating rooms, as well as skilled nursing facilities, hospices, etc. POCT has also been used to expedite treatment decisions and provide convenience for the patient. The following guideline provides information and suggestions for good laboratory practice and for producing reliable test results regardless of where testing is performed.

2 SCOPE

There are many potential sites where POCT can occur. Test operators include both those with and without healthcare backgrounds. Some settings for POCT include nurses and physicians in acute care units in hospitals and emergency rooms; cardiac perfusionists in operating rooms; visiting home nurses in patients' homes; emergency medical technicians in ambulances; nurses in schools and colleges; pharmacists in pharmacies; nonhealthcare workers at various employment settings, drug rehabilitation centers, law enforcement facilities, public screening sites, and insurance companies. A physicians' office laboratory (POL) is another example of a setting for POCT.

3 DEFINITIONS

NOTE: Some of these NCCLS definitions are found in NCCLS document NRSCL8–*Terminology and Definitions for Use in NCCLS Documents*. For more detailed source information, please refer to that document.

Accuracy, *n* - True or target value; freedom from error. The accuracy of results can be measured by comparing

them to results accepted as correct (e.g., standard methods), or by comparing them with those from another laboratory that uses a comparable method (this is "relative accuracy").

Analyte, *n* - 1) A substance or constituent for which the laboratory conducts testing; **NOTE:** For example, glucose, sodium, theophylline; 2) Any substance or property whose presence or absence, concentration, activity, intensity, or other characteristics are to be determined.

Antibody, *n* - A substance formed in the body in response to a foreign substance (an antigen) and that interacts only with that substance.

Anticoagulant, *n* - An agent that prevents coagulation of blood or blood products.

Antigen, *n* - Any substance that, when introduced into the body, causes the development of antibodies.

Bias, *n* - A quantitative measure of inaccuracy or systematic departure from accuracy under specified conditions of analysis. Types of bias include:

Interinstrument (between-instrument)
The difference between the results obtained using two specified instruments.

Intermethod (between-method)
The difference between the results obtained by two specified methods.

Interlaboratory (between-laboratory)
The average difference between the results obtained by two different laboratories performing the same analytical process under specified conditions.

Of an analytical process
The average difference between the results obtained by the analytical process in question under specified conditions of matrix, analyte concen-tration, etc., and the true or accepted result. Synonym for "systematic error."

Of a result
The difference between the result and the true or expected value.

Biohazard, *n* - A biological agent or condition that constitutes a hazard to human beings or their environment.

Blood, *n* - The "circulating tissue" of the body; consists of plasma in which are suspended cells, nutrients, metabolic products, and oxygen.

Calibration, *n* - The process of testing and adjustment of an instrument, kit, or test system, to provide a known relationship between the measurement response and the value of the substance being measured by the test procedure.

Calibration verification, *n* - The assaying of calibration materials in the same manner as patient samples in order to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results.

Calibrator, *n* - A material (e.g., solution) or device with known quantitative/qualitative characteristics (e.g., concentration, activity, intensity, reactivity) used to calibrate, graduate, or adjust a measurement procedure. The quantities of the analytes of interest in the calibrator are known. Calibrators with different quantities or analytes may be used to establish a quantity/response "curve" over a range of interest.

Coefficient of variation, *n* - A measure of relative precision.

Competency testing, *n* - Evaluating a person's ability to perform a test and to use a testing device. This includes all aspects of testing, from specimen collection to result reporting, and it is usually done with specimens containing known amounts of the analyte(s) for which the specimens are being tested.

Conjugate, *n* - 1) A material produced by attaching two or more substances together; 2) A compound formed by a label coupled with an antibody or antigen.

Control, *v* - To monitor the status of an analysis to maintain its performance within desired limits.

Control/control material, *n* - A device, solution, or lyophilized preparation intended for use in the quality control process. **NOTES:** a) The expected reaction or concentration of analytes of interest are known within limits ascertained during preparation and confirmed in use; b) Control materials are generally not used for calibration in the same process in which they are used as controls.

Correlation, *n* - The comparison of results between the test (new) method and the reference (old) method.

False-negative (result), *n* - A negative test result for a patient or specimen that is positive for the condition or constituent in question.

False-positive (result), *n* - A positive test result for a patient or speciment that is negative for the condition or constituent in question.

Hemolysis, *n* - The breakdown of red blood cells in serum or plasma, which frees the hemoglobin from the

cells and creates a reddish tinge. Hemolysis interferes with some laboratory tests.

Immunoassay, *n* - A diagnostic test that uses a specific antibody or antigen to detect the presence of an analyte.

Imprecision, *n* - The presence of random error, variability, or inconsistency.

Inaccuracy, *n* - The numerical difference between a value and the true value.

Lancet (lancing device), *n* - Sharp, needle-like device used to puncture skin to obtain blood (e.g., from finger or heel).

Lipemia, *n* - A condition in which too much fat or too many lipids are in the blood. A lipemia serum sample looks milky and turbid, and it can produce erroneous results.

Mean, *n* - The average of the numerical results obtained from a series of analyses.

Measurement range, *n* - Range of analyte concentrations over which meaningful results can be acquired.

Medical alert values (critical values), *n* - Assay values which may require immediate medical attention, due to dangerously abnormal levels of a particular analyte.

Performance characteristic, *n* - A property of a test that is used to describe quality. **NOTE:** Examples include accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

Plasma, *n* - The liquid portion of the blood that does not contain cells. If a chemical agent or anticoagulant is added to prevent clotting, a blood sample can be separated by centrifugation into cells and a plasma supernatant.

Point-of-care testing (bedside, near-patient testing), *n* - Testing performed outside a central laboratory environment, generally nearer to, or at the site of, the patient.

Precision (reproducibility), *n* - The measure of the closeness of the results obtained when analyzing the same sample more than once; the measure of agreement between replicate measurements of the same material.

Procedure manual, *n* - A handbook that contains the methods, materials, and other information needed to perform a test.

Proficiency testing (external quality assessment scheme), *n* - An external program in which samples are periodically sent to testing sites for analysis. Usually, the results are tabulated by the program and a participating site can compare its results with those of other sites that use a similar method.

Quality assurance (QA), *n* - A comprehensive set of policies, procedures, and practices used to monitor the laboratory's entire testing process and ensure that the testing site's results are reliable. QA includes monitoring; evaluating; taking corrective actions, if necessary, based on evaluations; and monitoring the corrective actions for the laboratory's pre-analytical, analytical, and post-analytical activities. These activities include, but are not limited to, record keeping, calibration and maintenance of equipment, quality control, proficiency testing, and training.

Quality control (QC), *n* - The set of procedures designed to monitor the test method and the results to

assure test system performance. QC includes testing control materials, charting the results and analyzing them to identify sources of error, and evaluating and documenting any remedial action taken as a result of this analysis.

Qualitative, *adj* - This term is applied to tests that detect whether a particular analyte, constituent, or condition is present or absent and sometimes assigned a positive degree, i.e., 1+, 2+, etc., may also be called semiquantitative tests.

Quantitative, *adj* - This term is applied to tests that give results expressing the numerical amount of an analyte in a specimen. This is in contrast to *qualitative* tests.

Reagent, *n* - A substance that produces a chemical reaction in a sample that allows an analyte to be detected and measured.

Reference interval, *n* - The range of test values expected for a designated population, e.g., 95% of persons presumed to be healthy (or normal).

Reportable range, *n* - The range of test-result values over which the laboratory can establish or verify the accuracy of the instrument, kit, or test system measurement response.

Semiquantitative, *n* - Tests that yield results in an approximate range of values (i.e., trace, moderate, etc.).

Sensitivity (Assay), *n* - Lowest analyte concentration reliably determined as non-zero with a minimum reliably detectable level.

Sensitivity (Clinical), *n* - The ability of a test to give a positive result for patients that have the disease or condition for which they are being tested; measured as

the ratio of positive tests to the total number of tests in those that have the disease; expressed as a percentage.

Serum, *n* - The liquid remaining after treated whole blood has coagulated.

Shift, *n* - In plots of daily QC points, an abrupt change or deviation in those values from one day to the next.

Site, *n* - The physical location where laboratory testing is performed.

Skin puncture, *n* - Breakage of skin with a needle or lancet to produce blood for collection and testing.

Specificity (Clinical)**,** *n* - The ability of a test to give a negative result for patients that do not have the disease or condition for which they are being tested; measured as the ratio of negative tests to the total number of tests in those that do not have the disease or condition; expressed as a percentage.

Stability, *n* - The capacity for a product to retain its composition, characteristics, and properties during specified conditions.

Standard deviation, *n* - A statistical measurement of the distance from the mean of a series of measurements. It is a measure of precision, reproducibility, or dispersion of a frequency distribution.

Test system, *n* - A unit or device used to measure or assess the presence or absence of a particular substance, or to quantitate that substance, found in blood or body fluids.

Total (therapeutic) turnaround time, *n* - A time interval that encompasses the entire testing process to obtain an analytical result. This is the time from when a health

care provider determines the need for a result to when they have the result to act upon.

Trend, *n* - In plots of daily QC points, a gradual change in a particular direction of those values over a period of time.

Validation, *n* - The action {or process} of proving that a procedure, process, system, equipment, or method used... works as expected and achieves the intended result.

Venipuncture, *n* - The procedures for collecting a blood sample from a vein. This is called "venous blood."

Verification, *n* - A procedure used to determine, with a high level of confidence, that a test system or device performs as claimed when used by the persons who routinely perform the patient testing.

Whole Blood, *n* - Blood containing all its cellular components that has not been centrifuged or had its plasma or serum removed.

4 POCT CONSIDERATIONS

The following includes many of the questions that should be asked before selecting the tests and instruments for each POCT setting:

- Who is responsible for testing, quality oversight, and supervision?
- Who holds the license or certificate for testing?
- What is the clinical need for POCT?
- Will POCT improve patient care, patient satisfaction or patient outcome?
- How will costs be affected?

- How are the tests justified?
- What is the purpose of the test (e.g., to screen, monitor, diagnose or rule in/rule out disease)?
- Who will test?
- Who will train?
- Who will review results?
- How will the results be reported?
- How will results be recorded?
- Will the POCT provide accurate, precise, and reliable test results?
- Who will select, purchase, and maintain the system and pay for reagents?
- How will charges to the patient be affected?
- What additional training is necessary and how much will it cost?
- Should testing be done in particular situations/areas if immediate confirmation by repeat testing cannot be performed when it is necessary?

If there is a *need* for the testing then POCT is justified. Initially, therefore, a "needs assessment" should be completed, which includes the needs of the patient, the provider, the payer, and the institution.

Needs can be identified within several areas:

- **Outcome**. Does providing clinically relevant data to the caregiver at the point of care on a real-time

basis improve the clinical outcome of patient care when compared to conventional testing methods?

- **Convenience**. The actual clinical outcome can be identical, but providing the results during the clinical examination or at the bedside allows the physician to counsel the patient. This can eliminate additional visits to the physician's office.

- **Patient compliance**. When the physician has access to the results and the patient at the same time and in the same place, he or she can address patient compliance with important therapeutic regimens on a face-to-face basis with the patient.

- **Patient needs**. Providing the patient with faster results can save time, travel, and delay in treatment.

- **Institutional needs**. Institutions may be defined as hospitals, clinics, physicians' office laboratories (POLs), home healthcare providers, healthcare management companies, or emergency medical services. To assess the overall need for POC at a specific institution, determine the direct and indirect costs of the particular device being evaluated, compare those costs to that of the device used in the laboratory, and evaluate the effect this will have on the delivery of services.

  For instance, the actual direct cost of a point-of-care test in a hospital can be higher than the cost of a conventional test generated in a central laboratory. However, if the point-of-care test can move a patient through the institution more rapidly and reduce the length of stay, there could be a net savings to the institution. It is important

to look at the entire "episode of care" and evaluate the cost/benefit ratio.

5 REGULATORY CONSIDERATIONS

In the U.S., in September of 1992, regulations implementing a law referred to as the Clinical Laboratory Improvement Amendments of 1988 (also known as CLIA '88) became effective. This act sets forth the conditions that all laboratories must meet to be certified, and therefore permitted to perform testing on human specimens. The regulations affect all laboratory testing sites in the country that test human specimens, including point-of-care testing. Under CLIA '88, laboratory tests are categorized as "waived tests," "provider performed microscopy," "tests of moderate complexity," or "tests of high complexity." A laboratory may perform tests within any one category or within any combination of categories.

Because all laboratories in the United States are required to meet them, the regulatory requirements should be considered early on. CLIA '88 applies to any testing, regardless of site, performed on human specimens for the diagnosis, prevention, or treatment of any disease, or for the assessment of the health of human beings. CLIA requires that all such testing meet the health and safety standards established by the Department of Health and Human Services (DHHS) and that the testing site (laboratory) be issued an appropriate certificate under CLIA.

Refer to Appendix A for the phone numbers of the state agencies that should be contacted for the regulations and to obtain information about licensure. To obtain information and the list of CLIA-approved accrediting organizations refer to Appendix B (HCFA) for the phone number of the Federal regional office in your area.

For users outside of the U.S., please refer to your appropriate regulatory requirements.

6 DEVELOPMENT OF POLICY

A written policy should be established to direct the POCT in a facility, e.g., hospital, clinic, POL, or home health care. The roles of authority, responsibility, and accountability must be clearly defined and maintained within the organizational structure (see Section 8). The policy applies uniformly for any approved methods. Following is an example of a stated policy:

> *To provide Point-of-Care Testing using methods approved by (person or group in authority). When POCT is performed, all issues will be approved by this authority*.

A person or group within the organization should be designated with the authority to:

6.1 *Designate Authority*

- Make and enforce policy
- Assign responsibility
- Address problems
- Make decisions about the program structure
- Provide administrative support
- Provide quality oversight.

6.2 *Assign Responsibility*

One or more key persons should be assigned the responsibility, or coordination of responsibility for the following activities:

- Evaluation of instruments
- Implementation of test methods
- Training of personnel
- Evaluation of QC results
- Maintenance of instruments
- Reporting of results
- Establishment of procedures on critical values

- Compliance with safety standards
- Compliance with regulatory standards
- Monitoring of test procedures
- Monitoring of proficiency testing as indicated
- Communicating with instrument operators
- Competency evaluation and retraining on a continual basis
- Quality assurance
- Assistance with billing policies
- Development of a working relationship with physicians, nursing staff, or other individuals involved in POCT.

6.3 ***Maintain Accountability***

Testing personnel should be accountable for the following activities:

- Understanding the principles and limitations of the procedure
- Performing and documenting QC, as appropriate
- Performing and documenting maintenance, as appropriate
- Maintaining proficiency in testing methods
- Performing and documenting test results according to procedure
- Following protocols for remedial actions or notification of responsible personnel.

7 PROCEDURES

Written procedures for each testing device and method are recommended and they should be included in a procedure manual. The following areas should be addressed in each procedure:

- Principle of operation
- Purpose of the test
- Specimen collection and handling
- Preparation of reagents and other materials
- Calibration and calibration verification
- Quality control procedures
- Stepwise instructions
- Reporting of results
- Reporting of medical alert (panic) values
- Limitations of the procedure
- Updates
- Literature references
- Remedial action when out-of-control
- Reference interval ("normal values")
- Specimen storage, stability, and preservation (if applicable)
- Action if test system inoperable
- Criteria for referral of specimens.

NOTE: Refer to the most current edition of NCCLS document GP2—*Clinical Laboratory Technical Procedure Manuals*, for further explanation of the items mentioned above. A sample procedure format appears in Appendix C.

8 ORGANIZATIONAL STRUCTURE

The effective implementation of POCT should be appropriate to the existing organizational structure for the site. Because patient encounters with the healthcare delivery system occur in a variety of settings, POCT takes place in many diverse sites. Each area for patient contact has its own particular organizational attributes.

The organizational structures surrounding the performance of POCT exist for the following purposes:

- Determination of the appropriateness of POCT for a given site, test, and patient
- Selection of the testing procedure
- Training and certification of testing personnel
- Assuring quality test performance through
  - Proficiency testing of the person performing the test
  - Proper performance, maintenance, and use of test equipment and supplies
- Timely reporting and patient record documentation of test results
- Maintaining documentation about test performance results and accuracy, reliability, and timeliness.

8.1 *Hospital-Based POCT*

POCT sites in U.S. hospitals that function without the benefit of clinical laboratory certification should seek inspection and become fully accredited by one of the HCFA-approved laboratory accreditation organizations. An organizational structure should include qualified persons who are responsible for POCT, including preanalytical, analytical, and postanalytical testing (e.g., patient preparation, test performance, and reporting of test results. Refer to the U.S. federal requirements in 42 Code of Federal Regulations, sections 493.1401 through 493.1495, and the state regulatory requirements necessary for each person to qualify for their respective positions. In the model described for hospital-based POCT in this document, the central laboratory supervises testing and assists multidisciplinary personnel performing POCT through the POCT committee and an established line of communication. A suggested format for the role of the laboratorian for supervision and consultation in POCT follows. In the next section, a suggested format for organization of the interface between laboratorians and nonlaboratory personnel is described. The structure is summarized in the figure. The personnel assignments are not intended to be rigid. For instance, the same person, if qualified, can perform more than one of these functions.

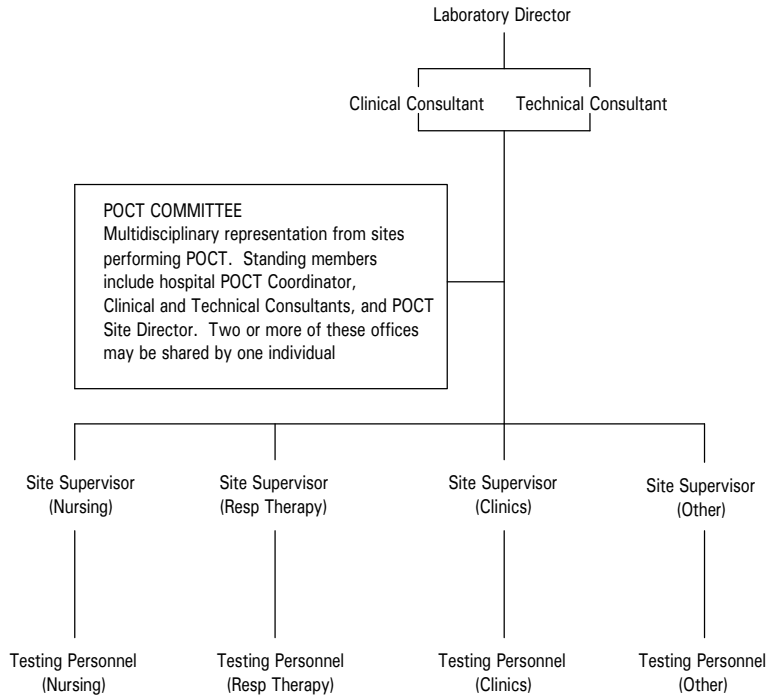
- *Laboratory Director*

  The director is responsible for the overall operation and administration of POCT, including: the training and evaluation of personnel competent to perform testing procedures; recording and reporting test results promptly, accurately, and proficiently; and for assuring compliance with the applicable regulations.

- *Clinical Consultant*

  The clinical consultant should be either a physician or a doctoral-level scientist. This person serves as the liaison between the laboratory and its clients in reporting and interpreting results.

POINT OF CARE ORGANIZATIONAL CHART
IN-HOSPITAL TESTING



- *Technical Consultant*

  The technical consultant is responsible for the technical and scientific oversight of the laboratory.

- *General Supervisor (for high-complexity testing)*

  The general supervisor is responsible for the day-to-day supervision or oversight of personnel performing POCT and reporting test results. The supervisor must be accessible to testing personnel at all times testing is being performed. The supervisor provides on-site, telephone, or electronic consultation to resolve technical

problems in accordance with policies and procedures established by the POCT Director.

- *Testing Personnel*

  Testing personnel are persons who are specifically charged with the performance of the test. In the case of POCT, these persons may or may not be actual laboratory personnel. In either case, the testing personnel should be appropriately trained in the performance of the test and their competency should be checked at periodic intervals, as described in the testing site's policy and procedure manual.

  The number of persons needed in each category listed above should be determined by the institution performing POCT. A more complete description of the qualifications and responsibilities of the personnel listed above can be found in the CLIA regulations, beginning with part 493.1403. For the most part, POCT is categorized under "Moderate Complexity" although many tests, such as blood glucose monitoring, fall in the waived category. Specific responses for personnel performing POCT can be found under "Personnel Standards for Moderate Complexity Testing."

8.2 *Nonhospital-Based POCT*

The oversight and responsibility for quality management of the POCT facility should become the responsibility of the parent or affiliated healthcare institution's director of pathology or director of laboratory medicine.

The parent or affiliated healthcare institution should appoint a POCT committee composed of representatives of laboratory medicine and/or clinical pathology, clinicians, and other nonlaboratory personnel involved in

performing POCT. A modified form of the organizational structure in Section 8.1 can be used.

9 PERSONNEL CONSIDERATIONS

POCT can take many forms and appear in many situations. Personnel guidelines for every possible site or test is beyond the scope of this document. Therefore, testing-site personnel is addressed for two situations: (1) testing performed within the hospital setting, on nursing units, by persons without formal laboratory training and (2) testing performed outside of the hospital by persons without formal laboratory training.

9.1 *Hospital Setting*

The following is one approach for conducting hospital-based POCT. This approach is an example of how POCT can be organized within a hospital or medical center; it has been adopted by the Department of Veterans Affairs.

- Each hospital should appoint a person, referred to here as the POCT site director, who possesses a doctoral level degree in medicine or a clinically relevant science (e.g., biochemistry) and has formal training in pathology and/or laboratory medicine. As noted above in Section 8.1, this person may also be the laboratory director or clinical/technical consultant. This person is responsible for seeing that all requirements are carried out in accordance with applicable national, local, and institutional regulatory and accreditation regulations.

- The POCT site director will serve as the chairholder of an appointed POCT committee, composed of persons representing ancillary testing sites or services. The POCT site director shall have administrative authority for issues relating directly to compliance with national, state, and institutional standards.

- For each defined testing activity outside of the main clinical laboratory under the direct supervision of the clinical laboratory, the POCT site director should appoint an on-site supervisor with supervisory authority over the testing personnel.

- The on-site supervisor must have education, training, and experience in the type of testing unique to the respective area. The onsite supervisor is responsible for:

  – Ensuring that all accrediting organizations requirements are adhered to in the testing area.

  – Ensuring that written and approved procedures and standards are adhered to in the testing area.

Hospital Point-of-Care Testing Coordinator (POCTC)

For areas where laboratory testing is performed by persons without formal training, the POCT site director can appoint a POCT testing coordinator. The POCT coordinator should be a fully qualified laboratory technologist with at least two years of experience in all areas of laboratory testing. **NOTE:** For smaller, more contained settings, the POCT supervisor and coordinator can be the same person.

The POCT coordinator advises and assists POCT site directors, supervisors, and testing personnel in:

- Selection of testing methodologies appropriate for the clinical use of the test results. This is important to ensure that there is consistency of patient test results, normal values, medical alert values, and

standardization of reporting of test results among sites where POCT is performed.

- Verification of methods and test procedures performed and the establishment of the laboratory's test performance charac-teristics, including the precision and accuracy of each test and test system.

- Establishment and oversight of a QC program appropriate for the testing performed (see Section 17).

- Enrollment and participation in a proficiency testing program commensurate with the testing services offered (see Section 20).

- Establishing acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, throughout sample analysis and reporting of test results.

- Resolving technical problems and ensuring that actions are taken whenever test systems deviate from the laboratory's established performance specifications.

- Evaluating the competency of all testing personnel and ensuring that staff maintains competency to perform test procedures and report test results promptly, accurately, and proficiently. Evaluation of the competency of the staff should include, but is not limited to, the following:

- Ensuring that each person performing tests receives regular in-service training and education appropriate for the type and complexity of testing performed.

- Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing.

- Monitoring the recording and reporting of test results.

- Review of intermediate test results or worksheets, QC records, proficiency testing results, and preventative maintenance records.

- Direct observation of performance of instrument maintenance and function checks.

- Assessment of test performance through testing of previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

- Assessment of problem-solving skills.

- Evaluating and documenting the performance of persons responsible for testing and providing such documentation to the testing personnel's manager.

9.2 *POCT Personnel Outside the Hospital*

- Persons without formal laboratory training who perform testing are strongly encouraged to form an association with a hospital or accredited laboratory for the purposes of training, quality assurance, and activities and information on compliance with standards.

- The director of the independent service, however, shall be responsible for compliance issues as well as personnel supervision in the absence of an administrative structure with formal access to a hospital structure.

- The director should design a structure to ensure compliance and implementation of testing, QC, etc., as specified in the policy and methods manuals.

10 METHOD AND INSTRUMENT CONSIDERATIONS AND SELECTION

Information (data) should be gathered on the analyte(s) being investigated for the POCT application in the area of intended use. If the facility is connected with a laboratory, advice should be sought from a laboratory professional. If not, much of the medical and scientific literature on *in vitro* devices is generic or applicable to particular configurations on *in vitro* devices. Assessment of the specifications and performance characteristics of POCT should begin with product information from the manufacturer. Gathering information by phoning and visiting sites where the method/instrument being considered is in use is also possible.

10.1 *Gathering Information*

There have been many attempts to define what is "appropriate" in terms of choosing tests and protocols. However, there is little published information on established practice guidelines for nonhospital testing sites, and the Federal Agency for Health Care Policy Research has only recently developed test-appropriate protocols that are recommended for a few common conditions.

The literature should include methods or instruments currently used in similar settings. This search can be initiated through various medical libraries (inquire into *Biological Abstracts*), or a university library. If these are not available, local libraries affiliated with large regional libraries or medical libraries have access to *Biological Abstracts*. Alternate searches can be conducted "on line" with the use of a personal computer, commercially available software programs, and a modem. Some of these include *MedLine* (National Library of Medicine), *Biosis* (Biological Abstracts), or *Grateful Med*.

The manufacturer or distributor of the POCT device should also be available for demonstrations of the test system or additional information.

10.2 *Beginning the Process*

The next step is to contact the manufacturers or suppliers of the methods/instruments to obtain information regarding the specifications, costs, QC, training, etc., for review.

After review of the manufacturer's literature, a manufacturer's representatives should be available to familarize personnel with the devices. Assessment of the methods instruments can then begin. This phase involves actual "hands-on" training, and experience and evaluation of the methods/instruments performance in the selected environment compared to the methods that have been utilized previously in this environment. This allows a manufacturer's representative to make an informed decision about the new system.

Generally, most methods of testing are separated into three categories: qualitative, semiquantitative, and quantitative testing.

The following points should be considered:

- ***Qualitative and Semiquantitative Methods***

Generally, qualitative and semiquantitative methods are tests that do not require instrumentation. These types of methods may require visual interpretation by the operator. An example of a qualitative test is a pregnancy test, which yields a positive or negative result. An example of a semiquantitative test is a visually read, whole-blood glucose test where results are presented as a range of values. The reliability of this visual reading can be evaluated by assessing several components:

- **Specimen type.** *Is it direct* (*i.e., whole blood, urine, saliva, etc.*)?

- **Specimen preparation.** *Is additional prepara-tion needed* (*i.e., centrifugation, filtering, pipetting*)?

- **Distinct endpoint.** *Is the endpoint distinct or does it have a "gray zone"? Is the visual cutoff point related to a numeric endpoint? Or does it only provide "+" or "-" results* (i.e., *Human Chorionic Gonadotrophin*, [hCG])*?* Several samples should be prepared, and then read and compared by various persons.

- **Quality control.** *Are controls available, and what type are recommended? Does the manufacturer provide a mechanism to monitor test system performance? How often should QC be run?*

- **Reproducibility.** *Are the results comparable between operators and from day to day?*

- **Results.** *Is the observed result what is expected?*

- ***Quantitative Methods***

  Generally, quantitative methods require the use of an instrument to determine the concentration of the analyte measured.

  – **Automation.** *Is the device partially or completely automated? What level of technical expertise is necessary to run the device? What are the operator-dependent variables?*

  – **Self-containment.** *Is it completely self-contained? Is it portable? Does it use a rechargeable battery?*

  – **Specimen type.** *Is it direct* (*i.e., whole blood, urine, saliva, etc.*)?

  – **Specimen preparation.** *Is additional preparation needed* (*i.e., centrifugation, filtering, pipetting*)?

  – **Read-out.** *Are the results displayed directly? Are there any conversion or calculations necessary?*

  – **Quality control.** *Are QC materials run at an appropriate frequency (i.e., each time the device is used, run on receipt of each new lot, and once a day, etc.)?* This should be frequent enough to monitor all the variables that may affect the testing system (e.g., different personnel, humidity and temp-erature changes, power, reagent pre-paration, reagent storage and stability, and variable light sources).

  – **Reproducibility.** *Are the results comparable between operators? Are the*

results re-producible between runs (i.e., days)?

– **Reportable ranges.** *What are the reportable ranges? Does it address the types of patients and intended uses of the particular application? What should be done when results are outside the reportable range of the instrument? Will alert values need to be considered?*

– **Results.** *Does the observed value fit the clinical picture? Do results agree with an established method?*

– **Data management.** *What are the requirements based on the intended use of the device?* It may not be necessary to have comprehensive data-handling capa-bilities. For instance, if the data is to be used immediately by the caregiver, and the patient test results are recorded in the patient's chart and the QC test results are also recorded in the patient's chart or on a separate log, storage of multiple results for retrieval at a later time may not be necessary.

Instrument printouts should be dated and labeled with patient identification (ID) information and QC ID when applicable. The instrument printouts can be placed in the patient's chart as a record of the test results or they can be saved in a logbook or file. If there is only one operator, the necessity to have operator ID numbers may be superfluous. However, operator ID and patient ID should be required for situations where the same device is used by many operators.

- **Data handling.** *Does it interface with the institution's information system? Can it be used for billing?*

- **Troubleshooting.** *Is any field service required? Is it available from the manufacturer?*

- **Maintenance.** *Is there any routine maintenance required or recommended?*

- ***Correlation***

  Once these issues are evaluated, the next step is to conduct a correlation study of the POCT device by comparing it to an accepted method. This is usually done with the help of a central laboratory. Refer to NCCLS document EP9–*Method Comparison and Bias Estimation Using Patient Samples.*

  In evaluating the data, it is important to note that because methods, instruments and reagent systems vary, the degree of comparison can be variable. The caregivers and the laboratory director should determine this variability by comparison to an established method, then assess the acceptability of the variation in relation to the intended use of the POCT device, whether for screening, therapeutic adjustment, diagnosis, etc.

Other Considerations

Other considerations that are common to both types of tests should include timing and any safety or public health considerations: What is necessary for sample disposal? What are the local regulations for the disposal of biohazardous material? Are there special handling

requirements that fall outside of the normal disposal scheme?

11 TRAINING

When selecting the system, the level of training that is required to implement a new method or instrument should be considered. This training may or may not be provided by the manufacturer or supplier. The training recommendations provided by the POCT manufacturer should be considered.

In-house training could be supplemented with training from the manufacturer. Outside consultants may provide training and/or guidance for POCT testing as well. Although materials from manufacturers can be useful, some of the actual training should be "in-house" and should include QC testing/guidelines (including frequency, documentation, troubleshooting of "out-of-range" controls), patient testing (including speci-men requirement, handling, reporting, and documentation), operator competency testing and proficiency testing consistent with the policies of the laboratory and/or institution, preventive maintenance of instrument, troubleshooting of instrument, and demonstration of instrument operation. For information on verification of training see NCCLS document GP21— *Training Verification for Laboratory Personnel.*

12 COST-ACCOUNTING CONSIDER-ATIONS

The decision to implement POCT may be, in part, determined by its cost, cost savings, effect on patient outcome, and revenue. Determining the cost of performing CT in comparison to the cost of laboratory services can be complex if one considers all of the components (device, reagents, personnel, QC, calibration materials, depreciation of device, etc.). Patient outcomes, length of stay, and additional ancillary procedures should also be considered, although these costs are even more difficult to assess. Revenue is a separate component and it varies based on reimbursement fee schedules, and the policies and procedures of the government and third-party payers.

Below is a brief description of the terms and tools used to identify the costs in performing laboratory tests. For a complete reference on laboratory cost accounting, refer to NCCLS document GP11– *Basic Cost Accounting for Clinical Services.*

Definitions:

Actual Costs can be defined as money expended for labor materials and all other expenses required to produce the test result. Actual cost can be further divided into the following categories:

- Direct Costs, *n* - test-specific costs that can be easily identified as associated with the test production, e.g., supplies, reagents, hands-on labor, and instrument costs.

- Indirect Costs, *n* - expenses that cannot be directly associated with a specific billable test but are necessary for overall production, e.g., management space, utilities. **NOTE:** Indirect costs are also referred to as "overhead."

Direct Cost Calculations

- Define all costs associated with each test as a specific direct or indirect per cost center.

  Include:

  - Supplies
  - Reagents
  - Personnel
  - QC materials
  - Calibration
  - Maintenance/service
  - Instrument depreciation/lease
  - Proficiency testing
  - Quality assurance.

- Determine specimen collection costs as either direct or indirect, depending on cost centers/chart of accounts and operations.

- Personnel cost determination: Personnel costs for a testing service should be analyzed on a test-by-test basis. Average cost-per-test result is only one indicator of the cost. Each device and procedure requires its own unique "hands-on" time.

  — Calculate the amount of time, in minutes, required to produce the test result from the point of specimen collection until the result is reported to the clinician.

    Include:

    - Specimen Collection

    - Preanalytical Tasks

      1. Enter order into log/ computer system.

      2. Perform instrument start-up procedures, i.e., calibration and priming.

      3. Prepare QC.

      4. Prepare reagents.

    - Analytical Tasks

      1. Perform test.

      2. Record results.

    - Postanalytical Tasks

1. Sort, file, report results.
2. Communicate urgent re-sults.
3. Perform shut-down pro-cedures.
4. Perform preventive maintenance.
5. Bill payer.

- Include an additional factor for personal fatigue and delay factor (PFD) of 15%.
- Determine the average annual salary cost for personnel performing the "hands-on" activities and add in the fringe benefit factor from the institution's/corporation's fiscal department.

$$\underset{(Test\ or\ Profile)}{Labor\ Costs} = \frac{Salary\ Cost}{Year} \times \frac{1\ Year}{2080\ Hours} \times \frac{1\ Hour}{60\ Min} \times \frac{\#\ Min}{Test\ or\ Run}$$

- Use the following basic formula*:

NOTE: 2,080 hours represents the ideal (paid) productivity (52 X 40 hours/week). A laboratory may use a different number of hours (fewer) depending on the philosophy/policy of the institution used to calculate productivity hours/FTE.

*From Travers, EM. *Managing Costs in Clinical Laboratories*. New York: McGraw-Hill Book Company, 1989, Appendix, pp. 227–228.

Other considerations within the cost analysis include:

- Extra facilities and equipment (e.g., refrigerators, plumbing, and electrical outlets)

- Capital equipment selection, purchase, maintenance, repair, and replacement
- Purchase and inventory control of test reagents, kits, gloves, and other disposables
- Staff recruiting, training, and continuing education.

The reader must consider his/her own costs within the setting in which POCT is performed. These will differ from site to site because of differences in salaries, materials, and the method or instrument that is being used. Consult the institution's financial policy for depreciation of the capital equipment expense.

13 COST/BENEFIT ANALYSIS

To objectively determine the value of POCT in any testing location, a thorough cost/benefit analysis is recommended. While a discussion of this analysis is beyond the scope of this document, a brief analysis evaluating the net effect should address the following considerations:

- Total turnaround time
- Length of patient stay (within department/within institution)
- Patient satisfaction
- Clinical decisions based on rapid results
- STAT testing requirements
- Follow-up testing
- Laboratory staffing levels
- Nonlaboratory staffing levels
- Therapeutic/pharmacy utilization

- Blood product utilization
- Physician convenience
- Test volume
- Patient compliance
- Patient/physician encounters
- Third-party reimbursement.

14 SAFETY AND WASTE DISPOSAL

The U.S. Occupational Safety and Health Administration (OSHA) requires that written protocols for worker safety be developed and enforced.

14.1 *Safety*

The director of POCT for the site(s) where POCT is performed is responsible for providing the following to employees: a safe workplace; personal protective equipment; TB testing; hepatitis B vaccination; post-exposure evaluation and follow-up; and a safety training program for employees who routinely work with blood or other infectious materials. Records that document this training must be kept.

OSHA requires that an employer provide the hepatitis B vaccine and vaccination series to all employees who have occupational exposure. The vaccine must be made available within ten working days of the initial assignment. Employees who decline receipt of the hepatitis B vaccination must sign a waiver.

When using hand-held devices, safety/waste disposal procedures should be considered, as well as the potential for their contamination and their effect on infection-control procedures. The work area for POCT is likely to be the patient's bedside stand or table. Similarly, disposable strips, cartridges, etc., used with hand-held devices or methods require disposal appropriate for biohazardous infectious waste. Portable

provisions for adequate decontamination and disposal can be necessary.

14.2 *Standard Precautions*

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to standard precautions. Standard precautions are new guidelines that synthesize the major features of universal precautions and body substance isolation practices. Standard Precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (Guideline for Isolation Precautions in Hospitals, Infection Control and Hospital Epidemiology, CDC, Vol 17;1:53-80.), [MMWR 1987;36(suppl 2S):2S-18S] and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure, refer to NCCLS document M29—*Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue*.

14.3 *Exposure-Incident Follow-Up*

After a report of an exposure incident involving a blood-borne pathogen, the employer must make available to the exposed employee a confidential medical evaluation and follow-up.

14.4 *Avoiding Accidental Skin Puncture with Sharps*

Among the most frequent causes of accidental needle sticks is the recapping of the needle after venipuncture. In addition, environmental services can be punctured when they handle containers in which used needles have been discarded. The best way to avoid these risks is to have a special container for disposal of needles, lancets, and/or scalpels. It should be small enough to be placed in the work area, spillproof, tamperproof, secured to a

wall or bench surface, opaque, have puncture-proof sides, and it should be autoclavable. The container must be labeled or color-coded in red to warn of biohazardous material. *Recapping needles increases the risk of needlesticks and should not be practiced*. OSHA rule 29 CFR §1919.1030(d)(2)(vii) specifically prohibits bending or recapping needles. Some states also regulate the handling of needles and other sharps.

14.5 *Personal Protective Equipment*

When an employee's duties involve occupational exposure, OSHA requires that an employer provide (at no cost to the employee) appropriate personal protective equipment such as gloves, gowns, laboratory coats, face shields or masks, and eye protection.

- Gloves must be provided and worn under the following circumstances:
  - Whenever handling and processing specimens
  - Whenever the operator has cuts, scratches, or breaks in the skin
  - In any situation in which hand contamination with blood, body fluids, or tissue is likely to occur
  - When performing finger or heel sticks
  - When performing phlebotomies, gloves should be changed after contact with each patient.
- Protective body clothing must be provided. Workers should wear long-sleeved laboratory coats which are buttoned closed and impervious to liquids, or an apron impervious to liquids. Reusable cloth or disposable gowns/coats may be used. The employer providing nondisposable coats

or gowns must also provide laundering at no cost to the employee.

- Masks, eye protection, or face shields should be available for any procedure that has the potential for spattering blood or body fluids.

14.6 ***Hand Washing***

Hand washing could be the single most important routine safety practice. Hands should be washed in the following situations:

- After removing gloves
- After completing work and before leaving the site
- Before touching eyes, mouth, glasses
- Before eating, drinking, smoking, applying cosmetics, changing contact lenses, and using lavatory facilities
- Immediately after contamination with a specimen or reagent
- After contact with each patient or before contact with another.

14.7 ***Food, Drink, Cigarettes, and Cosmetics***

Eating, drinking, smoking, and applying cosmetics are not permitted within the testing-site environment. This is because hands could be contaminated with infectious organisms.

14.8 ***Routine Cleaning and Disposal***

A 10%-solution of household bleach and water (one part bleach plus nine parts water) is one effective disinfectant for both bacterial and viral organisms. All work should be wiped and allowed to soak a minimum of 15 minutes. To retain potency and effectiveness, the 10%-solution must be prepared daily.

- If blood or other biohazardous material contaminates the POCT device, carefully wipe the area with bleach solution; be careful not to spill bleach into the measuring or internal components of the device.

- Spills that involve blood, body fluids, other infectious materials, and reagents can be cleaned up with paper towels. Apply a 10%- bleach solution to spill sites.

14.9 ***Infectious Waste Handling and Disposal***

Infectious waste (biohazard) containers should be conveniently located and of sufficient volume to accommodate the infectious waste generated at the site. They must be labeled or color-coded in red to warn of biohazardous material. The containers should be constructed of materials appropriate to the type of waste generated. Biohazard containers should be handled with gloved hands.

Disposal of medical and infectious waste must comply with all local ordinances, state and federal Environmental Protection Agency (EPA) regulations, and state and federal OSHA regulations. At nonhospital sites, arrangements must be made to comply with these agencies.

14.10 ***Electrical Precautions***

The site should have an adequate number of grounded electrical outlets. Equipment must have safe cords and plugs and it must be approved by *Underwriters Laboratories* or a similar group.

14.11 ***Safety Manual***

The director of the POCT site should provide a safety manual with specific policies for the items discussed previously. In addition, the following tools should be available:

- A list of the names and telephone numbers of persons to contact in an emergency

- Procedures for reporting accidents
- Procedures for cleanup of reagent and specimen spills
- An accident log where the person's name, type of accident, and the date are included. If the accident is a needlestick, also include the patient's name, telephone number, and any relevant medical diagnosis.

15 PATIENT PREPARATION/ SPECIMEN COLLECTION AND IDENTIFICATION

The following section addresses patient preparation and specimen collection and identification. Also, special precautions are discussed.

15.1 *Patient Preparation*

The patient should be suitably prepared to have their specimen collected for the specific analyte to be tested. This may include: appropriate seating, hydration, lack of interfering drugs, and fasting, if required.

15.2 *Specimen Collection*

Collect the appropriate specimen as indicated by the manufacturer's instructions which is consistent with institutional policies and procedures. Procedures should adhere to established standard precautions related to specimen collection guidelines such as those found in NCCLS document H4– *Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture*, and, for obtaining specimens from indwelling lines or catheters, NCCLS document H3– *Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture*. Volume and placement of the sample should conform to requirements specified by the manufacturer of the test reagent and instrument.

The following questions should be considered:

- What kind of specimen will be used?
- Is it appropriate for the test/analyzer?
- Will the specimen or test result be affected by the timing of the collection?

For additional information, refer to NCCLS videotapes on blood collection, H3-A4-V, *Quality Venipuncture: The Key to Accurate Results,* H4-A3-V, *Quality Microcollection,* and GP16-T-V2, *Urinalysis—The Inside Story: Evaluation.* For guidance on urine collection, see the most current edition of NCCLS document GP16—*Routine Urinalysis and Collection, Transportation, and Preservation of Urine Specimens*.

15.3 *Specimen Identification*

Each POCT site should develop a protocol to ensure that each result is associated with a patient name and patient identification number (ID#) for the purpose of accurate test documentation and billing. While many POCT analyzers or devices neither require nor guarantee that the result is associated with an ID number, these analyzers should require an ID number to be entered into the testing device before the result is displayed.

15.4 *Special Precautions*

To avoid transmission of blood-borne diseases between patients when performing POCT (e.g., appropriately discarding lancets, platforms of spring-loaded lancets, and to disinfect instruments contaminated by blood) precautions are needed. Other preanalytical considerations include the potential for contamination with IV fluid and potential interferences from hemolysis and lipemia. Procedures should adhere to the recommendations in the most current edition of NCCLS document M29—*Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue*.

16 CALIBRATION AND

"Calibration" refers to the analysis of one or more solutions that contain defined concentrations or

CALIBRATION VERIFICATION

activities of the substance being analyzed. An instrument or device calibration is performed to adjust or reset the instrument response to read out a particular concentration value. Therefore, user-calibration requires that an instrument have an adjustable or automatically adjusted read-out response.

A variety of calibration methods and the frequency with which calibrations must be performed depend upon the design of the analyzer, the stability of the instrument and reagents, the intended user, and the level of accuracy required.

Some instruments are not user-adjustable and, therefore, cannot be calibrated by the user. If an instrument/device is calibrated by the manufacturer, the user may want to periodically perform a calibration verification procedure such as that described in Section 16.2 of this document.

16.1 *Calibration*

Calibration of an instrument is dependent upon the technology and test method of the instrument. Therefore, instruments require varying degrees of calibration for optimal performance. For example, some systems require no calibration (e.g., enzyme assays that use factor calibration); some systems use one-point calibration (e.g., several blood gas devices); and some use two-point calibrations (e.g., blood gas and chemistry analyzers).

16.1.1 *Single-Use Disposable Test Cartridges, Strips, or Similar Materials*

Typically, these devices use a self-contained calibrator.

16.1.2 *Multiple-Use Testing Systems*

When two-point calibrations are required, the concentration of the primary calibrant (calibrating concentration) is usually at the midpoint of the analyte's

expected normal or reference interval. The second point should be outside the expected range. Usually, the second point is chosen to be at the high end of the analytical range. However, if the low end is of equal clinical importance, the user may want to periodically ascertain low-end accuracy, for example, by calibration verification.

16.2 *Calibration Verification*

Calibration verification, as defined in Section 16.2.1, applies to both single-use and multiple-use devices.

16.2.1 *Definition*

The purpose of calibration verification is to demonstrate the analyzer's accuracy of response over the reportable range of the analyzer. Calibration verification is often performed by analyzing a series of solutions containing a range of defined concentrations of the analyte, from low to high.

16.2.2 *Specifications*

Calibration verification can be useful for point-of-care devices. Usually, a series of three or more calibration materials should be used to verify calibration. The concentration levels should be appropriate for the technology and analyte being tested. If not provided, the manufacturer should be contacted to request these materials or for advice on where they can be obtained.

- For example, these calibration-verification materials may contain proteins such as albumin or hemoglobin, if appropriate.

  The concentrations of the calibration verification materials should cover the entire reportable range of concentrations and may include concentrations:

  — At the lower and upper limits of the reportable range

  — At the midpoint of the "normal" range

— At critical or medical-decision levels.

16.3 ***Frequency of Calibration and Calibration Verification***

General recommendations for frequency of calibration and calibration verification for multiple-use and single-use devices is described below. In the event that a device cannot be calibrated or possesses a long calibration time, a user may want to periodically perform calibration verification with a frequency of at least once every six months.

16.3.1 ***Multiple-Use Analytical Systems***

For instruments that the user can calibrate, the calibration should be done at the frequency recommended by the manufacturer. This applies to both multiple-use analytical cartridges, using either external or internal calibrators, and disposable single-use cartridges.

16.3.2 ***Single-Use Disposable Testing Devices***

Calibration verification should be done whenever a major change to the system occurs. It is reasonable to assume that these changes do not occur frequently and that manufacturer's instructions should be followed or, if necessary, verification frequency can be increased as determined by need or experience. The following are examples of major changes:

- A new sensor or optical unit installed
- A change of lots of the internal calibrators
- A critical component change to the device
- A software update
- A change or repair of major electronic components
- A shift in the trend of QC.

16.3.3 ***Evaluating Reliability of the +/- Cutoff Specified in***

The manufacturer must specify the concentration at which a positive test result (cutoff) occurs.

The user obtains or prepares two samples that contain concentrations approximately 30% above and 30%

Semiquantitative Tests on Patients' Samples

below the cutoff specified by the manufacturer. Each of these samples is run five times. If no more than one result from the high sample is "negative," and no more than one result of the low sample is "positive," there is >95% confidence that the test is accurate at the specified cutoff.

Frequency: This test should be done with every lot change of reagents and within six months.

17 QUALITY CONTROL

Quality control (QC) is a part of quality assurance in which a variety of tests and procedures are used to monitor and evaluate testing to ensure that test results on patients' specimens are reliable. QC testing should be performed by the testing personnel.

17.1 *Purpose of Controls*

Methods of QC are based on the analysis of controls. Control materials test the integrity of the analyzer's system and results with expected range values. Controls are tested before or along with the patients' specimen(s). When analyzed with patients' specimens, the purpose of controls is to detect gradual or sudden changes in the performance of the analytical process.

When an instrument or measuring device (used below interchangeably) is used, control results outside of preset limits (out-of-range) indicate some degree of change in the performance of the overall measurement system, such as within the instrument system (electronic, mechanical, or flow), reagent system, or within the control samples. The procedures to handle out of range control results are described in Sections 17.3.4 and 17.3.5.

The process of producing patient results involves sample handling, sensor calibration, electronic functions, result presentation and interpretation, and clinical utilization. An error anywhere along the path can result in patient mismanagement. Preanalytical error (sample handling),

analytical (sensor calibrations and equipment functions), and postanalytical (result presentation and interpretation) each contribute independently to the total error of a test result.

17.2 *Applicability of QC Procedures*

The design of QC procedures for point-of-care devices must accommodate the diversity and variety of locations where POCT is performed, such as:

- Hospitals
- Physicians' offices, clinics, etc.
- Field use, such as ambulances or helicopters
- Home use by visiting nurses.

To be effective, QC procedures on these devices should be designed for use and understanding by the least trained of potential users of the device.

17.3 *Considerations in Designing a QC Program*

The following considerations should be taken into account when designing a QC program.

17.3.1 *Schedule for QC Testing*

Control materials are used to monitor the stability of the method or test system. Control materials should be used with a frequency consistent with good laboratory practice, which is appropriate to the workload of the testing device, the type of test performed, the stability of the reagents, and the experience of the operator. The controls should be run within the time frame in which the accuracy and precision of a testing system is expected to be stable. The schedule for control testing, the levels tested, and the frequency are a function of the device, the skill level of the operator, the frequency of testing, the reliability of the test system, and the complexity of the organization in which the analysis is done. Cross-over testing of the effectiveness and acceptable limits of the new control material should be performed prior to the expiration date or the depletion of

the old control material. The following are key considerations for an adequate control testing program.

17.3.2 ***Levels to be Tested***

- QC materials should be analyzed using a schedule that complies with U.S. CLIA '88 requirements. As of this writing, CLIA '88 requires a minimum of two levels of control material to be run each day of testing. But some specialties such as hematology, coagulation, and blood gases have additional specific require-ments.

- The levels should be chosen to test the clinical decision points of the assay, whether high or low. For qualitative tests, these may be positive and negative controls.

17.3.3 ***Single vs. Duplicate Analysis***

Controls should be tested in a manner consistent with analysis of patient samples, i.e., if a patient is analyzed in duplicate, likewise the control should be analyzed in duplicate.

A single analysis of each control is usually adequate, with a repeat analysis of the control performed when unexpected results are obtained.

17.3.4 ***Single-Use Disposable Testing Cartridges, Strips, or Similar Materials***

Since repeat testing is not currently available on a single-use device, unexpected or out of range results on controls should be repeated by reanalyzing the same control using a new test cartridge. If this result is also out-of-range, a new control sample should be analyzed using another test device. If the controls are still out of range after a new control is assayed, the instrument should not be used until the problem is resolved and patient specimens should not be run. Such out-of-range results should be documented and carefully monitored for the possibility of rejecting and either discarding or returning the entire lot of test cartridges or devices.

Even though some manufacturers provide single-use disposable cartridges that contain internal/procedural checking devices, external QC material should be used more frequently as determined by the director or technical consultant of the POCT site.

17.3.5 ***Multiple-Use Testing Devices***

When a control result is out-of-range, the same level of control should be repeated. If this result is also out-of-range, a new control should be analyzed. If the result on this new control sample is also out-of-range, either the POCT coordinator, a skilled technologist, or the manufacturer should be consulted and patient specimens not analyzed until the problem is resolved. QC material should be analyzed using a schedule that complies with CLIA '88 requirements. As of this writing, CLIA '88 requires a minimum of two levels of control material to be run each day of testing.

17.3.5.1 ***Routine QC of Semi-quantitative Test Cartridges***

To evaluate the reliability of the control well in test cartridges (if present), controls at clinically important concentration ranges should be analyzed at the frequency recommended by the manufacturer, in compliance with regulatory agencies. This would typically be at each lot number change and not less than once every six months.

17.3.6 ***Review of QC Data***

The person(s) responsible for QA must oversee QC results on a routine basis. (See Section 23.1 on documentation of QC.)

17.3.7 ***Responsi-bilities of theManu-facturer In Providing Control Materials***

The manufacturer of the device may recommend or supply a series of control materials that will challenge the proper operation of the device.

It is the responsibility of the control manufacturer to recommend proper handling, storage, and usable life of the opened or reconstituted control material.

At each change of a reagent lot number, the

manufacturer should specify a protocol for analysis of QC material using the new lot of reagents, test cartridges, etc. The operator should ensure that QC results are within specified ranges before testing on patient specimens may continue.

17.4 *Guidelines for QC Applied to Various Testing Devices*

The following guidelines apply to multiple-use analytical devices and single-use materials.

Example: A device capable of analyzing 100 samples by a single analytical cartridge.

17.4.1 *Multiple-Use Analytical Devices*

QC material should be analyzed using a schedule that complies with CLIA '88 requirements. As of this writing, CLIA '88 requires a minimum of two levels of control material to be run each day of testing.

17.4.2 *Single-Use Disposable Test Cartridges, Strips, or Similar Materials Used Within a Testing Device Which Does Not Contact the Specimen*

The testing device must be quality checked for performance at least daily or on the day of an analysis before analysis of the patient's sample.

Example: A device uses a disposable test card that is inserted into the analyzer. The specimen is applied to the test card, is analyzed by and contained within the test card, and the test card is disposed of after one analysis.

Because analysis of QC material by the same cartridge used to test a patient's sample is not available on some single-use disposable cartridges, the following QC checks could be used:

- Internal procedural controls (supplied by the manufacturer) that monitor test performance and reagent reactivity.

- The manufacturer may supply an electronic-simulator device that is inserted into the testing device to verify proper operation (accuracy and sensitivity) of the device. The electronic simulator should check at

least two (or more) levels of response. It should be used (at least daily or before doing an analysis) per manufacturer's instructions or depending on local operating conditions of the institution or to meet regulatory requirements.

- Because an electronic simulator does not test the stability of the cartridge or test strip itself, the analysis of additional QC solutions should be done to monitor stability of reagents in the cartridges, test strips, etc. The frequency may be more often as determined according to the guidelines stated in Section 17.3.1.

- Electronic controls can be used to monitor the actual reaction rate and response curves to assess the analytic process.

- Control materials in a matrix similar to the patient sample may be incorporated into the POCT so that the biochemical principle of the POCT assay can be monitored.

18 REPORTABLE RANGE

Reporting of results must fall within the reportable range. The reportable range is the acceptable concentration (from low to high) that a device can reliably measure an analyte. Results falling below or above this range should not be reported with a numeric value. Policies need to include steps to be taken when a result falls outside of range, such as: repeating the test; repeating the test after diluting the specimen where appropriate; or referring the specimen to a laboratory.

19 MAINTENANCE

All users must follow the manufacturer's recommended schedule and protocol for maintenance. Cleanliness should be emphasized as a simple, yet important, routine practice. We recommend that the analyzer automatically prompt the user to perform the necessary maintenance items at the scheduled times. Furthermore, the analyzer

should require the user to answer the prompt before allowing further analyses.

20 EVALUATION/ SURVEILLANCE OF PROFICIENCY

Once POCT has been established, a mechanism for evaluating the accuracy of the testing system (equipment, reagents, and operators) must be implemented. Proficiency can be assessed on a periodic basis consistent with good laboratory practice, defined by the POCT director or clinical consultant. Complexity of testing, number of personnel, and the number of sites involved are factors to be considered when deciding the frequency of assessing competency.

It is recommended that POCT sites participate in Proficiency Testing Survey programs. POCT sites accredited under CLIA are required to participate in proficiency testing programs for certain analytes. These programs provide "blinded" specimens containing pre-determined concentrations of the analyte(s) being tested. After completing the test, the participants submit their results, which are statistically evaluated by the program sponsors. This provides the user with information on how well he/she is performing the test.

Several organizations provide proficiency testing programs. These include, for example: The College of American Pathologists (CAP) and the American Association of Bioanalysts (AAB). Refer to your state agency for proficiency testing programs in your area.

21 RESULT REPORTING/ RECORD KEEPING

Section 21 provides information on the reporting of results and record keeping.

21.1 *Confidentiality*

A POCT site is an extension of the patient/physician relationship. Therefore, all information is treated as confidential and communications are based on a "need-to-know" premise. Results should be reported to the

attending physician in a manner that respects the confidentiality of the patient.

Test request information and patient results should not be left in an open, visible environment for easy access by other patients. Electronic transmission of data requires that a facsimile instrument or computer workstation have restricted access.

Results of tests, like patient files, are confidential records. Utmost care in the recording and storage of patient information is necessary to ensure confidentiality. New employees should be trained in confidentiality procedures.

21.2 *Reporting and Forms*

It is important that results reach the ordering physician in a timely manner to affect patient care appropriately. POCT can expedite this process by providing faster results than obtained by a central laboratory. The physician has the responsibility to follow-up on results.

Oral reporting of test results should be followed by written results. If POCT occurs outside of a hospital, results must be recorded in a permanent record, and a mechanism established to ensure that this is done.

POCT devices that can "up-load" patient data to a Laboratory Information System (LIS) and/or Hospital Information System (HIS) are preferable. This ensures that the results will be transmitted to the patient's chart and provides a permanent record. Transmission in this fashion also facilitates billing activities.

If computer transmission is not available, report forms may contain the following information, if appropriate:

- Patient's name, ID number, chart or medical record number

- Date and time specimen was collected

- Specimen type (e.g., blood, urine)
- Date and time test was performed
- Name of person performing test
- Name of test(s) performed
- Results, recorded in permanent ink
- Condition of specimens, if unsatisfactory or inappropriate
- Ordering clinician
- Time that a medication was taken, if relevant (e.g., theophylline)
- Whether the test was done after a procedure, if it will affect POCT results
- Reference interval for the test result in the tested population.

The length of time that these records must be kept varies with state regulations. These records should be located on the patient's chart and at the testing site. A running log format, kept by the person doing the tests, is convenient and lends itself to the advantages of separate testing records.

The POCT site must have procedures that:

- Ensure the security of the records and the confidentiality of the results
- Prevent the loss of test results
- Designate persons who may release laboratory test

results and to whom the results may be released

- Require the reporting of certain infectious diseases and disorders (some states).

The POCT site must provide or be provided with "reference intervals" for normal and abnormal results.

21.3 ***Reporting Patient Results***

For reporting patient results, the following questions should be considered:

- Has it been verified that control results are acceptable?

- Have the procedures for specimen preparation, reagent preparation, calibration, and instrument maintenance outlined in the written procedure and operator's manual been followed? For example, was the correct anticoagulant used? Was the specimen drawn from a line or from an arm with an IV running?
- Has the written procedure sheet for the test in question been followed?

Patient History

- Are results comparable to results from previous tests?

- Is the patient on any drugs that could affect the results?

- Has the patient started a new regimen, such as diet or exercise that could affect the results?

- Are the test results compatible with the patient history, clinical signs, and symptoms?

21.4 ***Medical Alert Values***

When certain test results are much higher or lower than normal, the patient might need immediate medical

attention by a physician. If a "Medical Alert Value" is reached:

(1) Repeat the test on the same system to confirm the result. Follow established practices for verification of results.

(2) Notify a physician if the result is confirmed and document that the physician was notified.

"Medical alert" (also referred to as critical, or panic values) must also be defined. Medical alerts demand immediate attention. They must be communicated immediately by testing-site personnel to the physician.

There must be clear responsibility and authority to deal with abnormal results:

- Ensure that the test-site has established procedures for the immediate notification of appropriate personnel when results of tests exceed predetermined "alert," "critical," or "emergency" limits

- Ensure that test results are available within a clinically useful time frame

- Ensure that there is a mechanism to record results on a patient's chart (if appropriate).

22 INTERPRETATION OF RESULTS

Preanalytical, biological, and analytical variations should be taken into account for correct interpretation of a test result.

Examples of preanalytical variations include:

- Incorrect test request
- Incorrect specimen handling and preparation
- Incorrect specimen identification.

Examples of analytical variations include:

- Instrument variation
- Specimens inappropriately sampled
- Inappropriate verification
- Inappropriate reference interval for specific test method.

Examples of biological variation include:

- Gender
- Age
- Stress
- Physical activity
- Posture
- Patient diet (fasting/nonfasting)
- Interference by medication
- Variation due to inappropriate normal range because the person differs from that population.

It should be stressed that results are not static or absolute; test results are usually interpreted in conjunction with other test results and clinical symptoms.

23 QUALITY CONTROL AND QUALITY ASSURANCE DOCUMENTATION

QC data are kept as permanent records to document the performance of testing. There should be evidence of periodic review of the QC data by the supervisor, POCT site director or POCT coordinator.

23.1 *QC Documentation*

Documentation includes keeping written or electronic (computerized) records that are clear, up to date, and readily accessible. For each test, QC data must be generated and recorded every time that the control is run. These records may be in the form of daily worksheets or logs. The person performing the tests should sign and date the log sheets. Examples of log sheets may be provided by the manufacturer or laboratory. See Appendix D for a sample QC log sheet and Appendix E for a sample

preventive maintenance record form.

This record keeping provides a means by which the POCT site can demonstrate that its tests and methods were operating within acceptable limits at the time the patient results were produced.

As stated previously, QC can be uploaded and stored on an LIS system for later review by assigned personnel.

23.2 *QA Documentation*

QA records should demonstrate:

- A clear and up-to-date compilation of QC data demonstrating that controls are run as specified in the laboratory's QC procedures.

- Dates of all patient tests and control results. This provides a link between the control and patient results. When control results were within the established limits at the time patient results were produced, it is assumed that patient results were reliable, valid, and reportable.

- A permanent record of control and patient results that can be reviewed by the laboratory director.

- Lot number of reagents and control materials and expiration dates.

- Name of instrument or test system and serial number of instrument used.

- Log of test operator training and periodic proficiency evaluation results.

The POCT site should not omit recording "bad" or "out-of-control" data. Using the QC log, chart, or computer system, the testing personnel can easily and clearly track QC activities. Notes should be made in the following

situations:

- When new lots of reagent are introduced
- When different testing personnel begin to perform the test
- When instrument maintenance has been performed
- When and what responses are made to "out-of-control" results.

23.3 *General Recommendations for QA*

Following are some general recommendations for QA.

23.3.1 *Identification of Operator and Sample*

There should be an approved operator ID and patient or sample ID for all samples tested, whether a patient specimen or QC test is performed. Wherever there are multiple users of POC devices, entry of these IDs should be required by the POC device.

23.3.2 *Multiple Devices within a Test Center or Site*

Where results may be compared routinely, only one brand of POCT device should be used for a particular test within an institution. We recognize that it may not be possible to have a single type of device for a particular test at all sites. In those instances, the laboratory is reminded that they are responsible for having a procedure in place to compare results between the different methods.

23.3.3 *Electronic Storage of QC Data*

Testing devices should have a mechanism that is capable of automatic storage of QC results and quality checks for at least a month. This data must be "downloaded" or retained before it is automatically deleted by the device.

23.3.4 *Retention of QC Records*

Records of QC results and checks must be kept for at least two years for professional users such as hospitals, clinics, or physicians' offices; this is recommended for alternate sites as well.

24 RISK MANAGEMENT/ LIABILITY

The POCT site director, chief of service, and/or director of independent, out-of-hospital services should be aware that POCT is not without risk of liability. Potential risks include but are not limited to:

- Risks incurred by the person performing the sampling and/or testing
- Risks incurred by the patient as a result of sampling
- Calibration or QC errors resulting in erroneous reporting of results
- Potential breaches of compliance with regard to assignment of untrained personnel. Personnel responsible for POCT are advised to seek counsel from his/her institutional legal representative with regard to these regulations.

Established professionals (e.g., nurses, medical technologists, physician assistants, and emergency medical technicians) whose members function under a state practice act and who perform POCT, should contact their regulatory bodies (i.e., state board, etc.) for information on the professional liability, appropriateness, and extent of POCT that is approved under the practice act for the specific state.

Bibliography

CDC. *Recommendations for Waivered Category Criteria*. CLIAC meeting; August 17, 1993; Atlanta Georgia.

Geyer S. Management of POC Testing. CLMA Seminar; San Antonio, TX; 1993.

Travers EM. *Managing Costs in Clinical Laboratories*. New York: McGraw-Hill Book Company; 1989: 227–228.

CAP. Alternative Site Testing Conference: Venturing Beyond the Boundaries of the Clinical Laboratory. January 29 - February 1, 1995; Arlington, Virginia.

Laboratory Requirements (42 CFR Part 493). Federal Register, 1993: 1401-1495.

Department of Veterans Affairs Policy Manual, M-2, Part VI, Ch. 10; February 8, 1993.

Appendix A. State Agencies Regulating Medical Laboratories for HCFA and the State*†

AL Alabama Department of Public Health
Division of Licensure and Certification
P.O. Box 303017
Montgomery, AL 36130-1701
Tel: 334.206-5100

AK Office of Health Facilities and
Licensure
Dept. Of Health and Social Services
4730 Business Park Blvd.
Suite 18
Anchorage, AK 99503-7137
Tel: 907.561.8081

AZ Arizona Dept. Of Health
Laboratory Licensure and Certification
3443 N. Central Suite 810
Phoenix, AZ 85012
Tel: 602.255.3454

AR Division of Health Facility Services
Arkansas Department of Health
5800 W. 10th St, Suite 400
Little Rock, AR 72205-9916
Tel: 501.661.2201

CA California Department of Health Services
Laboratory Field Services
Division of Laboratory Science
2151 Berkeley Way, Annex 12
Berkeley, CA 94704
Tel: 510.873.6327

CO Colorado Department of Public Health & Environment
Div. of Laboratories
CDH-CLIA Programs
PO Box 17123
Denver, CO 80217
Tel: 303.692.3295

CT CLIA Laboratory Program
Department of Public Health
P.O. Box 340-308
Hartford, CT 06134-0308
Tel: 860.509.7400

DE Office of Health Facilities Certification and Licensure
3 Mill Road, Suite 308
Wilmington, DE 19806
Tel: 302.577.6666

DC Department of Consumer and Regulatory Affairs
614 "H" Street NW
Suite 1007
Washington, DC 20001
Tel: 202.727.7200

FL State of Florida
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308
Tel: 850.487.3063

GA Georgia Department of Human Resources
Office of Regulatory Services
Diagnostic Service Unit
2 Peachtree St. 33-391
Atlanta, GA 30303-3167
Tel: 404.657.5447

HI Hawaii Department of Health
CLIA Program
2725 Waimano Home Road
Pearl City, HI 96782
Tel: 808.453.6692

ID Laboratory Improvement Section
Bureau of Laboratories
2220 Old Penitentiary Road
Boise, ID 83712-8299
Tel: 208.334.2235 x245

IL Illinois Department of Public Health
Division of Health Care Facilities and Programs
525 W. Jefferson Street
Fourth Floor
Springfield, IL 62761
Tel: 217.782.7412

IN Indiana State Department of Health
Division of Acute Care Services
2 North Meridian Street
Box 1964
Indianapolis, IN 46204
Tel: 317.233.7502

IA Iowa Department of Inspections and Appeals
Division of Health Facilities
Lucas State Office Building 3rd Floor
Des Moines, IA 50319-0083
Tel: 515.281.3765

KS Kansas Department of Health and Environment
Laboratory Certification
Forbes Field
Bldg. 740
Topeka, KS 66620
Tel: 785.296.1638

KY Division of Licensing & Regulation
Dept. of Human Resources
275 E. Main Street
Frankfort, KY 40621-001
Tel: 502.564.2800

LA Department of Health and Hospitals
Health Standards Section
P O Box 3767
Baton Rouge, LA 70821-3767
Tel: 504.342.9324

ME CLIA Laboratory Program
Division of Licensing and Certification
Bureau of Medical Services
Maine Department of Health
State House-Station 11
Augusta, ME 04330
Tel: 207.624.5402

MD Office of Licensing and Certification Programs
Div. of Laboratory Licensure
4201 Patterson Ave., 4th Floor
Baltimore, MD 21215
Tel: 410.764.4695

*The information provided is current as of May 1999. The most current list can be found at http://www.hcfa.gov./medicaid/clia/saaddres.htm

†For labs in Virgin Islands, see New York. For labs in Guam, American Samoa, or Saipan, see Hawaii.

MA Department of Public Health
Clinical Laboratory Program
305 South Street, Rm 224
Jamaica Plain, MA 02130
Tel: 617.983.6739

MI Michigan Department of Consumer and Industry Services
525 West Ottawa
Box 30664
Lansing, MI 48909
Tel: 517.241.2648

MN Minnesota Department of Health
Survey and Certification Section
85 East 7th Place, Suite 300
(Zip code for street address is 55101)
Box 64900
St. Paul, MN 55164-0900
Tel: 651.215.8704

MS Licensure and Certification
Mississippi Department of Public Health
P.O. Box 1700
Jackson, MS 39215-1700
Tel: 601.354.7219

MO Missouri Department of Health
CLIA Section
P.O. Box 570
Jefferson City, MO 65102
Tel: 573.751.6318

MT Certification Bureau
Department of Public Health and Human Services
Cogswell Building
P.O. Box 202951
Helena, MT 59620-2951
Tel: 406.444.1451

NE Nebraska State Health Department
Health Facilities
Licensure & Inspection
Regulation and Licensure
P.O. Box 95007
Lincoln, NE 68509-5007
Tel: 402.471.4972

NV Nevada State Health Division
Bureau of Licensure and Certification
1550 E. College Parkway, #158
Capitol Complex
Carson City, NV 89710
Tel: 702.687.4475

NH CLIA Laboratory Program
Health Facilities Administration
Department of Health and Human Services
6 Hazen Drive
Concord, NH 03301
Tel: 603.271.4832

NJ Clinical Laboratory Improvement Service
State of New Jersey
Department of Health & Senior Services
CN 360
Trenton, NJ 08625-0360
Tel: 609.292.0016

NM Special Operations
Health Facility Licensing and Certification Bureau
Public Health Division/Dept. of Health
525 Camino De Los Marquez, Suite 2
Santa Fe, NM 87501
Tel: 505.827.4200

NY State of New York
Department of Health
CLIA Unit
Empire State Plaza
P.O. Box 509
Albany, NY 12201-0509
Tel: 518.485.5352

NC North Carolina Department of Human Services
CLIA Certification
P.O. Box 29530
Raleigh, NC 27626-0530
Tel: 919.733.3032

ND North Dakota Department of Health
Health Resources Section
State Capital
600 E. Boulevard Avenue
Bismarck, ND 58505-0200
Tel: 701.328.2352

OH Ohio Department of Health
Laboratory Certification Program
246 N High St, Fifth Floor
Columbus, OH 43266
Tel: 614.644.1845

OK Oklahoma State Department of Health
Special Health Services
Medical Facilities
1000 NE 10th
Oklahoma City, OK 73117-1299
Tel: 405.271.6576

OR Center for Public Health Laboratories
Health Division
PO Box 275
Portland, OR 97207-0231
Tel: 503.229.5854

PA Pennsylvania Department of Health
Bureau of Laboratories
P.O. Box 500
Exton, PA 19341-0500
Tel: 610.363.8500

PR Commonwealth of Puerto Rico
Puerto Rico Health Department
Office of Certification and Licensure
Former-Ruiz Soler Hospital
Road No. 2
Bayamon PR 00619
Tel: 787.782.0120 (Ext 2222)

RI CLIA Laboratory Program
Division of Facilities Regulation
Department of Health
3 Capitol Hill
Providence, RI 02908
Tel: 401.277.4526

SC South Carolina Department of Health and Environmental Control
Bureau of Health Licensure & Certification
2600 Bull Street
Columbia, SC 29201
Tel: 803.737.7205

SD South Dakota Dept. of Health & Certification
615 E. 4th St.
Pierre, SD 57501-5070
Tel: 605.773.3694

TN Tennessee Health Care Facilities
Cordell Hall Bldg, 1st Fl.
425 5th Avenue North
Nashville, TN 37247-0508
Tel: 615.741.7023

TX Health Facility Compliance Division
Texas Department of Health
1100 W 49th Street
Austin, TX 78756-3199
Tel: 512.834.6650

UT Bureau of Laboratory Improvement
Division of Laboratory Services
Utah Department of Health
46 North Medical Drive
Salt Lake City, UT 84113-1105
Tel: 801.584.8469

VT Vermont Department of
Health Laboratory
195 Colchester Ave.
Burlington, VT 05402-1125
Tel: 802.863.7565

VA Virginia Department of
Health
Office of Health Facility
Regulation
3600 Centre Suite 216
3600 W. Broad Street
Richmond, VA 23230
Tel: 804.367.2104

WA Office of Laboratory Quality
Assurance
Department of Health
1610 NE 150th Street
K17-9
Seattle, WA 98155-9701
Tel: 206.361.2806

WV West Virginia Department
of Health
Health Facilities Licensure
and Certification
1900 Kanawha Blvd. East
Bldg. 3 Rm 550
Charleston, WV 25305
Tel: 304.558.0050

WI Wisconsin Department of
Health and Family Services
Division of Supportive
Living
Clinical Laboratory
Unit/BQA
P O Box 309
Madison, WI 53701-0309
Tel: 608.266.5753

WY Wyoming Department of
Health
Laboratory Licensure &
Certification
First Bank Bldg. 8th Fl.
2020 Carey Ave.
Cheyenne, WY 82002-
0480
Tel: 307.777.6057

Appendix B. HCFA Regional Offices*

Region I (CT, ME, MA, NH, RI, VT)

Room 2275
JFK Federal Building Government Center
Boston, MA 02203
(617) 565-3308
FAX# (617) 565-4835

Region II (NY, NJ, PR, VI)

26 Federal Plaza Rm 3800
New York, NY 10278
(212) 264-1121
FAX# (212) 264-6814

Region III
(DC, DE, MD, PA, VA, WV)

The Public Ledger Building
150 S. Independence Mall West
2nd Floor, Suite 216
Philadelphia, PA 19106-3499
(215) 861-4291
FAX# (215) 861-4280

Region IV (AL, FL, GA, KY, MS, NC, SC, TN)

The Atlanta Federal Center
61 Forsyth Street, Suite 4T20
Atlanta, GA 30303-8909
(404) 562-7438
FAX# (404) 562-7477

Region V (IL, IN, MI, MN, OH, WI)

15th Floor
105 West Adams
Chicago, IL 60603-6201
(312) 886-5311
FAX# (312) 353-3419 or (312) 353-0252

Region VI
(AR, LA, NM, OK, TX)

CLIA Program
1301 Young Street, Room 833
Dallas, TX 75202
(214) 767-0322
FAX# (214) 767-0322 or (214) 767-0270

Region VII (IA, KS, MO, NE)

601 East 12th Room 242
Kansas City, MO 64106
(816) 426-3184
FAX# (816) 426-6769

Region VIII (CO, MT, ND, SD, UT, WY) 1961

5th Floor
1961 Stout Street
Denver, CO 80294
(303) 844-4721 Ext. 451
FAX# (303) 844-3753

Region IX (AZ, CA, HI, NV, US Pacific Islands)

75 Hawthorne Street, 4th Floor
San Francisco, CA 94105
(415) 744-3696
FAX # (415) 744-2692

Region X (AK, ID, OR, WA)

Mail Stop RX-48
2201 6th Avenue
Seattle, WA 98121
(206) 615-2313
FAX# (206) 615-2435

*The information provided is current as of 8 February 1998. The most current list can be found at http://www.hcfa.gov/medicaid/clia/regionof.htm

Appendix C. Sample Procedure Format

Name of Center/Site Performing Test:

Procedure	

Prepared by	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

Distributed to	# of Copies	Distributed to	# of Copies

Principle:

Specimen:

Patient Preparation:

Type:

Handling Conditions:

Equipment and Materials:

Equipment:

Appendix C. (Continued)

Materials:

Preparation:

Performance Parameters:

Storage Requirements:

Calibration:

Standard Preparation:

Calibration Procedure:

QC:

Procedure (Stepwise):

Calculations:

Reporting Results:

Medical Alert Values:

Procedure Notes:

Reference Intervals:

Procedures for Abnormal Results:

Reporting Format:

Limitations of the Procedure:

References:

Appendix D. Sample QC Log Sheet

QUALITY CONTROL LOG

Test:_____

Control Lot Number:_____

Date Taken	Control Value	Performed By	Corrective Action Accept	Reject

_____

Supervisor Signature/Date

Appendix E. Sample Preventive Maintenance Record Form

Instrument _____

Month _____

Activity	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

_____
Supervisor Signature/Date

Appendix F. Sources for Practice Parameters and ACP Guidelines

American Medical Association, Office of Quality Assurance. *Directory of Practice Parameters: Titles, Sources and Updates*, 1994. American Medical Association, Chicago, Illinois. (http://www.ama-assn.org)

ECRI, *Health Care Standards, Official Directory*, ECRI, Plymouth Meeting, Pennsylvania.

Hospital Association of New York State, *Compendium of Clinical Protocols and Criteria and Efficacy Research: Guidelines and Ongoing Research*, New York State Hospital Association, Albany, New York.

Blue Cross and Blue Shield, Technology Management Department, Health Benefits Managements Division, *Medical Necessity Program: A Series of Clinical Guidelines in the Appropriate Use of Medical Technologies, Developed for Blue Cross and Blue Shield*, Blue Cross and Blue Shield, Chicago, Illinois. (http://www.bcbsil.com)

American College of Physicians, *Clinical Efficacy Reports*, American College of Physicians, Philadelphia, PA. (http://www.apconline.org)

American College of Physicians, *Common Diagnostic Tests: Use and Interpretation*, American College of Physicians, Philadelphia, PA. (http://www.apconline.org)

U.S. Public Health Service, Preventive Services Task Force, *Guide to Clinical Preventive Services, A Report of the U.S. Preventive Services Task Force*, William and Wilkins, Baltimore, MD. (http://www.phs.os.dhhs.gov)

U.S. Public Health Service, Agency for Health Care Policy and Research has available a number of clinical practice guidelines which can be obtained by calling 1.800.358.9295 or by writing to AHCPR, Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907.(http://www.phs.os.dhhs.gov)

Summary of Comments and Subcommittee Responses

AST2-P—*Point-of-Care In Vitro Diagnostic (IVD) Testing; Proposed Guideline*

General

1. Recommend using the term "reference interval" instead of "reference range" throughout the document.

- **The subcommittee agrees with the recommendation; the term "reference interval" is used in the approved guideline.**

2. It seems too long and complicated for out-of-hospital uses (e.g., pages 16-21 seem duplicative; could part 14 just refer to M29-A?) Why not just refer to manufacturer's instructions for calibration, etc., in part 16?

- **The document is intended to be both an educational and "how-to" document and as such should provide as much information and guidance as possible to the primary audience which is non-laboratory personnel.**

3. How will addresses in the appendixes be kept current?

- **The addresses will be updated under the normal NCCLS procedures for review of documents. The regional offices listed in the appendixes should be able to provide any changes for states within their region.**

4. It should be noted anyone conducting a lab test– even POCT– is 'testing' personnel, and therefore must be laboratory personnel.

- **The subcommittee believes that the term "laboratory personnel" implies employment by and with a laboratory and POCT is most often performed by nonlaboratory healthcare personnel.**

5. The document covers a wide spectrum of POC instruments and methods, from blood gas analyzers to hand-held glucose meters. The technology is becoming simpler, more reliable and less operator-dependent, yet the guidelines appear very demanding and prescriptive in the areas of calibration verification and quality control. In a time when cost pressures are affecting every element of the healthcare system, it is fair to ask that expensive requirements be justified– supported by data that show they are needed. And conversely, to allow flexibility for innovative future products that produce quality results with less calibration and QC monitoring than we know today.

- **Calibration, verification, and quality control are fundamental aspects of medical testing. The subcommittee believes that these provisions in AST2-A appropriately ensure the quality and accuracy of patient care.**

6. The U.S. regulatory focus of the document is inconsistent with NCCLS's strategy to become more international in scope and influence. Constant references to CLIA, CDC, OSHA, EPA, UL, and the Dept. of VA, as well as CLIA-related terms like "complexity," are inappropriate and should be made more generic.

- **In developing AST2-A the subcommittee decided that the U.S. focus should be maintained. The subcommittee concluded that the majority of readers would be U.S. nonlaboratory personnel. Therefore, the AST2-A guideline was written to specifically address requirements needed to implement a POCT program and provide as much information as possible in doing so. Every effort was made to include statements such as "in the U.S." to remind the reader that these are U.S. compliance issues. To exclude these agencies would not serve our U.S. readers well.**

7. Testing personnel needs to be clearly defined and/or limited in each area performing testing. The scope of the testing staff needs to fit the role of the desired result of the POCT testing (i.e., to decrease the length of stay in a hospital setting will differ from that of a POL testing). It is a proven fact that the cost of the POCT testing varies directly with the size of the trained staff performing the testing. The costs increase with training, competency testing, proficiency testing, and documentation of large numbers; not to mention the increase of time required to meet the regulation standards.

- **Section 9 – Personnel Considerations, and Section 12 – Cost Accounting Considerations, address these issues.**

8. Hospital-based POCT must be kept under the jurisdiction of the laboratory. This would include any and all testing on units, clinics, diagnostic treatment departments, and any multitask staff job requirements. Testing would follow the same standards as set forth by the laboratory, and meet all accrediting agency requirements.

- **Although in many hospitals, POCT under central laboratory jurisdiction is preferred, it is not mandatory if another hospital-based POCT site wishes to obtain independent certification.**

9. The guidelines do little to address testing or instrumentation that does not require or allow for calibration. Numerous instruments are at the waived level and allow for no operator adjustments, yet can malfunction just as moderate level instruments.

- **Sections 16.1.1 and 17.3.4 address calibration and quality control for single-use tests.**

10. The guidelines do little to address the simple waivered-level testing quality assurance policies.

- **The quality assurance recommendations in the guideline are applicable types of point-of-care testing.**

11. The guideline should address not only the CLIA '88 regulations, but also those of JCAHO and CAP. This is important since many of the most commonly used POC tests fall into the "waived" category under CLIA (e.g., glucose, hemoglobin, pregnancy test). Under JCAHO and CAP accreditation, testing personnel are still required to follow good laboratory practice.

- **In Section 20, recommendations for evaluating the proficiency of testing personnel have been addressed.**

Abstract

12. Add burn units and emergency transport vehicles to the second sentence of the Abstract and the Introduction.

- **The text is revised to address this comment.**

Foreword

13. The Foreword contains the term "nonlaboratory personnel." Although it is understood in this document to mean those personnel who are neither traditionally educated nor trained in clinical laboratory practice, if they are performing tests under a CLIA certificate in compliance with federal law, they are, in fact, laboratory (testing) personnel. Thus, the term "nonlaboratory personnel" is inaccurate, and "untrained laboratory personnel" is recommended as an alternative (page xi).

- **See response to Comment 4.**

14. The last sentence of the fourth paragraph should be revised to read ". . . involved to support and interpret the results of these services."

- **The subcommittee agrees; the text has been revised as recommended.**

Section 3.0 (pages 2-8 [now pages 1-9])

15. The definition of accuracy (page 2) should be clarified by stating "The accuracy of results can be measured by comparing them with those from another laboratory that uses an accepted method (this is "relative accuracy").

- **The definition has been revised to address this comment.**

16. Revise the definition for accuracy to state, ". . . results accepted as correct, i.e. standard methods, . . ."

- **The definition has been revised to address this comment.**

17. The definition for conjugate (page 4) needs more explanation.

- **The definition has been revised and is consistent with the definition of conjugate stated in NCCLS document NRSCL8*S*Terminology and Definitions for Use in NCCLS Documents.***

18. Increase the scope of the definition for control (page 4) by a simple addition (in bold): "A material, such as, ...serum, or a device ..." The second sentence should be deleted because it is too limiting. Concentrations are not needed to monitor a process and knowing the concentration or value might be beneficial, but it is not a requirement. In fact, in the first sentence, the definition specifically allows the use of a device, or, presumably, an internal monitor, which permits the flexibility needed to accommodate some current and future technologies.

- **The definition is consistent with the definition of control stated in NCCLS document NRSCL8–*Terminology and Definitions for Use in NCCLS Documents.***

19. Revise the definition of medical alert values (critical values) (page 5) to state, "Assay values which require immediate medical attention, due to dangerously abnormal levels of a particular analyte."

- **The definition has been revised to address this comment.**

20. In the definition on quality assurance (QA) (page 6), more than the testing is evaluated by QA, i.e., patient and physician satisfaction, send-out process, etc.

- **The subcommittee agrees; the text has been revised.**

21. The second sentence of the definition for quality control (page 6 [now page 7]) should be revised to read, "...and evaluating and documenting any remedial action taken as a result of this analysis."

- **The subcommittee agrees; the text has been revised as recommended.**

22. Add statement to the definition for qualitative, "Sometimes assigns a degree of positive, i.e. 1+, 2+, etc."

- **The definition has been revised as recommended.**

23. Definition for skin puncture (page 8) – it is more than breakage of the skin.

- **The subcommittee believes the current wording appropriately defines the term.**

24. The definition for sensitivity (assay) (page 7) would be further clarified by adding "minimum reliably detectable level" to the end.

- **The definition has been revised as recommended.**

Section 4.0 (pages 9-11 [now pages 9-12])

25. A bullet should be added to Section 4.0, "Who will have quality oversight and responsibility for compliance for accreditation certification and regulatory requirements?"

- **The first bullet in Section 4 has been expanded to include quality oversight. Also, in Section 6.1 entitled "Designate Authority," a sixth bullet has been added that states: "Provide quality oversight."**

26. A bullet should be added to Section 4.0, "Will this improve patient satisfaction?"

- **The recommended text has been incorporated into an existing bullet.**

27. In Section 4.0 under "cost and reimbursement," (page 11), what about charge determination?

- **This section deals with points that "need to be considered," and does not necessarily provide an explanation of each issue. Subsequently, the bullet indicated, on "cost and reimbursement," has been deleted.**

Section 5.0

28. Section 5.0 adds nothing to helping a point-of-care laboratory establish a quality system. In fact, the document, as currently written, is in conflict with the CLIA regulation for what needs to be done if the test is categorized as moderately complex. A reminder that U.S. labs are regulated under CLIA is sufficient. This can be accomplished by just including paragraph 2 of this section.

- **Section 5.0 has been revised to provide a broader scope of regulatory considerations. In addition, Section 5.0 is intended to provide educational information for nonlaboratory healthcare personnel performing POCT.**

29. Section 5.0, second paragraph, state that regulatory requirements should be considered first instead of early on.

- **The subcommittee does not believe the recommended change is needed.**

Section 6.1

30. A bullet should be included to Section 6.1, "Provide quality oversight."

- **The section has been revised to incorporate the recommended statement.**

Section 6.2

31. Add two bullets to Section 6.2, "Establish charges" and "Meet with the physicians and nursing staff."

- **The following two bullets have been added:**
  - **Assistance with billing policies**
  - **Development of working relationship with physicians, nursing staff, or other individuals involved in POCT.**

Section 7.0

32. The following written procedures should be included in addition to the items listed in Section 7.0: instrument performance checks and preventative maintenance, patient preparation, calculation of results, clinical interpretations, interferences, unacceptable specimens, imprecision, linearity, and sensitivity.

- **The recommended written procedures in Section 7 coincide with the recommended format in NCCLS document GP2—*Clinical Laboratory Technical Procedure Manuals* which is referenced in this section. Most of the commentor's recommendations are included under existing bulleted procedures. Users may add procedures as necessary to their manual.**

33. Incorporate "Purpose of Test" into the menu on procedures (page 14 [now page 15]).

- **The subcommittee agrees; the text is revised.**

34. Move the bullets on specimen collection and handling and stepwise instructions under bullet (1), principle of operation, and move preparation of reagents and other materials" nearer to the beginning, for proper flow of procedure.

- **The subcommittee has rearranged the bullets so the procedures appear in the same order as they do in NCCLS document GP2—*Clinical Laboratory Technical Procedure Manuals*.**

Section 8.0

35. A bullet should be included in Section 8.0, "Timely reporting and patient record documentation of test results."

- **An additional bullet is included as recommended.**

Section 8.1

36. The point-of-care organizational chart for in-hospital testing needs clarifications. The medical center director could be the pathology/laboratory medical director.

- **Sections 8 and 9 of the guideline have been revised to clarify the recommendations related to the organizational structure of the point-of-care testing program and to use terminology consistently throughout the document.**

37. The laboratory director, clinical consultant, and the technical consultant are not shown on the organizational chart: this is confusing. Their responsibilities should be designated as overseeing the POCT laboratory.

- **See response to Comment 36.**

38. The designation of point-of-care director is confusing and has more than one meaning in the document. Clarification of a single role for the point-of-care director needs to be done. I recommend using point-of-care testing director at the top of the organizational chart, and inserting individual point-of-care site directors for each particular testing site (nursing, clinics, others). Consistency in terminology needs to be used throughout the document.

- **See response to Comment 36.**

39. Section 8.1, last paragraph under "Testing Personnel" (pages 18-19 [now page 19]): a significant portion of POCT is in the waived category, e.g., whole blood glucose monitors. This section should be modified to address the fact. Modify to: "...part 493.1403, which describes requirements for moderate complexity testing. However, most POCT would be categorized as either waived or moderate complexity testing."

- **The subcommittee agrees; the text has been revised as recommended.**

40. The proposed "POCT Organizational Flow Chart" is too top heavy. POCT testing occurs at the base level, and should be designed for less-skilled staff to perform (with quality assured), therefore, reflecting a cost benefit. The definition of Point of Care Site Director is not needed, and most definitely not a doctoral-level position. Suggest the following organization, with members working as a committee:

    A. Medical director
    B. POCT coordinator
    C. Numerous technical/technologist representatives (depending on the size of the operation)
    D. Site manager/nursing manager
    E. Testing staff.

- **See response to Comment 36.**

41. Include medical records and information services on the point-of-care committee in the organizational chart and in Section 8.2, nonhospital based POCT.

- **See response to Comment 36.**

42. The point-of-care testing flow chart (page 17 [now page 18]) is needlessly complex. While each hospital will create its own structure, we have deliberately kept ours very simple. Our hospital has a broad certified clinical pathologist as the director of point-of-care testing, to whom a point-of-care testing coordinator (medical technologist) reports. The coordinator is responsible for ensuring that the various point-of-care testing sites conform to the requirements of the program. Technical concerns (e.g., instrument selections, Q.C., and proficiency testing) are handled by technical specialists within the appropriate clinical laboratory section. Our experience has shown that a point-of-care testing committee with broad representation from laboratory, nursing, administration, and physician end-users (critical care, anesthesiology, emergency) is essential to the success of the program, and this deserves emphasis.

- **See response to Comment 36.**

Section 9.1

43. The hospital should appoint a POCT site director who is a qualified pathologist. CLIA '88 regulations and the standards or private accreditation agencies notwithstanding, in my opinion, there is no basis for qualifying a person with a doctoral level degree as a clinical laboratory director unless that person has formal education and training in all laboratory disciplines being directed. Therefore, it is recommended that the hospital POCT site director either be a qualified pathologist or at least a person, with or without a doctoral degree, who has appropriate training and experience in each laboratory specialty involved in POCT.

- **The first bullet in Section 9.1 has been revised to address the comments**.

44. The POCT site director should be a medical or doctoral level degree individual.

- **See response to Comment 43**.

45. Revise bullet 3, under Hospital Point-of-Care Testing Coordinator, "The hospital POCT coordinator should establish and oversee a QC program."

- **The text has been revised to address the comment.**

46. Recommend putting the "Note" on page 23 at the front of Section 9.1.

- **The text has been revised as recommended.**

Section 10.2

47. The information on data management needs to be corrected. QC data has to be documented for review and documentation of problems. Also, the statement that instrument printouts can be saved in a logbook implies the patient results do not need to be recorded on the patient's chart, and they must be.

- **The subcommittee intended to address the location of quality control results. The section does not suggest that patient results be omitted from the chart.**

Section 10.2

48. Section 10.2, Qualitative and Semiquantitative Methods: Quality control cannot "ensure," i.e., guarantee, performance. Change to "monitor."

- **The text has been revised as recommended.**

49. Establish the running of controls to reflect each 8 hr. shift. Mandate the running of controls to precede patient testing or reporting results.

- **The subcommittee refers the user to regulatory requirements for when to perform quality control. The subcommittee recommends that the user follow (at the very least) the manufacturer's recommendations.**

50. Revise the statement under the bullet "Qualitative and Semiquantitative Methods" to read, "Generally, qualitative and semiquantitative methods do not require instrumentation."

- **The text has been revised to address this comment.**

51. Under "Qualitative and Semiquantitative Methods" and "Quantitative Methods," -specimen preparation, filtering and pipetting are not appropriate for POCT.

- **Although rarely required, the subcommittee believes these statements are appropriate, especially when the text procedure calls for performing these steps.**

52. Under "Quantitative Methods," - reportable ranges, add, "What to do when results are outside the range of the instrument?"

- **The text has been revised to address this comment.**

Section 11.0

53. Training is one of the essential parts of the successful POC testing program in facilities. Although training from manufacturers can be useful, actual training should be "in-house" and should include: overview of instrument; principle of test/instrument; facility's policy and procedure of instrument; operation of instrument; Q.C. testing/guidelines (including frequency, documentation, troubleshooting of "out-of-range" controls); patient testing (including specimen requirement, handling, reporting and documentation); operator competency testing and proficiency testing; preventive maintenance of instrument; troubleshooting of instrument; and return demonstration of instrument operation.

- **The subcommittee agrees; the text has been revised to address this comment.**

54. Training must be done regularly as staff changes frequently, especially nursing.

- **Section 11 has been revised to address this comment.**

Section 12.0

55. Cost considerations seem more related to hospital/medical center point-of-care testing.

- **Section 12 has been revised to provide recommendations that can be related to nonhospital POCT and hospital-based POCT.**

56. Management is included in both indirect and direct costs. Is this appropriate?

- **Management costs are generally considered to be indirect costs. Section 12 has been revised to include management cost under indirect cost only.**

57. In the second bullet under "Direct Cost," the amount of time to calculate under labor determinations should be clarified to mean personnel time.

- **The bullet has been revised as recommended.**

58. Other considerations in the cost analysis should include quality assurance and proficiency testing.

- **Proficiency testing and quality assurance have been added under the first bullet under "Direct Cost Calculations."**

59. Section 12.0, paragraph 1, third sentence: Change "must" to "should" to provide flexibility. Cost comparisons in this area have proven to be difficult. I suggest including references to the recent CAP conference that described some of the pitfalls an evaluator might encounter.

- **The text has been revised to use the word "should" instead of "must." The reference will be included in the bibliography section of the document.**

60. Neither Section 12.0 on cost accounting beginning on page 29 (now page 31) nor Section 13.0 on cost/benefit analysis beginning on page 33 (now page 34) appear to include test volume as a consideration. Although I do not have references, I have been assured by colleagues that several studies have been published which show point-of-care testing to be significantly more costly than testing performed in a central laboratory.

- **Test volume has been added to Section 13, Cost/Benefit Analysis.**

61. In the first paragraph of Section 12.0, QC and calibration materials should also be considered a component.

- **The subcommittee agrees; the text has been revised as recommended.**

62. Under direct cost calculations, include "proficiency testing cost" and "calibration costs" in the first bullet and "billing" in the fourth bullet under postanalytical tasks.

- **The text has been revised as recommended.**

Section 13.1(now Section 13)

63. Recommend to expand the bullets in Section 13.1 (now Section 13.0) to include total turn-around time for initial test order to provider utilization of test results, patient satisfaction, patient outcome and reimbursement.

- **The text has been revised to include total turnaround time and a definition has been included in Section 3.**

64. Revise the second bullet of Section 13.1 to state, "Length of patient stay . . ." and third bullet, "Patient comfort, patient satisfaction."

- **The text has been revised as recommended.**

Section 13.2 (now Section 13)

65. For POLs, many of the "In-Hospital Considerations" also apply, including TAT, clinical decisions based on rapid results, STAT testing requirements, laboratory and nonlaboratory staffing levels and physician's convenience. In addition, the desires of the patient are also a consideration.

- **The subcommittee agrees; the text has been revised to address the comment.**

Section 14.1

66. Revise the first paragraph of Section 14.1 to state, ". . . providing personal protection equipment, making available TB testing and hepatitis B vaccination . . ."

- **The text has been revised as recommended.**

Section 14.4

67. In some situations when no disposal containers are available, recapping is the safest option. In those cases, recapping may be done using a one-handed procedure.

- **The subcommittee followed OSHA guidelines for the disposal of needles. Users are asked to refer to OSHA rule 29 CFR §1919.1030(d)(2)(vii) and NCCLS document M29– *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue*, for more information.**

68. The correct term is "environmental services" instead of cleaning staff.

- **The text has been revised as recommended.**

Section 14.5

69. Section 14.5, under the bullet, "Protective Body Clothing" revise statement, "Workers should wear a long-sleeved laboratory coat which is buttoned closed and *impervious to liquids*" or *"an apron impervious to liquids*." Contaminated fluids will go through the usual laboratory garment.

- **The text has been revised as recommended**.

Section 14.6

70. Under "Facial Protection." While the listed devices do protect against direct spattering, they offer little in the way of protection to themselves, others in the laboratory or to the environment as a result of aerosols. Laboratories that handle any potential infectious material (as listed under Section 14.2) need total protection offered only by an appropriate biological safety cabinet used as directed.

- **The subcommittee believes that this issue is not applicable in the POCT setting.**

Section 14.7

71. Section 14.7, include a bullet, "Jewelry should be removed."

- **The subcommittee believes that this issue is not applicable in the POCT setting.**

Section 14.9

72. Bleach is not the only antiviral, antibacterial agent. Provide recommendations of other solvents that are equivalent.

- **The subcommittee believes that bleach is the most practical agent for use in a POCT setting. Users are**

referred to hospital laboratories and NCCLS document M29– *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue*, for more information.

Section 15.3

73. Specimen identification should include patient's name as well as a patient identification number.

- **The text has been revised as recommended.**

Section 16.0

74. The protocols and procedures outlined in Section 16, "Calibration and Calibration Verification" are too stringent and prescriptive. These protocols are based on traditional practices that might be appropriate for some currently available complex instruments, but new, sophisticated instruments and devices are also in use that make these procedures unwarranted and not cost- effective. For example, I cannot understand why three levels of a control are needed for devices that are designated to add convenience as an added value to health care. I suggest that the user be advised to consult the literature and the technical experts from the manufacturers of systems being considered. The manufacturer should be responsible for explaining how the system is calibrated (whether it is on-site or at the factory) and what steps are taken to provide confidence that the calibration is still effective in the user's hands. This might include the tedious approach of this document, but it might be an internal monitor, or a recommendation that is much more simple to perform—I hesitate to prescribe one method that is applicable to all eventualities. I recommend a sampling technique for periodic evaluation as an alternative. For instance, a small random sample of whole blood glucose monitors can be evaluated against a method from the central laboratory on a weekly or monthly basis. This would achieve the same objective as calibration verification: to verify that results meet the accuracy needs of the test in this environment.

- **Section 16 has been revised to address this comment.**

75. Since it is not practical to perform serial dilutions, the calibrators providing the highest level of reportable range must be used.

- **The subcommittee has included Section 16.3.3 for informational use.**

76. The discussion on reportable range appears to be inadequate. Specific guidelines should be included to address the necessary actions to be taken when patient results are outside of the instrument's reportable range.

- **The subcommittee agrees and has added a new Section 18 entitled, "Reportable Range."**

Section 17.0

77. Establish the use of tri-level controls and determine how to proceed if one control is out. Also, include paralleling new controls prior to the expiration date of old controls.

- **Not all POCT testing involves three levels of controls. Users are recommended to refer to manufacturer's instructions. Parallel testing is addressed in Section 17.3.1.**

78. Establish policy coordinating POCT and the clinical laboratory.

- **Section 8 addresses the organizational structure of POCT.**

Section 17.3.1

79. The second sentence should end with the statement, ". . . and the manufacturer's recommendations will have been sufficiently reviewed by the FDA."

- **Not all quality control materials are required to be reviewed. Unassayed controls are exempted from premarket notification and premarket approval. However, the manufacturer should comply with good manufacturing requirements and other general controls.**

Sections 17.3.4 and 17.3.5

80. It should be noted in Sections 17.3.4 and 17.3.5 that patient results must not be reported if control testing is out of range; and upon resolving the problem, where control results are within range, patient test results subsequent to resolving the problem can be reported.

- **The text of Sections 17.3.4 and 17.3.5 have been revised to address this comment.**

Section 17.4.2

81. The guideline recommends to use electronic test-simulator cards for single-use disposable test cartridges. The fact of the matter is that electronic test-simulator cards can only test the electronic circuitry in the instrument. The electronic simulator cannot evaluate reliability of the sensor card; therefore, it should not be used as a substitute for the QC solutions. The most effective means of ensuring reliability of patients' results is to run quality control solutions on sensor card samples from a given lot, preferably on a regular basis. The QC test should be performed in addition to the use of electronic simulator.

- **Section 17.4.2 has been revised to address this comment**.

Section 20.0

82. Section 20.0, entitled "Evaluation/Surveillance of Proficiency," first seems to confuse competency with proficiency. The issue of competency testing should be addressed in a separate section, for it is not proficiency testing.

- **The subcommittee agrees; information on competency testing has been added to the guideline in Section 9.1.**

83. POCT sites need only participate in proficiency testing if they have their own separate CLIA certificate. In-hospital POCT sites that come under the central laboratory's CLIA certificate would not be required by HCFA to participate in proficiency testing, unless POCT was the central laboratory's primary method for each test performed. Since it is highly doubtful that the central laboratory's primary method would involve the use of point-of-care testing devices, only a semiannual comparison of each POCT method/instrument to the central laboratory's primary method would be required. Proficiency testing is costly enough; let us not require more than is necessary to assure the accuracy of laboratory testing.

- **Proficiency testing is recommended for compliance with good laboratory practice. The POCT user is only required to meet regulatory requirements.**

84. A testing site doing only waived testing should still participate in proficiency testing as part of good laboratory practice. Some current providers of PT programs (e.g., AAFP, CAP, AAB) could be listed.

- **Section 20 has been revised to include these programs.**

Section 21.3.1

85. I'm not sure the POCT site will have the information to answer the questions on patient history as recommended in Section 21.3.1.

- **The subcommittee lists these only as recommendations.**

Section 22.0

86. There must be a written system in operation to routinely detect clerical errors, significant analytical errors and unreliable laboratory results. The system must provide for timely correction of errors.

- **The subcommittee believes the information provided is adequate for the target audience.**

87. Add "age" as a bullet under "Example of biological variation include:"

- **The text has been revised as recommended.**

Section 23.0

88. There should be evidence of periodic review of the QC data by the supervisor, POCT site director, or POCT coordinator.

- **The subcommittee agrees; the comment has been included in the text of Section 23.0.**

Section 23.2

89. Revise the bullet under the second paragraph of Section 23.2 to read, "When and what responses are made to 'out-of-control' results."

- **The bullet has been revised as recommended.**

Appendix D and Appendix E

90. Appendixes D & E should include a line at the bottom for supervisor review signature.

- **The subcommittee agrees; the appendixes have been revised as recommended.**

Related NCCLS Publications*

EP9-A **Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (1995)**. This document discusses procedures for determining relative bias between two methods or devices and the design of a method comparison experiment using split patient samples and analysis of data.

GP2-A3 **Clinical Laboratory Technical Procedure Manuals—Third Edition; Approved Guideline (1996)**. These guidelines address design, preparation, maintenance, and use of technical procedure manuals in the clinical laboratory.

GP11-A **Basic Cost Accounting for Clinical Services; Approved Guideline (1998)**. GP11-A provides principles and techniques to help laboratory managers establish a workable cost accounting system.

GP16-A **Routine Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline (1995).** GP16-A provides descriptions of routine urinalysis test procedures that address materials and equipment, macroscopic examinations, clinical analyses, and microscopic evaluations. Additional information outlining specimen collection, acceptable specimen criteria, and storage considerations is included.

GP16-T-V2 **Urinalysis - The Inside Story: Evaluation**. This videotape provides an overview of equipment, proper techniques, and quality that must be maintained to ensure accurate results of routine urinalysis is provided.

GP21-A **Training Verification for Laboratory Personnel; Approved Guideline (1995).** This guideline provides background and recommends an infrastructure for developing a training verification program that meets quality/regulatory objectives.

H3-A4 **Procedures for the Collection of Diagnostic Blood Specimens by Veni-puncture—Approved Standard; Fourth Edition (1998).** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.

H3-A4-V **Quality Venipuncture: The Key to Accurate Results**. This videotape highlights the most critical and common aspects of specimen collection by venipuncture to ensure accurate test results.

H4-A3 **Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture—Third Edition; Approved Standard (1991)**. H4-A3 provides detailed description and explanation of proper collection techniques and hazards to patients due to inappropriate specimen collection by skin puncture procedures.

H4-A3-V **Quality Microcollection**. This video tape gives details on the importance of blood collection and handling using the skin-puncture method. The tape also illustrates how to obtain the highest quality skin-puncture specimen for laboratory testing. It is divided into six sections: safety; advantages; supplies; skin-puncture procedure; handling and labeling; and a review of the skin puncture procedure.

*Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

M29-A **Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue—Approved Guideline (1997)**. A consolidation of M29-T2 and I17-P, this document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure.

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