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Wellness Testing Using IVD Devices; Approved Guideline

This document provides procedures and recommendations for implementing a quality wellness testing program.

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Wellness Testing Using IVD Devices; Approved Guideline

Abstract

Wellness Testing Using IVD Devices; Approved Guideline (NCCLS document AST3-A) provides useful information to directors of wellness testing services to assist them in implementing a quality program. The guideline addresses preanalytical and postanalytical considerations and safety and training issues related to wellness testing using IVD devices. While the guideline does not specify which tests should be included in a wellness program,it includes recommendations for providing accurate and adequate information as well as referring participants to clinicians for subsequent follow-up, depending on the results obtained from common wellness tests.

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Wellness Testing Using IVD Devices; Approved Guideline

Volume 19 Number 4

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Contents

Foreword

For many years, NCCLS has been the leading standards organization for medical testing. Through NCCLS, individual laboratories and healthcare institutions, laboratory and clinical professional societies, manufacturers and suppliers of products for medical testing, and regulatory and scientific agencies of federal and local governments cooperate to develop, evaluate, and implement voluntary standards and guidelines that support the delivery of quality patient care. The NCCLS consensus process has generated a vital professional dialogue within the clinical laboratory testing community, as well as more recently, with those professionals involved in providing medical testing services outside the traditional clinical laboratory.

Advances in technology and implementation of the use of portable instruments have made laboratory testing more available to the general public through wellness testing programs. This document addresses wellness testing programs which provide simple screening tests using *in vitro* diagnostic (IVD) devices intended to aid in the diagnosis of asymptomatic/preclinical disease or to confirm a state of health. (It is important to note that, in the United States, testing provided by wellness programs is considered laboratory testing, and federal and local regulatory requirements for such testing apply.)

The performance of wellness testing at sites other than the conventional clinical laboratory is on the increase and gaining popularity. In addition to the obvious concerns of accuracy of test results and safety at the testing site, wellness testing programs present major issues. These issues deal with public education, awareness of test benefits, understanding the significance of a result, and most importantly, follow-up for those at risk.

This guideline provides useful information to directors and operators of wellness testing services to assist them in implementing a quality program. It addresses preanalytical and postanalytical considerations and safety and training issues related to wellness testing using IVD devices. Recommendations for providing participants in wellness testing with accurate and adequate information, along with recommendations for referring participants to clinicians for subsequent follow-up are also provided.

Wellness screening is a useful and important healthcare tool. When applied properly, this tool can provide better quality of life and can cut healthcare costs. This guideline is intended to improve service to the public by providing recommendations on establishing protocols and assigning responsibilities to people offering wellness testing services. It is written to help all those involved in providing these services. Guidelines for the conduct of wellness testing can have a positive effect on the quality of service provided to recipients.

Key Words

Alternative site, in vitro diagnostic devices (IVD), safety, universal precautions, wellness testing.

Wellness Testing Using IVD Devices; Approved Guideline

1 Introduction

Wellness testing at sites other than the conventional clinical laboratory is increasing and is being conducted in a variety of public locations, such as shopping malls, health clubs, pharmacies, the workplace, and others.

Participant testing in wellness programs is different from most medical laboratory testing. Usually the wellness test request is participant-initiated and, often, the participant is not associated with a healthcare practitioner who is obligated to review results and take appropriate action. *The responsibility for understanding and implementing safe and effective performance of wellness testing rests with the provider*. Therefore, for the testing program to be effective, it should provide the medical reasoning necessary to choose appropriate tests, inform the participant about the interpretation of those tests, and recommend further action.

To assist providers of wellness testing, this guideline includes recommendations for training and educating operators of *in vitro* diagnostic (IVD) devices, including how to adhere to universal precautions when handling human body specimens and disposing of biohazardous waste. While this guideline does not specify which tests to include in a wellness program, it does include recommendations for referring participants to clinicians for subsequent follow-up.

2 Scope

Healthcare providers, industrial corporations, municipal governments, schools, pharmacies, shopping malls, and health departments may provide wellness testing facilities for the public. Usually, requests for tests in wellness testing programs are self-initiated and participants expect to receive informative, interpretative information. This guideline provides recommendations to directors of wellness testing programs to assist them in providing a quality wellness testing program and recommendations on training wellness testing operators in giving participants accurate and adequate information. This information should be developed according to good risk communication principles (see Appendix A of NCCLS GP14-A).

Wellness testing programs provide information on risk factors and health status. Distribution of wellness literature (not necessarily related to testing) is an integral role of wellness centers. Operators should be prepared to provide the participant pertinent information on the test. This guideline, focuses on ways to create public awareness of relevant wellness tests, their significance and follow-up, as well as effective means for referring those found to be at risk to healthcare facilities.

Although AST3-A focuses on IVD devices, it does not cover technical issues that pertain to test methodology or performance.

3 Definitions[a]

Alternative site, *n* - Any location, other than a hospital or commercial laboratory, used in the collection and testing of human specimens for the purpose of obtaining results used in the diagnosis of disease, risk of disease, or other health conditions.

Hazardous material, *n* - Any substance that poses an immediate or potential threat to human health or to the environment, and which requires special handling, processing, or disposal because it is toxic, infectious, carcinogenic, explosive, or reactive.

In vitro diagnostic (IVD) devices, *n* - Those reagents, instruments, and systems intended for use in the diagnosis of disease or other health conditions and to assist in curing, detecting, mitigating, treating, or preventing disease. **NOTE:** These devices are intended for use in the collection, preparation, testing, and examination of specimens taken from the human body.

Operator, *n* - A person who collects the specimen and/or performs the test.

[a] 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.

Diagnostic specimen, *n* - Any human or animal material that is to be used for diagnostic testing, including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids.

Reference range//Reference interval//(Normal range) *n* - The range of test values expected for a designated population of individuals. **(US CFR493 February 28, 1992) NOTE:** For example, 95 percent of individuals that are presumed to be healthy (or normal).

Reportable range, *n* - The range of test values over which the relationship between the instrument, kit, or system's measurement response is shown to be valid. **(US CFR493 February 28, 1992)**

Training, *n* - The education, instruction, or discipline of a person. **NOTE**: The term "training" is used in this document in a general sense. Training is addressed in the discussion of safety issues and in the discussion of pre- and postanalytical variables.

Standard precautions, *n* - Those precautions (as defined and recommended by the Centers for Disease Control and Prevention) to be observed by operator during the collection and handling of human biological specimens. (See Section 5.2.5.)

Wellness testing, *n* - Any diagnostic testing intended to aid in the recognition of asymptomatic/preclinical disease, or to confirm a state of health.

4 Criteria for Choosing Tests

When choosing tests that will be performed as part of a wellness program, consider testing for disorders in which there is a high frequency of occurrence (e.g., heart diseases, cancer, hypertension, diabetes) and effective intervention, as well as for other disorders for which treatments are available. Also, consider using tests that are inexpensive, easy to perform, reliable, and accurate.

5 Safety

5.1 Components of a Safe Environment

It is important that the testing program ensure a safe environment, which includes the following components:

- Protection of operators, participants, bystanders, and observers from harm.
- Ability to respond to emergencies.
- Appropriate infection-control standards.
- Privacy of the participant and confidentiality of results.
- Availability by telephone of a consultant familiar with *wellness* testing issues, such as test interpretation.

Key elements of a safe environment are addressed in the following NCCLS documents: H3 *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture;* M29 *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue;* and GP5 *Clinical Laboratory Waste Management.*

5.2 Safety Recommendations

5.2.1 Emergency Plan

A plan should be in place that will ensure immediate access to appropriate services to handle medical emergencies, such as fainting and excessive bleeding. Appropriate supplies, such as spirits of ammonia or fruit juice, should be available for use in the treatment of fainting or other medical emergencies. If federal, state, or local ordinances require that operators be certified in cardiopulmonary resuscitation (CPR), an appropriate mechanism for meeting this regulation should be included in the emergency plan.

5.2.2 Incident Documentation and Reporting

Establish organizational operating procedures for documenting and reporting incidents, such as an exposure incident, i.e., a specific eye, mouth, other mucous membrane, nonintact

skin, or parenteral contact with blood or other potentially infectious material that results from the performance of an employee's duties.[1]

5.2.3 Health Policies

Establish practices and procedures that maintain organizational employee health policies and conform to state regulations concerning healthcare workers. All pertinent infectious and contagious diseases should be covered in these policies and practices. For example:

- Where required by the sponsoring organization or by local ordinance, operators should be tested for tuberculosis (TB) and found to have negative TB skin test or negative chest film results. In the case of a positive result for a TB skin test or chest film, take appropriate action as required by the organization or local ordinance.

- Provide education and training on standards for protective clothing and equipment. NCCLS document M29 *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue,* deals specifically with these issues.

- Establish baseline hepatitis B antibody titers on test operators and offer the hepatitis B vaccine. If an operator declines the offer of the vaccine, it should be documented.

- Follow standard precautions (see Section 5.2.5).

5.2.4 Infection-Control Standards

Implement infection-control standards that are consistent with current regional regulations. Establish procedures for response in the case of accidental exposure (e.g., a needlestick).

Using a vigorous rubbing technique, cleanse the finger of the participant with either iodophor or isopropyl alcohol for 15 to 30 seconds, and let the area dry completely before attempting a fingerstick. This is a general recommendation. More stringent requirements may be necessary for specific tests e.g., coagulation test, blood glucose, and blood lead. (See NCCLS document H4 *Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture* which describes the technique for cleansing the skin-puncture site, and C40 *Analytical Procedures for the Determination of Lead in Blood and Urine*.)

5.2.5 Standard Precautions

Because it is often impossible to know which might be infectious, all patient blood specimens are to be treated with standard precautions. 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*.

These precautions include the following guidelines:

- Use gloves for fingerstick and any other type of specimen collection.

- Change gloves between patients.

- Operators using spring-loaded lancet devices should replace the lancet and platform or endcap after each use, unless the entire unit is disposable. Do not use spring-loaded lancet devices without replaceable platforms.

- Use a 0.5%-sodium hypochlorite and water solution to clean surfaces that are contaminated with blood and body fluids. This solution may be made by mixing 1 volume of household bleach with 9 volumes of water.

- Keep the testing area clean.

- Discard used material immediately after use.

- Dispose of capillary tubes and lancets in a closable, leakproof, puncture-resistant sharps container that is labeled "biohazardous waste."

- Process puncture-resistant sharps disposal containers according to established safety standards.

- Discard nonsharp articles in a biohazard bag; do not mingle this refuse with food or other unrelated refuse.

- Dispose of infectious waste in compliance with applicable regional regulations concerning medical waste.

5.3 Creation of an Organized Testing Environment that Facilitates Success

The physical environment in which wellness testing is performed is important to the success of the program. For example, well-planned programs for smooth handling of participant flow leave participants with favorable impressions of the experience and, generally, contribute to an improved quality of outcome. Also, operators work and adhere to quality control procedures more effectively in such an environment.

This document is not a comprehensive plan for the organization and operation of public wellness-testing programs, although these elements are important. Wellness-testing programs should include the following elements:

- Settings that provide easy access for everyone (including rural and poor urban populations, the elderly, and patients using wheelchairs) and that are conducive to handling the flow of participants. The layout should provide privacy during sampling, ensure confidentiality of results, and promote communication between participants and staff.

- Adequate staffing and equipment to minimize the likelihood of a stressed, hurried environment that is not associated with high quality.

- A clean and appropriate location.

- A test system used as specified in the manufacturer's literature.

Venipuncture wounds resulting from specimen collection should be covered with a sterile gauze adhesive strip (bandage) following sample collection. Keep participants in the testing area until bleeding from the fingerstick or phlebotomy ceases.

Wellness-testing programs should be operated in accordance with applicable federal, state, and local regulations.

6 Operator Training and Responsibilities

Give staff at public wellness-testing centers training that facilitates the performance of their duties. They should be taught by healthcare professionals with experience in the detection and measurement of analytes, and in the management of the information evaluated in a wellness-testing environment. As information and/or procedures change, training of staff should continue. Training programs should include hands-on practice and testing of competency, both on paper and in practice, followed by documentation of performance. The assessment tool used should demonstrate achievement of a requisite level of knowledge, as well as skills in the tasks required.

6.1 General Training Recommendations

Educate all wellness-testing staff on the following topics:

- Purpose and objectives of the testing program.

- Importance of professional appearance and conduct.

- Procedures to deal with emergency situations, such as fainting and anxiety reactions.

- Methodology and importance of accurate measurements, careful reporting, and documentation of wellness-testing activities.

- Safe setup and operation of the equipment.

- Infection control, hazardous waste disposal, and other safety measures.

- Calibration of the equipment and reportable range.

- Quality assurance standards and procedures.

- Test-specific storage and preservation of specimens. When testing is provided at a remote testing site, the testing laboratory must be identified.

- Process and skills involved in education, counseling, classification, referral, and follow-up of participants.

- Written documentation of training.

Because errors in measurement frequently originate in poor sampling methods, staff who collect blood from participants should be properly trained and have documented competency when venipuncture is involved. They should have a clear understanding of skin-puncture and/or phlebotomy specimen-collection methodology.

Staff should receive education on and demonstrate an understanding of safe techniques for infection control and prevention.[b]

6.2 Responsibilities of the Director

The director of a wellness-testing program performs specific responsibilities. The director should be qualified to manage the operator who performs testing and should meet applicable regulatory requirements (e.g., in the U.S., CLIA[2]). The director should be accessible to the staff for consultation, as needed. The director is responsible for the overall operation of the program, including employing competent operators, providing for accurate and reliable test results, and assuring compliance with applicable regulations. In addition, the director is responsible for:

- Maintaining the quality of all aspects of the testing process (preanalytic, analytic, and postanalytic), including the effectiveness of quality control, quality assurance, and proficiency testing programs.

- Determining the requirements for a participant consult form and the pertinent content as appropriate.

- Ensuring: that test systems are appropriate and provide the quality of results required for the population tested; that performance characteristics have been verified; that acceptable levels of analytic performance are maintained; and that appropriate reference ranges are established.

- Ensuring medical review and interpretation of results.

- Ensuring that information is available to participants on matters related to the quality, significance, and interpretation of test results. This information should be developed and approved by a healthcare practitioner credentialed and skilled in preparing patient information, particularly on testing processes and on test interpretation. Educational information should be written in simple, clear language.

- Ensuring that the physical environment of the site is safe and appropriate for the testing performed.

- Employing a sufficient number of test operators who have the appropriate education, training, or experience and monitoring their performance to ensure competency.

- Ensuring that an approved procedure manual is available to operators.

- Ensuring that records are kept for a period of time which is consistent with regulatory requirements and other legal considerations.

- Considering whether to survey participants for satisfaction with service and to find out whether recommendations were followed.

6.3 Selection, Training, and Responsibilities of the Test Operator

6.3.1 Selection and Training of Test Operators

Every operator who performs testing for wellness programs should meet applicable federal and state regulatory requirements for education, training, and experience. Before analyzing specimens, every operator should have documented education and training appropriate for the testing performed. Such training should furnish the operator with the following skills:

[b] In the U.S., this should include education on the CDC recommendations for preventing the transmission of infectious disease in healthcare settings.

- The skills required for proper specimen collection (including participant preparation, if applicable), labeling (e.g., full donor name, identification number of donor, date/time of collection, identification of phlebotomist), handling, preservation, processing, transportation, storage, and disposal.

- The skills required to perform testing procedures, including proper kit or instrument use, per the manufacturer's instructions.

- The skills required to perform preventive maintenance, troubleshooting, and calibration procedures related to each test system.

- The skills required to implement quality control procedures and to verify the validity of participant results through the evaluation of control results.

- A working knowledge of reagent stability, storage, and preparation, as applicable to the test methods.

- An awareness of the factors that affect test results such as interfering substances: specimen turbidity and environmental conditions.

Regardless of their background (e.g., as nurses, laboratory technicians, or technologists) all operators should be trained appropriately. Training conducted by individuals experienced in laboratory procedures and protocol should consist of classroom instruction and direct hands-on experience in: setup and operation of the test method or system; in detecting problems; in performing required maintenance; and in performing quality control procedures. Operators should have an adequate, documented, supervised field experience operating the devices before testing on their own. Provide supplemental training where the quality assurance program (see Section 7) detects a departure from expected quality that is traceable to performance.

6.3.2 Responsibilities of the Operator

Test operators are responsible for specimen collection, processing, test performance, troubleshooting, maintaining patient confidentiality, and reporting results. Each operator should perform only tests or functions authorized by the director and for which the person has the appropriate technical skills and education, training, or experience.

Additional operator responsibilities include:

- Following procedures for specimen handling and processing, test analyses, and reporting test results.

- Adhering to quality control policies, documenting all quality control activities, instrument and method calibrations, performance and maintenance.

- Following established corrective action policies and procedures whenever test systems are not within established acceptable levels of performance.

- Identifying problems that could adversely affect test performance or reporting of test results and either correcting the problems or notifying superiors.

- Documenting all corrective actions when test systems deviate from established performance specifications.

6.4 Training Staff Who Provide Educational Information

Testing center operators who provide educational information to participants should receive training in the delivery of accurate educational messages. This includes teaching skills for clear, credible, and persuasive educational counseling. The operator providing participant education should be skilled in providing documentation on the referral and follow-up process (see Section 9).

7 Quality Assurance (QA)

Written quality assurance (QA) policies and procedures should be established to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, and postanalytic). The quality assurance policies should be consistent with all applicable regulatory requirements. The QA program should evaluate the effectiveness of the testing center's policies and procedures, identify and

correct problems, assure accurate and reliable test results, and ensure the adequacy and competency of the staff. Based on the results of these evaluations, the director should then approve and update all policies and procedures, as necessary. All QA activities should be documented.

The QA program should provide an ongoing mechanism to assess and revise the following items, as necessary:

- Test-specific procedures for specimen collection, labeling, preservation, and transport; criteria and policies for accepting or rejecting specimens.
- Information to be obtained from participants.
- The test result report and the accuracy, reliability, clarity and timeliness of reporting systems; record storage and retrieval.
- Quality control policies and procedures plus documented corrective actions taken when problems are identified, for example, with control results, reference ranges, or reported results. Quality control procedures and calibrations when required should be performed at the testing site, and should be performed by the same personnel performing patient testing.
- Policies and procedures that ensure operator competency.
- Written documentation of quality control and patient results, incident and other relevant information. Logs (records) should be documented and the logs (records) should be available for inspection for a duration determined by the program.
- Evaluate and compare test results when the same test is performed using more than one method or instrument, or in multiple testing sites.
- Identify and evaluate participant test results that appear inconsistent with criteria, such as age, sex, pertinent clinical data, distribution of overall test results, and relationship to other test parameters, when available.
- Document and resolve problems in communication between the program staff/operators and participants receiving the results; and complaints received by the program.
- Document and assess problems identified during QA reviews, discuss them with staff, and take necessary action to prevent recurrence.

8 Preanalytical Testing Considerations

Testing of participants in wellness programs is different from most medical laboratory testing. Usually, the wellness test request is participant-initiated and, often, the participant is not associated with a healthcare practitioner who is obligated to review results and take appropriate action. *Therefore, the testing program should provide the medical reasoning necessary to choose the appropriate tests and inform the participant about those tests. Information on participant preparation for testing should include any dietary, medication, and activity instructions. These written instructions are specific to each test. Written instructions about time, place, and organization of specimen-collection mechanisms, as well as participant preparation should also be explicit in the public relations and promotional materials for each event.*

The specimen-collection process should be orderly and organized. Respect the privacy of participants. Provide participants who react unfavorably to blood collection (phlebotomy or skin puncture) with a private, quiet place to recline while they regain composure. Enforce universal precautions procedures. For more information on blood collection procedures, refer to NCCLS document H3 *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture* as well as NCCLS document H4 *Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture.*

Specimen labeling and preparation should adhere to standard practices. Because sampling occurs in a nonlaboratory setting, pay special attention to time and temperature requirements for specimen centrifugation, transport, and storage.

9 Postanalytical Considerations and Providing Participant Information

The most important postanalytical consideration is the appropriate use of the wellness testing result. Participant-initiated testing is frequently performed without a healthcare practitioner who will accept responsibility for each participant's result. The director is responsible for the medical review of the results.

The primary goal of medical review is to decide how to advise the participant. The review process determines the content of that advice and the timeliness or urgency of its delivery. Most participants can be described as "well," "worried but well," or "relatively asymptomatic with an occult condition." It is rare to encounter a seriously abnormal result that requires that the participant be notified immediately. However, a policy should exist for that contingency. The participant has the following choices:

- Do nothing with the recommendation.
- Review normal results with their physicians at the time of their next regular appointment.
- Make an immediate appointment with an appropriately credentialed healthcare practitioner to discuss the results.

The advice to the participant should provide clear guidance in choosing among the alternatives and should be developed in consultation with and approval by an appropriately credentialed healthcare practitioner. Take care to prevent a participant from unilaterally deciding to alter compliance with previous physician orders.

Protect the results of participant-initiated testing with standard confidentiality policies. Results can be shared only with the participant's permission. Results should not be given to a healthcare practitioner not associated with the wellness program without specific permission from the participant. Therefore, policies should exist that address transmission of the participant's results.

The participant rightfully expects to receive informative, interpretive information. To provide a result without addressing the medical assessment of the result is to avoid legal and medical responsibility, as well as to ignore the participant's appropriate expectations. A wellness letter should be developed providing participants with general and descriptive comments about each test provided and the language level appropriate for the targeted population. The letter should be developed by someone skilled in effective risk communication to consumers.[3,4] For example it is suggested the letter include:

- the limitations of the test.
- normal/reference range of results.
- the interpretation of the test result(s).
- cautions to observe which may affect the test result.
- associated risk factors.
- the need for physician follow up.
- a telephone number for additional information (as available).

When specific abnormalities or combinations of abnormalities are encountered, a participant rightfully expects to receive additional information. Brief explanatory paragraphs should be included with a wellness letter if abnormalities are encountered.[3] The participant needs to know if the abnormality requires immediate attention from a healthcare practitioner, attention at a convenient time from a healthcare practitioner, or if it is of relatively little concern.

Records should be kept for a period of time which is consistent with regulatory requirements and other legal considerations.

References

1. Occupational Safety and Health Administration. Occupational Exposure to Bloodborne Pathogens; Final Rule (29 CFR Part 1910.1030). *Federal Register*. December 6, 1991;235:64175-64182.

2. Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988; Final Rule (42 CFR Part 405). *Federal Register*. February 28, 1992 (57 FR 7002).

3. Witte DL, Angstadt DS, Schweitzer JK. Chemistry profiles in wellness programs: Test selection and participant outcomes. *Clin Chem.* 1988;34:1447-1450.

4. Witte DL. Wellness testing: Design and experience of an established program. *Clin Lab Med.* 1993;13:481-490.

Summary of Comments and Subcommittee Responses

AST3-P: *Wellness Testing Using IVD Devices; Proposed Guideline*

General Comments

1. The guideline correctly points out the proliferation of wellness testing in a variety of settings, but fails to analyze who is providing the testing at such site. Consequently, it presents a very uneven level of detail. Much more discussion should be dedicated to: requirements of a wellness testing program, records required to be maintained on site vs. at the core laboratory, regulatory agencies who may need to be involved with setting up and maintaining the site, some basic discussion of the complexity model from CLIA, the whole question of licensure in general.

- **The subcommittee thanks the commenter and has incorporated revisions where appropriate. Revisions on maintaining records are located in Sections 6.2 and 9. Regulatory agencies are not listed because they would vary from region to region and a compiled list would be difficult to generate. The issue on licensure is also related to the local and regional regulatory requirements. A discussion of the complexity model from CLIA would be limited to the U.S. which would be inconsistent with NCCLS s objective of globalizing its documents.**

2. The more common "wellness testing" site is the temporary "health fair." Again, most health fairs are sponsored by some sort of parent testing organization and testing is not typically performed on site. The guidelines should identify what procedures should be in place for remote specimen collection. If some of these sites do perform testing, several questions should be addressed by the guideline, including: What procedures and records would need to be on site? Who should be custodian of testing records? What QC/QA practices should be followed for a temporary testing location. At what point does the result undergo medical review?

- **The subcommittee thanks the commenter and has incorporated revisions regarding the concerns mentioned where appropriate. Revisions regarding remote specimen testing are in Section 6.1. Revisions regarding QC/QA practices are included in Section 7, bullet 4.**

3. Overall, the document attempts to set guidelines for wellness testing in general. It is our recommendation that AST3-P be revised to address four types of wellness testing situations as depicted in the following matrix.

	Temporary Site	Permanent Site
Testing performed on site	X	X
Testing not performed on site	X	X

- **Section 5.3 was revised to emphasize that the subcommittee did not intend to provide a comprehensive plan for the organization and operation of a public wellness-testing plan. They also believe that the requirements are the same and do not want to be repetitious. However, after carefully discussing this recommendation, specimen preservation has been added for those cases in which the specimens are not tested on site.**

4. I could not find reference to the concept of informed consent of the participant. The informed consent provides the wellness testing site an opportunity to describe the testing process and what the participant can expect. It is especially important to mention that, depending on the wellness event, blood may or may not be taken. An individual that comes for a "cholesterol screening" may be ready only for a dietary overview of the foods that he/she is consuming and will be very surprised when blood is withdrawn from them and tested. Finally, a signed informed consent

form should cover many legal issues. An example included in the proposed guidelines would be very helpful.

- **Due to differences in regional requirements and specific test requirements, the subcommittee encourages users to design their own consent form with the information described in the text.**

5. This document is just another version, albeit easier to understand, of the CLIA test that appears in the Federal Register. Cannot we as laboratorians add anything of value to the current federal law to aid those individuals that are performing or directing wellness testing? There were a few statements, for instance "after sample collection, use bandages to cover the puncture site," that I would think would be helpful. Drawing from my experience of directing a wellness program with no outside help, I would have liked to see examples of good workflow design, patient throughput design, checklists for training, checklists for pre- and post-wellness testing (check inventory/supply, review QC), ideas for analyzers (throughput, batch vs random access) and their different demands.

   Of most help would have been the sample follow-up letter to participants and suggested test-specific explanatory addenda for abnormal test results. Many of us who use NCCLS documents go directly to the examples and use these as our reference points.

- **The subcommittee agrees that the document should provide aid to those individuals that are performing or directing wellness testing and has tried to design AST3-A to do so. The subcommittee believes the suggested examples are beyond the scope of the document.**

6. In my experience, wellness testing itself has not been performed by individuals with similar titles/credentials that appear on the members of the subcommittee. I realize the context of this document is for the "Director" of the program but the document does not define the word. It is stated in the Foreword that the document is to "assist them (the Director) in implementing a quality wellness testing program." If NCCLS has decided to recognize only those individuals that meet the Director qualifications as defined in CLIA 88 then it should be stated. It has been my experience that the individuals responsible for "directing" or implementing and working in the wellness testing arena are: RNs, nutritionists, LPNs, MTs, MLTs, phlebotomists, and medical assistants. I understand that NCCLS Subcommittee on Wellness Testing should not necessarily require all its subcommittee members to be individuals from these groups but at least one representative would seem appropriate for this subcommittee. NCCLS may distribute the documents to these individuals but comments are entirely different from voting privileges.

- **As part of the consensus review process, the subcommittee solicited as much input as possible from all user groups, including individuals actually performing wellness testing and "directors" of wellness testing programs. Use of the term "director" in this document is clarified in Section 6.2 which recommends they meet applicable regulatory requirements.**

Section 5.2.5

7. The ninth bullet, last should be "standards," not "standards."

- **The editorial correction has been made.**

8. The fourth bullet, on cleansing the finger is a part of a collection procedure, not universal precautions. This could be included under 5.2.4 Infection-Control Standards.

- **The fourth bullet has been moved to Section 5.2.4 and the following sentences have been added: This is a general recommendation. More stringent requirements may be necessary for a specific test (e.g., blood lead).**

Section 5.3

9. "After sample collection, use bandages to cover the puncture site..." Fourth bullet: I would suggest changing the wording to state "All puncture wounds resulting from specimen collection must be covered with a sterile gauze adhesive strip (bandage) following sample collection" (Mass DPH Regulations on Public Screening). Some of our wellness testing sites used gauze alone (not bandaid like and without adhesive) and we found gauze lying on the floor down the hall from the site. This incident caused a major infectious disease issue!

- **The first sentence of the fourth bullet has been revised to incorporate the commenter s suggested wording.**

Section 6.1

10. Second paragraph, last sentence - Change "sample-collection" to "*specimen-collection*" to be consistent with other NCCLS documents.

- **The commenter s suggestion has been incorporated.**

Section 6.2

11. Second bullet, last line - Add "*(normal ranges)*" between "ranges" and "are" to improve the clarity of the guideline by including new and old terminology.

- **The subcommittee defined reference range in Section 3, Definitions.**

12. This section is silent on "Reportable Range" which is part of CLIA requirements. Therefore, the subcommittee may wish to address and/or include it in order to be consistent with federal code. *Federal Register*/Vol. 57, No. 40/Friday, February 28, 1992/Rules and Regulations/Page 7140: *Reportable Range* means the range of test values over which the relationship between the instrument, kit, or system s measurements response is shown to be valid.

- **In Section 6.1, the following new seventh bullet has been added: Calibration of the equipment and reportable range. Reportable range has also been defined in Section 3: Definitions.**

13. This section does not actually address professional qualifications for director of wellness testing program.

- **In the Foreword and Section 6.2, the guideline emphasizes that the wellness program and the director should meet applicable regulatory requirements. Because these requirements may vary, the subcommittee encourages the user to inquire about the applicable regulatory requirements.**

14. My reading of this statement appears to limit the review to a Physician (M.D., D.O.). It could be that it is because of my hospital background that I interpreted this statement as a responsibility of a physician. Although later in the document it is explained, this statement appears confusing as to what "medical review" means. Does "medical review" mean only a physician can review and interpret this result? Or does this mean that only a physician can review data generated at the wellness site? Clearly, for many tests a physician reviewing and interpreting the results is not necessary.

- **In the fourth bullet, the subcommittee replaced "providing" with "ensuring."**

Section 6.3.1

15. First bullet - Insert "(*e.g., full donor name, identification number of donor, date/time of collection, identification of phlebotomist*)" between "labeling" and "handling" to help reduce specimen misidentification.

- **The commenter's suggestion has been incorporated.**

16. Last bullet - Add "*(e.g., interfering substances: specimen turbidity, environmental conditions)*" between "factors" and "that" to emphasize the importance of recognizing and/or controlling variables that can influence the accuracy of test results.

- **The commenter's suggestion has been incorporated.**

Section 6.3.2

17. Fourth bullet - Add "This includes the quarantine of test results until accuracy has been verified." This reminder of quarantining suspect results may help ensure the accuracy of reported assay values.

- **The subcommittee believes that this statement would be redundant and that it is covered in other places of the document.**

Section 7

18. Survey participants for satisfaction with service and to find out whether recommendations were followed. This is especially important when the recommendation was to make an immediate appointment with a healthcare practitioner.

- **The following bulleted statement has been added to Section 6.2. "Considering whether to survey participants for satisfaction with service and to find out whether recommendations were followed."**

19. Add the word "written" after the word "Establish." QA policies and procedures should be in writing.

- **The commenter's suggestion has been incorporated.**

20. The QA program should also include a review of not only the criteria for unacceptable specimens but also a policy for action to be taken if the specimen is unacceptable.

- **The first bullet has been revised to: "Test-specific procedures for specimen collection, labeling, preservation, and transport; criteria and policies for accepting or rejecting specimens."**

21. The document should have a mention that Quality Control (if required, i.e. for analyzers) should be performed at the screening site. Many times I have found individuals wishing to perform the QC back at our hospital (sometimes the day prior), then bringing the instrument to the testing site and then testing patients. Had something happened in transport? One would never know.

- **The following sentence has been added to the fourth bullet: "Quality control procedures and calibrations when required should be performed at the testing site."**

22. If multiple analyzers/methods are used in one site there should be a correlation between them established. This is to avoid CLIA requirement problems for tests of moderate and high complexity and to ensure all stations agree with one another. Or, if follow-up will be performed

at the institution that is sponsoring the wellness testing has a laboratory, then a correlation should be established between the testing site and the reference laboratory.

- **This issue has been addressed in the seventh bullet.**

Section 9

23. First paragraph - In the second sentence, change "healthcare practitioner" to "licensed physician. "Healthcare practitioner" should be included in Section 3: Definitions, or a more recognized description should be used in the text.

- **The subcommittee does not agree with this suggestion because the statement is not specifically directed towards physicians.**

24. Second paragraph, sixth sentence - "The usual situation involves . . . . discuss the results." The whole sentence is somewhat difficult to read and fully understand. For example, "who "is" choosing to do nothing with the recommendation" is not clear.

- **This sentence has been revised and divided into bullets.**

25. I would like to see the more important issues bulleted and not mixed-in with flowing paragraphs. The proposed guidelines bullet other information but not the pre- and post-analytical considerations.

- **Section 9 has been revised and has incorporated bullets as suggested.**

26. Fourth Paragraph: It would be helpful to a director of a wellness program if NCCLS gave some information to help outline what good interpretive information means and what should be included in general and descriptive comments.

    Our state agency requires, and is good advice, all individuals to be provided with a confidential written test report that includes pertinent educational materials including, but not limited to, the following information:

    the limitations of the test
    the interpretation of the test result(s)
    associated risk factors
    the need for physician follow up
    a telephone number for additional information (if additional information is available)

    I would also suggest including:

    normal/reference range of results
    cautions to observe which may affect the test result (could be covered under limitations of the test

- **The subcommittee agrees with the commenter's advice and has incorporated the above bulleted items into Section 9.**

Related NCCLS Publications*

C40-P **Analytical Procedures for the Determination of Lead in Blood and Urine; Proposed Guideline (1998).** Guidance for the measurement of lead in blood and urine, including specimen collection, measurement by GFAAS and ASV, quality assurance, and quality control.

GP5-A **Clinical Laboratory Waste Management; Approved Guideline (1993)**. GP5-A offers guidance on the safe handling and disposal of chemical, infectious, radioactive, and physical waste generated in the clinical laboratory.

GP14-A **Labeling of Home-Use In Vitro Testing Products; Approved Guideline (1996).** This document contains specifications and recommendations for label preparation for over-the-counter in vitro testing products.

GP21-A **Training Verification for Laboratory Operator; Approved Guideline (1995).** The document 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 Venipuncture; 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.

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

M29-A **Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Approved Guideline (1997).** 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.

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

NOTES

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