GP14-A
Vol. 16 No. 2
Replaces GP14-T
Vol. 11 No. 24

June 1996

Labeling of Home-Use In Vitro Testing Products; Approved Guideline

This document contains specifications and recommendations for label preparation for over-the-counter in vitro testing products.

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Labeling of Home-Use In Vitro Testing Products; Approved Guideline

Abstract

Labeling of Home-Use In Vitro *Testing Products; Approved Guideline* (NCCLS document GP14-A) outlines the information that should be available to the home user of in vitro testing products. GP14-A is intended for use primarily by manufacturers. The document will enable the manufacturer to facilitate proper use of its products by providing sufficient information to the user in a usable format.

In Section 2, GP14-A briefly describes the information that should appear on the outside of the product's package. Section 3 describes the information that should appear on the package insert. In addition, Section 4 describes methods for premarket testing of the product's labeling and documentation; Section 5 gives a brief overview of premarket performance testing of the product by clinical laboratorians and by the target market population.

[NCCLS. Labeling of Home-Use In Vitro Testing Products; Approved Guideline. NCCLS document GP14-A (ISBN 1-56238-299-3). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1996.]

GP14-A
ISBN 1-56238-299-3
ISSN 0273-3099

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Volume 16 Number 2

Rosanne M. Savol
Amiram Daniel, Ph.D.
Michael T. Kafka, M.D.
Helen Claire Ogden-Grable, M.T.(ASCP)
Rose Mary Romano
Carol Vetter, M.S.
Diane T. Wassel, R.Ph., M.S.A.

Suggested Citation

[NCCLS. Labeling of Home-Use In Vitro Testing Products; Approved Guideline. NCCLS document GP14-A (ISBN 1-56238-299-3). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1996.]

Proposed Guideline
August 1989

Tentative Guideline
December 1991

Approved Guideline
June 1996

ISBN 1-56238-299-3
ISSN 0273-3099

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Committee Membership

Area Committee on Alternative Site Testing

Robert L. Habig, Ph.D. **Chairholder**	**Bayer Corporation** **Tarrytown, New York**

Subcommittee on Labeling of Home-Use Diagnostic Products

Rosanne M. Savol **Chairholder**	**Bayer Corporation** **Elkhart, Indiana**
Amiram Daniel, Ph.D.	Olympus Corporation Lake Success, New York
Michael T. Kafka, M.D.	St. Luke's Regional Medical Center Sioux City, Iowa
Helen Claire Ogden-Grable, M.T.(ASCP)	Naples Community Hospital Naples, Florida
Rose Mary Romano	National Cancer Institute Bethesda, Maryland
Carol Vetter, M.S.	FDA Center for Devices/ Radiological Health Rockville, Maryland
Diane T. Wassel, R.Ph., M.S.A.	Brandywine Regulatory Services Exton, Pennsylvania

Advisors

Martin A. Batchelder	Hendersonville, North Carolina
Kenneth D. McClatchey, M.D., D.D.S. *Board Liaison*	University of Michigan Medical School Ann Arbor, Michigan
Julie A. Alexander M.T.(ASCP), M.A. *Staff Liaison*	NCCLS Wayne, Pennsylvania

Foreword

In the early years of NCCLS, the labeling of laboratory reagents and instruments was recognized as an important part of clinical laboratory practice. In 1971, NCCLS formed a committee that produced an approved voluntary consensus standard for commercially distributed reagents and instruments. That document, GP1-A2 (formerly ASL-1), *Labeling of Clinical Laboratory Reagents*, responded to the community's desire for certain product information for the many in vitro diagnostic kits and reagent/instrument systems that were available for use in the clinical laboratory. (GP1-A2 has since been discontinued.)

The NCCLS consensus labeling standard emerged at the same time that the Food and Drug Administration (FDA) promulgated regulations for the labeling of in vitro diagnostic products. Because many of the same people participated in creating the voluntary NCCLS standard and the mandatory labeling regulations, the two documents were similar. Both the NCCLS standard and the FDA regulations identified the minimum information required for product labeling and made allowances for appropriate and applicable interpretation according to variations in products and intended users of the products. In one respect, however, there was a difference.

The FDA regulation required that certain information about a test be provided in the package insert in a specified order and format. From a regulatory point of view, that made sense. The agency wanted to see products labeled in a way that presented essential technical information and facilitated the comparison of products. The NCCLS document was less concerned with labeling format. A manufacturer of a home-use testing product could use the national voluntary consensus standard somewhat more easily and adapt the information to a new community of users—the general public.

Testing in the home is not a new practice. Some diabetics were encouraged to monitor their blood sugar long before even the commercial tablets and strips were introduced in the 1940s and 1950s. They were taught to do Benedict's tests in the kitchen using a copper sulfate solution prepared at the pharmacy. The testing did help some diabetics learn to control their disease better. But the practice of home testing for diabetics did not achieve a substantial level of acceptance until the convenient, rapid tests for urine glucose and ketones appeared in the late 1950s and 1960s, along with all the other commercially available kits, reagents, and instruments for the professional clinical laboratory.

Consequently, the FDA labeling regulations and the NCCLS standard were written with laboratory professionals as the target audience. It made sense at the time. The few manufacturers who sold products to home testers recognized that the structured regulations were not designed for telling the lay user how to do the test. For example, a lay user does not want to read about the history of the test or the chemical principles before finding the instructions on how to get the answer. So, they adjusted and provided simplified instructions "for the diabetic," in addition to the required FDA information.

In the 1980s, self-monitoring of blood glucose became accepted medical practice and pregnancy tests appeared on pharmacy shelves. Also, ovulation kits and fecal occult blood tests were developed for home use. During this period, manufacturers wrestled with the labeling requirements and, with the FDA, addressed the labeling of home-use diagnostics to serve the lay user. Companies began to use consumer communication techniques, such as graphics, large print, and simple language, when creating their labeling and packaging materials.

In a relatively short time, it became apparent that the collective experience of manufacturers, the government, and health care professionals could be formalized as a consensus guideline within the traditional NCCLS structure. This approved guideline for the labeling of home-use testing products is the result of this effort.

Please Note

The format of GP14-A is different than that used for most NCCLS documents. As advocated in this guideline for use in the labeling of home-use in vitro diagnostic products, GP14-A: *Labeling of Home-Use In Vitro Testing Products; Approved Guideline*, is presented using the "ragged-right" format (see pages 15–16 and Comment 2 in the Summary of Comments and Subcommittee Responses for discussion of the "ragged-right" format).

Labeling of Home-Use In Vitro Testing Products; Approved Guideline

1 Scope

The goal of the guideline is to promote effective communication of product information to the user of tests designed for home use. The guideline recommends to manufacturers of home-use in vitro testing products the information they should provide to consumers of the products, in what manner this information should be provided, and how labeling information should be validated to promote proper use of health care testing products.

Note: The methods and examples provided in this document represent one way to comply with the guideline. Other approaches may be considered equally valid and appropriate, and are not intended to be excluded.

2 Labels

The cartons and labels for home-use in vitro testing products must comply with all federal regulations applicable to packaged consumer commodities. (See the Bibliography for pertinent regulatory documents.)

2.1 Outside Container or Wrapper

Within the limits of the legal requirements, the manufacturer should provide (on the outside of the package) information that is important for the consumer to know before deciding whether to buy a product. Consider including the following information, as applicable:

- Name of the product
- A brief description of intended clinical use (i.e., screening, monitoring or diagnosis), including who would use it and the conditions for its use
- A brief description of contraindications for use (if applicable)
- Contents (i.e., number of tests in the package—if that information is necessary for proper lay use of the test)
- Warnings and precautions
- Storage and safe handling instructions
- Lot numbers and expiration dates
- Name and address of manufacturer, packer, or distributor
- Materials required but not included in the test kit (e.g., distilled water).

2.2 Reagent Labels

The following elements of reagent labeling are presented in priority order. If reagent information is not found on the label, instructions should direct the reader to other sources (e.g., outside container, wrapper, or package insert).

(1) Reagent name

(2) Lot number and expiration date

(3) Manufacturer

(4) Particular instructions about hazardous chemicals and handling, if any

(5) Kit identification (if applicable).

3 Package Insert

The following elements of product labeling are presented in a logical order, but the information may be adapted to a particular product in different formats.

The various sections of the package insert should be preceded by capitalized, boldface headings or otherwise highlighted for easy reference. Appendix A provides some examples of "better" and "poorer" presentations of information to appear in package inserts.

3.1 Intended Use

State the intended use of the product (i.e., whether intended for screening, monitoring, or diagnosis of a disorder or condition) and the rationale for its use, including who should use the test, the conditions for its use, and any contraindications.

Consumers might not understand the meaning of the terms "screening," "monitoring," and "diagnosis." Following is one way of stating the intended uses of the product:

- Screen—"To test for the presence or absence of hidden blood in the stool"

- Monitor—"To check for changes in blood glucose (sugar) levels"

- Diagnose—

"To indicate pregnancy"

"To detect a streptococcal ("strep") infection"

"To predict ovulation."

3.2 How The Test Works

Provide information on the scientific basis of the test in lay terms. Provide a brief explanation of what the test measures and what its results indicate, as well as any limitations of the test as they relate to its intended use. Briefly explain how the product works, including the following information:

- When to test
- How to collect a specimen
- How to prepare and use reagents
- How long it takes to get a result
- How often the test should be used to monitor a condition or to obtain a specific result.

3.3 Contents of the Kit

Explain all components of the kit and the function each component performs in detail. (For easy reference, assign numbers or letters to illustrations of kit components and their descriptions so that they correspond to each other.) Provide an illustration of the entire kit that identifies each of the components. Instruct consumers (in boldface type) to familiarize themselves with the test components before they begin testing. Where appropriate, provide information about handling and disposal of components. Provide information about chemical components/concentrations when necessary for consumer safety and/or proper use of the test.

3.4 Materials Needed But Not Provided

It is necessary to provide a list and/or illustrations of additional materials or equipment needed but not provided with the product. Include such specifications as types, sizes, numbers, and quality. Also, include precautions on substitution of materials, if they are relevant.

3.5 Storage

State conditions for proper storage of the product (temperature, light, humidity, etc., as necessary) in lay language. Express storage temperature in degrees Fahrenheit (degrees Celsius may be used in addition, at the manufacturer's option). If the product must be mixed or reconstituted before use, supply storage information for the components both before and after manipulation. Give an expiration date based upon the stated storage instructions, and advise the user that use of products after the expiration date can cause test results to be inaccurate.

In the case of a test kit that consists of more than one component, ensure that the stated expiration date is the earliest of the dates assigned to any component. If an alteration of the product is indicated by visible signs (e.g., color change, turbidity, etc.), bring these signs to the attention of the consumer. Also, explain the effect of improper storage of testing materials on test results.

3.6 Warnings and Precautions

Express appropriate warnings and precautions in terms that are readily understood by the average consumer. This information may precede the step-by-step instructions. Although the statement "For In Vitro Diagnostic Use," must appear in the labeling, it is advisable to explain what this means (e.g., "To be used outside the body" or "Do not swallow"). The following information may also be included:

- Instructions for safe handling, spill clean up, and disposal of any hazardous reagents or materials
- Precautions concerning interpretation of results, although they may appear in another section instead of in the section on warnings
- Warnings that failure to follow instructions can cause inaccurate results
- Instructions not to mix components of multiple kits and/or save unused components
- The advice to contact a local poison control center if a reagent is swallowed (if applicable).
- The need to protect kit materials from heat and light (if applicable).
- A description of test site conditions (e.g., lighting, temperature, humidity, flat surfaces), if certain test site conditions are required.

3.7 Instructions

3.7.1 Pre-Instruction Statement

The following statements should appear prominently on the front of the package insert and/or on the kit container or wrapper, as well as before the instructions for performing the test:

PLEASE READ ALL OF THE INFORMATION IN THE PACKAGE INSERT/LEAFLET BEFORE USING THE TEST

IF YOU DO NOT UNDERSTAND THE INSTRUCTIONS, CONSULT _____ . CALL (800)___ – ____ (specify days and times to call), **OR WRITE TO _____.**

Put these statements in boldface type, capital letters, and set them off by using a box or other means of highlighting.

3.7.2 User Preparation

User preparation instructions are to precede the step-by-step instructions and may include an explanation of the following:

- Items that should or should not be ingested (e.g., specific foods and beverages, drugs, vitamin or mineral preparations) and for how long before testing
- Other precautions, such as not using the fecal occult blood test kit in situations where the woman being tested is menstruating or when the patient has bleeding hemorrhoids
- Any preparations consumers should make for the performance of the test

3.7.3 Test Instruments

If the testing procedure requires the use of an in vitro device (e.g., meter or instrument), provide simple illustrations; use color when necessary to show instrument features. Information provided with the device may explain, as applicable:

- Features and their functions
- Operation programming and checks
- Display messages and their meaning
- Battery loading
- Cleaning and maintenance of the instrument
- Calibration procedures
- Any precautions or other special considerations
- Any reagent, strip, or component specifications.

3.7.4 Step-By-Step Instructions

Provide illustrations when appropriate, next to the corresponding text and, preferably, in color. One example is a test in which the results are in the form of a color-change. In reading the test results, the user can compare the color obtained in the test to the color shown in an illustration. The color shown in the illustration represents either positive or negative results.

Specimen collection and preparation information should include:

- Under what conditions and when the specimen should be collected
- Preparation of the container to hold the specimen
- Any additives or preservatives needed to maintain specimen integrity
- Known interfering substances
- Recommended storage, handling, or shipping instructions for keeping the specimen stable (including references to temperature and time
- Amount of specimen needed, how to collect it, and how and where to put it. Include illustrations where necessary.

The following information should also be included:

- Amount of reagent needed, how to prepare it, and how and where to put it
- Instructions for combining the specimen and reagent
- Instructions for special handling or preparation of test components and reaction mixture (e.g., rinsing test stick with cold water for a specified number of seconds before inserting into a vial containing a reagent)
- Time needed for the various steps
- Specific instructions regarding proper temperature, time or other factors that can affect test results, and the implications of exceeding or falling short of the limits including examples of failures to follow directions, as well as their consequences, where appropriate
- Next to the step in question, warnings that apply to that particular step
- Illustrations, where necessary.

If a positive and/or negative control material or an internal control material is provided, or is available for use with the product, include detailed information on use of the control(s). Explain the meaning of control results and the frequency for performance of control tests.

3.8 Results

The "Results" section describes how test results are read (scored) and evaluated; it should follow the "Test Procedure" section. Key elements of the "Results" section are described below. Present each of these elements as separate subsections.

3.8.1 Important Notes on Reading Results

Concisely emphasize any important points or conditions that should be considered for proper reading of results. For example, if test results are critically dependent on the reaction time of a sample and reagents, instruct the user to read results precisely at a specified time. Note if the end point can be missed or continue to develop. Also, state any special procedures or conditions for reading end point reactions (e.g., use of incandescent lighting vs. fluorescent lighting) here, along with the implications of not adhering to the procedures.

3.8.2 Reading of Results

Explain the procedure for obtaining test results. For results that require a calculation, provide an example.

3.8.3 Interpretation of Test Results

It is important to explain the meaning of each possible test outcome. In cases where certain results are obtained (e.g., an equivocal result), an additional test or tests might be needed. For quantitative tests, include a table showing the significance of a particular value or range of values. Explain the limitations of the test and state any intrinsic and extrinsic factors that can affect the test.

3.8.4 Follow-Up

Provide clear and concise information about appropriate user follow-up (e.g., advice to consult with a physician and/or other licensed practitioner to retest at a later time, given a particular test result). Also, explain the meaning of false-positive and false-negative test results and cite possible sources and implications of false results.

If they have signs or symptoms, advise consumers to consult health care professionals, regardless of test outcome.

3.8.5 Troubleshooting

Present possible explanations and any corrective action to be taken for unexpected results (e.g., failure of the positive or negative controls to perform properly). Instruct the user not to run the test if any control fails repeatedly. As a minimum, make a telephone number (toll-free is preferable) available for more direct consumer support.

3.9 Performance Characteristics

It is important for consumers to realize that few, if any, in vitro testing products are definitive indicators of health status. Moreover, it is also important that consumers realize it is highly unlikely any in vitro testing product can claim to perform perfectly. Thus, information on product performance characteristics should reflect both the merits and limitations of the test procedure.

Therefore, a brief discussion of how the test was evaluated should be included and the results of the key studies upon which the test's performance is based should be presented. For the sake of simplicity, present the test results as a demonstration of the test's "accuracy" level.

3.10 Accuracy and Reliability

The following examples show how information about the test's "accuracy" level could be presented in a home-use in vitro testing product package insert. (Data may be described in text or tabular form, depending on which is more appropriate. Conduct tests to see which is easier for users to understand.) The product used in the examples (the "ABC Test") is a qualitative test based on a simple color reaction that could result from interaction of a sample (urine) and test reagents. In the examples, the presence of a "given analyte" is known to be indicative of a "given condition." The performance of the "ABC Test" is based on test efficiency (i.e., true positive plus true negative results divided by the total number of samples tested).

Example 1: *Information About the Accuracy of the Test Based on a Laboratory Evaluation:*

The ability of the "ABC Test" to correctly identify urine samples containing (or not containing) a given analyte was evaluated in a laboratory setting. Two hundred urine specimens (100 taken from normal persons and 100 taken from persons known to have a given condition) were tested for the presence of the analyte. The results are shown in Table 1.

Table 1. Laboratory Evaluation of the "ABC Test" to Determine Test Accuracy

# of Urine Samples Tested	"ABC Test" Results*	Correct Diagnosis	ABC Accuracy
200	95 Positive	100 Condition Present	97.5% (195/200)
	105 Negative	100 Condition Absent	

* Five false-negative test results occurred (i.e., the test was negative for samples from patients in which the condition was present).

Example 2: *Information about the Accuracy of Test Results Based on the User:*

Two hundred consumers, not experienced in medical testing, as well as 200 experienced laboratory technologists, performed the "ABC Test" on urine specimens with and without the substance (analyte) to be detected by the test. Based on actual diagnoses, the accuracy of the test when used by consumers was 96%. Test accuracy when used by technologists was 97.5%.

Data showing accuracy of tests when used by consumers and laboratory technologists could also be presented using one of the following tables (Tables 2 and 3). **(NOTE**: The numbers and percentages are not intended to correspond to any in the above paragraphs.)

Table 2. Accuracy of Test Results Based on the User

In Diagnosing Condition		In Diagnosing Absence of Condition	
Consumers	Lab Technician	Consumers	Lab Technician
97%	98%	96%	97.5%

Table 3. Accuracy of Test Results Based on the User

Consumer Results		Technologist Results		Correct Diagnosis	
Negative	Positive	Negative	Positive	Positive	Negative
95	105	97	103	100	100

3.11 Expected Values

This section provides information on the reference values established for various populations. Such information could be combined or included with the "Performance Characteristics" section of the package insert. Express expected values or results in lay terms. For example: "In adults, the normal range for (a given analyte) is 35 to 80 U/mL. Results below 35 U/mL are considered abnormally *low* and results above 80 U/mL are considered abnormally *high* (reference)."

3.12 Record of Results

For products that require a series of tests, include a section where date, time, and results of each test can be recorded. This section could be used to provide a physician with a list of test results.

3.13 Manufacturer

Include the name and address of the manufacturer or distributor and a way to reach the customer service department.

3.14 Date of Issuance

Note the date of the latest revision of the insert.

3.15 Labeling Changes

Highlight significant labeling changes in, for example, the preinstruction statement (Section 3.7.1) and the instructions for use (Section 3.7.3). This is especially important for testing products used often or over time, such as glucose-monitoring devices where users will assume that the same procedure is to be followed unless they are alerted to modifications.

4 Premarket Message Testing

The labeling for a home-use in vitro testing product is essentially a "health message." Premarket message testing methods should be designed to meet the objectives of program planners. During the planning and concept development stages, focus group and individual in-depth interviews are useful qualitative research techniques. Interview larger samples of respondents during the message development stage. Use readability testing as a first step in pretesting draft instructions, followed by pretesting with consumers. Self-administered questionnaires for pretesting printed materials with target audiences are inexpensive pretesting methods.

If manufacturers have pretested products designed using a similar format, extensive premarket message testing is not necessary each time a new product is developed. However, the consumer questionnaire is appropriate for every clinical or field trial of a new over-the-counter (OTC) product.

4.1 Pretesting

Pretesting is the systematic and formal gathering of target audience reactions to labeling messages before they are issued in final form. It is one type of evaluation conducted in the early or formative stages of message development.

Pretesting can help determine which of several labeling presentations is most effective, or it can identify strengths and weaknesses in a presentation. The findings can be used to revise and improve materials before they are distributed to the market.

4.2 What Does Pretesting Measure?

Pretests of instructions are usually designed to assess the effectiveness of the instructions in the following areas: attention, comprehension, personal relevance, believability, and acceptability.

Additional gauges of message effectiveness can include assessing target audience perceptions of the utility of the information contained in an item and the extent to which the consumer finds instructions attractive, interesting, convincing, or alarming. Individual production elements within an item can also be pretested.

Understanding the characteristics of the consumer—attitudes, beliefs, and behaviors—is important to the production of effective instructions. Involving consumers in the development of the message through pretesting can ensure more effective communication.

4.3 Pretesting Methods

The pretesting methods chosen depend on the nature of the instructions, the target consumer audiences, and the amount of time and resources available for pretesting. There is no formula for selecting the perfect method for pretesting. Choose and shape methods to meet each pretest need; give careful consideration to objectives and the resources required.

The following five pretesting methods, adapted from marketing and communication research, are used by health communicators in developing messages. They are summarized in Table 4.

4.3.1 Method 1: Readability Testing

A readability test is used to indicate whether a message is written at a level that can be comprehended by its target audience, as measured by reading time, amount recalled, questions answered, or some other quantifiable measure of a reader's ability to process a text. Conversely, readability formulae use counts of language variables such as the number of polysyllabic words and the number of words in sentences. Such formulae measure the structural difficulty of written text. They do not measure other factors that affect the understandability of text, such as conceptual difficulty, content, and organization of information. The premise of readability formulae is that the reading level required to understand a message is usually higher when its sentences are long or when more polysyllabic words are used.

The SMOG readability formula is one of the simplest tests to use without sacrificing accuracy of prediction. (The SMOG formula was developed by G. Harry McLaughlin. The name is a take-off on Gunning's fog index; references for the fog index and other readability formulae are included in the bibliography. Appendix B describes how to apply the SMOG readability test to print materials.)

4.3.2 Method 2: Focus Group Interviews

Also called "exploratory group sessions," focus group interviews are used to obtain (in the early stages of health communication development) insights into target consumer audience perceptions, beliefs, and language. Focus group interviews are conducted with a group of about eight to ten respondents. Using a discussion outline, a moderator keeps the session on track while allowing respondents to talk freely and spontaneously. As new topics related to the outline emerge, the moderator probes further to gain useful insights.

Focus group interviews are especially useful in the concept development stage of the communication process. They provide insights into target audience beliefs on a health issue, allow program planners to obtain perceptions of message concepts, and help trigger creative ideas. The group discussion stimulates respondents to talk freely, thus providing valuable clues for developing instructions in the consumers' own language.

Focus groups should not be used when individual response or quantitative information is needed. For example, when assessing the final copy for a package insert, it is more important to gather individual rather than group reactions. The former are more indicative of the person's actual comprehension, perceptions, and intentions for use of the product.

4.3.3 Method 3: Individual In-Depth Interviews

Individual, in-depth interviews are used for pretesting issues that must be probed deeply or in cases in which individual, rather than group, responses are needed. Such interviews can last from a half-hour to an hour and are used to assess comprehension, as well as emotional reactions, attitudes, and prejudices. These are not normally elicited in the more common public opinion interviews.

Individual, in-depth interviews, similar to focus group sessions, should be conducted by experienced interviewers who usually follow a discussion outline. A structured questionnaire can be used in those cases where the pretester is concerned with obtaining respondents' reactions to a core set of items. A list of possible pretest questions is included in Appendix C.

4.3.4 Method 4: Central Location Intercept Interviews

Central location intercept interviews involve stationing interviewers at a point frequented by persons from desired target consumer audiences and asking them to participate in the pretest. There are two advantages to this. First, a high traffic area can yield a number of interviews in a reasonably short time. Second, a central location for hard-to-reach consumers can be a cost-effective means of gathering data.

A typical central location interview begins with the interception. Potential respondents are stopped and asked whether they are willing to participate. Then, specific screening questions are asked to see whether they fit the criteria used to determine the target audience for the pretest. If so, they are taken to the interviewing station—a quiet stop at a shopping mall or other site—and are shown the pretest materials. Respondents are then asked a series of questions to assess recall, comprehension, and reactions to the materials.

Although the respondents intercepted through central location interviews might not be statistically representative of the entire target population, the sample is larger than that used in focus groups or individual, in-depth interviews. Program planners often use the central location technique at the message development stage when assessments of comprehension, attention, believability, and other reactions are essential.

4.3.5 Method 5: Self-Administered Questionnaires

Self-administered questionnaires and pretest materials are distributed to respondents whose participation was sought in advance. Respondents are asked to review the materials on their own, to complete the questionnaire, and then to return the materials and completed questionnaire within a specified amount of time.

Make the questionnaire a reasonable length so that respondents will complete it. Open-ended questions can be used to assess comprehension and overall reactions to instructions; closed-ended questions can be used to assess such factors as personal relevance and the believability of the instructions. Attention or recall cannot be measured with this technique because the respondents' exposure to the instructions cannot be controlled.

Table 4. Summary of Section 4.3 Pretesting Methods

Type of Pretest	Characteristics
Readability test	• Estimates grade level of text
	• Word/sentence length are key factors
Focus group	• For gathering group impressions of design, style, effectiveness, etc.
	• Used in concept development
	• For generating ideas
	• Require groups of 8–10 persons
	• Require an experienced moderator
Individual, in-depth, interviews	• To obtain information that is difficult to obtain in group setting (fewer inhibitions)
	• Comprehension/recall of information
	• For pre-specified information (but not to completely exclude open-ended questions)
Central location intercept interviews	• At place frequented by target audience
	• Many interviews conducted quickly
	• Cost effective
	• Recall, comprehension, reaction
Self-administered questionnaires	• Questionnaires are sent in advance
	• Large respondent sample is possible
	• Recall/comprehension is hard to measure
	• Sampling error is a problem

5 Clinical Testing

5.1 Clinical Laboratory Testing

The first part of the performance evaluation determines whether the product performs as designed and manufactured. The clinical laboratory can subject the products to performance evaluations such as those described in NCCLS documents (see the "Related NCCLS Publications" section at the end of this document).

5.2 Consumer Testing

The second part of such testing involves the consumer population. Recruit the target market population to conduct the test under the supervision (but without assistance or interference) of trained personnel. It is important that the users test the same simulated patient specimens or calibrators as used in the performance evaluation, if feasible. This removes from the test the bias associated with testing one's own specimens.

Conduct the test according to labeling instructions *without* any outside assistance. The number of participants in such a test may vary, but it should approximate the number of samples used in the first phase of the test.

At the end of this phase of the test, the data are collected and condensed, and the product performance is evaluated by comparing the resulting performance parameters to those obtained by the clinical laboratory personnel. The difference between these two sets indicates the adequacy (or inadequacy) of the design of the test and/or the clarity of the instructions.

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Appendix A: Making Printed Materials Easier to Read

Tips for Clear Writing

Generally, health writing tests at a higher reading level than some other subjects because health-related words characteristically have more syllables. Often the writer cannot avoid using technical language. However, the effects of these words on readability can be minimized by writing short, concise sentences and by defining difficult words or terms. Following are some basic guidelines for preparing printed messages.

(1) **Organize the material**

- Group related information or instructions for easy reference.
- Use titles and subtitles (set off by boldface, all capitals, etc.) to define the organization and flow of ideas and tasks/subtasks to be performed.
- Use boldface, italics, all capitals, contrasting color, boxing of text, or underlining to emphasize important words, ideas, and instructions. Do not overuse highlighting techniques, or they will lose their effectiveness.
- Begin the material with an introduction to state the purpose and orient the reader.
- Place general warnings early in the text; warnings that apply to specific instructional steps should accompany those steps.
- Use a summary to reinforce major points or important tips for proper testing.
- Use appropriate visual aids (charts, photographs, graphics) next to the related ideas and instructions in the text, using numerals or letters to relate illustrations and corresponding text.

(2) **Structure each paragraph**

- Present one topic per paragraph.
- Start each paragraph with a strong topic sentence.
- Vary the length of sentences.
- Use examples to clarify ideas with which the reader may not have had experience.

(3) **Structure each sentence**

- Keep sentences short (approximately 9 to 10 sentences per 100 words).
- Vary the length of sentences.
- Use the active rather than the passive voice.
- Present one idea per sentence.
- Use simple sentence structure.
- Use sentences that make a statement or give a command.
- Use sentences that make positive, not negative, statements when possible.

(4) **Choice of words**

- Use simple, short words, when possible (Figures 1 and 2 following this appendix).

Appendix A: Making Printed Materials Easier to Read (Continued)

- Use commonly understood words and expressions (when specialized vocabulary is essential, a parenthetical definition or a glossary should be included as part of the text).
- When numbers are written in words, include numerals in parentheses following the words.
- Use abbreviations only when commonly understood.
- If temperature is expressed in degrees Celsius, also include it in degrees Fahrenheit.

Guidelines for Good Graphics

Good graphics can help readers overcome resistance to reading a text or even help them understand the material more easily. A few tips follow:

(1) **Highlight**

- Highlighting techniques are a way of emphasizing important aspects of the document by calling attention to them visually (e.g., to alert reader to important labeling changes, precautions, warnings, and special notes about proper testing techniques; see Figure 3 following this appendix).
- Highlighting techniques include boldface, italics, boxing-in of text, color, and white space.
- Highlighting techniques provide visual relief, emphasize important points, set off examples, or set off sections of text and the various tasks or steps to be performed (e.g., use of control materials, collecting the specimen, reading the results).
- Avoid overuse of highlighting techniques; consistent use throughout the text is important.

(2) **Specify type size**

- For most labeling, 10-point or larger type is the most readable size (if the type is too small, readers may skip over material or develop eyestrain). Use 10-point type (this document is printed in 10-point type) or *larger* depending on the target user. For example, persons with diabetes are often older and have vision loss. A larger type size can be necessary for such an audience (see Figure 4 following this appendix).

(3) **Regulate line length**

- The best line length is 50 to 70 characters. This length is less tiring to the eye. Short lines tend to make the eye jump back and forth; long lines may strain the eye as it tries to stay on course.

(4) **Use white space in margins and between sections**

- White space can make the document look better and easier to read.
- A text with too little white space can look dense.
- White space surrounding a title or example can isolate and emphasize its importance.

(5) **Use "ragged"-right margins**

- "Ragged" right margins are less formal than "justified" text and create a more relaxed contemporary look:

Appendix A: Making Printed Materials Easier to Read (Continued)

Ragged:

Excellence in typography is the result of nothing more than an attitude. Its appeal comes from the understanding used in its planning. Excellence in typography is the result of nothing more than an attitude. Its appeal comes from the understanding used in its planning. Excellence in typography is the result of nothing more than an attitude. Its appeal comes from the understanding used in its planning.

Justified:

Excellence in typography is the result of nothing more than an attitude. Its appeal comes from the understanding used in its planning. Excellence in typography is the result of nothing more than an attitude. Its appeal comes from the understanding used in its planning. Excellence in typography is the result of nothing more than an attitude. Its appeal comes from the understanding used in its planning.

- "Ragged" right margins reduce production costs (easier to make corrections on unjustified type).
- Some readers find "ragged"-right margins make a text easier to read because:
  - It is easier for readers to keep their place in the text because the right profile distinguishes one line from another
  - The eye does not have to adjust to different spacing between letters, as it does with justified type.

(6) **Use all capital letters for highlighting only**

- Using all capitals interferes with the legibility of the text.
- All capitals make a text harder to read because the shapes of the letters do not significantly vary.
- All capitals take up more space and take longer to read.
- Used sparingly, all capitals can effectively highlight key messages or words.

(7) **Select clear illustrations** (Figures 5 and 6 following this appendix)

- Clear, simple, and uncluttered drawings or photographs illustrate steps to be performed or test kit components (some photographs do not reproduce well—it is a good idea to try printing or copying a photograph *before* committing to using it).
- Place textual information corresponding to the illustration next to the illustration (use of numerals or letters identifying the picture and related text also is helpful to the reader).
- Ensure that illustrations accurately portray instructions (e.g., if one drop of reagent is to be used, one drop should be shown in the illustration).
- Identify test kit components in illustrations by using numbers or letters; this allows easy reference to these components later in the text using the appropriate letter or number.
- Depict timing instructions by simple pictures of clocks showing the beginning and ending times.
- Use colored illustrations, especially where they enhance the user's ability to correctly perform the test, to read and interpret the results, and to troubleshoot problems.
- Be consistent with illustrations in respect to format, font, and placement of headings.
- Place illustrations next to the corresponding text.

Test Procedure

1. Wash your hands with mild soap. (Using warm water normally increases circulation and makes it easier to get a large drop of blood for the test.)
2. Turn on the meter by pressing the "ON" key. The display will show XXX, 999, XXX XXX for 2 sec and then the calibration code will appear for 2 sec.
3. Remove one test strip from a test strip vial.
4. Prick finger with lancet, following the manufacturer's instructions.
5. Apply one drop of blood to the test pad on the strip, making sure the test area is covered.

Poorer

Test Summary

1. Press POWER. XXXX appears.
2. Obtain a large hanging drop of blood.
3. Press START - During countdown, prepare to apply blood.
4. At XXXX - Apply blood, covering entire pad.
5. .....

Better

Figure 1. 6-point vs. 14-point print size.

3.	Clean the site to be punctured thoroughly using an acceptable method such as soap and warm water or an alcohol swab. Dry thoroughly. (From an insert with a 12th grade reading level)

Poorer

3.	**Wash hands** with soap and warm water. Dry thoroughly. (From an insert with a 7th-grade reading level)

Better

Figure 2. Compare wording.

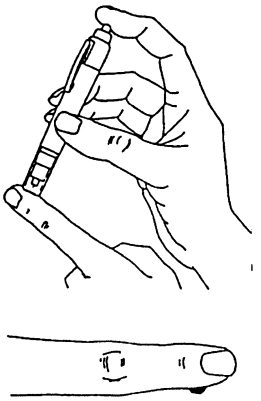
4.4 Prick your finger with a sterile lancet and massage gently if necessary to obtain a large drop of blood. Quickly turn your finger upside down so that the drop is hanging from the finger. With practice, you will be able to make the drop quite large without it actually falling off your finger. Do not proceed to the next step until your blood sample is ready.

Poorer

Obtain a drop of blood as follows:

1. Prick your finger. Note: To lessen the discomfort, prick the side of the finger.

2. Hold your finger downward and squeeze it firmly to form a large hanging drop of blood.



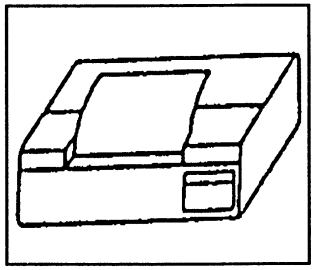
Better

Figure 3. Understandability.

6. After you have blotted the reagent strip, immediately open the test door and insert the reagent strip into the strip guide with the reacted test pads facing down toward the test window. Immediately close the test door.

CAUTION: If the reagent strip is not properly inserted and the test door is not closed before the instrument timer reaches 1 (five short beeps), inaccurate results or E r r will be displayed.

Poorer



6. After you have blotted the reagent strip, immediately open the test door and insert the reagent strip into the strip guide with the reacted test pads facing down toward the test window. **Immediately** close the test door.

CAUTION: If the reagent strip is not properly inserted and the test door is not closed before the instrument timer reaches 1 (five short beeps), inaccurate results or **E r r** will be displayed.

Better

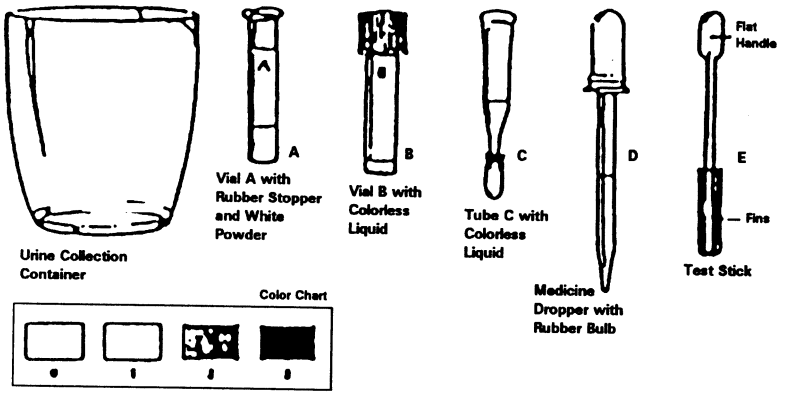
Figure 4. Illustrate and highlight.

KIT CONTENTS:

The kit contains:
10 Test Sticks
10 Vial A's with a white powder...
10 Vial B's with a colorless...
10 Vial C's with a colorless...
One Medicine Dropper
One Color Chart
10 Cups with Lids
.....

Poorer

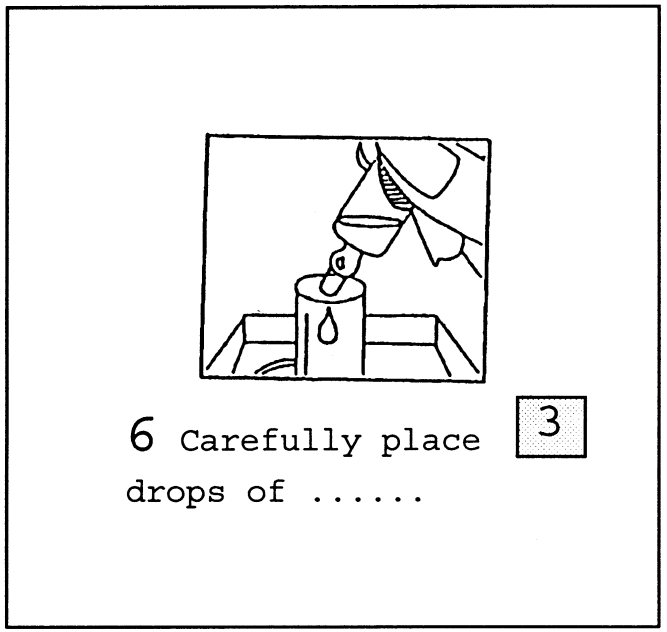
Familiarize yourself with the contents of your kit.



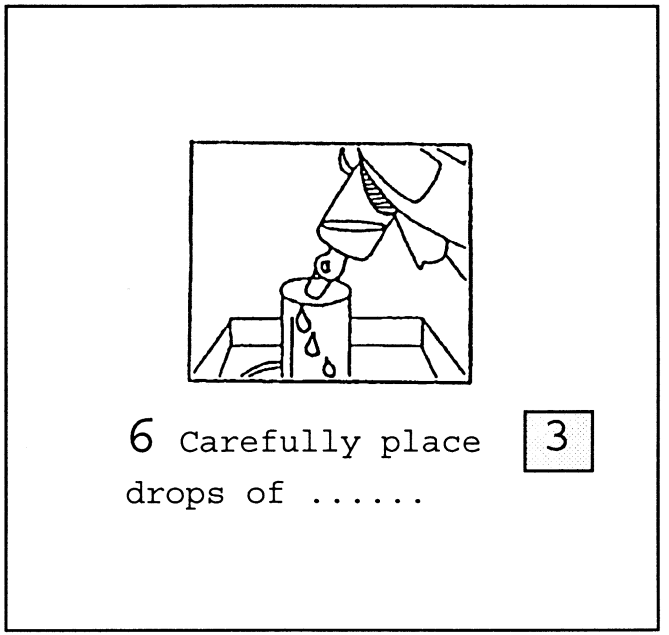
KIT CONTENTS
The kit contains:
10 Test Sticks
10 Vial A's with a white powder...
10 Vial B's with a colorless...
10 Vial C's with a colorless...
.....

Better

Figure 5. Illustrate kit contents.



Poorer



Better

Figure 6. Accuracy of illustrations.

Appendix B: The SMOG Readability Formula

In calculating the SMOG reading grade level, it is best to begin with the entire written work that is being assessed; follow these four steps:

(1) Isolate ten consecutive sentences near the beginning, in the middle, and near the end of the text.

(2) In these thirty sentences, circle all the words containing three or more syllables, including repetitions of the same word, and add the number of words circled.

(3) Estimate the square root of the number of polysyllabic words. This is done by finding the nearest perfect square, and taking its square root.

(4) Finally, add a constant of three to the square root. This number gives the SMOG grade, or the reading grade level that a person must have reached to understand the text.

A few additional guidelines will help to clarify these directions:

- A sentence is defined as a string of words punctuated with a period (.), an exclamation point (!), or a question mark (?).
- Hyphenated words are considered one word.
- Numbers that are written out are considered; if in numeric form in the text, pronounce them to determine whether they are polysyllabic
- Count proper nouns, if they are polysyllabic.
- Read abbreviations as they would be read when not abbreviated.

Not all pamphlets, fact sheets, or other printed materials contain 30 sentences. To test a text that has fewer than 30 sentences:

(1) Count the polysyllabic words in the text.

(2) Count the number of sentences.

(3) Find the average number of polysyllabic words per sentence as follows:

$$Average = \frac{Number\ of\ Polysyllabic\ Words}{Number\ of\ Sentences}$$

(4) Multiply that average by the number of sentences.

(5) Add that figure to the total number of polysyllabic words.

(6) Find the square root and add the constant of 3.

Appendix B (Continued)

Perhaps the quickest way to administer the SMOG grading test is by using the SMOG conversion table. This is done by simply counting the number of polysyllabic words in the chain of 30 sentences and looking up the approximate grade level on the chart.

SMOG Conversion Table*

Polysyllabic Words	Approximate Grade Level (± 1.5 Grades)
0–2	4
3–6	5
7–12	6
13–20	7
21–30	8
31–42	9
43–56	10
57–72	11
73–90	12
91–110	13
111–132	14
133–156	15
157–182	16
183–210	17
211–240	18

*Developed by Harold C. McGraw, Office of Educational Research, Baltimore County Schools, Towson, MD.

Appendix C: Standard Questions Used for Pretesting Messages

In pretesting announcements or printed materials such as booklets, a standard set of core questions to assess communication, believability, personal relevance, and other target-audience reactions are used. These standard questions are listed below to assist program planners in developing pretest questionnaires. (The questions can be modified by changing the words in parentheses and deleting or adding to fit the particular item that is being pretested.)

(1) **Communication/Comprehension**

What was the *main idea* this (message) was trying to get across to you?

_____

_____

What does this (message) ask you to do?

_____

_____

What action, if any, does the (message) recommend that people take? (Probe: What other actions?)

_____

_____

In your opinion, was there anything in the (message) that was confusing?

_____

_____

Which of these phrases best describes the (message)?

Easy to understand
Hard to understand

(2) **Likes/Dislikes**

In your opinion, was there anything in particular that was worth remembering about the (message)?

_____

_____

What, if anything, did you particularly like about the (message)?

_____

_____

Appendix C (Continued)

Was there anything in the (message) that you particularly disliked or that bothered you? If yes, what?

(3) **Believability**

In your opinion, was there anything in the (message) that was hard to believe? If yes, what?

Which of these words or phrases best describes how you feel about the (message)?

Believable
Not believable

(4) **Personal Relevance/Interest**

In your opinion, what type of person was this (message) talking to?

Was it talking to...
Someone like me
Someone else, not me

Was it talking to...
All people
All people, but especially (the target audience)
Only (the target audience)

Which of these words or phrases best describes how you feel about the (message)?

Informative
Not informative

Did you learn anything new about (health subject) from this (message)? If yes, what?

(5) **Other Target Audience Reactions**

Target audience reactions to pretest materials can be assessed using pairs of words or phrases or using a 5-point scale. The following is an example of how this is done:

Listed on this sheet of paper are several pairs of words or phrases with the numbers 1 to 5 between them. Indicate which number best describes how you feel about the (message). The higher the number, the more you think the phrase on the right describes it. The lower the number, the more you think the phrase on the left describes it. You could also pick any number in between. Now let's go through each set of words. Please tell me which number best describes your reaction to the (message).

Appendix C (Continued)

Practical	1 2 3 4 5	Not Practical
Too Short	1 2 3 4 5	Too Long
Discouraging	1 2 3 4 5	Encouraging
Comforting	1 2 3 4 5	Alarming
Well Done	1 2 3 4 5	Poorly Done
Not Informative	1 2 3 4 5	Informative

(6) **Behavioral Intent**

If you receive a positive (negative) test, what are your next steps?

(7) **For Assessing Artwork**

Just look at the drawing (or picture). What do you think it says?

_____

_____

Is there anything in this drawing (or picture) that would bother or offend people you know?

_____

_____

Summary of Comments and Subcommittee Responses

GP14-T: *Labeling of Home-Use In Vitro Testing Products; Tentative Guideline*

General

1. There is inconsistency in the use of numbers and bullets. The document often uses numbers for listing rather than for sequences; sometimes numbers, sometimes bullets are used to denote sequence. Numbers and bullets are used correctly in Appendix B. We recommend that the correct use of numbers and bullets be incorporated into the guideline.

- **The subcommittee agrees and the document is revised.**

2. We recommend the guideline be formatted with "ragged-right" margins [see p. 28, item (5)], because use of this in labeling is advocated in this document.

- **The subcommittee agrees and the document is revised.**

3. To ensure consistency in use and understanding of such terms, a "Definitions" section should be added to define such terms as "precaution," "warning," "contraindication," etc.

- **The subcommittee refers the reader to FDA document G91-9, *Device Labeling*, for these definitions.**

Section 2.2

4. I suggest adding the following at the end of the paragraph: "Direct the user to reagent information not on the label."

- **The text is revised to read, "If reagent information is not found on the label, instructions should direct the reader to other sources, e.g., the package insert."**

Section 3.2

5. We recommend that the last sentence be modified in the following manner: "How the product works should be explained *briefly*, including information on..."

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

Section 3.6

6. We recommend that the following items be added to this section:

   (4) Examples of failures to follow directions, as well as their consequences, where appropriate.

   (5) The advice to contact a local poison control center if a reagent is swallowed.

- **Item (4) from the comment was added to Section 3.7.4; item (5) was added to this section, with the qualifier, "if applicable."**

Section 3.7.1

7. ALL CAPS sentences do not set a good example; overuse of highlighting reduces impact. We might want to set the sentences off by boxing them in since these are key instructions; focus testing supports this approach.

Summary of Comments and Subcommittee Responses (Continued)

- **The subcommittee agrees that overuse of capital letters is not advised, but it believes that it should be up to the company or individual person to decide which option will be used to highlight information. The text is revised to include the option of using a box to set off text.**

Section 3.7.3

8. I suggest rewriting the introductory sentence as follows: "If the testing procedure requires the use of an in vitro device (e.g., meter, instrument, etc.), simple illustrations should be provided; use color when necessary to show instrument features. Information provided with the device should explain..."

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

Section 3.7.4

9. I suggest rewriting the introductory sentence as follows: "Illustrations should be provided when appropriate, next to the corresponding text, and preferably in color. An example might be a test in which the results are in the form of a color change. In reading the test results, the user could compare the color obtained in the test to the color shown in an illustration, the illustrated color representing positive or negative results."

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

Section 3.7.4.2

10. We recommend addition of the following items to this section:

    (7) Warnings applying to a specific step should be inserted next to the step in question.

    (8) State the consequences of failure to follow instructions when such failure has an impact on test results.

- **The subcommittee agrees; this information is included as generic recommendations in this section.**

Section 3.9

11. Our organization believes that a straightforward statement of the percent of accuracy attained in consumer and laboratory studies would be the most meaningful information for a lay user. More complicated descriptions of evaluation of the test's performance and key studies beyond accuracy percentages would be confusing and of no value to a lay user's ability to properly use and interpret a simple qualitative test.

- **The subcommittee believes that the idea behind this comment is already conveyed by the current text.**

Section 3.10

12. The guideline seems to suggest that the same number of consumers and experienced laboratory technologists should perform accuracy testing. An example of 200 each (consumers and professionals) is used in Example 2, Table 3. Because laboratory accuracy is based upon the number of tests and not the number of laboratory professionals performing the tests, equal numbers of consumers and professionals would not be meaningful.

- **The purpose of this section is to discuss presentation of information, not to present protocols for how to obtain this information.**

Summary of Comments and Subcommittee Responses (Continued)

13. I find the presentation of "Examples 1 and 2" to be far too complex for the average lay user. I do not believe that the concepts of false-positive and false-negative results are easily comprehended. Also, although I have not taken the time to actually submit the text to readability indices, such as the SMOG, FOG, or FRY tests, I would be surprised if the result was determined to be between the sixth- to eighth-grade levels. I realize that the discussion of this type of scientific material in a more conversational format is difficult, and I hope that you find the following suggestion to be helpful:

    Example 1: "In clinical trials, the ABC Test was compared to a standard laboratory test with over 200 samples. The overall accuracy of the ABC Test was 97.5%."

    Example 2: "In clinical trials, the ABC Test was tested by both experienced laboratory technologists and regular consumers with over 200 samples. When compared to a standard laboratory method, the ABC Test was 97.5% accurate when tested by the technologist and 96% accurate when tested by the consumer."

    Although these data are not as complete as the tables listed in the current examples, it conveys the information in a familiar form. Additionally, most manufacturers offer "800 Help-Lines" that the motivated consumer may call to obtain more information. The discussion of false-positive and false-negative results may be handled better verbally with a phone call.

- **Results may be described in textual or tabular form. Text may be used if it is more appropriate. Test to see which is easier for users to understand. Which to use is the decision of the manufacturer. The subcommittee agrees that the text given in the comment is one option.**

Section 3.14

14. I suggest changing the sentence to read as follows: "The date of the latest revision of the instructions should be noted."

- **The sentence was revised to read, "Note the date of the latest revision of the insert."**

Section 3.15

15. I recommend changing "Label" to "Labeling," both in the title and in the first sentence (see also Table of Contents). "Labeling" is the generic term that encompasses labels, instructions, insert, etc.

- **The subcommittee agrees; the title and text are revised.**

Section 4

16. I suggest placing sentence 5 ("Larger samples...") before sentence 4 ("Readability testing...").

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

Section 4.3

17. We recommend that the distinctions among different pretest methods be clarified by developing a chart (see attached) that quickly summarizes the differences and similarities among them. This will help readers more easily select an appropriate test method.

- **The chart was added as a supplement to the text.**

Summary of Comments and Subcommittee Responses (Continued)

Section 4.3.1

18. Substitute *read* for *understand* in sentences 2 and 5 of the first paragraph. Readability tests do not ensure that the reader can understand, or comprehend, the text.

- **The text is revised to clarify the aim of readability testing. See Section 4.3.1 of GP14-A.**

Appendix A

19. Because "Guides for Good Graphics" is presented in Appendix D, we might want to present the graphics in Appendix A together with the principles listed in that section.

- **The subcommittee agrees and the figures are placed closer to the appropriate text; call-outs referring to those figures are also added.**

20. In Figure 3, we recommend that the steps in the "Better" example be numbered because it presents a *sequence* of numbers which follow.

- **The steps are now numbered.**

21. "Poorer" and "Better" should be *above* the respective graphics, as in the case of the other examples.

- **The figures are revised so that the labeling and format are consistent with the current editorial style of NCCLS documents.**

Appendix D (now Appendix A)

22. In item (1), the third bullet, I suggest adding the following sentence: "Don't overuse highlighting techniques, or they will lose their effectiveness."

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

23. In item (1), the fifth bullet, I suggest changing the wording to read: "General warnings should be placed early in the text, and warnings that apply to specific instructional steps should accompany those steps."

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

24. In item (7), we recommend the following bullets be added:

    - Be consistent in illustrations with respect to format, font, placement of headings, etc.
    - Place illustrations next to the corresponding text.

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

Related NCCLS Publications

EP5-T2 **Precision Performance of Clinical Chemistry Devices—Second Edition; Tentative Guideline (1992).** EP5-T2 offers guidelines for designing an experiment to evaluate the precision performance of clinical chemistry devices, recommendations on comparing the resulting precision estimates with manufacturer's precision performance claims and determining when such comparisons are valid, and manufacturer's guidelines for establishing claims.

EP6-P **Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline (1986).** EP6-P contains a method for evaluating whether an instrument or quantitative analytical method meets the manufacturer's linearity claim. It offers guidelines for manufacturers' use when stating a claim of an assay's linear range.

EP7-P **Interference Testing in Clinical Chemistry; Proposed Guideline (1986).** EP7-P contains background information and procedures for characterizing the effects of interfering substances on test results.

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

EP10-T2 **Preliminary Evaluation of Quantitative Clinical Laboratory Methods—Second Edition; Tentative Guideline (1993)**. EP10-T2 discusses experimental design and data analysis for preliminary evaluation of the performance of an analytical method or device.

GP10-A **Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline (1995)**. GP10-A discusses the design of a study to evaluate the clinical accuracy of laboratory tests, procedures for preparing ROC curves, a glossary of terms, and information on computer software programs.