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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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Healthcare professionals in all specialities are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

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.

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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."