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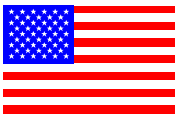
Tubes and Additives for Venous Blood Specimen Collection; Approved Standard —Fifth Edition

This document contains requirements for venous blood collection tubes and additives, including technical descriptions of ethylenediaminetetraacetic acid (EDTA), sodium citrate, and heparin compounds used in blood collection devices.

A standard for national application developed through the NCCLS consensus process.



NCCLS...

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

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Abstract

NCCLS document H1-A5—*Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition* is a performance standard for manufacturers of venous blood collection tubes and additives and users of venous blood collection tubes. H1 addresses requirements for the materials, construction, and labeling of venous blood collection tubes, and it provides methods for the evaluation of venous blood collection tube and closure assemblies. Specifications for the additives heparin, ethylenediaminetetraacetic acid (EDTA), and sodium citrate are also included.

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Contents

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Foreword

This standard contains information on venous blood collection tubes and additives. It is written for manufacturers of venous blood collection tubes, additives, and related devices; for all clinical laboratory personnel; and those who are responsible for acquisition, handling, and using the equipment described in this document.

H1 addresses requirements for the materials, construction, and labeling of venous blood collection tubes, and it provides methods for the evaluation of venous blood collection tube and closure assemblies. Specifications for the additives heparin, ethylenediaminetetraacetic acid (EDTA), and sodium citrate are also included.

NCCLS consensus documents are developed through an open process that ensures wide review and broad application. This unique approach leads to standards and guidelines for medical testing and healthcare services that address identified needs of both its global and national constituents. Most NCCLS consensus documents are intended for global application. Under certain circumstances, however, an NCCLS standard or guideline may be intended for primary use in a specific country or region.

NCCLS document H1-A5—*Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition* is one such consensus document. While H1-A5 is a useful resource for a wider audience, it is intended primarily to help the U.S. user navigate through stringent U.S. regulations. Since occupational exposure practices are heavily regulated and widely "country-specific," the Area Committee on Hematology determined that it would not be feasible to develop a comparable guideline intended for global application at this time. We hope that development of such a guideline may be possible in the future, as part of a long-term effort to harmonize regulations and practices.

The imprint of the flag and the unique tagline on the cover call attention to its national focus, and differentiate H1-A5 from our global consensus documents.

Changes in This Document

Location	Information Changed
Section 10.3	Requirement for tube sterility. The following text has been added: "All blood collection tubes for clinical diagnostic testing must be sterile…"
Section 12	This section has been reintroduced as Appendix A, Evaluation of Venous Blood Collection Tubes.
Section 13	This section has been reintroduced as Appendix B, Evaluation of the Closure Assembly.
Section 14	This section has been reintroduced as Appendix C.
Table 1	Table 1 was substantively modified to accommodate the extensive use of plastic blood collection tubes.

Materials previously presented in Sections 12, 13, and 14 have been reintroduced as appendixes. This supplemental information is intended to assist in use of the standard but has been positioned as appendixes to improve and facilitate the readability of the document.

Table 1 has been substantively modified to accommodate the extensive use of plastic blood collection tubes by laboratories. Changes in materials, closure color, additives, and tube configurations are of a complex nature and so varied that an updated table including all this information would resemble a manufacturer's catalog.

Key Words

Additive, anticoagulant, chelation, chelation values, chromogenic substrate method, ethylenediamine-tetraacetic acid (EDTA), EDTA-containing devices, EDTA salts, heparin, heparin-containing devices, heparin quantitation, lithium heparin, plasma, sequestration, serum, thixotropic gel, trisodium citrate, tube closure, venous blood collection tubes

Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition

1 Scope

This standard discusses single-use, venous blood collection tubes. Normally, such tubes are used in conjunction with double-ended needles to provide a reliable, closed system for blood specimen collection and transportation for subsequent, general laboratory analysis. While the system inherently protects both the patient and the individual collector, care should be taken to protect the patient from microbial contamination. This precaution is met by the use of tubes with sterile interiors and the use of directions to prevent backflow from tube to patient.

The standard also provides a description, mode of action, specifications, and assay methods for additives to blood collection devices, including ethylenediaminetetraacetic acid (EDTA), heparin, and sodium citrate.

This standard is not intended to restrict the availability or use of venous blood collection tubes other than those specifically mentioned in this document. The standard does not address tubes used for highly specific tests (e.g., trace metal analysis).

Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to the most current edition of NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections.*

2 Introduction

This standard contains information on venous blood collection tubes and additives. It is written for manufacturers of venous blood collection tubes, additives, and related devices; for all clinical laboratory personnel; and those who are responsible for acquisition, handling, and using the equipment described in this document.

H1 addresses requirements for the materials, construction, and labeling of venous blood collection tubes, and it provides methods for the evaluation of venous blood collection tube and closure assemblies. Specifications for the additives heparin, ethylenediaminetetraacetic acid (EDTA), and sodium citrate are also included.