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

This standard contains requirements for the materials, manufacturing, and labeling of venous and capillary blood collection devices.

A standard for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Advancing Quality in Health Care Testing

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Abstract

Clinical and Laboratory Standards Institute document H01-A6—*Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition* is a performance standard for manufacturers of venous and capillary blood collection tubes and additives for serum, plasma, and whole blood testing. H01 addresses requirements for the materials, construction, and labeling of venous and capillary blood collection tubes and tube assemblies.

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Foreword

Historically, venous blood was collected using a syringe and needle. This process has evolved to closed vacuum systems. Normally, venous blood collection 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 must be taken to protect the patient from microbial contamination. This precaution is met by using tubes with sterile interiors and preventing backflow from tube to patient.

Capillary blood is still collected in an open mode using various devices, some of which include microcollection tubes and capillary tubes. (For more details, refer to CLSI document H04.[1]) The health care professional's risk of exposure to blood is higher with this type of device due to collection in an open mode. Therefore, the health care professional must use particular care with capillary blood collection tubes.

This standard contains information on tubes and additives for venous and capillary blood collection. It is written for manufacturers of venous and capillary blood collection devices and for assay/instrument manufacturers. Requirements for the materials, construction, and labeling of these devices are detailed in this document.

The current CLSI guideline GP34, *Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection*,[2] is the complementary document to this standard that provides guidance for conducting validation and verification testing for these blood collection devices for tube manufacturers, assay/instrument manufacturers, and clinical laboratories.

Key Words

Additive, anticoagulant, capillary blood collection, ethylenediaminetetraacetic acid (EDTA), heparin, thixotropic gel, trisodium citrate, tube closure, venous blood collection tubes

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

1 Scope

This document addresses requirements for the materials, manufacturing, and labeling of venous and capillary blood collection devices. Capillary blood collection devices addressed in this document include only microcollection devices (see Section 3.2).

The document also provides a description, mode of action, and specifications for most common anticoagulants found in blood collection devices.

2 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are 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 all known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the US Centers for Disease Control and Prevention.[3] For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to all known infectious disease, refer to CLSI document M29.[4]

3 Terminology

3.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

3.2 Definitions

additive – in a specimen collection tube, any ingredient that is placed in a collection container to facilitate an intended function (eg, to prevent the blood from clotting or to prevent glycolysis); **NOTE:** While the container closure is not considered an additive, it may contain or be coated with additives, which, if they come into contact with the specimen, may be considered additives.

anticoagulant – agent that prevents coagulation of blood or blood products.

assembly – the tube and the closure.

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