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## GP39-A6

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

Sample

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

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### Abstract

Clinical and Laboratory Standards Institute document GP39-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. GP39 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.<sup>1</sup>) 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*,<sup>2</sup> 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

## **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.<sup>3</sup> 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.<sup>4</sup>

### **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.

**capillary blood** – blood obtained by skin puncture or incision that contains a mixture of undetermined proportions of blood from arterioles, venules, and interstitial and intracellular fluids.

**closure coating** – lubricant or other material applied to the container closure.

**clot activator** – material used to initiate the clotting mechanism.

**draw** – quantity of blood drawn into the venous blood collection tube from a venipuncture; **NOTE:** For testing purposes, the conditions are defined as follows: 101 kPa (760 mmHg) pressure and 20 °C ambient temperature. The temperature of the blood collected is assumed to be 37 °C.

**expiration date** – date after which the product, when stored under recommended conditions, should no longer be used.

**glycolytic inhibitor//antiglycolytic agent** – agent that inhibits the utilization of glucose by blood cells.

**label** – printed, written, or graphic information placed on a device or container (ISO 15197).<sup>5</sup>

**lot number//control number** – an alphanumeric and/or symbolic identification placed on the label by the manufacturer that enables traceability to the manufacturing history of the product.

**microcollection devices** – proprietary systems or kits with matched components that are used to simplify the processes of collection, storage, centrifugation, and separation of the blood constituents less than 1 mL in volume.

**nominal tube size** – description of the approximate external diameter and length of a tube in millimeters.

**package insert** – instructions for use and other information supplied with the material that is not attached to any part of the package (modified from ISO 15197).<sup>5</sup>

**sample** – one or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production (ISO 15189)<sup>6</sup>; **NOTE:** For example, a volume of serum taken from a larger volume of serum (ISO 15189).<sup>6</sup>

**specimen (patient)** – the discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole.

**thixotropic separator gel** – inert material that undergoes a temporary change in viscosity during centrifugation; **NOTE:** It has a density intermediate to cells/clot and plasma/serum.

**tube** – rigid part of the assembly that contains the specimen.

**tube closure** – component that allows needle penetration into the container and that can be removed or pierced to obtain an aliquot of the specimen; **NOTE:** A tube closure is often referred to as a stopper.

**tube coating** – material applied to the interior surface of the tube.

**tube interior** – inside surfaces of the tube and closure that come into contact with the blood specimen.

**venous blood** – deoxygenated blood found in the veins that is high in carbon dioxide having released oxygen and absorbed CO<sub>2</sub> in the tissues.

## The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI document HS01—*A Quality Management System Model for Health Care*. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are as follows:

- |                                    |           |  |  |  |
|------------------------------------|-----------|--|--|--|
| Documents and Records Organization | Personnel | Equipment Purchasing and Inventory Process Control | Information Management Occurrence Management Assessments—External and Internal | Process Improvement Customer Service Facilities and Safety |
|------------------------------------|-----------|--|--|--|

GP39-A6 addresses the QSEs indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Documents and Records Organization	Personnel	Equipment	Purchasing and Inventory	Process Control	Information Management	Occurrence Management	Assessments—External and Internal	Process Improvement	Customer Service	Facilities and Safety
				X GP34 H04						M29

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

### Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow, which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

GP39-A6 addresses the clinical laboratory path of workflow steps indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
	X H04							

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

## Related CLSI Reference Materials\*

- GP34-A**      **Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline (2010).** This document provides guidance for conducting verification and validation testing for venous and capillary blood collection tubes.
- H04-A6**      **Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Sixth Edition (2008).** This document provides a technique for the collection of diagnostic capillary blood specimens, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process, and transfer diagnostic capillary blood specimens are also included.
- M29-A3**      **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

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\* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

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