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GP34-A

Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline

This document provides guidance for conducting validation and verification testing for venous and capillary blood collection tubes.

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

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Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline

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Abstract

Clinical and Laboratory Standards Institute document GP34-A—*Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline* is a guideline for manufacturers of venous and capillary blood collection tubes and users of blood collection tubes for serum, plasma, and whole blood testing. GP34 provides guidelines for validation and verification of test (examination) performance.

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Contents

Foreword

Currently, no guideline is available for either *in vitro* diagnostic (IVD) manufacturers or clinical laboratories to validate or verify use of the various venous and capillary blood collection tubes within each of the following laboratory medicine disciplines: chemistry, immunochemistry, hematology, and coagulation. However, for microbiology assays or culture methods, several documents address validation and quality control of collection tubes (see CLSI documents M40, M47, and M15).[1-3]

This guideline contains information on tubes for venous and capillary blood collection. It is written for manufacturers of venous and capillary blood collection devices; for assay/instrument manufacturers; and for those who are responsible for acquisition, handling, and use of the equipment described in this document.

Specimen collection devices, especially venous and capillary blood collection tubes, are classified as IVD devices. Because these devices are used to collect patient blood samples that are analyzed on highly sensitive clinical instrumentation, it is extremely critical for accurate and precise test results that these collection devices be verified for use on this instrumentation.

IVD manufacturers are challenged by regulatory agencies to ensure safety and efficacy of their devices as part of the validation process before release of the devices for use in the clinical laboratory. Tube manufacturers can use this guidance document to establish and standardize their validation process for both current and new blood collection tubes. In addition to this document, CLSI standard H01, *Tubes and Additives for Venous Blood Specimen Collection*[4]—a complementary document to this guideline—details the requirements for materials, manufacturing, and labeling of blood collection devices.

Additionally, accrediting organizations challenge clinical laboratories to ensure the acceptability or compatibility of their venous and capillary blood collection devices, with their current instrumentation and patient population.[5] This type of verification will help the clinical laboratories ensure accurate and precise test results for their collection device and test system.

Key Words

Capillary blood collection, instrumentation, validation, venous blood collection tubes, verification

Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline

1 Scope

This document provides step-by-step recommendations for validation and verification of venous and capillary blood collection devices. Capillary blood collection devices addressed in this document include only microcollection devices (see Section 3.2). It also includes guidance for ascertaining the acceptability/compatibility for clinical performance in chemistry, immunochemistry, hematology, and coagulation. This guideline does not address validation and verification for clinical performance in immunohematology, molecular diagnostics, arterial blood gas analysis, proteomics, or genomics.

The focus and procedures of this document are for quantitative measurement only. For qualitative measurement, the study requires a different study design.

This document is written for manufacturers of venous and capillary blood collection devices; assay/instrument manufacturers; all clinical laboratory personnel; and those who are responsible for acquisition, handling, and use of the equipment described in this document.

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.[6] 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.[7]

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 Comité Européen de Normalisation (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 focuses on harmonization of terms to facilitate the global application of standards and guidelines.

In order to align the use of terminology in this document with that of ISO, the terms *preexamination*, *examination*, and *postexamination* were adopted. For the sake of introduction and to avoid confusion, the subcommittee chose to include the ISO terms parenthetically where the US terms appear. In addition, the term *sample* replaces the term *specimen* where appropriate, and *measurand* replaces *analyte*. The users of

