CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

CLSI PRE06™

Evaluation of External Transport Systems

CLSI PRE06 describes processes for evaluating an external transport system.

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

CLSI PRE06-Ed1
February 2026

Evaluation of External Transport Systems

Joe Wiencek, PhD, DABCC, FADLM
Sheryl Thiessen, MA, RT(CSMLS), MLS(ASCP)
Jose C. Jara Aguirre, MD, DABP, FASCP, FACSc, FCAP
Ghaith Altawallbeh, MSC, PhD, DABCC
Sophie Arbefeville, MD
J. Rex Astles, PhD, DABCC, FADLM
Alicia G. Branch, PhD
Kelly Doyle, PhD, DABCC, FADLM
Christopher Farnsworth, PhD, DABCC, FADLM
Kevin Forbes
Sucheta Banerjee Kurundkar, PhD, MBA
Angela Mariani, PhD
Bal Mukund Mishra, MS, PhD, MB(ASCP)^{CM}
Mads Nybo, MD, PhD
Ronnie Pedersen, PhD
Christina Pierre, PhD, DABCC, FADLM
Ghazaleh Pourmahram, PhD, MICR
Melissa Richard-Greenblatt, PhD, D(ABMM), FCCM, DTM&H

Abstract

CLSI PRE06—*Evaluation of External Transport Systems* describes processes for evaluating an external transport system. Specimens are commonly transported from external, off-site locations to the laboratory, where they are eventually examined. The system is comprised of any number of distinct and interdependent processes encompassing numerous variables that affect the system in unpredictable ways. Taken as a whole, the sending site, receiving site, examining laboratory, and all of the transportation modes and the components used, including the specimen carriers, dataloggers, and the supporting quality management system, make up the external transport system. Each component, route, and mode of transport should be individually and collectively evaluated. To ensure the integrity of the specimens transported, the sending site, receiving site, and examining laboratories are collectively responsible for evaluating the entire transport process, including its individual parts if warranted. Means to mitigate adverse conditions, such as extreme weather, should be communicated between each facility in real time. CLSI PRE06 presents important considerations for each part of the transport process, as well as best practice recommendations for assessing the suitability of an existing system or when changes are made within that system.

CLSI. *Evaluation of External Transport Systems*. 1st ed. CLSI guideline PRE06 (ISBN 978-1-68440-307-3 [Print]; ISBN 978-1-68440-308-0 [Electronic]). Clinical and Laboratory Standards Institute, USA, 2026.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Suggested Citation

CLSI. *Evaluation of External Transport Systems.* 1st ed. CLSI guideline PRE06. Clinical and Laboratory Standards Institute; 2026.

CLSI PRE06-Ed1

ISBN 978-1-68440-307-3 (Print)

ISBN 978-1-68440-308-0 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic) Volume 46, Number 2

Contents

Contents (Continued)

Foreword

The process of transporting laboratory specimens ranges from the very simple, such as carrying the specimen from the patient's bedside to the on-site laboratory, to the very complex, in which the specimen journey can encompass many critical and vulnerable steps that originate from an off-site collection location to its final destination at the examining laboratory.

Many of these processes involve outside entities such as courier services, occur over public roads, railways, waterways, or airways, and are affected by environmental and time variables. Most of these variables are outside the laboratory's control.

Any facility that packages, stores, transports, or receives medical laboratory specimens, including sites where specimens are collected or processed, central laboratories, and larger referral laboratory centers, has an important role in assuring that transported specimens are not adversely affected by the total transportation process.

CLSI PRE06 provides risk-based recommendations for assessing acceptable performance of each element of the transportation system so that the laboratory is aware of potential limitations and can take steps to mitigate any adverse effects. Included is guidance on continued monitoring and managing of the quality of the external transport process.

Much of the currently available literature focuses on internal transport systems (ie, processes that take place within a facility or campus), where the specimen journey is generally under the control of the on-site laboratory or parent organization. Internal transport systems include transport means such as hand delivery, an on-site pneumatic tube system, or the use of autonomous robotic carriers. No published guidance document provides in-depth information on the selection, implementation, evaluation, and ongoing performance verification of an external transport system based on the materials used, the packing configuration within the temporary storage and transport containers, and the environmental and physical conditions encountered during the transport. CLSI PRE06 is intended to cover that need by identifying many relevant elements to consider before selecting or implementing an external system, and ways to monitor ongoing performance to ensure the system meets its intended use.

CLSI PRE06 is an evaluation, rather than a validation or verification, of a given system because there are many interdependent variables with no defined performance criteria for the majority of the materials and processes involved. The laboratory must determine the acceptability of each element individually and collectively based on its needs.

CLSI PRE06 provides a flexible approach to assess the suitability of the entirety of a transport system, including:

- The background and general characteristics of common and emerging external transport system devices and tools for monitoring the system
- A summary of the background research on the effects of external transport conditions on specimen integrity, including: climates; microclimates; temperature fluctuations and extremes; altitude; vibrational, accelerative and decelerative forces; humidity, etc.
- Criteria to assess equipment performance, in the absence of any manufacturer's performance claims, including:
- Implement a tracking system for specimens
  - Internal and outdoor storage containers (eg, lockboxes)
  - Specimen transport containers
  - Data acquisition products (eg, dataloggers such as global positioning services, temperature monitoring, etc.)
- Considerations specific to different specimen types such as whole blood, plasma, serum, body fluids, urine, tissue, etc.
- Considerations for new and emerging technologies

- A risk assessment approach to map or define the external transport system to understand the unique, sometimes site-specific, issues that can affect the stability of the specimens that an examining laboratory might receive
- The means to evaluate the system, including the storage and transport containers, to ensure specimens will remain unaffected by external conditions until they arrive in the laboratory
- The means to monitor the variety of environmental climates, including seasonal variability and microclimates, and physical conditions to which the specimen can be exposed between the originating collection site and the final examining laboratory
- Recommendations on how to minimize adverse effects due to the transport conditions, including the name and arrival time of the transportation device/vehicle at the specimen arrival location.
- Evaluation criteria to consider when implementing a new system, including new technologies entering the market, such as uncrewed aerial systems (ie, drones)

NOTE: The content of CLSI PRE06 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

agitation
climate
external
humidity
microclimates
stability
temperature
transport

Chapter 1

Introduction

Evaluation of External Transport Systems

1 Introduction

1.1 Scope

CLSI PRE06 focuses on evaluation criteria for a laboratory's external transport system, which can involve collective responsibilities with other entities such as physician offices, specimen collection sites, centralized laboratories, commercial courier services, or large referral laboratories. CLSI PRE06 covers external transport methodologies (courier systems, storage and transport containers, and portable incubators), routes and processes, as well as new modes of transport (eg, drones).

CLSI PRE06 does not discuss the evaluation of an internal specimen delivery system, including a pneumatic tube system or internal autonomous robotic carriers.

The intended users of CLSI PRE06 are health care providers, accrediting organizations, government and regulatory agencies, and *in vitro* diagnostic (IVD) industry manufacturers. Governmental agencies can use CLSI PRE06 to establish regulatory and accreditation requirements relevant to external transport systems. By defining performance expectations, CLSI PRE06 assists industry partners when they design the components used within these systems to develop their product or service to meet the needs of their medical laboratory customers.

CLSI PRE06 will not discuss in-depth the requirements for Transportation of Dangerous and/or Hazardous Goods (TDG). Although some mention is necessary, regulations change and are often determined by national or local agencies. Each organization must adhere to the regulations under which it operates.

CLSI PRE06 will not include specimen handling and transport as it pertains to human safety (eg, for virology specimens see CLSI M29[1]).

1.2 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 bloodborne pathogens. Published guidelines are available that discuss the daily operations of diagnostic medicine in humans and animals while encouraging a culture of safety in the laboratory.[2] 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 diseases, refer to CLSI M29.[1]

1.3 Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization whenever 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 different countries and regions and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. CLSI recognizes

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

PRINT ISBN 978-1-68440-307-3

ELECTRONIC ISBN 978-1-68440-308-0

CLSI PRE06-Ed1