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Quality Control of Microbiological Transport Systems; Approved Standard

This document provides criteria to assist manufacturers and end users of transport devices in providing and selecting dependable products for the transport of microbiological clinical specimens.

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

NCCLS

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Quality Control of Microbiological Transport Systems; Approved Standard

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Abstract

NCCLS document M40-A—*Quality Control of Microbiological Transport Systems; Approved Standard* presents the criteria that shall be considered when choosing a microbiological transport device, to facilitate sample preservation. Quality control considerations for the manufacturer and testing laboratory are presented, as well as techniques, control organisms, and acceptability criteria. This document provides a consistent protocol for initial testing of microbiological transport devices by manufacturers and a method by which laboratories can validate manufacturer claims and compare devices.

NCCLS. *Quality Control of Microbiological Transport Systems; Approved Standard*. NCCLS document M40-A (ISBN 1-56238-520-8). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

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Foreword

In 1893, Councilman first described making transport swabs by wrapping cotton pledgets around the end of wires, enclosing these wires in test tubes, and sterilizing them in a hot air sterilizer.[1] After sterilization, the wires, “still enclosed in the test tubes,” were carried to the wards where the wire could be removed and used to rub the pharyngeal membrane of patients suspected to have diphtheria. After collection, the test tubes were labeled and sent to the laboratory where specimens could be plated.

The development of transport devices was a result of public health concerns.[2] Maintaining organism viability during transport to the public health laboratory was imperative for isolation and identification of the agents responsible for relevant infectious diseases. During the 1930s, 1940s, and 1950s, infections of public health concern, particularly gonorrhea and bacterial diarrhea, were the driving force behind development of transport media and devices.[3] Most studies focused on evaluation of performance rather than establishment of an acceptable standard of expected performance.[4] It is difficult to determine when systematic quality control began to be applied to transport systems. However, it was Rubbo and Benjamin who noted that certain batches of cotton wool used on swabs were associated with faster microbial death rates than others and that this phenomenon (toxicity) could be countered by the addition of serum onto the transport swabs.[5]

Within the hospital setting, use of transport devices for various “routine cultures” began as investigators determined variability in recovery from specimens plated at the bedside compared to those routed to the laboratory via established mechanisms.[6] Today, a number of factors contribute to the increasing emphasis on the use of transport devices to maintain specimens for microbiological testing. These include increased use of outpatient treatment that has accompanied shortened hospital stays, and centralization of laboratory services due to both managed care and shortage of individuals with expertise in clinical microbiology. Standardization of the quality control of transport devices is long overdue.

As new technologies provide the opportunity to redefine the method of recovery or detection of organisms of interest, standardizing the quality control testing and acceptance criteria will become important to assure the highest level of care to patients. This document on quality control of transport devices will assist in standardization of the performance of these devices.

In the United States, basic manufacturing requirements for medical devices, including *in vitro* diagnostic (IVD) devices, were established via the Medical Device Amendments of 1976. This legislation gave the Food and Drug Administration (FDA) authority to regulate medical devices (premarket notification, [510(k)] and premarket approval [PMA]), and develop consistent manufacturing requirements (Good Manufacturing Practices). Good Manufacturing Practices include the requirement to perform product quality control testing prior to distribution. Each manufacturer is required to establish the type of testing to be performed, as well as acceptance criteria based on the product and its intended use. Additionally, the European Union (EU) has recently adopted the Medical Device Directive 93/42/EEC and the *In Vitro* Diagnostic Device Directive 98/79/EC that have requirements very similar to those in the U.S. The Directives include provisions to utilize harmonized standards as a method of demonstrating conformity to the Directive requirements. Likewise, the FDA has recently formalized the use of these types of standards by manufacturers to demonstrate performance in premarket submissions. Further discussion of regulatory considerations for these markets can be found in Appendix B.

Acknowledgment

This standard was developed through the cooperation of the NCCLS Area Committee on Microbiology and its Subcommittee on Quality Control of Microbiological Transport Systems, and Committee E13, Culture Media of the Department for Medical Standards (Normenausschuss Medizin) at the German Standards Institution (Deutsches Institut für Normung [DIN]). Representatives of both NCCLS and DIN participated in the development of each organization's respective standard. It is expected that this effort will advance the international harmonization of this important microbiology standard, thereby improving healthcare delivery worldwide.

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Key Words

Acceptable performance, acceptance criteria, biological properties, control strains, microbiological, microbiological testing, molecular transport, performance criteria, quality control, regulatory considerations, specimen transport, standards, storage conditions, transport devices, transport medium, viral transport

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Quality Control of Microbiological Transport Systems; Approved Standard

1 Scope

It is clear that the transport of clinical specimens is a critical component for accurate diagnosis. The preservation of inherent, interpretive attributes of microorganisms and/or nucleic acids can be quickly compromised when the transport conditions or transport devices are suboptimal. The advent of antigen detection methods, methods for amplification and detection of genetic elements, and the requirement for local or distant transport of these specimens to a testing facility has imposed further considerations on manufacturers to provide products that will not compromise the ability of the laboratory to provide clinically relevant data to physicians. Clinicians should be able to collect and submit specimens to the laboratory with a reasonable assurance that the transport device will maintain the viability of microorganisms and/or preserve nucleic acids present in the specimen. Laboratorians should be able to retrieve specimens from containers, devices, and transport media with a reasonable assurance that representative components of the specimen were maintained during transport.

This standard provides criteria to the manufacturers and end users of transport devices to assist in provision of dependable products for the transport of microbiological clinical specimens. Manufacturers will be able to state whether or not the performance characteristics of a particular product satisfy the performance standards as specified in this document. Furthermore, manufacturers shall state whether or not any additional testing is required prior to the use of a particular product.

In this document, except as specifically noted, quality control consists of an assessment of the performance characteristics of a complete device and not the individual components. There are multiple variables involved in the manufacture of a transport device, including, but not limited to, the container, transport medium, collection device, packaging, and atmosphere. It is fundamental that the assessment of the device be directed at measurable performance characteristics for the particular device.

This document is not intended to provide proprietary information on product development, but rather to provide to the device user assurance that manufacturer claims are met following standardized testing and acceptance criteria. It provides guidance to the manufacturer in addressing critical issues related to specimen integrity specific to the type of testing to be performed, e.g., bacterial and viral culture, or nucleic acid detection. This document does not address the technique of transport device manufacture, but focuses on the methods for quality control testing and acceptance criteria to provide a product suitable for analysis of clinical specimens for agents of disease.

Transport devices are essential components of the preanalytical process of microbiology laboratory testing. It is recognized that these early steps in the total testing process are critical to production of clinically relevant information. Patients, physicians, healthcare providers, and laboratorians expect products that meet the highest standards of laboratory practice. This document will facilitate this goal.[a] And while it is beyond the scope of this document to address the design of devices, it is imperative that device design promotes correct use, and that laboratorians select devices that best serve the user needs of the physician and the patient.

Although a discussion of specimen transport conditions is beyond the scope of this document, it is recognized that temperature has a significant effect on preservation of microorganisms in various transport devices. There are a number of recent studies that have compared performance of transport devices inoculated with various organisms at room temperature (20 ºC to 25 ºC) and cold temperature (4 ºC to 8 ºC). These studies have found simulated transport performance at cold temperatures to be

[a] For example, in the U.S., the Clinical Laboratory Improvement Amendments (CLIA) guidelines place the responsibility for acceptance of quality specimens on the laboratorian.

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