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Abbreviated Identification of Bacteria and Yeast; Approved Guideline

This document provides the minimum identification criteria that can be used to rapidly identify organisms commonly isolated from clinical specimens.

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

NCCLS...

Serving the World's Medical Science Community Through Voluntary Consensus

NCCLS is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

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- the acceptance of a document as a consensus standard or guideline.

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Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

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Abstract

Many microorganisms commonly isolated in human diagnostic microbiology laboratories exhibit specific morphologic or biochemical traits that can be determined rapidly upon obtaining a pure colony. When such rapidly obtained parameters allow reliable identification of the organism with a high degree of certainty, the necessity of performing more time-consuming tests is decreased, and timely patient care is enhanced.

NCCLS document M35-A—*Abbreviated Identification of Bacteria and Yeast; Approved Guideline* includes the minimum identification criteria that can be used to rapidly identify a limited number of organisms commonly isolated from patient specimens. Although these tests do not rule out an occasional misidentification, those errors may not have important consequences with regard to patient outcome. Those situations in which rapid test results may have limitations are described. With those exceptions, confirmatory identification is not clinically useful and need not be done.

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The Quality System Approach

NCCLS subscribes to a quality 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 through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1—*A Quality System Model for Health Care.* The quality system approach applies a core set of "quality system essentials (QSEs)," basic to any organization, to all operations in any healthcare service's path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

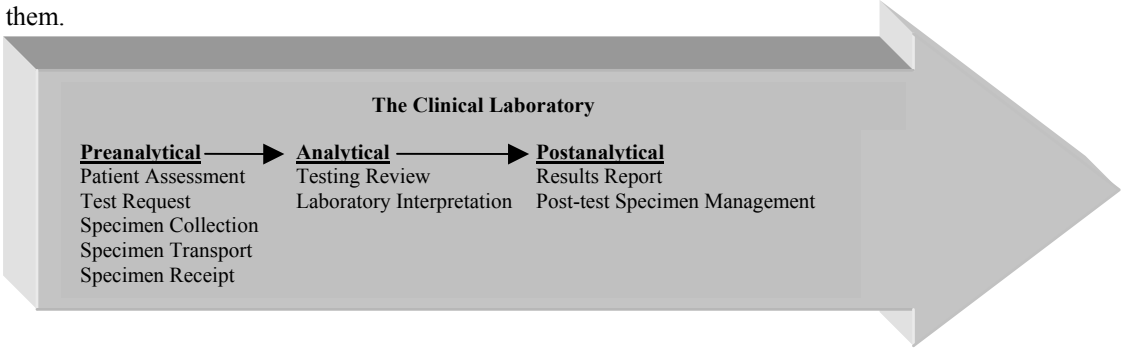
M35-A addresses the following Quality System Essentials (QSEs)

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
					X						

Adapted from NCCLS document HS1— *A Quality 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, GP26-A2 defines a clinical laboratory path of workflow which consists of three sequential processes: preanalytical, analytical, and post analytical. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information. The arrow depicts the sequence, from left to right, that any clinical laboratory follows. In addition, the necessary steps or subprocesses are listed below them.



Most of NCCLS's documents relate to the clinical laboratory, so the most common path of workflow will be that depicted above. The path of workflow for other healthcare activities, e.g., respiratory services, imaging services, etc., or for other types of organizations, e.g., medical device manufacturers, will differ from that of the clinical laboratory. All such paths of workflow describe the sequence of activities necessary to produce the organization's or an entity's specific product or services. For those documents that relate to other paths of workflow, the icon will reflect different process steps.

M35-A addresses the following steps within the Clinical Laboratory Path of Workflow

Preanalytical					Analytical		Postanalytical	
Patient Assessment	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpretation	Results Report	Post-test Specimen Management
					X	X	X	

Adapted from NCCLS document HS1— *A Quality System Model for Health Care.*

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Foreword

Microorganisms isolated in the clinical microbiology laboratory demonstrate unique biochemical and morphologic characteristics. These characteristics provide a mechanism for determination of microbial identity to the genus (and sometimes, species) level. Identification of pathogenic bacteria and yeast provides the basis for guidance of treatment with antimicrobial and antifungal agents. In the clinical microbiology laboratory, the need for accurate reporting to the clinician of microbial identification is coupled with a demand for rapid turnaround time to allow for initiation of therapy. These requirements often demand the expenditure of resources in a healthcare environment where laboratory personnel are faced with ever increasing financial and manpower constraints. The recognized need for finding cost-effective approaches to diagnostic microbiology obviates the use of time- and resource-consuming, comprehensive microbial identification techniques. M35 was created to supplement this effort.

This document contains instructions and flowcharts outlining the minimal characteristics required to identify the listed microorganisms to genus, and in some cases, to species, with enough reliability (≥ 95% accuracy) for clinical laboratory reports. It is expected that additional organisms will be added to successive versions of the document, and NCCLS would appreciate being informed of any problems that occur as a result of using the guidelines in this document for determining patient results.

Protocols for noncommercial tests used for abbreviated identifications are listed in separate appendixes at the end of this document.

Standard Precautions

Because it is often impossible to know what might be infectious, all human specimens are to be treated as infectious and handled according to “standard precautions.” Standard precautions are new guidelines that combine the major features of “universal precautions and body substance isolation” practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996; Vol 17;1:53-80.), [MMWR 1987;36(suppl 2S):2S-18S] and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure, refer to NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections*.

Key Words

Biochemical characteristics, microbiological identification

Abbreviated Identification of Bacteria and Yeast; Approved Guideline

1 Introduction

A variety of methods can be used to identify microorganisms of clinical importance. The most well characterized employ a battery of biochemical and enzymatic tests that are used after characterization based on initial gram stain and colony morphological characteristics. Often these methods require time and materials that add to the cost of the final identification. Even simple tests such as the bacitracin and optochin disk tests require overnight incubation. Waiting for results of these test methods may unnecessarily delay reporting of clinically important isolates and may slow the laboratory workflow.

Although many laboratorians use rapidly determined characteristics, such as odor, immediate enzymatic reactions (spot tests), and other criteria for "presumptive" or initial identification, many of these rapid methods have not been standardized or validated. The methods described in this guideline are those believed to yield a result reliable enough for clinical decision-making but are cost-effective, take less time, and are easier to perform than conventional methods. Several authors have examined the cost savings of using rapid methods or the overall patient care benefits (economic and general) that rapid reporting of results yield.[1,2,3] Tests that may be included in this category are single-tube, slide, spot, agglutination, disk, chromogenic media, fluorogenic, enzymatic, microscopic, morphologic, or plate methods that can be performed within a few hours. Proprietary multitest and molecular-based systems are not included. A critical factor in the performance of these tests is the competency and experience of the microbiologist. Initial correct interpretation of colonial and gram stain characteristics is essential to achieving the desired results.

Laboratory directors, managers, and supervisors are responsible for assuring that these methods are only used in situations in which the competency of the tester is adequate. Isolates to be tested should have been determined by the experienced tester to have a high likelihood of verifying the suspected identification. Inexperienced laboratorians should be under the direct supervision of an experienced technologist or use alternate methods until proficiency has been achieved.

Isolates conforming to the reactions described in the appendix will identify the named organism with >95% accuracy, and their identification can thus be reported without qualification, with the caveats listed below. Confirmation by additional procedures is unnecessary. It should also be emphasized that lack of a positive result in the rapid tests included here does not rule out the identification of any isolate. It simply indicates the need for further testing.

2 Scope

Many laboratories use FDA-approved commercial systems for identification of microorganisms, because they lack the confidence in or resources for performing in-house validations of alternative methods. Use of such panels has resulted in greater standardization and more accurate taxonomic identifications, albeit at relatively higher cost. M35-A—*Abbreviated Identification of Bacteria and Yeast; Approved Guideline* provides well-documented, published studies to guide laboratories in choosing rapid, reliable, and often less expensive alternatives for laboratories that otherwise could not adopt such methods. This guideline shares the experience and expertise of other microbiologists for reporting bacterial and yeast identifications more rapidly than by traditional methods.