A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2013 Recommendations by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM)^a

Ellen Jo Baron,^{1,2} J. Michael Miller,³ Melvin P. Weinstein,⁴ Sandra S. Richter,⁵ Peter H. Gilligan,⁶ Richard B. Thomson Jr.,⁷ Paul Bourbeau,⁸ Karen C. Carroll,⁹ Sue C. Kehl,¹⁰ W. Michael Dunne,^{11,12} Barbara Robinson-Dunn,¹³ Joseph D. Schwartzman,¹⁴ Kimberle C. Chapin,¹⁵ James W. Snyder,¹⁶ Betty A. Forbes,¹⁷ Robin Patel,¹⁸ Jon E. Rosenblatt,¹⁸ and Bobbi S. Pritt¹⁸

¹Department of Pathology, Stanford University School of Medicine, Stanford, California; ²Cepheid, R&D, Sunnyvale, California; ³Microbiology Technical Services, LLC, Dunwoody, Georgia; ⁴Department of Medicine and Pathology, Robert Wood Johnson Medical School, New Brunswick, New Jersey; ⁵Department of Clinical Pathology, Cleveland Clinic, Cleveland, Ohio; ⁶Department of Pathology and Laboratory Medicine, University of North Carolina School of Medicine, Chapel Hill, North Carolina; ⁷Department of Pathology, NorthShore University HealthSystem, Evanston, Illinois; ⁸Scientific Affairs, BD Diagnostics, Sparks, Maryland; ⁹Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, Maryland; ¹⁰Department of Pathology, Medical College of Wisconsin, Milwaukee, Wisconsin; ¹¹bioMerieux, Inc, Durham, North Carolina, and ¹²Department of Pathology and Immunology, Washington University School of Medicine, St. Louis, Missouri; ¹³Department of Pathology, William Beaumont Hospital to Beaumont Health System, Royal Oak, Michigan; ¹⁴Department of Pathology, Geisel School of Medicine at Dartmouth, Lebanon, New Hampshire; ¹⁵Department of Pathology, Brown Alpert Medical School, Providence, Rhode Island; ¹⁶Department of Laboratory Medicine, University of Louisville, Kentucky; ¹⁷Department of Pathology, Virginia Commonwealth University Medical Center, Richmond, Virginia; and ¹⁸Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, Minnesota

The critical role of the microbiology laboratory in infectious disease diagnosis calls for a close, positive working relationship between the physician and the microbiologists who provide enormous value to the health care team. This document, developed by both laboratory and clinical experts, provides information on which tests are valuable and in which contexts, and on tests that add little or no value for diagnostic decisions. Sections are divided into anatomic systems, including Bloodstream Infections and Infections of the Cardiovascular System, Central Nervous System Infections, Ocular Infections, Soft Tissue Infections of the Head and Neck, Upper Respiratory Infections, Lower Respiratory Tract infections, Infections of the Gastrointestinal Tract, Intraabdominal Infections, Bone and Joint Infections, Urinary Tract Infections, Genital Infections, and Skin and Soft Tissue Infections; or into etiologic agent groups, including Tickborne Infections, Viral Syndromes, and Blood and Tissue Parasite Infections. Each section contains introductory concepts, a summary of key points, and detailed tables that list suspected agents; the most reliable tests to order; the samples (and volumes) to collect in order of preference; specimen transport devices, procedures, times, and temperatures; and detailed notes on specific issues regarding the test methods, such as when tests are likely to require a specialized laboratory or have prolonged turnaround times. There is redundancy among the tables and sections, as many agents and assay choices overlap. The document is intended to serve as a reference to guide physicians in choosing tests that will aid them to diagnose infectious diseases in their patients.

Keywords. laboratory diagnosis; microbiology testing; specimen processing; physician-laboratory communication; medical laboratories.

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^aAlthough accurate and authoritative, IDSA considers adherence to the recommendations in this guide to be voluntary, with the ultimate determination regarding their application to be made by the physician in the light of each patient's individual circumstances.

Correspondence: Ellen Jo Baron, PhD, Cepheid, R&D, 1315 Chesapeake Terrace, Sunnyvale, CA 94089, USA (ejbaron@stanford.edu).

CSF, cerebrospinal fluid; DFA, direct fluorescent antibody; EIA, enzyme immunoassay; GI, gastrointestinal; IFA, indirect fluorescent antibody; IIF, indirect immunofluorescence; MRSA, methicillin-resistant *Staphylococcus aureus*; NAAT, nucleic acid amplification test; PMN, polymorphonuclear neutrophil; RPR, rapid plasma reagin (test for syphilis); RT, room temperature; VRE, vancomycin-resistant enterococcus; WBC, white blood cell

EXECUTIVE SUMMARY

Introduction

Unlike other areas of the diagnostic laboratory, clinical microbiology is a science of interpretive judgment that is becoming more complex, not less. Even with the advent of laboratory automation and the integration of genomics and proteomics in microbiology, interpretation of results still depends on the quality of the specimens received for analysis. Prokaryotic microorganisms, while genetically less complex than multicellular eukaryotes, are uniquely suited to adapt to environments where antibiotics and host responses apply pressures that encourage their survival. A laboratory instrument may or may not detect those mutations, so a specialist in microbiology is needed to facilitate microbiology laboratory result interpretation. Clearly, all microbes grow, multiply, and die very quickly. If any of those events occur during specimen collection, transport, or storage, the results of analysis will be compromised and interpretation could be misleading. Therefore, attention to preanalytical specimen management in microbiology is critical to accuracy.

Physicians need confidence that the results provided by the microbiology laboratory are accurate, significant, and clinically relevant. Anything less is below the community standard of care. In order to provide that level of quality, however, the laboratory requires that all microbiology specimens be properly selected, collected, and transported to optimize analysis and interpretation. Because result interpretation in microbiology depends entirely on the quality of the specimen submitted for analysis, specimen management cannot be left to chance, and those that collect specimens for microbiologic analysis must be aware of what the physician needs as well as what the laboratory needs, including ensuring that specimens arrive at the laboratory for analysis as quickly as possible after collection (Introduction-Table 1).

At an elementary level, the physician needs answers to 3 very basic questions from the laboratory: Is my patient's illness caused by a microbe? If so, what is it? What is the susceptibility profile of the organism so therapy can be targeted? To meet those needs, the laboratory requires very different information. The microbiology laboratory needs a specimen that has been appropriately selected, collected, and transported to the

Table Introduction-1. Transport Issues (General Guide)^a

| Specimen Type | Specimen Required | Collection Device, Temperature, and Ideal Transport Time |
|---|--|--|
| Aerobic bacterial culture | Tissue, fluid, aspirate biopsy, etc | Sterile container, RT, immediately |
| | Swab (2nd choice) – flocked swabs are recommended | Swab transport device, RT, 2 h |
| Aerobic and anaerobic bacterial culture | Tissue, fluid, aspirate, biopsy, etc | Sterile anaerobic container, RT, immediately |
| | Swab (2nd choice) – flocked swabs are effective | Anaerobic swab transport device, RT, 2 h |
| Fungus culture; AFB culture | Tissue, fluid, aspirate, biopsy, etc | Sterile container, RT, 2 h |
| | Swab (2nd choice) (for yeast and superficial mycobacterial infections only) | Swab transport device, RT, 2 h |
| Virus culture | Tissue, fluid, aspirate, biopsy, etc | Viral transport media, on ice, immediately |
| | Swab – flocked swabs are recommended | Virus swab transport device, RT, 2 h |
| Suspected agent of bioterrorism | Refer to Centers for Disease Control and Prevention website: http://emergency.cdc. gov/documents/PPTResponse/ table2specimenselection.pdf | |
| Serology | 5 mL serum | Clot tube, RT, 2 h |
| Antigen test | As described in the laboratory specimen collection manual | Closed container, RT, 2 h |
| NAAT | 5 mL plasma | EDTA tube, RT, 2 h |
| | Other specimen | Closed container, RT, 2 h |

Abbreviations: AFB, acid-fast bacillus; NAAT, nucleic acid amplification test; RT, Room Temperature.

^a Contact the microbiology laboratory regarding appropriate collection and transport devices and procedures since transport media such as Cary-Blair or parasite preservative transport for stool specimens, boric acid for urines, specialized containers for *Mycobacterium tuberculosis* are often critical for successful examination. The time from collection to transport listed will optimize results; longer times may compromise results.

laboratory for analysis. Caught in the middle, between the physician and laboratory, are those who select and collect the specimen and who may not know or understand what the physician or the laboratory needs to do their work. Enhancing the quality of the specimen is everyone's job, so communication between the physicians, nurses, and laboratory staff should be encouraged and open with no punitive motive or consequences.

The diagnosis of infectious disease is best achieved by applying in-depth knowledge of both medical and laboratory science along with principles of epidemiology and pharmacokinetics of antibiotics and by integrating a strategic view of host-parasite interactions. Clearly, the best outcomes for patients are the result of strong partnerships between the clinician and the laboratorian specialist. This document illustrates this partnership and emphasizes the importance of appropriate specimen management to clinical relevance of the results. One of the most valuable laboratory partners in infectious disease diagnosis is the certified microbiology specialist, particularly a specialist certified as a Diplomate by the American Board of Medical Microbiology (ABMM), the American Board of Pathology (ABP), or the American Board of Medical Laboratory Immunology (ABMLI) or their equivalent certified by other organizations. Clinicians should recommend and medical institutions should provide this kind of leadership for the microbiology laboratory or provide formal access to this level of laboratory expertise through consultation.

Impact of Specimen Management

Microbiology specimen selection and collection are the responsibility of the medical staff, not usually the laboratory, although the certified specialist may be called upon for consultation or assistance. The impact of proper specimen management on patient care is enormous. It is the key to accurate laboratory diagnosis and confirmation, it directly affects patient care and patient outcomes, it influences therapeutic decisions, it impacts hospital infection control, it impacts patient length of stay, hospital costs, and laboratory costs, and influences laboratory efficiency. Clinicians should consult the laboratory to ensure that selection, collection, transport, and storage of patient specimens are performed properly.

Tenets of Specimen Management

Throughout the text, there will be caveats that are relevant to specific specimens and diagnostic protocols for infectious disease diagnosis. However, there are some strategic tenets of specimen management and testing in microbiology that stand as community standards of care and that set microbiology apart from other laboratory departments such as chemistry or hematology. Ten points of importance are:

1. Specimens of poor quality must be rejected. Microbiologists act correctly and responsibly when they call physicians to clarify and resolve problems with specimen submissions.

2. Physicians should not demand that the laboratory report "everything that grows," thus providing irrelevant information that could result in inaccurate diagnosis and inappropriate therapy.

3. "Background noise" must be avoided where possible. Many body sites have normal microbiota that can easily contaminate the specimen. Therefore, specimens from sites such as lower respiratory tract (sputum), nasal sinuses, superficial wounds, fistulae, and others require care in collection. 4. The laboratory requires a specimen, not a swab of a specimen. Actual tissue, aspirates, and fluids are always specimens of choice, especially from surgery. A swab is not the specimen of choice for many specimens because swabs pick up extraneous microbes, hold extremely small volumes of the specimen (0.05 mL), make it difficult to get bacteria or fungi away from the swab fibers and onto media, and the inoculum from the swab is often not uniform across several different agar plates. Swabs are expected from nasopharyngeal and viral respiratory infections. Flocked swabs have become a valuable tool for specimen collection and have been shown to be more effective than Dacron, rayon, and cotton swabs in many situations. The flocked nature of the swab allows for more efficient release of contents for evaluation.

5. The laboratory must follow its procedure manual or face legal challenges. These manuals are usually supported by the literature.

6. A specimen should be collected prior to administration of antibiotics. Once antibiotics have been started, the flora changes, leading to potentially misleading culture results.

7. Susceptibility testing should be performed on clinically significant isolates, not on all microorganisms recovered in culture.

8. Microbiology laboratory results that are reported should be accurate, significant, and clinically relevant.

9. The laboratory should be allowed to set technical policy; this is not the purview of the medical staff. Good communication and mutual respect will lead to collaborative policies.

10. Specimens must be labeled accurately and completely so that interpretation of results will be reliable. Labels such as "eye" and "wound" are not helpful to the interpretation of results without more specific site and clinical information (eg, dog bite wound right forefinger).

The microbiology laboratory policy manual should be available at all times for all medical staff to review or consult and it would be particularly helpful to encourage the nursing staff to review the specimen collection and management portion of the manual. This can facilitate collaboration between the laboratory, with the microbiology expertise, and the specimen collection personnel, who may know very little about microbiology or what the laboratory needs in order to establish or confirm a diagnosis.

Welcome and engage the microbiology laboratory as an integral part of the healthcare team and encourage the hospital or the laboratory facility to have board-certified laboratory specialists on hand or available to optimize infectious disease laboratory diagnosis.

How to Use This Document

The full text of this document, available online, is organized by body system, although many organisms are capable of causing disease in more than one body system. There may be a redundant mention of some organisms because of their propensity to infect multiple sites. One of the unique features of this document is its ability to assist clinicians who have specific suspicions regarding possible etiologic agents causing a specific type of disease. Another unique feature is that in most sections, there are targeted recommendations and precautions regarding selecting and collecting specimens for analysis for a disease process. Within each section, there is a table describing the specimen needs regarding a variety of etiologic agents that one may suspect as causing the illness. The test methods in the tables are listed in priority order according to the recommendations of the authors and reviewers.

When room temperature (RT) is specified for a certain time period, such as 2 hours, it is expected that the sample should be refrigerated after that time unless specified otherwise in that section. Almost all specimens for virus detection should be transported on wet ice and frozen at -80° C if testing is delayed >48 hours, although specimens in viral transport media may be transported at room temperature when rapid (<2 hours) delivery to the laboratory is assured.

History and Update

The document has been endorsed by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM). Future modifications are to be expected, as diagnostic microbiology is a dynamic and rapidly changing discipline.

Notes

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