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Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection; Approved Guideline

This document provides guidance for laboratorians performing human immunodeficiency virus testing and for the interpretation of results by health care providers in advanced diagnostic laboratories.

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

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Abstract

The accurate diagnosis of human immunodeficiency virus (HIV) infection is essential for limiting the spread of infection and for the appropriate clinical management of persons infected with HIV. Over the past several years, numerous tests and testing strategies have been developed and are used by laboratorians and clinicians to diagnose HIV infection. CLSI document M53-A, *Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection; Approved Guideline*, provides an extensive review of existing laboratory methods commonly used to test for HIV infection. This guideline also offers recommendations for how to best use and interpret these tests accurately and effectively to diagnose HIV infection.

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Foreword

Since the advent of human immunodeficiency virus (HIV) testing, laboratory-based methods have undergone tremendous change. The routine use of nucleic acid tests, the introduction of antigen-antibody combination tests, and the widespread implementation of rapid testing methods, including the use of different specimen types, have changed the way HIV infection is diagnosed. Although these tests may offer improved sensitivity, specificity, and more rapid turnaround times, clinicians and laboratorians are asked to determine which tests to perform and how to best interpret the results.

There is increasing momentum to establish universal routine testing programs for HIV infection in order to limit the spread of infection and to identify individuals who may benefit from earlier initiation of antiviral therapy. In 2006, the Centers for Disease Control and Prevention issued a recommendation for routine HIV screening of all patients in the health care setting.[1] Concurrent with these recommendations, laboratorians and clinicians have used a number of new tests and testing strategies to diagnose HIV infection. Although there is an increased demand to use these tests, adequate consensus guidelines have not been proposed to assist in the appropriate use and interpretation of these tests and testing strategies.

This guideline was developed to provide an extensive review of existing laboratory methods commonly used to test for HIV infection and offer recommendations for how to best use and interpret these tests to accurately establish the diagnosis of HIV infection and effectively report these results to health care providers. This guideline is intended for use in the diagnosis of HIV-1 and HIV-2 infection in advanced diagnostic laboratories and point-of-care settings, and may not be applicable in resource-limited settings.

Key Words

Algorithms, differentiation testing, enzyme immunoassay, HIV initial testing, HIV supplemental testing, HIV-1, HIV-2, immunofluorescence assay, line immunoassay, nucleic acid testing, Western blot

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1 Scope

This document provides an overview of the natural history and response to human immunodeficiency virus (HIV) infection, an in-depth review of initial and supplemental tests for the diagnosis of HIV infection, and initiation of a quality control (QC) program for HIV testing. This guideline also addresses special situations that commonly confound HIV testing, including the diagnosis of acute and recent HIV infection, initial and supplemental testing during pregnancy, labor and delivery, and newborn testing. Special attention is also given to testing for HIV-1, non-B subtype, and HIV-2 testing. In addition, diagnostic testing algorithms are provided to assist clinicians and laboratorians in the stepwise use of these tests, as well as a framework for additional testing and the interpretation of results. Furthermore, reporting criteria for commonly obtained test results are also provided.

This guideline is intended for use in the laboratory diagnosis of HIV infection in the health care setting, and does not address methods or strategies for screening the blood supply or organ or tissue donation. Furthermore, this guideline is not intended for use outside the clinical setting and does not address issues for diagnosing HIV from nonhuman material, environmental surfaces, or postmortem. Although some of the proposed tests and testing strategies may be universally applicable, the guidelines are primarily intended for advanced diagnostic laboratories, and may not address testing methods or strategies in more resource-limited settings.

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 Centers for Disease Control and Prevention (CDC).[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 document M29.[3]

3 Terminology

3.1 A Note on 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 the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization for Standardization (ISO), and 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 and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.