



CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE.

2nd Edition

M53

Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection

Sample

This guideline includes recommendations for performing human immunodeficiency virus testing and for 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.

Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection

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Abstract

Clinical and Laboratory Standards Institute guideline M53—*Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection* provides an extensive review of existing laboratory methods commonly used to test for HIV infection. The accurate diagnosis of HIV infection is essential for limiting the spread of infection and for the appropriate clinical management of persons infected with HIV. Numerous tests and strategies have been developed and are used by laboratorians and clinicians to diagnose 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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Contents

Abstract	i
Committee Membership	iii
Foreword	vii
Chapter 1: Introduction	1
1.1 Scope	2
1.2 Background	3
1.3 Standard Precautions	8
1.4 Terminology	8
Chapter 2: HIV Testing and Interpretation Process	15
Chapter 3: Tests for Diagnosing HIV Infection	17
3.1 Laboratory Immunoassays	19
3.2 Single-Use HIV-Screening Devices	25
3.3 Molecular Assays	29
3.4 Rarely Used Assays (Available but Not Preferred or Recommended)	32
Chapter 4: Approaches for Diagnostic Testing	33
4.1 Initial and Supplemental Testing	34
4.2 <i>In Vitro</i> Diagnostic Device Modification and Laboratory-Developed Tests	39
4.3 Notification of Significant Results	39
4.4 Postexamination Specimen Retention	40
Chapter 5: Algorithms for Selecting HIV Testing Protocols	41
5.1 Recommended (Preferred) Algorithms	43
5.2 Alternative Algorithms	47
5.3 Resolving Inconclusive or Persistently Indeterminate Results	51

Contents (Continued)

Chapter 6: Special Situations for HIV Testing	53
6.1 Acute HIV Type 1 Infections	54
6.2 Determining Recent Infection to Estimate Incidence of HIV Infection	56
6.3 HIV Type 1 Group M, Non-B Subtype Infection.....	59
6.4 HIV Type 2.....	60
6.5 HIV Types 1 and 2 Combination Initial and Supplemental Testing in Pregnancy	62
6.6 Testing in Children Younger Than 24 Months of Age (Algorithm VII).....	63
6.7 HIV Type 1 Seroreversion or Incomplete Anti-HIV Type 1 Antibody Response.....	66
6.8 HIV Experimental Vaccine or Chimeric Antigen Receptor T-Cell Therapy (Lentivirus Vector) Recipients	66
6.9 Natural Viral Nonprogressors (Elite Controllers).....	67
6.10 Testing in Preexposure Prophylaxis and Postexposure Prophylaxis.....	68
6.11 Cerebrospinal Fluid Testing in HIV-Associated Central Nervous System Disorders	69
6.12 Self-Collection and Self-Testing.....	70
Chapter 7: Tests for Managing HIV Type 1 Infection	71
7.1 CD4+ T-Cell Subset Monitoring	72
7.2 Quantitative HIV Type 1 RNA Tests.....	72
7.3 HIV Type 1 Drug-Resistance Tests	74
Chapter 8: Quality Management System Process Management for HIV Testing	83
8.1 Establishing an HIV Testing Quality Control Program	84
8.2 HIV Control Materials	84
8.3 HIV Proficiency Testing Programs.....	85
8.4 Quality Control Considerations for Rapid Tests.....	85
Chapter 9: Conclusion	87
Chapter 10: Supplemental Information	89
References	90
Additional Resources	113
Appendix A. Rarely Used Assays (Available but Not Preferred or Recommended)	114
Appendix B. Reporting Comments Suggested for Initial and Supplemental HIV Diagnostic Test Results	126
The Quality Management System Approach	134

Foreword

Since HIV testing was introduced, laboratory-based methods have undergone tremendous change. The routine use of nucleic acid testing, 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 turnaround times, clinicians and laboratorians need 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 to limit the spread of infection and to identify individuals who may benefit from earlier initiation of antiviral therapy. The Centers for Disease Control and Prevention has issued recommendations for routine HIV screening of all patients in the health care setting. Concurrent with these recommendations, laboratorians and clinicians have used several new tests and testing strategies to diagnose HIV infection. Although an increased demand for these tests exists, adequate consensus guidelines have not been proposed to assist in the appropriate use and interpretation of these tests and testing strategies.

Overview of Changes

This guideline replaces the previous edition of the approved guideline, M53-A, published in 2011. Several changes were made in this edition, including:

- Reorganizing the text to follow the testing path of workflow
- Expanding the scope to include testing recommendations for resource-limited settings and for managing patients with HIV type 1-positive infections
- Adding an HIV testing and interpretation process flow chart
- Revising the algorithms used to select HIV testing protocols and associated text
- Deleting all references to HIV test “generations”
- Updating:
 - Information on currently available and preferred HIV tests
 - Test principal figures
 - Information on molecular testing
 - Recommended approaches for HIV diagnostic testing
 - Special situations for HIV testing
 - QC information

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

KEY WORDS

algorithms

HIV-1

phenotypic drug-resistance test

antibody differentiation assay

HIV-2

single-use devices

antibody discrimination assay

immunoassay

supplemental test

enzyme immunoassay

initial test

Western blot

genotypic drug-resistance test

nucleic acid test

Sample

Chapter 1

Introduction

Sample

Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection

1 Introduction

1.1 Scope

This guideline provides:

- An overview of the natural history and response to HIV infection
- An in-depth review of initial and supplemental tests used for diagnosing HIV infection
- Tests for monitoring and managing HIV type 1 (HIV-1) infections
- Recommendations for initiating an HIV QC program

This guideline also discusses special situations that commonly cause confusion in HIV testing, including:

- Diagnosis of acute and recent HIV infection
- Testing for HIV-1, group 1, non-B subtype, and HIV type 2 (HIV-2) infections
- Initial and supplemental testing during pregnancy, labor, and delivery
- Newborn testing
- HIV-1 seroconversion or incomplete antibody (Ab) response
- Recipients of HIV vaccines or chimeric antigen receptor T-cell (CAR-T) therapy
- Viral suppressors (elite controllers [ECs])
- Testing for pre- and postexposure prophylaxis
- Testing for CSF for HIV-associated central nervous system (CNS) disorders
- Self-collection and self-testing

Also included are:

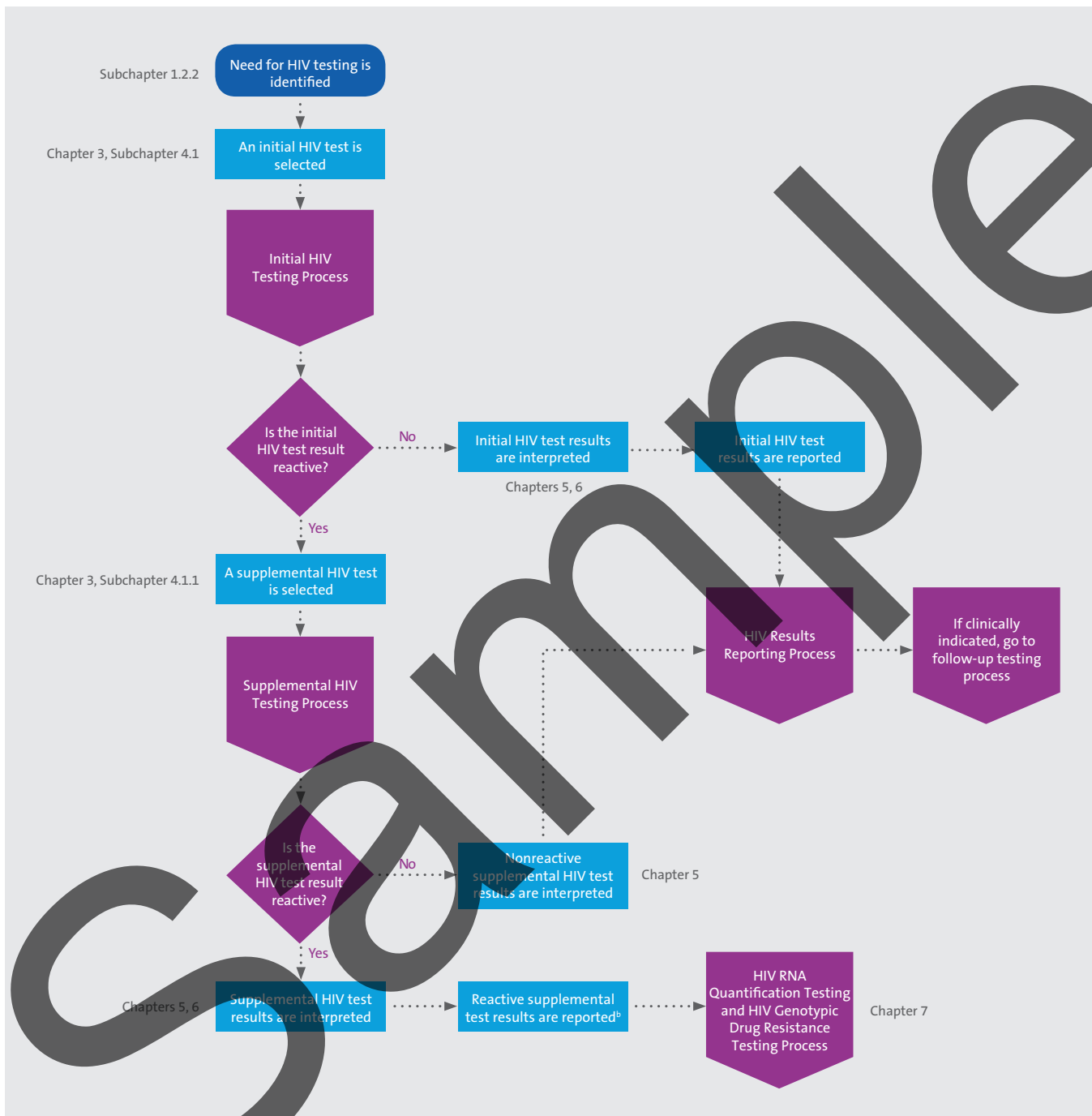
- Diagnostic testing algorithms to assist clinicians and laboratorians in the stepwise use of HIV tests
- A framework for determining the need for additional testing
- Results interpretation
- Reporting criteria for commonly obtained test results

This guideline is intended for use in diagnosing HIV-1 and HIV-2 infections in both advanced diagnostic laboratories and point-of-care (POC) settings, including resource-limited environments. It does not:

- Discuss methods or strategies for screening the blood supply or organ or tissue donation.
- Provide recommendations for use outside the clinical setting.
- Cover issues for diagnosing HIV from nonhuman material, environmental surfaces, or postmortem samples.

2 HIV Testing and Interpretation Process

Figure 4 shows the process flow chart for selecting HIV tests and interpreting results.

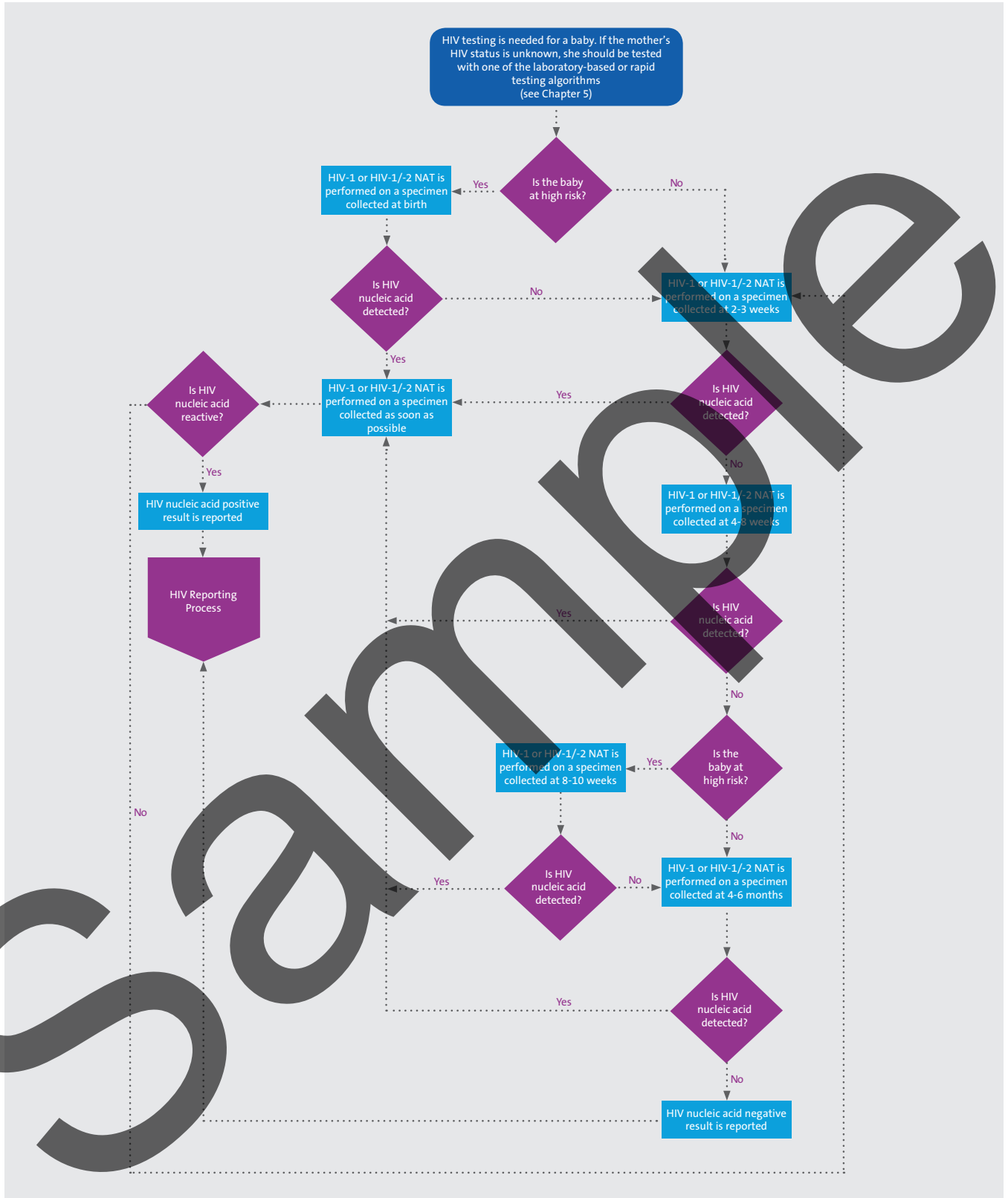


Abbreviations: HIV, human immunodeficiency virus; RNA, ribonucleic acid.

^a Five basic symbols are used in this process flow chart: oval (signifies the beginning or end of a process), arrow (connects process activities), box (designates process activities), diamond (includes a question with alternative “Yes” and “No” responses), pentagon (signifies another process).

^b Additional supplemental (confirmatory) testing may be needed depending on which algorithm is selected.

Figure 4. HIV Testing and Results Interpretation Process^a



Abbreviations: HIV, human immunodeficiency virus; HIV-1, human immunodeficiency virus type 1; HIV-1/-2, human immunodeficiency virus types 1 and 2; NAT, nucleic acid test.

Figure 21. Algorithm VII: Testing in Babies With Known or Suspected Perinatal HIV Exposure

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