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INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

WS 293-2019

Diagnosis for HIV/AIDS

(English Translation)

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Preview: page 1 of 5 shown, 13 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/ws-293-2019

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Table of Contents

Foreword
1 Scope
2 Terms and definitions
3 Abbreviations
4 Diagnosis basis
4.1 Epidemiological history
4.2 Clinical manifestations (see Appendix A for various clinical manifestations)
5 Diagnostic principles
6 Diagnosis
6.1 HIV infection
6.2 AIDS
7 Clinical stage of HIV/AIDS
7.1 Adults and young people aged 15 or older (including 15 years old)
7.2 Children under 15 years old
37 Months

Foreword

Chapter 6 of this standard is mandatory and the rest are recommended.

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard replaces WS 293-2008 Diagnostic Criteria for AIDS and HIV Infection.

Compared with WS 293-2008, the main technical changes of this standard are as follows.

- Revised the definition of the term "HIV-infected person" (see 2.3, 2008 edition 2.3) - Removed the term "latency period" "S/CO value" (see 2.5, 2.12 of the 2008 edition);

-- Revised the term "seroconversion" to "HIV serum antibody positive" (see 2.7, 2008 edition 2.8) - Revised the definition of the term "window period" (see 2.8, 2.9 of the 2008 edition);

- Revised the definition of the term "HIV antibody screening test" (see 2.10, 2.11 of the 2008 edition);

-- Revised the term "HIV antibody confirmation test" as "HIV supplementation test" and definition (see 2.11, 2008 version 2.13);

Preview: page 2 of 5 shown, 13 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/ws-293-2019

- Added the term "CD4 T lymphocyte count" "Percentage of CD4 T lymphocytes" (see 2.12, 2.13);

- Removed the term "highly active antiretroviral therapy" (see 2.14 of the 2008 edition);

- Revised the term "history of iatrogenic infection" as "historic exposure history" (see 2.15 and 4.1.4, 2008 editions 2.21 and 4.1.4);

-- Removed the term "clinical manifestations" and modified the term "HIV encephalopathy" to "HIV-related neurological symptoms" and related the definition of bed symptoms is moved to Appendix A (see A.1~A.5 in Appendix A, 2.15~2.19, 2.22 in 2008);

- Added abbreviations CPs, VL (see Chapter 3);

-- Removed the acronym HAART (see Chapter 3);

-- Revised the clinical manifestations of HIV infection and moved the specific description to Appendix A (see 2008 edition 4.2);

- Revised the description of serological test results from "positive"/"negative" to "reactive"/"no response" (see 4.3.2.1, 4.3.1 of the 2008 edition);

-- Revised HIV nucleic acid test "positive test results" as "positive nucleic acid qualitative test results or quantitative test > 5 000 CPs/mL" (See 4.3.3.2, 4.3.2.2 of the 2008 edition);

- Revised "CD4 cell test" as "immunological test" (see 4.3.4, 2008 version 4.3.3);

-- Revised the diagnostic criteria for HIV-infected persons. "Adults and young people aged 15 or older (including 15 years old)" as "adults, adolescents and 18" "Children over the age of one month", "Children under the age of 15" are "children 18 months of age and younger" and have revised the diagnostic criteria.

Incorporate nucleic acid testing into diagnostic criteria (see 6.1, 6.1 of the 2008 edition);

-- Revised "Clinical Staging of HIV/AIDS" (see Chapter 7, Chapter 7 of the 2008 edition);

- Increased the clinical manifestations of HIV infection in Appendix A;

-- Revised Appendix B (see Appendix A of the 2008 edition).

This standard was drafted. China Center for Disease Control and Prevention, STD/AIDS Prevention and Control Center, Peking Union Medical College Hospital, China Medical University, Shanghai Municipal Center for Disease Control and Prevention, Military Medical Research Institute of the Chinese People's Liberation Army Academy of Military Sciences, and Beijing Ditan Medical College affiliated to Capital Medical University Hospital, Beijing You'an Hospital, Capital Medical University, China Food and Drug Control Research Institute, Yunnan Provincial Center for Disease Control and Prevention, National Health Health Commission Clinical Laboratory Center, Guangzhou Eighth People's Hospital, Beijing Entry-Exit Inspection and Quarantine Bureau, Henan Provincial Center for Disease

Preview: page 3 of 5 shown, 13 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/ws-293-2019

Control and Prevention.

1 Scope

This standard specifies the diagnostic basis, diagnostic principles, diagnosis and clinical stage of AIDS and HIV infection.

This standard applies to the diagnosis of AIDS and HIV infection in various medical and health institutions and their staff at all levels across the country.

2 Terms and definitions

The following terms and definitions apply to this document.

HIV human immunodeficiency virus;HIV Human immunodeficiency virus the pathogen that causes AIDS.

AIDS acquired immunodeficiency syndrome; AIDS Acquired immunodeficiency syndrome Caused by HIV infection, a progressive immune function defect characterized by a decrease in human CD4 T lymphocytes, which may be secondary to each A comprehensive disorder of opportunistic infections, malignant tumors, and central nervous system disorders.

HIV infected person

Individuals who have not progressed to the AIDS stage after HIV infection.

AIDS patient AIDS patient Patients who develop to the AIDS stage after HIV infection.

CD4

T lymphocyte CD4 positive T lymphocyte Helper T lymphocytes expressing CD4 molecules are the main target cells for HIV infection.

Opportunistic infection Infectious diseases that occur when immune function is low.

HIV serum antibody positive for HIV seroconversion the HIV antibody in the serum of the body after infection with HIV changes from no reaction to a reactive process.

Window period

Infection markers such as HIV antibodies, antigens or nucleic acids in HIV-infected humans can be detected in the previous period.

Note: The blood in the window period is already infectious. The window period for the detection of HIV antibodies, antigens and nucleic acids by existing diagnostic techniques is 3 weeks, 2 weeks and 1 after infection, respectively.

Around the week.

Preview: page 4 of 5 shown, 13 in the full document. Complete English PDF, instant download:
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Viral load

The amount of HIV RNA in the patient's plasma (clear) is an indicator of the quantitative detection of HIV nucleic acid. The test results use HIV RNA per milliliter of plasma (clear).

The copy number or international unit is expressed (CPs/mL or IUs/mL).

2.10

HIV antibody screening test A preliminary method for detecting the presence or absence of HIV antibodies in blood or body fluids of a human body, as well as methods for simultaneously detecting HIV antibodies and antigens.

Note: The results of a reaction or no reaction of HIV antibodies or antigens were detected. Commonly used detection methods are enzyme-linked immunosorbent assay (ELISA), chemiluminescence or exemption Epidemic fluorescence test, immunoagglutination test, immunochromatographic test, immunodiafiltration test and antigen-antibody combined test.

2.11

HIV supplement test

After obtaining the results of the screening test, in order to accurately determine whether to continue to detect the presence or absence of HIV antibodies or nucleic acids in the blood or body fluids of the body, Including antibody confirmation test and nucleic acid test.

Note: Antibody confirmation tests include immunoblot assays, strip/linear immunoassays, immunochromatographic assays, immunodiafiltration assays, and alternative assays under specific conditions.

The nucleic acid test includes a nucleic acid qualitative test and a nucleic acid quantitative test.

2.12

CD4

T lymphocyte count CD4 positive T lymphocyte count the number of CD4 T lymphocytes contained in peripheral blood per cubic millimeter (or per microliter).

2.13

CD4

Percentage of T lymphocytes CD4 positive T lymphocyte percentage Percentage of CD4 T lymphocytes in peripheral blood as a percentage of total lymphocytes.

2.14

Occupational exposure history People who work on HIV/AIDS or who may be exposed to HIV work have a history of accidental contact with HIV at work.

Preview: page 5 of 5 shown, 13 in the full document. Complete English PDF, instant download:
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