

ICS 11.020
CCS C 59

WS

**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

WS 291-2008

Replacing WS 291-2008

**Diagnosis for leprosy
(English Translation)**

Issued on: March 6, 2018

Implemented on: August 1, 2018

Issued by: National Health Commission

Table of Contents

Foreword
1 Scope
2 Terms and definitions
3 Diagnosis basis
3.1 New patient diagnosis basis
3.2 Diagnosis of leprosy patients
3.3 Diagnosis basis for relapsed patients
4 Diagnostic principles
5 Diagnosis
5.1 New patient diagnosis criteria
5.2 Diagnostic criteria for leprosy response
5.3 Diagnostic criteria for patients with recurrence
6 Differential diagnosis

Foreword

Chapter 5 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 291-2008 "Diagnostic Standards for Leprosy".

Compared with WS 291-2008, the main technical changes of this standard are as follows.

- Revised the Diagnostic Basis section (see Chapter 3, Chapter 3 of the 2008 edition);
- Removed the original damage biopsy histological examination clause (see 3.1.3.2 of the 2008 edition);
- increased the histological examination of skin damage (see 3.2.2);
- Added diagnostic criteria for leprosy response (see 5.2);
- Deleted the MDT program and treatment (see Table D.2 of the 2008 edition);
- Revised the clinical cure (clinical inactivity) standard section (see F.2);
- Increased the method of inoculation of *M. vaginalis* by mouse footpad (see Appendix G).

This standard was drafted. China Center for Disease Control and Prevention, Leprosy Control Center, Guangdong Provincial Center for Dermatology and Venereology, Jiangsu

Province Prevention and Control Center, Shanghai Dermatology Hospital.

1 Scope

This standard specifies the diagnostic basis, diagnostic principles, diagnosis and differential diagnosis of leprosy.

This standard applies to the diagnosis of leprosy in various types of medical and health institutions and their medical staff at all levels.

2 Terms and definitions

The following terms and definitions apply to this document.

Mycobacterium leprosy mycobacterium leprae; ML Leprosy Intracellular parasites, positive for acid-fast staining, arranged in bundles or clustered, have special properties for Schwann cells and reticuloendothelial cells Affinity.

Acid-fast bacillus anti-fast bacillus; AFB when dyeing by Ziehl-Neelsen method, the bacteria can be red-dyed red by carbolic acid, and can not be acidized under the specified conditions after coloring.

Decolorized bacilli. Acid-fast bacilli include *M. leprae*, *Mycobacterium tuberculosis* and some other mycobacteria.

Bacterial morphology index the sum of the complete bacteria of each part (coating film) divided by the sum of the whole bacteria and non-intact bacteria of each part (coating film), generally as a percentage table Show.

Bacterial density index when the skin tissue fluid smear is examined, the sum of the density of the leprosy bacteria of each of the bacteria-detecting parts (coating film) and the spot of the investigation (coating film) the ratio of the totals (the result is one digit after the decimal point).

Leprosy endemic area in the county (district), there are areas where there are new leprosy patients in the local resident population within 3 years.

Leprosy nodular erythema nodosum leprosum; ENL an acute or subacute hypersensitivity reaction of the body to ML antigen in patients with leprosy during chronic disease is the main cause of leprosy type II response to be expressed, belongs to the antigen-antibody complex type hypersensitivity reaction with complement involvement.

Leproy reaction

In patients with leprosy, the original skin lesions suddenly appear red, swollen or new skin lesions, or severe peripheral nerve swelling Pain, new disability, called type I (reverse) reaction; or leprosy nodular erythema, iritis, lymphadenitis, orchitis or hair the case where

some or all of the heat is expressed is called a type II reaction.

Early case patient at early stage Newly diagnosed cases with short duration (generally within 1 year) and no disability or irreversible nerve damage.

Advanced patient at advanced stage Newly diagnosed cases with long-term (more than 2 years) lesions with extensive or severe disability and/or nerve damage.

2.10

Relapsed patient

Complete the prescribed course of treatment, show normal efficacy, and clinical, bacterial or histopathology after clinical cure (clinical inactivity) Patients with evidence of disease reactivation.

3.1.1 History of epidemiology

3.1.1.1

Living in areas where leprosy is endemic, there has been close contact with untreated leprosy patients.

3.1.1.2

There are leprosy patients among relatives, neighbors or colleagues and have had close contact with them before they have been diagnosed.

3.1.2.1 Clinical lesion performance

3.1.2.1.1

Skin damage is 1 to 5 pieces, with rash or plaque, dry surface, clear edges, numbness and sweating (see A.2.1 in Appendix A).

3.1.2.1.2

Skin damage is 6 or more, asymmetrically distributed, with rash or plaque, yellowish red, tan or reddish Star-shaped or immune area lesions. The surface of the skin lesion is dry or smooth, the edges are clear, and some skin lesions are numb and sweat.

3.1.2.1.3

Skin damage is frequent, widely distributed symmetrically, with a smooth surface and blurred edges. Light spots, invasive erythema, nodules, spots Block or diffuse infiltration. In the early cases, the skin lesions were normal or decreased, and the eyebrows were intact. In the advanced cases, the skin lesions disappeared and the eyebrows fell off.

3.1.2.2 Peripheral nerve damage performance

3.1.2.2.1

Single peripheral nerve trunks are large and hard, some patients are accompanied by eye, hand, foot or facial disfigurement (see A.2.2).

3.1.2.2.2

The peripheral nerve trunk is asymmetrical and coarse, the number is 2 or more, the texture is hard, and some patients are accompanied by nerve dryness or eyes, hands, Foot or facial disability.

3.1.2.2.3

Early no peripheral nerve trunk is thick. Late peripheral nerve trunks are mild or moderately symmetrical, soft, and the number is 2 or on, there are numbness and disability of the hands and feet.

3.1.3 Laboratory inspection

3.1.3.1

AFB is positive in one or more parts of routine skin examinations (see Appendix B).

3.1.3.2

Histological examination of skin lesions (see Appendix C).

a) Destruction of the epidermis basement membrane, leukocyte invasion into the epidermis, epithelioid cell granuloma in the dermis, and Lang Lang giant cells, granulomas Surrounded by dense lymphocytes, the nerve branches are destroyed and illegible. The granuloma is negative for acid-fast bacilli, and the S-100 protein is free.

Epidemtidal staining showed damaged nerve branches in the granuloma; cutaneous nerve examination showed intraneural inflammation or epithelioid cell granuloma.

b) There is a stenosis under the epidermis, "no infiltration zone", epithelial-like cell granuloma in the dermis, surrounded by sparse lymphocytes around the granuloma.

Langhan giant cells with little or no, granulomatous inner nerve branches are difficult to identify, granuloma is positive for acid-fast bacilli, bacterial density 1+~ 3+.

c) The epidermis is atrophied, and there is no obvious "no infiltration zone" under the epidermis. In the dermis, tissue cells and foam cell granuloma are seen, and lymphocytes are less or None, the nerve bundle membrane changes onion, and inflammatory cells infiltrate in the nerve branches. Acid-fast bacilli in granulomas and nerve branches Check positive, bacterial density is 4 or above.