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

GB/T 18639-2023

Replacing GB/T 18639-2002

Diagnostic techniques for rabies

狂犬病诊断技术

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Foreword

This document complies with the provisions of GB/T 1:1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents" Drafting: This document replaces GB/T 18639-2002 "Rabies Diagnostic Technology": Compared with GB/T 18639-2002, except for structural adjustment and compilation In addition to editorial changes, the main technical changes are as follows:

---Changed the scope of application of various diagnostic methods listed in this document (see Chapter 1, Chapter 1 of the:2002 edition);

---Added abbreviations (see Chapter 4);

--- Added clinical diagnosis (see Chapter 5);

---Deleted "Inspection of Endocardial Bodies" (see Chapter 2 of the:2002 edition);

---Added direct rapid immunohistochemical detection (see Chapter 8), nested RT-PCR detection (see Chapter 9), and real-time fluorescence RT-PCR 4 detection methods: detection (see Chapter 10) and real-time fluorescent recombinase polymerase amplification (RT-RPA) detection (see Chapter 11);

---Refining the detection operation into virus isolation and detection in cell culture and virus isolation and detection inoculated into the mouse brain (see Chapter 12, Chapter

13 Chapter, Chapter 4 of the:2002 edition);

---Added comprehensive judgment (see Chapter 14);

--- Added biosecurity measures for rabies diagnostic testing (see Appendix A): Please note that some content in this document may be subject to patents: The publisher of this document assumes no responsibility for identifying patents: This document is proposed by the Ministry of Agriculture and Rural Affairs of the People's Republic of China: This document is under the jurisdiction of the National Animal Health Standardization Technical Committee (SAC/TC181): This document was drafted by: Institute of Military Veterinary Medicine, Academy of Military Medicine, Academy of Military Sciences: The main drafters of this document: Hu Rongliang, Zhang Shoufeng, Miao Fafa, Chen Teng, Wang Xiaohu, Zhang Fei, Wang Ying, Luo Shengjun, Jiang Yiqian, and Mi Lijuan: The previous versions of this document and the documents it replaces are as follows:

---First published as GB/T 18639-2002 in:2002:

---This is the first revision:

As a viral infectious disease with a case fatality rate of almost 100%, the final diagnosis of rabies relies on laboratory diagnostic technology: Since GB/T 18639-2002 was first promulgated, laboratory diagnostic technology for rabies has continued to develop: Based on direct immunofluorescence detection The antigen detection method of DFA has been determined as the "gold standard" by the World Health Organization (WHO) and the World Organization for Animal Health (WOAH); RT-PCR and real-time fluorescence RT-PCR technologies for infection diagnosis through specific amplification of viral nucleic acids are widely used; detection Rapid immunohistochemical detection of viral antigens in neural tissue (dRIT) is recommended by WHO; recombinase-polymerase amplification based on isothermal amplification Increased automation technology (RPA) has also been widely used in recent years: The above detection methods are in common with the virus isolation technology specified in GB/T 18639-2002: It has become a commonly used and reliable method for the current laboratory diagnosis of rabies, and is included in the WOAH "Terrestrial Animal Diagnostic Tests and Vaccines Manual" and Listed and recommended in WHO's "Laboratory Techniques for Rabies": At the same time, the method based on histopathological technology in Chapter 2 of GB/T 18639-2002 Negribodies examination has been gradually eliminated due to low sensitivity: my country's health and disease control, animal epidemic control, animal quarantine and scientific research institutions have simultaneously carried out research on the above-mentioned rabies laboratory diagnostic technology: At present, It has been widely used, and relevant equipment and supporting testing reagents are in stable supply: Based on the above progress, refer to WHO and WOAH recommended technology technology, GB/T 18639-2002 is revised based on the

actual situation in my country and relevant research results, aiming to standardize the diagnosis of animal rabies in my country: and quarantine methods, improve detection levels to effectively guide the implementation of prevention and control measures, ensure the health and safety of humans and animals, and provide a basis for my country's gradual realization of dog-borne transmission play an active role in the elimination of transmitted rabies: The nucleic acid amplification primers and probe sequences listed in this document were designed through comprehensive analysis of the sequences of domestic rabies epidemic strains: It has been obtained and verified by a large number of experiments, and its detection sensitivity and specificity are not lower than the primer and probe sequences recommended by international organizations: In addition, crazy The detection of canine neutralizing antibodies is an important means for evaluating animal immunity effects: It is usually not used for animal rabies diagnosis and is therefore not included in this document: Rabies Diagnostic Technology

1 Scope

GB/T 18639-2023 is the Chinese national standard on diagnostic techniques for rabies, in the field of health care technology. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 27 November 2023 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 June 2024. Classification: ICS 11.220, CCS B41. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document describes the clinical diagnosis, sample collection, storage and transportation, direct immunofluorescence assay (DFA), direct immunofluorescence assay, and Rapid immunohistochemical test (dRIT), nested RT-PCR test, real-time fluorescent RT-PCR test, real-time fluorescent recombinase polymerase amplification Methods for RT-RPA detection, cell culture virus isolation and detection, mouse brain inoculation virus isolation and detection, and comprehensive judgment: This document is applicable to rabies diagnosis during animal quarantine, disease surveillance and epidemiological investigations:

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative citations in the text: Among them, dated references For referenced documents without dates, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments)

applies to this document: document:

GB/T 6682 Specifications and test methods for water used in analytical laboratories

GB/T 34740-2017 Direct immunofluorescence diagnostic method for animal rabies

3 Terms and definitions

There are no terms or definitions to be defined in this document:

4 Abbreviations

The following abbreviations apply to this document: AEC:3-Amino-9-Ethylcarbazole (3-Amino-9-Ethylcarbazole) holequencher1) Ct: Cycle threshold (Cyclethreshold) DMF:N,N-Dimethylformamide (N,N-Dimethylformamide) FAM: Carboxyfluorescein fluorophoreFAM)