USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

Voluntary Report – Voluntary - Public Distribution **Date:** September 03, 2021

Report Number: CH2021-0108

Report Name: Microbiologic and Parasite Standards and Monitoring for Laboratory Animals

Country: China - People's Republic of

Post: Beijing

Report Category: FAIRS Subject Report, Biotechnology - Plants and Animals

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Report Highlights:

On July 9, 2021, China notified "Laboratory animal—Microbiological and parasitical standards and monitoring" to the WTO TBT Committee as G/TBT/N/CHN/1613. The comment period ends September 9, 2021. This standard will replace two other standards.

On July 9, 2021, China notified “Laboratory animal—Microbiological and parasitical standards and monitoring” to the WTO TBT Committee as G/TBT/N/CHN/1613. The comment period ends September 9, 2021. This standard, which can be found in the original Chinese at this link, will replace two other standards. It establishes the microbes and pathogens that need to be tested for by species and animal grade. The preface of the standard contains a description of the principal changes from the prior standards.

Interested parties should submit their comments to by September 9, 2021. Comments can be submitted to:

WTO/TBT National Notification and Enquiry Center of the People's Republic of China
Tel: +86 10 57954633 / 57954627
Email: tbt@customs.gov.cn

The translation begins here.

Preface

This document was drafted in accordance with the provisions of GB/T1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules of Standardization Documents".

The main technical changes of this revision and the previous version are as follows:

1. "Classification and Monitoring of Laboratory Animal Microbiology" (GB14922.2-2011) and "Classification and Monitoring of Laboratory Animal Parasitology" (GB14922.1-2 001) are merged;
2. Canceled the classification of clean animals;
3. Revised the concept of various grades of animals and added environmental requirements;
4. Adjusted the necessary test items and the test items when necessary. The test animal items mainly include three categories: animal violent pathogens, zoonotic pathogens, and pathogens that greatly interfere with animal experiments:
   The detection items of Yersiniapseudotuberculosis, Yersinia enterocolitica and Pathogenic dermal fungi in the bacteria items have been deleted for rats and mice. Escherichiacoli O115a, C, K(B)) was changed to Citrobacterrodentium. Added Corynebacteriumbovis test items and Norovirus for immunodeficiency mice. Deleted Mouse Adenovirus (Mad) in the virus project, and changed the mousepox virus to the detection project when necessary. The parasite partly deleted Encephalitozoon cuniculi and Pneumocystis carinii. Pneumocystis carinii was changed to Pneumocystis spp.;
   Guinea pigs, hamsters, and rabbits deleted Yersinia enterocolitica in the bacterial project, Pathogenic dermal fungi and Streptobacillus moniliformis. The rabbit test item Pneumocystiscarinii was changed to Pneumocystisspp. Parasite deleted Encephalitozoon cuniculi;
   Monkey changes the B virus to a detection item when necessary;
5. Added the selection of sentinel animals as detection animals;
6. The required test items have been revised: refer to the items that must be tested during the quality evaluation and grade determination of laboratory animals;

7. The test items when necessary have been revised: refer to items that need to be tested when required by the relevant administrative department; when the disease is prevalent; during import and export; or when special laboratory requirements are required.

This document was proposed and technically managed by the National Laboratory Animal Standardization Technical Committee (SAC/TC281).

This document was drafted by the National Laboratory Animal Standardization Technical Committee.

The main drafters of this document: Wei Qiang, Xiang Zhiguang, Fu Rui, Zhang Yu, Li Wenlong, Liu Enqi, Lu Longbao, Yuan Bao, Guo Lianxiang, Han Xue, Wu Xuying.

The previous editions of this document and the documents replaced are as follows:

--GB14922.1 Laboratory animal microbiology classification and monitoring was first released in January 1994, and it was revised for the first time in 2001. This is the second revision.
--GB14922.2 Laboratory animal microbiological classification and monitoring, first published in January 1994, first revised in 2001, the second revision in 2011, this is the third revision.
-- This revision merges the two standards into one, GB14922 Laboratory animal—Microbiological and parasitical standards and monitoring

Laboratory animal—Microbiological and parasitical standards and monitoring

1 Scope

This document specifies laboratory animal microbiology, parasite classification and monitoring.

This document is applicable to guinea pigs, hamsters, rabbits, dogs, and monkeys; SPF-free and above mice and rats.

2 Normative references

The contents of the following documents constitute the indispensable clauses of this document through normative references in the text. Among them, for dated reference documents, only the version corresponding to that date is applicable to this document: For undated reference documents, the latest version (including all amendments) is applicable to this document.

GB/T 14926.1～14926.64 Laboratory animals, Microbiological detection methods

GB /T 18448.1～18448.10 Laboratory animals, Parasite detection methods

3 Terms and definitions

3.1 Conventional (CV) animal

Laboratory animals that are bred in an ordinary environment and do not carry the pathogens of zoonotic diseases and the pathogens of severe animal infectious diseases that cause serious harm to the health of animals and/or humans. Referred to as ordinary animals.

3.2 Specific pathogen free (SPF) animal

Raised in an environment above the barrier, except for pathogens that should be eliminated by ordinary animals, no laboratory animals that are harmful to animal health and/or interfere with scientific research are not carried. Referred to as a specific pathogen-free animal or SPF animal.

3.3 Germ free (GF) animal

Raised in an isolated environment, there are no experimental animals that can detect any living organisms in the animals. Referred to as sterile animals.

4 Classification of laboratory animal microbiology grades

4.1 Conventional (CV) animal

4.2 Specific pathogen free (SPF) animal

4.3 Germ free (GF) animal

5 Testing standards and indicators

5.1 Appearance indicators

Experimental animals should be healthy and normal in appearance.

5.2 Pathogen indicators

The pathogen indicators are shown in Table 1, Table 2 and Table 3.

5.3 Virus indicators

The virus indicators are shown in Table 4, Table 5 and Table 6.

5.4 Parasite indicators

See Table 7, Table 8 and Table 9 for parasite indicators.

Table 1 Pathogenic bacteria detection items of mice and rats

Animal Class		Pathogen	Animal Species	
			Mice	Rats
Germ free (GF) animal	Specific pathogen free (SPF) animal	*Salmonella spp.*	●	●
		Mycoplasma spp.	●	●
		Corynebacterium kutscheri	●	●
		Tyzzer's organism	●	●
		Pasteurella pneumotropica	●	●
		Klebsiella pneumoniae	●	●
		Bordetella bronchiseptica		●
		Streptobacillus moniliformis	○	○
		Staphylococcus aureus	○	○
		Streptococcus pnemoniae	○	○
		Pseudomonas aeruginosa	○	○
		β-hemolyticstreptococcus	○	○
		Citrobacter rodentium	○	○
		Pneumocystis spp.	○	○
		Corynebacterium bovis	◎	
No bacteria can be found			●	●

Note: ● The required test items must be negative; ○ The test items when necessary must be negative.
◎Only detect immunodeficiency animals

Table 2 Pathogenic bacteria detection items of guinea pigs, hamsters and rabbits

Animal Class			Pathogen	Animal Species		
				guinea pigs	hamsters	rabbits
Germ free (GF) animal	Specific pathogen free (SPF) animal	conventional (CV) animal	*Salmonella spp.*	●	●	●
			Yersinia pseudotuberculosis	○	○	○
			Pasteurella multocida	●	●	●
			Bordetella bronchiseptica	●	●	
			Tyzzer's organism	●	●	●
			Pasteurella pneumotropica	●	●	●
			Klebsiella pneumoniae	●	●	●
			Staphylococcus aureus	○	○	○
			Streptococcus pnemoniae	○	○	○
			β-hemolyticstreptococcus	○	○	○
			Pseudomonas aeruginosa	○	○	○
			Pneumocystis spp.			●
No bacteria can be found				●	●	●
Note: ● The required test items must be negative; ○ The test items when necessary must be negative.						

Table 3 Pathogenic bacteria detection items of canine and monkey

Animal Class		Pathogen	Animal Species	
			Canine	Monkey
specific pathogen free (SPF) animal	conventional (CV) animal	*Salmonella spp.*	●	●
		Pathogenic dermal fungi	●	●
		Brucella spp.	●	
		Leptospira spp.	∆	
		Shigella spp.		●
		Mycobacterium tuberculosis		●
		a）Leptospira spp.	●	
		Yersinia enterocolitica	○	○
		Campylobaceter jejuni	○	○
Note: ● The required test items must be negative. ○ The test items when necessary must be negative. ∆ The test items when necessary can be immunized. a） Not immune, negative is required.				

Table 4 Virus detection items of mice and rats

Animal Class		Virus	Animal Species	
			Mice	Rats
Germ free (GF) animal	Specific pathogen free (SPF) animal	*Hantavirus (HV)*	○	●
		Mouse Hepatitis Virus (MHV)	●	
		Sendai Virus (SV)	●	●
		Pneumonia Virus of Mice (PVM)	●	●
		Reovirus type III (Reo-3)	●	●
		Minute Virus of Mice (MVM)	●	
		Rat Parvovirus (KRV & H-1)		●
		Ectromelia Virus (Ect.)	○	
		Lymphocytic Choriomeningitis Virus (LCMV)	○	
		Theiler's Mouse Encephalomyelitis Virus(TMEV)	○	
		Polyoma Virus (POLY)	○	
		Rat Coronavirus (RCV)/Sialodacryoadenitis Virus (SDAV)	○	○
		Murine Norovirus(MNV)	◎	
No virus can be found			●	●
Note: ● The required test items must be negative; ○ The test items when necessary must be negative. ◎Only detect immunodeficiency animals				

Table 5 Virus detection items of guinea pigs, hamsters, and rabbits

Animal Class			Virus	Animal Species		
				guinea pigs	hamsters	rabbits
Germ free (GF) animal	Specific pathogen free (SPF) animal	Conventional (CV) animal	*Lymphocytic Choriomeningitis Virus (LCMV)*	●	●	
			Rabbit Hemorrhagic Disease Virus (RHDV)			▲
			Sendai Virus(SV)	●	●	●
			Rabbit Hemorrhagic Disease Virus (RHDV)			●
			Pneumonia Virus of Mice (PVM)	●	●	
			Reovirus type III (Reo-3)	●	●	
			Rotavirus （RRV）			●
No viruses can be found				●	●	●
Note: ● The required test items must be negative. ▲ The required test items can be immunized. a) Not immune, negative is required.						

Table 6 Virus detection items of canine and monkey

Animal Class		Virus	Animal Species	
			Canine	Monkey
specific pathogen free (SPF) animal	conventional (CV) animal	*Rabies Virus （RV）*	▲	
		Canine Parvovirus （CPV）	▲	
		Canine Distemper Virus （CDV）	▲	
		Infectious Canine Hepatitis Virus （ICHV）	▲	
		Cercopithecine Herpesvirus Type 1 （BV）		○
		Simian Retrovirus D （SRV）		●
		Simian Immunodeficiency Virus （SIV）		●
		Simian T Lymphotropic Virus Type 1 （STLV-1）		●
		Simian Pox Virus （SPV）		●
		Canine common animals are not immune to 4 kinds of canine viruses	●	
Note: ● The required test items must be negative ▲ The required test items, immune is required; ○ The test items when necessary must be negative.				

Table 7 Parasites detection items of mice and rats

Animal Class		Pathogenic parasites	Animal Species	
			Mice	Rats
Germ free (GF) animal	Specific pathogen free (SPF) animal	*Ectoparasites*	●	●
		Toxoplasma gondii	●	●
		Flagellates	●	●
		Ciliates	●	●
		All Helminths	●	●
No parasites to be found			●	●
Note: ● The required test items must be negative				

Table 8 Parasites detection items of guinea pigs, hamsters, and rabbit

Animal Class			Pathogenic parasites	Animal Species		
				guinea pigs	hamsters	rabbits
free (GF)	ogen free	entio conv	*Ectoparasites*	●	●	●
			Toxoplasma gondii	●	●	●

			Flagellates	●	●	●
			Ciliates	●		
			All Helminths	●	●	●
			Eimaria spp.		○	○
			Encephalitozoon cuniculi			○
			No parasites to be found	●	●	●
Note: ● The required test items must be negative; ○ The test items when necessary must be negative.						

Table 9 Parasites detection items of canine and monkey

Animal Class		Pathogenic parasites	Animal Species	
			Canine	Monkey
specific pathogen free (SPF) animal	conventional (CV) animal	*Ectoparasites*	●	●
		Toxoplasma gondii	●	●
		Flagellates	●	●
		All Helminths	●	●
		Entamoeba spp.	○	●
		Plasmodium spp.		●
Note: ● The required test items must be negative; ○ The test items when necessary must be negative.				

6 Test procedure

6.1 The animals to be tested shall be jointly sampled and inspected according to the requirements of bacteria, fungi, viruses and parasites on the day of inspection.

6.2 The testing procedure is shown in Figure 1:

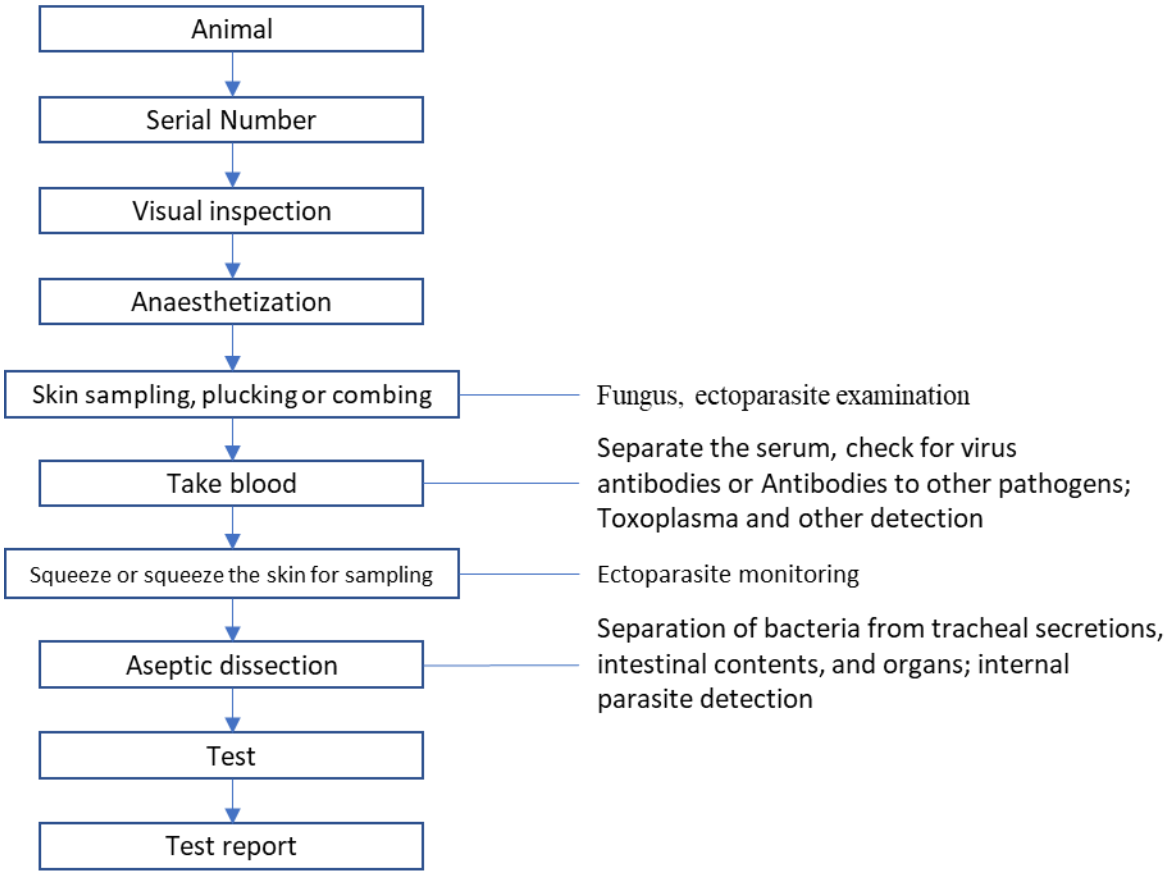

Figure 1 Testing procedure

7 Test method

According to GB/T 14926.1～14926.64 and the provisions of laboratory animals, it shall be divided into items.

8 Test rules

8.1.1 Test frequency

8.1.1 Conventional (CV) animal: Animals are tested at least once every three months.

8.1.2 Specific pathogen free (SPF) animal: Animals are tested at least once every three months.
8.1.2.1 germ free (GF) animal: Animals are tested once a year. Check the animal's living environment specimens and fecal specimens every 2 to 4 weeks.

8.2 Sampling requirements

8.2.1 Adult animals should be selected for testing.

8.2.2 Sampling quantity: each production and reproduction unit of mice, rats, hamsters, guinea pigs and rabbits; and each production and reproduction group of dogs and monkeys. According to the number of animals, the sampling quantity is shown in Table 10.

Table 10 Number of samples taken from different production and breeding units or breeding groups of experimental animals

Group size（pcs）	Number of samples[a]）
<100	Not less than 5
100～500	Not less than 10
＞500	Not less than 20
a） Each isolator detects 2 pcs.	

8.3 Sampling and inspection

8.3.1 Animals should be selected at different positions (for example, the four corners and the center) of each production and breeding unit, or sentinel animals should be selected according to regulations.

8.3.2 The animal inspection container shall be numbered and marked in accordance with the requirements of the animal level, packaged, and delivered to the laboratory safely, with an inspection form indicating the animal breed, grade, quantity and test items.

8.3.3 When there are no special requirements, live sampling of rabbits, dogs and monkeys can be carried out in the production and reproduction unit.

8.4 Classification of test items

8.4.1 Required test items: refer to the items that must be tested during the quality evaluation and grade determination of laboratory animals.

8.4.2 Test items when necessary: refer to items that need to be tested when required by the relevant administrative department; when the disease is prevalent; during import and export; or when required by special experiments.

9 Result judgment

Among the tested animals of each grade, if a certain index does not meet the requirements of the grade standard index, it will be judged as not meeting the grade standard.

10 Report

According to the test results, a report is issued.

Attachments:

No Attachments.