



**WOAH International Standards.
Promoting Member Engagement in the
Process for their Elaboration.**

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*Animal health is our health.
It's everyone's health*
rr-africa.woah.org



World Organisation
for Animal Health
Founded in 1924



2023

12th
Edition

Vol. 1

Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

(mammals, birds and bees)



World Organisation
for Animal Health



Presentation Outline

❖ Introduction

❖ Structure of the *Terrestrial Manual*

❖ Structure of a Disease chapter

❖ Intended Use of the *Terrestrial Manual*

❖ WOAHA International Standards

Introduction

The *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* of the World Organisation for Animal Health (WOAH, founded as OIE) aims to facilitate international trade in animals and animal products and to contribute to the improvement of animal health services world-wide.

The principal target readership is laboratories carrying out veterinary diagnostic tests and surveillance, plus vaccine manufacturers and regulatory authorities in the WOAH Member Countries.

The objective is to provide internationally agreed diagnostic laboratory methods and requirements for the production and control of vaccines and other biological products.

Introduction

- The *Terrestrial Manual*, covering infectious and parasitic diseases of mammals, birds and bees, was **first published in 1989**.
- Each successive edition has extended and updated the information provided.

Structure of the *Terrestrial Manual*

- The eighth edition (2018) includes over 99 updated and 17 new chapters. This edition has a slightly different structure from former editions:
- **Part 1:** contains **ten introductory chapters** that set general standards for the management of veterinary diagnostic laboratories and vaccine production facilities;
- **Part 2 :** comprises **specific recommendations and includes eight new chapters of recommendations for validation of diagnostic tests and three new chapters of recommendations for the manufacture of vaccines;**

Structure of the *Terrestrial Manual*

- **Part 3** : comprises [chapters on WOAAH listed diseases](#) and other diseases of importance to international trade and
- **Part 4**: is the [list of WOAAH Reference Centres](#) at the time of publication (the [list of WOAAH Reference Centres](#) is updated by the World Assembly of Delegates (of WOAAH Member Countries) each year.
 - The revised list is available on the WOAAH Web site)

Structure of the Disease chapter in the TM

1. Summary

- Brief description of
 - the disease,
 - the detection of the pathogenic agent,
 - the requirements for vaccines.

2. Introduction

Extended description of:

the disease including its importance and epidemiology

the diagnosis of the disease

and requirements for vaccines where possible

Structure of the Disease chapter in the TM

3. Diagnostic techniques

3.1 Table 1 : Test methods available for diagnosis of the specific disease chapter X and their purposes.

Rationale of tests to be used

3.2 Detection and Identification of the pathogenic agent:

- Samples collection
- Description of the diagnostic methods used :
 - Isolation of the agent
 - Detection of the antigens
 - Detection of the antibodies
 - Molecular detection

Structure of the Disease chapter in the TM

4. Requirements for Vaccines

4.1 Background: rationale and intended use of the product

4.2 Outline of production and minimum requirements for conventional vaccines:

- ✓ Characteristics of the seed

- ✓ Method of manufacture:
 - ✓ procedure, requirements for substrates and media, in process control, final product batch tests (sterility/purity, safety and efficacy, batch potency)

- ✓ Requirements for regulatory approval :
 - ✓ Safety requirements
 - ✓ Efficacy requirements
 - ✓ Stability

4.3 Vaccines based on biotechnology

4.4 References

4.5 Reference Lab website

Intended Use of the TM

TM is to provide internationally agreed diagnostic laboratory methods and requirements for the production and control of vaccines and other biological products.

Diagnostic Lab :

Use TM as a Bench book in Vet. Diagnostic Lab.

TM should be easy to read, clear and precise to foster application of diagnostic methods.

Minimum list of references is given to help end-users to further understand the diagnostic methods.

Reference Labs' addresses are available for any supports.

Intended Use of the TM

Vaccine Manufacturers and Regulatory Authorities

TM provides minimum requirements for vaccines production followed by Vaccine Manufacturers to guarantee safety, efficacy, stability and potency of vaccine, etc.;

Regulatory authorities use these minimum requirements to assess dossiers of vaccines submitted for market authorisation certificate.



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Thank you for your kind Attention