Session 2 - Mandate and Terms of Reference of OIE Reference Laboratories and Collaborating Centres:

International Reference Reagents and Interlaboratory Assays

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Overview

- Role of the OIE Biological Standards Commission
- Role of the OIE Reference Laboratories
- International Standard Sera
- Interlaboratory comparison
- Summary
Role of the Biological Standards Commission

- Developing internationally agreed standards for laboratory tests and vaccines
- To promote the international standardisation of diagnostic tests, including the preparation and distribution of standard reagents
Role of OIE Reference Laboratories

- Activity related to the mandate of OIE reference labs:
  - International harmonisation and standardisation of methods for diagnostic testing or the production and testing of vaccines
  - Preparation and supply of international reference standards for diagnostic tests
To ensure that a given antibody assay is capable of measuring antibody activity to a specified level of diagnostic sensitivity.
Guidance available to Reference Laboratories

- OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases (2nd edn. 2008)
International Reference Standard

- International Reference Standard
  - or primary reference standard.
  - represents the standard by which all others are compared and calibrated.

- Secondary standards are prepared by direct comparison with the International Reference Standard
Approach

- Three primary reference standards:
  - A strong positive
  - A weak positive
  - A negative standard

- Selected and standardised by a designated Reference Laboratory using an internationally accepted Standard test protocol and internationally accepted reagents
Selection of materials for use as International Reference Standards

- Types of material
- Safety
- Positive reference standards
- Negative reference standards
Characteristics of International Reference Standards

- Strong positive reference standard
- Weak positive reference standard
- Negative reference standard
Preparation of Reference Standards

- Constitution of the standards
- Stability and storage
- Batch control
- Labelling
- Data sheets
Approval of Reference Standards by OIE

- An International Reference Standard may not be issued under the name of OIE unless it has been endorsed by the OIE Standards Commission acting under authority of the OIE International Committee.
Currently available OIE-approved international standard sera

- African Horse Sickness
- Aujeszky’s disease
- Contagious bovine pleuropneumonia
- Equine infectious anaemia
- Bluetongue
- Bovine brucellosis
- Brucella abortus
- Caprine and ovine brucellosis
- Classical Swine Fever
- Enzootic Bovine Leukosis
- Equine influenza
- Equine viral arteritis
- Foot and mouth disease
- Infectious bovine rhinotracheitis
- Peste des petit ruminants
- Rabies
- Rinderpest
Further International Reference
Reagents in preparation

- Notifiable avian influenza
- Rabies
- Dourine
- Porcine brucellosis
Interlaboratory comparison

- Any evaluation of assay performance and/or laboratory competence in the testing of defined samples by two or more laboratories
Proficiency testing

- When interlaboratory test comparison is conducted for the express purpose of determining a laboratory’s capability to conduct specific tests it is referred to as proficiency testing.
Summary

OIE Reference Laboratories are encouraged to:

• support the international harmonisation and standardisation of methods for diagnostic testing or the production and testing of vaccines

• prepare and supply of international reference standards for diagnostic tests