4. Laboratory requirements for viral diseases

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Table of contents

4.1. Introduction

Laboratories play a critical role in the surveillance, diagnosis and monitoring of diseases in general and in particular for those of viral aetiology. Establishment of the virology laboratory performing a reliable diagnosis is a prerequisite for effective disease management. The choice of the system used in a certain laboratory to confirm or rule out a viral infection would primarily depend on the facilities and resources available and the level of knowledge available for the specific virus under study.

Generally, in virology the following diagnostic methods can be used:

(1) Isolation and identification of viruses

(2) Detection of viral nucleic acid and sequencing

(3) Detection of viral antigens

(4) Detection of virus-specific antibodies.

Virtually all these techniques can be applied to fish virology, but in practice, only the first two methods are widely available, have been sufficiently validated and consequently are recognized by the scientific community.

With reference to detecting fish virus antigens or antibodies, a few laboratory assays have been developed and described (mainly ELISA tests) therefore, they are used mainly for research purposes.

4.2. General management

Veterinary laboratories must be managed under a quality assurance system according to international standards (i.e. ISO/IEC 17025) and ideally should also be accredited by a recognized accreditation body.

The laboratory should ensure that its procedures are robust, reliable and repeatable. The quality standards require that each diagnostic test used in the laboratory should be validated. Standard material must be used for positive and negative controls and participation in proficiency tests (when available) is always recommended. A one way organization is recommended.

Useful information about the general management of veterinary diagnostic laboratory and test validations can be found in the following links:

http://www.oie.int/index.php?id=2439&L=0&htmfile=chapitre_quality_management.htm

http://www.oie.int/index.php?id=2439&L=0&htmfile=chapitre_validation_diagnostics_assays.htm

4.3. The minimum requirement for the virology laboratory

For laboratories running cell isolation, the following minimum requirements are necessary:

Two rooms/units (one “clean room” for cell maintenance and one “diagnostic room” for sample processing and inoculation) equipped with:

- 1 biological safety cabinet
- 1 optical microscope (at least one equipped with fluorescence)
- 1 or more thermostatic chamber (temperature range 15-25°C)
- Pipetting systems of different volumes
- 1 refrigerated centrifuge
- 1 or more fridge/freezer
- 1 balance
- 1 pH meter

Separate cleaning room equipped with autoclave is also necessary.

Liquid nitrogen container may be necessary for stocking cells.

4.4. The minimum requirement for the molecular biology laboratory

For laboratories running a molecular diagnostic, the following minimum requirements are necessary:

At least two separate rooms for genetic material extraction and analysis and master mix preparation. Each room should be equipped with:

- 1 safety/chemical cabinet,
- 1 or more fridge/freezer,
- 1 electrophoresis system,
- 1 magnetic stirrer and vortex,
- 1 or more thermal cycler / real-time PCR platform,
- Gel documentation system,
- 1 refrigerated centrifuge,
- 1 or more microcentrifuge,
- Pipetting systems of different volumes,
- 1 balance,

- 1 or more microcentrifuge,
- 1 pH meter,
- Sequencing platform (optional).

Additional equipment includes icemaker, water bath, spectrometer, microwave oven and ultra pure water production system, ultra low freezer (-80°C).

Separate cleaning room equipped with autoclave is also necessary.

Additional information can be found at the following link:

http://apps.searo.who.int/PDS_DOCS/B4249.pdf

4.5. Biosafety requirements

Fish virus can be classified as notifiable and/or causing World Organisation for Animal Health (OIE) listed diseases according to the criteria set out in Chapter 1.2 of the OIE Aquatic Animal Health Code. The majority of fish pathogens, however, are not classified under a biohazard ranking system. This makes difficult to decide an appropriate biocontainment level for laboratory work and transport. Luckily, only a few fish bacteria and no viruses have the ability to produce a zoonotic disease. With reference to fish viruses, no zoonotic potential has ever been reported. Therefore a risk analysis is generally considered not necessary and for this reason, biosafety level 1 is generally accepted for laboratories working with fish viruses. Only in specific cases (activities with GMO cell or GMO viruses) may there be additional biosafety requirements. For the minimum biosafety requirements please consult the WHO and OIE websites:

https://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

http://apps.who.int/medicinedocs/documents/s22409en/s22409en.pdf?ua=1

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.04_BIOSAFETY_BIOSECURITY.pdf