



FMD and CSF Coordination Action



New developments: Diagnostic techniques, Validation, Quality control and Reference standards for CSF

FMD and CSF Coordination Action - Workpackage 5,
Diagnostics
IVI – Mittelhäusern, Switzerland





Information gathering report on new developments in CSF diagnostic techniques, validation, quality control of CSF diagnostics and reference standards

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1. Introduction and Summary

Rapid and accurate diagnosis is of utmost importance in the control of highly contagious diseases such as classical swine fever (CSF). It is an essential means to safeguard animal welfare by limiting the spread of the infection and to keep economic losses due to mass culling of animals as low as possible.

It is absolutely crucial that all CSF diagnostic methods, reagents and vaccines are properly validated. Their characteristics need to be well known and documented, so it can be clearly shown that they are fit for purpose.

While most of the more recently developed CSF vaccines and some diagnostic kits are validated according to World Organisation for Animal Health (OIE) standards, not all of the well-established traditional vaccines and diagnostic tests were subject to these validation procedures and requirements. Thus, in order to assess the currently available CSF diagnostic tests and vaccines, a literature review was performed. In addition, evaluation data on diagnostic tests were kindly provided by National Reference Laboratories for CSF in various European countries. Current strategies for differentiating infected from vaccinated animals were reviewed, as well as information on the control of CSF in wildlife.

The results were published in 2006 (Blome et al., 2006).

An inventory of reference materials available at the CSF laboratories was established within “WP 2.2 Strategic integration - shared resources” of the Network of Excellence “Epizone”.

This database is now available at <http://www.epizone-eu.net/cps/databases>.

2. Materials and Methods

To assess CSF diagnostics and vaccine performance a literature review was conducted. In addition, CSF NRLs in Europe were contacted and asked to provide their evaluation data on various diagnostic tests.

Information was collected and analyzed and data were made available to the other laboratories on a restricted access site in the www:

(http://viro08.tiho-hannover.de/download/eurl_downloads.htm).

An inventory of reference materials available at the CSF laboratories was established within “WP 2.2 Strategic integration - shared resources” of the Network of Excellence “Epizone” in cooperation with WP5 of the “Coordination Action on FMD and CSF”.

The structure of the database and the information it should contain was decided upon in advance within a group of experts consisting of virologists and database specialists. Afterwards, CSF laboratories were asked to provide information on CSFV strains and isolates, monoclonal antibodies and polyclonal antiserum directed against CSFV available in their labs. Laboratories provided the information in preformatted MS-Excel datasheets, which were then imported into a SQL database. The database is accessible at:

<http://www.epizone-eu.net/cps/databases>.

However, access to this database is restricted and users need to register and to obtain passwords.

In order to produce a panel of reference materials for different diagnostic methods animals were experimentally infected with various strains of CSFV at the premises of the CRL. Serial bleedings were collected and characterized and are now available as reference panel for PCR analyses and Ag-ELISA. However, due to animal welfare reasons only limited amounts are available.

Furthermore, pigs were infected with various strains of CSFV, representing all genotypes. Large amounts of serum were collected when pig were euthanized. After characterization and validation sera are now available to the NRLs for PCR, virus isolation and Ag-ELISA (CSFV positive serum) as well as for neutralisation assays and Ab-ELISA (CSFV antibody positive serum). Upon demand they will be distributed by the CRL.

3. Results / Discussion

- An assessment of classical swine fever diagnostics and vaccine performance was performed and published (Blome et al., 2006).
- Information on evaluation data from the CSF NRLs was collected and analyzed. Data were made available to the other laboratories on a restricted access site in the world wide web (http://viro08.tiho-hannover.de/download/eurl_downloads.htm).
- An inventory/database of reference materials available at the CSF NRLs was established in cooperation with Epizone. This database is available at <http://www.epizone-eu.net/cps/databases>.
- Reference materials to be used for RT-PCR, virus isolation and Ag-ELISA (CSFV positive serum/blood/tissue) as well as for neutralisation assays and Ab-ELISA (CSFV antibody positive serum) have been produced and characterized. Upon demand they are available from the CRL (crl@tiho-hannover.de).
- In cooperation with the FMD subgroup of this workpackage and in collaboration with the Society for Veterinary Epidemiology and Preventive Medicine (SVEPM) a workshop took place in the context of the “Second International Meeting on the Design and Analysis of Diagnostic Test Evaluation Studies” in Brussels in June 2006. The objective of this workshop was to optimise and harmonise guidelines on diagnostic test validation.
- Additionally, a workshop on inter-laboratory comparison testing was conducted in November 2007 together with the FMD subgroup. In the context of this meeting a questionnaire on the participants experience with proficiency testing was circulated. The main topic of the workshop was to reach an agreement on the definition, differences and intentions of ringtests, proficiency tests and interlaboratory comparison tests. Subject to the aim of testing different samples and test schema should be used. It was decided that the final classification (diagnosis) of a sample tested in various tests is regarded more important than the results in single tests.

- As results of the workshop on interlaboratory comparison testing, an advisory board has been established for the interlaboratory comparison test, which is conducted by the CRL for CSF on an annual basis. This advisory board has already given its recommendations for the ILCT 2008.
- In the context of the interlaboratory comparisons test, individual evaluations will be given to each of the participating laboratories. Under-performing laboratories will receive special attention from the CRL and will be given the possibility to repeat the test.

References

Blome, S., A. Meindl-Böhmer, W. Loeffen, B. Thuer, V. Moennig (2006): Assessment of classical swine fever diagnostics and vaccine performance. *Rev. Sci. Tech. Off. int. Epiz.*, **25** (3), 1025-1038.