OIE Reference Laboratory Reports Activities

Activities in 2019

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Name of disease (or topic) for which you are a designated OIE Reference Laboratory:	Swine vesicular disease
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Name (including Title) of Head of Laboratory (Responsible Official):	Dr. Giorgio Varisco Scientific Director, Acting Director General
Name (including Title and Position) of OIE Reference Expert:	Dr. Emiliana Brocchi Head of National/OIE/FAO Reference Centre for FMD and SVD, Head of Biotechnology Laboratory
Which of the following defines your laboratory? Check all that apply:	Governmental

ToR 1: To use, promote and disseminate diagnostic methods validated according to OIE Standards

1. Did your laboratory perform diagnostic tests for the specified disease/topic for purposes such as disease diagnosis, screening of animals for export, surveillance, etc.? (Not for quality control, proficiency testing or staff training)

Yes

Diagnostic Test	Indicated in OIE Manual (Yes/No)	Total number of test performed last year	
Indirect diagnostic tests		Nationally	Internationally
Competitive ELISA (OIE prescribed test for screening)	Yes	89,776 (ref lab)+ 330,000 (other regional labs)	0
IgG-specific ELISA	Yes	470	0
IgM-specific ELISA	Yes	470	0
Virus Neutralization Test	Yes	480	0
Direct diagnostic tests		Nationally	Internationally
Realtime RT-PCR (3D-fragment)	Yes	1589	0
Conventional RT-PCR (3D-fragment)	Yes	173	0

ToR 2: To develop reference material in accordance with OIE requirements, and implement and promote the application of OIE Standards.
To store and distribute to national laboratories biological reference products and any other reagents used in the diagnosis and control of the designated pathogens or disease.

2. Did your laboratory produce or supply imported standard reference reagents officially recognised by the OIE?

No

3. Did your laboratory supply standard reference reagents (non OIE-approved) and/or other diagnostic reagents to OIE Member Countries?

Yes

Type of reagent available	Related diagnostic test	Produced/ provide	Amount supplied nationally (ml, mg)	Amount supplied internationally (ml, mg)	No. of recipient OIE Member Countries	Region of recipients
Assembled reagents for 5B7-competitive ELISA (capture and conj. mAbs, inactivated SVDV antigen, control sera)	5B7-Competitive ELISA (OIE prescribed test for Ab detection)	Produced and provided	For testing of 497,000 sera in regional labs + 100,000 sera at NRL	For testing of 4,300 sera (Poland)	1 + Italy	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
Assembled reagents for SVDV IgG-ELISA	SVDV IgG-ELISA for Ab detection class IgG	Produced and provided	For testing of 500 sera (NRL Italy)		1 (Italy)	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
Assembled reagents for SVDV IgM-ELISA	SVDV IgM-ELISA for Ab detection class IgM	Produced and provided	For testing of 500 sera (NRL Italy)		1 (Italy)	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
5B7 capture mAb	Competitive or sandwich ELISA (for Ab or Ag detection)	Produced and provided		17 ml	2	☐Africa ☒Americas ☐Asia and Pacific ☒Europe ☐Middle East
5B7 peroxidase-conjugated mAb	Competitive or sandwich ELISA (for Ab or Ag detection)	Produced and provided		13 ml	2	☐Africa ☒Americas ☐Asia and Pacific ☒Europe ☐Middle East

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to OIE Member Countries?

No

ToR 3: To develop, standardise and validate, according to OIE Standards, new procedures for diagnosis and control of the designated pathogens or diseases

6. Did your laboratory develop new diagnostic methods validated according to OIE Standards for the designated pathogen or disease?

No

7. Did your laboratory develop new vaccines according to OIE Standards for the designated pathogen or disease?

No

ToR 4: To provide diagnostic testing facilities, and, where appropriate, scientific and technical advice on disease control measures to OIE Member Countries

8. Did your laboratory carry out diagnostic testing for other OIE Member Countries?

No

9. Did your laboratory provide expert advice in technical consultancies on the request of an OIE Member Country?

Yes

Name of the OIE Member Country receiving a technical consultancy	Purpose	How the advice was provided
ITALY	Maintenance of national active surveillance.	Coordination and regular monitoring of serological and virological surveillance on regional and national basis.
ITALY	Revision of the SVD National Surveillance Plan.	Technical consultancy to the central authority for the revision of the SVD National Surveillance Plan in light of the acquired SVDV free status of Italy
SWITZERLAND	Definition of VNT titre of the EU SVD reference serum	Technical consultancy to the NRL about inter-laboratory variation of VNT titres of the SVD reference serum

ToR 5: To carry out and/or coordinate scientific and technical studies in

collaboration with other laboratories, centres or organisations

10. Did your laboratory participate in international scientific studies in collaboration with OIE Member Countries other than the own?

Yes

Title of the study	Duration	Purpose of the study	Partners (Institutions)	OIE Member Countries involved other than your country
Development of SVD-VLP isotype ELISAs	2 years	Availability of further in-house confirmatory assays to reduce the Singleton Reactor cases and the use of Virus Neutralization test	Canadian Food Inspection Agency	CANADA

ToR 6: To collect, process, analyse, publish and disseminate epizootiological data relevant to the designated pathogens or diseases

11. Did your Laboratory collect epizootiological data relevant to international disease control?

No

If the answer is no, please provide a brief explanation of the situation:
The disease was never reported during 2019. Given the mostly sub-clinical occurrence of SVD and lack of knowledge about active surveillance in place in the majority of member countries, evidence-based knowledge on SVD epidemiology in the world is not available. Apparently, except in Italy, SVD surveillance in very few Member Countries is limited to import-export specific requirements.

12. Did your laboratory disseminate epizootiological data that had been processed and analysed?

Yes

If the answer is yes, please provide details of the data collected:
Epidemiological data and results of the SVD National Surveillance and Eradication Plan implemented in Italy are regularly reported to international bodies (EU Commission, OIE).

13. What method of dissemination of information is most often used by your laboratory? (Indicate in the appropriate box the number by category)

a) Articles published in peer-reviewed journals: 1
M. Yang, K. Gagliardi, L. McIntyre, W. Xu, M. Goolia, T. Ambagala, E. Brocchi, S. Grazioli, K. Hooper–McGrevy, C.

Nfon, A. Clavijo.
Development and evaluation of swine vesicular disease isotype–specific antibody ELISAs based on recombinant virus–like particles. Transbound Emerg Dis. 2019 Sep 20. doi: 10.1111/tbed.13363

b) International conferences: 0

c) National conferences: 1
National Workshop on SVD updates for experts of Italian Regional laboratories and official veterinarians. 5th November 2019, Ministry of Health, Rome.
Lessons provided:
Overview of SVD epidemiology in Italy and in the world.
Phylogenetic analysis of the strains circulated in Italy from 1992 to 2015.
Molecular diagnostics of SVDV.
Serology and false positives issues (Singleton reactors).
SVDV Proficiency tests: scopes and overview of results of proficiency tests organised by the National/OIE reference Laboratory in several subsequent years.
National SVD surveillance perspectives in the light of the recently recognised SVD-free status.

d) Other:
(Provide website address or link to appropriate information) 1
Epidemiological data and results of the SVD National Surveillance and Eradication Plan implemented in Italy are regularly reported to international bodies (EU Commission, OIE).

A dedicated Integrated Information System is maintained for the collection and analysis of data of the surveillance activities for SVD in Italy (www.cerves.it); it provides an archive of laboratory results since 2000.

ToR 7: To provide scientific and technical training for personnel from OIE Member Countries
To recommend the prescribed and alternative tests or vaccines as OIE Standards

14. Did your laboratory provide scientific and technical training to laboratory personnel from other OIE Member Countries?

Yes

a) Technical visits: 5
b) Seminars: 1
c) Hands-on training courses: 1
d) Internships (>1 month): 0

Type of technical training provided (a, b, c or d)	Country of origin of the expert(s) provided with training	No. participants from the corresponding country
a) Technical visit of an Argentinian delegation (5 members from Ministry and labs) to learn about scientific support and diagnostic tools of official labs, with focus on FMD and SVD technical visit	Argentina	5
c) One-week training to a student for thesis preparation on tools (testing procedures and strategy) adopted for SVD eradication in Italy.	Italy	1
b) see point 13 c)	Italy	32

ToR 8: To maintain a system of quality assurance, biosafety and biosecurity relevant for the pathogen and the disease concerned

15. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)
ISO 17025	CERTIFICATO DI ACCREDITAMENTO.pdf

16. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
5B7-Competitive ELISA (OIE prescribed test for screening)	Accredia - Italy System Accreditation Service
Virus Neutralizazion Test	Accredia - Italy System Accreditation Service
Sandwich ELISA for antigen detection (mAbs-based)	Accredia - Italy System Accreditation Service
Conventional RT-PCR 3D-gene	Accredia - Italy System Accreditation Service
Real Time RT PCR 3D-gene	Accredia - Italy System Accreditation Service
The other tests in use (Virus Isolation, IgG and IgM ELISA) are IZSLER-coded tests,	

17. Does your laboratory maintain a “biorisk management system” for the pathogen and the disease concerned?

Yes

(See Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter 1.1.4)

ToR 9: To organise and participate in scientific meetings on behalf of the OIE

18. Did your laboratory organise scientific meetings on behalf of the OIE?

No

19. Did your laboratory participate in scientific meetings on behalf of the OIE?

No

ToR 10: To establish and maintain a network with other OIE Reference Laboratories designated for the same pathogen or disease and organise regular inter-laboratory proficiency testing to ensure comparability of results

20. Did your laboratory exchange information with other OIE Reference Laboratories designated for the same pathogen or disease?

Yes

21. Was your laboratory involved in maintaining a network with OIE Reference Laboratories designated for the same pathogen or disease by organising or participating in proficiency tests?

Yes

Purpose of the proficiency tests: [1]	Role of your Reference Laboratory (organiser/ participant)	No. participants	Participating OIE Ref. Labs/ organising OIE Ref. Lab.
The Proficiency Test 2019, organized by the FMD-EURL (ANSES-France & Sciensano-Belgium), included evaluation of laboratory capability to early detection and differential diagnosis of FMD/SVD outbreaks using virological and serological methods. Testing panels comprised live viruses for FMDV/SVDV detection, typing and sequencing and serum samples for SVD serological tests.	Participant	> 30	Participating Labs: NRLs of EU member countries, the OIE reference Lab for SVD, The Pirbright Institute-UK and some EU candidate countries Organising labs: ANSES (France) & Sciensano (Belgium)

[1] *validation of a diagnostic protocol: specify the test; quality control of vaccines: specify the vaccine type, etc.*

22. Did your laboratory collaborate with other OIE Reference Laboratories for the same disease on scientific research projects for the diagnosis or control of the pathogen of interest?

No

ToR 11: To organise inter-laboratory proficiency testing with laboratories other than OIE Reference Laboratories for the same pathogens and diseases to ensure equivalence of results

23. Did your laboratory organise or participate in inter-laboratory proficiency tests with laboratories other than OIE Reference Laboratories for the same disease?

Yes

Note: See Interlaboratory test comparisons in: Laboratory Proficiency Testing at: http://www.oie.int/en/our-scientific-expertise/reference-laboratories/proficiency-testing see point 1.3

Purpose for inter-laboratory test comparisons[1]	No. participating laboratories	Region(s) of participating OIE Member Countries
Organisation of the annual inter-laboratory test to monitor the harmonisation and performance of the 5B7-competitive ELISA for SVDV Ab detection, carried out in 10 Italian regional laboratories for the national surveillance plan.	10 regional labs in Italy	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East

ToR 12: To place expert consultants at the disposal of the OIE

24. Did your laboratory place expert consultants at the disposal of the OIE?

No

25. Additional comments regarding your report: