

OIE Reference Laboratory Reports Activities

Activities in 2021

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Name of disease (or topic) for which you are a designated OIE Reference Laboratory:	Foot and mouth disease
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Name (including Title) of Head of Laboratory (Responsible Official):	Dr. Piero Frazzi General Director
Name (including Title and Position) of OIE Reference Expert:	OIE Reference Expert: Tbd
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	
		Nationally	Internationally
Indirect diagnostic tests			
Competitive ELISA - Ab to SP type O	yes	969	208
Competitive ELISA - Ab to SP type A	yes	969	208
Competitive ELISA - Ab to SP type Asia 1	yes	969	208
Competitive ELISA - Ab to SP type SAT 2	yes	969	208
VNT - Ab to FMDV type O	yes	0	204
VNT - Ab to FMDV type A	yes	0	750
VNT - Ab to FMDV type Asia 1	yes	0	204
NSP Ab ELISA (3ABC trapping ELISA)	yes	2	204
Direct diagnostic tests			

**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
Ready-to-use kit: FMDV Antigen Detection ELISA and serotyping (O, A, Asia1, C, SAT1-2) (1 kit= 5 plates)	Ag detection and serotyping ELISA	Produced and provided	0	N. 135 kits	27	<input checked="" type="checkbox"/> Africa <input type="checkbox"/> Americas <input checked="" type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input checked="" type="checkbox"/> Middle East
Ready-to-use ELISA kit for FMDV NSP antibodies (1 kit=5 plates)	FMDV NSP Ab ELISA (3ABC trapping ELISA)	Produced and provided	0	N. 35 kits	8	<input type="checkbox"/> Africa <input type="checkbox"/> Americas <input checked="" type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input checked="" type="checkbox"/> Middle East
Ready-to-use ELISA kit for FMDV SP-Ab Type O (1 kit=5 plates)	Solid-phase competitive ELISA (SP-Ab type O)	Produced and provided	0	N. 87 kits	20	<input checked="" type="checkbox"/> Africa <input type="checkbox"/> Americas <input checked="" type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input checked="" type="checkbox"/> Middle East
Ready-to-use ELISA kit for FMDV SP-Ab Type A (1 kit=5 plates)	Solid-phase competitive ELISA (SP-Ab type A)	Produced and provided	0	N. 81 kits	21	<input type="checkbox"/> Africa <input type="checkbox"/> Americas <input checked="" type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input checked="" type="checkbox"/> Middle East
Ready-to-use ELISA kit for FMDV SP-Ab Type Asia1 (1 kit=5 plates)	Solid-phase competitive ELISA (SP-Ab type Asia1)	Produced and provided	0	N. 55 kits	18	<input type="checkbox"/> Africa <input checked="" type="checkbox"/> Americas <input checked="" type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input checked="" type="checkbox"/> Middle East
Ready-to-use ELISA kit for SP-Ab Type SAT2 (1 kit=5 plates)	Solid-phase competitive ELISA (SP Ab type SAT2)	Produced and provided	0	N. 16 kits	7	<input checked="" type="checkbox"/> Africa <input type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input checked="" type="checkbox"/> Middle East

Ready-to-use ELISA kit for SP-Ab Type SAT1 (1 kit=5 plates)	Solid-phase competitive ELISA (SP Ab type SAT1)	Produced and provided	0	N. 8 kit	7	<input checked="" type="checkbox"/> Africa <input type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input checked="" type="checkbox"/> Middle East
Ready-to-use Master Mix for FMDV rtRT-PCR	rtRT-PCR 3D region	Assembled and provided	0	N. 8 tubes, each tube for 50 reactions	4	<input type="checkbox"/> Africa <input type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
N. 24 different monoclonal antibodies specific for different FMDV serotypes	Varius test, research programm	Produced and provided	0	N. 9 tubes 2ml each, 15 tubes 1 ml each. 33 ml of concentrated MAb	2	<input type="checkbox"/> Africa <input type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> 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?

No

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
Field vaccine trials to estimate efficacy of FMD vaccines adopted in the country and to improve vaccination strategies	1,5 years	Study of strength, kinetic and duration of the immune response to vaccination with the multivalent vaccines used in the country, in order to acquire knowledge on vaccination effectiveness and optimize FMD control program	AQTA-Food Safety Agency of the Republic of Azerbaijan	AZERBAIJAN
OIE twinning Project	3 years	antigen profiling of the FMDV strains circulating in East Africa	The Pirbright Institute	UNITED KINGDOM
Development of a multiplex lateral flow device for on-field identification and serotyping of foot-and mouth disease virus	on going	development and validation of a multiplex LFD, based on well characterized monoclonal antibodies (MAbs), for FMD diagnosis and simultaneous serotyping of FMDV O, A and Asia 1 in a single strip	University of Turin (Italy); The Pirbright Institute, SAP Institute Turkey, Foot and Mouth Disease Laboratory, Kenya	UNITED KINGDOM

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 Laboratory does not cover a specific endemic region, it rather collaborates with individual countries, or other research institutes, or international organizations; however, as a member of the Network of OIE Reference Labs for FMD, it contributes to the collection of epizootiological data by reporting the results of activities and studies conducted. This role is indeed more related to initiatives and programmes of international Organizations (ex. OIE, FAO, EUFMD, FMDWRL).

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:

Diagnostic results and phylogenetic analyses for field samples collected in northern Tanzania during 2012-2018

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: 4

1. Paton, David; Di Nardo, Antonello; Knowles, Nick; Wadsworth, Jemma; Pituco, Maristela; Cosivi, Ottorino; Rivera, Alejandro; Bakkali-Kassimi, Labib; Brocchi, Emiliana; de Clercq, Kris; Carrillo, Consuelo; Maree, Francois; Singh, Raj; Vosloo, Wilna; Park, Min; Sumption, Keith; Ludi, Anna; King, Donald.

The history of foot-and-mouth disease virus serotype C: the first known extinct serotype? *Virus Evolution*, 2021, 7 (1): veab009. doi: <http://orcid.org/0000-0002-9097-2262>

2. Foglia EA, Lembo T, Kazwala R, Ekwem D, Shirima G, Grazioli S, Brocchi E, Pezzoni G

Combining Multiple Assays Improves Detection and Serotyping of Foot-and-Mouth Disease Virus. A Practical Example with Field Samples from East Africa.

Viruses. 2021 Aug 10;13(8):1583. doi: 10.3390/v13081583

3. Richard Bradhurst, Graeme Garner, Mark Hovari, Maria de la Puente, Koen Mintiens, Shankar Yadav, Tiziano Federici, Ian Kopacka, Simon Stockreiter, Ivanka Kuzmanova, Samuil Paunov, Vladimir Cacinovic, Martina Rubin, Jusztina Szilagyi, Zsofia Szepesine, Kokany, Annalisa Santi, Marco Sordilli, Laura Sighinas, Mihaela Spiridon, Marko Potocnik, Keith Sumption.

Development of a transboundary model of livestock disease in Europe.

Transboundary and Emerging Diseases, 2021, 1–20. <https://doi.org/10.1111/tbed.14201>

4. Design of multiplexing lateral flow immunoassay for detection and typing of foot-and-mouth disease virus using pan-reactive and serotype-specific monoclonal antibodies: evidence of a new hook effect

Simone Cavalera, Alida Russo, Barbara Colitti, Sergio Rosati, Chiara Nogarol, Efrem Alessandro Foglia, Santina Grazioli, Giulia Pezzoni, Fabio Di Nardo, Thea Serra, Matteo Chiarella, Claudio Baggiani, Emiliana Brocchi and Laura Anfossi. Accepted to *Talanta*

b) International conferences: 4

1. A multiplex lateral flow device for on-field identification and serotyping of Foot-and-Mouth disease virus. Efrem

Alessandro Foglia, Santina Grazioli, Giulia Pezzoni, Laura Anfossi, Sergio Rosati, Emiliana Brocchi. DISCONTOOLS "Filling the knowledge gaps in animal disease control" – 20 October 2021, Bruxelles.

2. Preliminary experiments for the development of a new serotyping assay for Foot-and-Mouth disease virus. Efrem Alessandro Foglia, Giulia Pezzoni, Santina Grazioli, Emiliana Brocchi. EAVLD 2021 Virtual Meeting – 17 November 2021

3. Exploring Foot -and-mouth disease virus antibody interactions using bio-layer interferometry. Abrew shaw, Alison Burman, amin Asfor, Anna Ludi, Emiliana Brocchi, Santina Grazioli, Donald King. Scientific Meeting of the Global Foot-and-Mouth Disease Research Alliance 1-3 November 2021-Buenos Aires, Argentina - virtual event

4. A universal test for quality of conventional FMD vaccine: VP4 to distinguish between intact and dissociated antigen. Stephen Berryman, amin Asfor, Amina Yasmin, Santina Grazioli. Emiliana Brocchi, Tobias Tuthill. Scientific Meeting of the Global Foot-and-Mouth Disease Research Alliance 1-3 Novembre 2021-Buenos Aires, Argentina - virtual event

c) National conferences: 1

National workshop on FMD updates for laboratory expert of Italian Regional laboratories.

10 November – virtual event

d) Other:

(Provide website address or link to appropriate information) 2

1. Annual Meeting of National Reference Laboratories in EU for FMD, organized by EURL, ANSES-Maison Alfort France 14 October, online edition.

Combining multiplex assays improves detection and serotyping of foot-and-mouth Disease virus. A practical example with field samples from East Africa. (E. Foglia)

2. 16th Annual meeting of the Network of OIE/FAO Reference Laboratories for FMD, 23-24 November, online edition. Report on activities conducted by the FMD Reference Laboratory during 2021 www.foot-and-mouth.org

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?

No

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
Competitive ELISA – SP antibodies (FMDV serotype O, A, C, Asia1, SAT1, SAT2)	Accredia: Italy System Accreditation Service
VNT for SP-Ab detection against each of the 7 FMDV serotypes	Accredia: Italy System Accreditation Service
NSP Ab ELISA (3ABC trapping ELISA)	Accredia: Italy System Accreditation Service
FMDV Antigen detection and serotyping ELISA	Accredia: Italy System Accreditation Service
Realtime RT-PCR (3D and 5'UTR regions)	Accredia: Italy System Accreditation Service
Other assays (Virus Isolation, VP1 sequencing, Topotypes-specific realtime RT-PCR) are IZSLER-coded tests	Accredia: Italy System Accreditation Service

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?

Yes

Title of event	Date (mm/yy)	Location	Role (speaker, presenting poster, short communications)	Title of the work presented
Knowledge-sharing on official Recognition of foot and mouth disease-free status. Organised by OIE, General Administration of customs of the peopple's Republic of china (GACC) Asian Development bank in collaboration with Urumqi customs District of GACC and Harbin Veterinary Research Institute, Chinase Academy of Agricultural Sciences	25-26 November 2021	virtual event	OIE/FAO lab expert, speaker	Elements of foot and mouth Disease (FMD)-free status
16th OIE/FAO FMD Laboratory Network Meeting	23-24 November 2021	virtual event	Lab expert, Short communication	Updates from the OIE/FAO reference lab- IZSLER
5th virtual GF-TADs Foot-and-Mouth Disease roadmap meeting for the Middle East, combined with Epi and Lab networks meeting	6-9 December 2021	virtual event	Participant	Lab expert

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.
FMD/SVD Proficiency Test 2021, organized by the FMD-EURL. It aimed evaluate the existing ability of each laboratory to diagnose FMD/SVD outbreaks using virological and serological methods, according to the given outbreak scenario. Panels 1-live viruses for FMDV/SVDV detection, typing and sequencing; Panel 3 for FMDV serological investigation and PVM; Panel 4 for SVD serological investigations.	participant	>30	FMD National Reference Laboratories of EU member countries and laboratories from others European countries. Organizing Lab: EURL (ANSES/France)
Interlaboratory Method Validation Test (IMVT), organized by the FMD-EURL. It aimed to assess the reproducibility of a new one-step triplex real-time RT-PCR for FMD detection developed by FMD-EURL.	participant	10	10 FMD National Reference Laboratories of EU member countries. Organizing Lab: EURL (ANSES/France)
FMD/SVD Proficiency Test 2021 (PHASE XXXIII: 2021), organized by the FMD-WRL, with the request to employ the test systems in use in each lab to address the scenarios that accompany the samples. Panels 1-live viruses for FMDV detection, typing and sequencing, with interpretation of the FMDV status for the individual samples and cases outlined in the scenario; Panel 2 for FMDV serological investigation with interpretation of the FMDV status and post-vaccination immunity.	participant	>25	OIE/FAO Reference Laboratories for FMD and NRL of other OIE Member countries Organizing Lab: FMDWRL/The Pirbright Institute, UK

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?

Yes

Title of the project or contract	Scope	Name(s) of relevant OIE Reference Laboratories
Research agreement to development of new and improved diagnostic ELISAs and reagents	Six different projects finalized to improve and apply new technology for FMD serology and antigen detection.	The Pirbright Institute, UK
Post- vaccination serology	Harmonisation and calibration of VNT methods	the Pirbright Institute (UK), Sciensano (Belgium) , ANSES (France)

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
1) Participation at the FMD Proficiency Test 2021 organized for EU NRLs and WRL.	see point 21	<input type="checkbox"/> Africa <input type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
2) Organization of a national Proficiency Test for FMD, to build and maintain preparedness of regional laboratories to support the NRL in case of emergency. The 2021 national PT included serological investigations and realtime RT-PCR for the 3D gene	3) N. 10 Italian regional Laboratories	<input type="checkbox"/> Africa <input type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> 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?

Yes

Kind of consultancy	Location	Subject (facultative)
Member of the Scientific Commission for Animal Diseases (SCAD)	Paris, OIE	Assistance in identifying the most appropriate strategies and measures for disease prevention and control. Evaluation of Member Country submissions regarding their animal health status
Continuous remote assistance and advice is regularly provided to various Member countries for elaboration and interpretation of results recorded with the diagnostic kits supplied for FMD diagnosis and serology		

25. Additional comments regarding your report: