OIE Reference Laboratory Reports Activities

Activities in 2020

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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 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 Lab
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 – Ab to SP type O	yes	1349	544
Competitive ELISA – Ab to SP type A	yes	1349	464
Competitive ELISA – Ab to SP type Asia1	yes	1349	464
Competitive ELISA – Ab to SP type SAT2	yes	1349	
VNT – Ab to FMDV type O	yes		241
VNT – Ab to FMDV type A	yes		482
VNT – Ab to FMDV type Asia1	yes		
NSP Ab ELISA (3ABC trapping ELISA)	yes		467
Direct diagnostic tests		Nationally	Internationally
Virus Isolation	yes		68
Real Time PCR-3D region	yes		31
Real Time topotypes-specific	no		155 (31x5)
Ag detection and serotyping ELISA (MAbs-based)	yes		20
VP1 sequencing	yes		53

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	n/a	N. 104 kits	26	☒Africa ☐Americas ☒Asia and Pacific ☒Europe ☒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	n/a	N. 58 kits	9	☒Africa ☐Americas ☒Asia and Pacific ☒Europe ☒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	n/a	N. 1329 kits	28	☒Africa ☐Americas ☒Asia and Pacific ☒Europe ☒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	n/a	N. 223 kits	27	☐Africa ☐Americas ☒Asia and Pacific ☒Europe ☒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	n/a	N. 899 kits	26	☐Africa ☐Americas ☒Asia and Pacific ☒Europe ☒Middle East
Ready-to-use ELISA kit for FMDV SP-Ab Type SAT2 (1 kit=5 plates)	Solid-phase competitive ELISA (SP-Ab type SAT2)	produced and provided	n/a	N. 18 kits	16	☒Africa ☐Americas ☒Asia and Pacific ☒Europe ☒Middle East

Ready-to-use ELISA kit for FMDV SP-Ab Type SAT1 (1 kit=5 plates)	Solid-phase competitive ELISA (SP-Ab type SAT1)	produced and provided	n/a	N. 5 kits	5	☒Africa ☐Americas ☒Asia and Pacific ☒Europe ☐Middle East
Ready-to-use Master Mix for FMDV rtRT-PCR	rtRT-PCR 3D region	assembled and provided	n/a	N. 24 tubes, each tube for 50 reactions.	12	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
N. 18 different monoclonal antibodies specific for FMDV type O	various tests, reasearch programs	produced and provided	n/a	20 tubes, 1 ml each, 20 concentrated mAbs	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
TURKEY	Use of serological assays to estimate immunity	Opinions provided to colleagues of the Turkish NRL for criteria to define the assays protection thresholds and choice of best suited monoclonal antibodies to set up serological ELISAs
TUNISIA	Design of a new BSL3 laboratory	Evaluation of the project of a new BSL3 lab and advice provided to colleagues of the Tunisian national lab
EGYPT	FMDV vaccine quality	Advice provided to the Veterinary Serum and Vaccines Research Institute about appropriateness and availability of methods and products for the measurement of FMD virions (146S)

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 year	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. strategies	National Food Agency of the Ministry of Agriculture LELP, Tbilisi, Georgia; EUFMD	GEORGIA
Field vaccine trials to estimate efficacy of FMD vaccines adopted in the country and to improve vaccination strategies	1.5 year	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.	Scientific Center for Risks Assessment and Analysis in Food Safety Area CJCS, Yerevan, Armenia; EUFMD	ARMENIA
Retrospective studies by serological and virological investigations in Northern Tanzania to inform predictive models of foot-and-mouth disease spread	2 years	1) To time outbreaks of specific serotypes and inform epidemiological models of disease spread. 2) Exploitation and validation of IZSLER kits for use in East Africa 3) Exploitation of realtime RT-PCR specific for topotypes circulating in East Africa region (virus pool n. 4) 4) Phylogenetic analyses to reveal sources of FMDV introduction and untangle dynamics of spread	University of Glasgow, UK; Sokoine University of Agriculture and The Nelson Mandela African Institution of Science and Technology, Tanzania	TANZANIA

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 epizootological 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: 6
1. Nthiwa D, Bett B, Odongo D, Kenya E, Wainaina M, Grazioli S, Foglia E, Brocchi E, Alonso S. Seroprevalence of foot-and-mouth disease virus in cattle herds raised in Maasai Mara ecosystem in Kenya. Prev Vet Med. 2020 Mar;176:104929. doi: 10.1016/j.prevetmed.2020.104929.
2. Asfor A, Howe N, Grazioli S, Berryman S, Parekh K., Wilsden G, Ludi A, King DP, Parida S, Brocchi E, Tuthill TJ. Detection of antibodies against a conserved capsid epitope as the basis of a novel universal serological test for foot-and-mouth disease. Journal of Clinical Microbiology (JCM). J Clin Microbiol. 2020 May 26;58(6):e01527-19. doi: 10.1128/JCM.01527-19.
3. Clare F. J. Browning, Antonello Di Nardo, Lissie Henry, Tim Pollard, Lynne Hendry, Aurore Romey, Anthony Relmy, Phaedra Eble, Emiliana Brocchi, Santina Grazioli, Donald P. King, Anna B. Ludi. An inter-laboratory exercise to compare two ELISA kits used for foot-and-mouth disease virus non-structural protein serology. J Vet Diagn Invest. 2020 Nov;32(6):933-937. doi: 10.1177/1040638720962070.
4. Grazioli S, Ferris NP, Dho G, Pezzoni G, Morris AS, Mioulet V, Brocchi E. Development and validation of a simplified serotyping ELISA based on monoclonal antibodies for the diagnosis of foot-and-mouth disease virus serotypes O, A, C and Asia 1. Transbound Emerg Dis. 2020;67:3005–3015.
5. Michael Eschbaumer, Andrea Vögtlin, David J Paton, Charles K Nfon, Emiliana Brocchi, Labib Bakkali Kassimi, David J Lefebvre, Kris De Clercq, Donald P King, Stéphan Zientara, Christian Griot, Martin Beer. Non-discriminatory exclusion testing as a tool for the early detection of foot-and-mouth disease incursions. Front Vet Sci. 2020 Nov 19;7:552670. doi: 10.3389/fvets.2020.552670.
6. 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, in press

b) International conferences: 4
1. E.A. Foglia, D. Ekwem, G. Pezzoni, M. Calzolari, S. Grazioli, J. Buza, G. Shirima, R. Reeve, E. Brocchi, T. Lembo. The role of local and regional livestock movements in Foot-and-Mouth Disease spread in East Africa. EuFMD OPEN SESSION Special Edition; 8-17 December 2020, Virtual Event
2. S. Grazioli, L. Anfossi, C. Nogarol, C. Cavalera, E.A. Foglia, G. Pezzoni, S. Rosati, E. Brocchi. A multiplex lateral flow device for on-field identification and serotyping of Foot-and-Mouth Disease virus. EuFMD OPEN SESSION Special Edition; 8-17 December 2020, Virtual Event
3. G. Pezzoni, E.A. Foglia, S. Grazioli, D. Ekwem, R. Kazwala, T. Lembo, G. Shirima, E. Brocchi. Diagnostic performance of Foot-and-Mouth Disease virus detection and serotyping assays with field samples from East Africa. EuFMD OPEN SESSION Special Edition; 8-17 December 2020, Virtual Event
4. E.A. Foglia, T. Chaligava, S. Kharatyan, G. Pezzoni, S. Grazioli, C. Pötzsch, F. Rosso, E. Brocchi. Field trial to estimate effectiveness of vaccination program against Foot-and-Mouth disease in Transcaucasian countries – Georgia and Armenia. EuFMD OPEN SESSION Special Edition; 8-17 December 2020, Virtual Event

c) National conferences: 0

d) Other:
(Provide website address or link to appropriate information) 1
15th Annual meeting of the Network of OIE/FAO Reference Laboratories for FMD, 3-5 December, online edition. Report on activities conducted by the FMD Reference Laboratory during 2020
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 IZSLER.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
Conventional RT-PCR (3D region)	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
Online meeting: Activités de suivi de la réunion REPIVET-RELABSA (10 - 12 février 2020) pour l'amélioration de la surveillance et la détection précoce des FAST en Afrique du Nord	04/20	virtual	participant	participation to discussion
15th OIE/FAO FMD Laboratory Network Meeting	12/20	virtual	short communication	Updates from the OIE/FAO reference lab-IZSLER
EuFMD-FAST Open Session 2020 Virtual Edition	12/20	virtual edition	speaker and 4 poster contributions	see point 13

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 2020, 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	38	Participating labs:25 FMD National Reference Laboratories of EU member countries (of which 4 are OIE Ref Labs), 13 laboratories from others European countries (including 5 candidate countries and 6 countries supported by EuFMD) Organising Lab: EURL-ANSES, France
FMD/SVD Proficiency Test 2020 (PHASE XXXII: 2019/20), 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	Participating labs: OIE/FAO Reference Laboratories for FMD and NRL of other OIE Member countries. Organising 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 for Development of new and improved diagnostic ELISAs and reagents	Research on - Incorporation of recombinant products (Integrin, VLPs) in ELISA kits - Development of new prototype tests (pan-SP serology, evaluation of 146S integrity, multiplex onsite tests) -Cross-reactivity of FMDV serological ELISAs - Analysis of Post-vaccination immunity - Antigenic and molecular characterization of candidate vaccine strains - Analysis of mAbs affinity and relationship with neutralizing activity	1) IZSLER, Italy 2) The Pirbright Institute, UK

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
Participation at the FMD Proficiency Test 2020 organized for EU NRLs	see point 21	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
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 2020 national PT included serological investigations and first implementation of the realtime RT-PCR for the 3D gene.	N. 10 Italian regional Laboratories	☐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?

Yes

Kind of consultancy	Location	Subject (facultative)
Member of the Scientific Commission for Animal Diseases (SCAD)	OIE offices and virtual meetings	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: