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:	Foot and mouth disease
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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	1052	2706
Competitive ELISA – Ab to SP type A	yes	1052	2706
Competitive ELISA – Ab to SP type Asia 1	yes	1052	306
Competitive ELISA – Ab to SP type SAT 2	yes	1052	2400
Competitive ELISA – Ab to SP type SAT 1	yes		1880
VNT – Ab to FMDV type O	yes		718
VNT – Ab to FMDV type A	yes		455
VNT – Ab to FMDV type Asia 1	yes		99
VNT – Ab to FMDV type SAT2	yes		136
NSP Ab ELISA (3ABC trapping ELISA)	yes		2713
Direct diagnostic tests		Nationally	Internationally
Virus Isolation (IB-RS2, BHK21, LFBK)	yes		
Real Time PCR-3D region	yes		162
Real Time topotypes-specific	no		716
Ag detection and serotyping ELISA (Mabs-based)	yes		146
VP1 sequencing	yes		34

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. 252 kits	50	☒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. 140 kits	14	☒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. 1675 kits	42	☒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. 380 kits	40	☒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. 135 kits	29	☐Africa ☐Americas ☒Asia and Pacific ☒Europe ☒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		N. 56 kits	14	☒Africa ☐Americas ☒Asia and Pacific ☒Europe ☒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		N. 24 kits	7	☒Africa ☐Americas ☐Asia and Pacific ☒Europe ☒Middle East
Ready-to-use Master Mix for FMDV rtRT-PCR	RealTime RT-PCR 3D region	Assembled and provided		N. 25 tubes, each tube for 50 reactions	13	☒Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
BHK-38 cell line	FMDV culture suspension			N. 10 frozen vials	1	☒Africa ☐Americas ☐Asia and Pacific ☐Europe ☐Middle East
BHK-21 cell line	FMDV culture, monolayer			N. 2 frozen vials	1	☒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?

Yes

Name of OIE Member Country seeking assistance	Date (month)	No. samples received for provision of diagnostic support	No. samples received for provision of confirmatory diagnoses
ALGERIA	January 2019	N. 6 epithelium samples	0
LIBYA	May 2019	N. 16 suspect samples (epithelium, swabs, blood on FTA cards)	0

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
ALGERIA	FMD diagnosis and serotyping by molecular assays	Provision of SOPs and references for topotype-specific rt RT-PCR
UKRAINE	FMD National Vaccine Bank for emergency	Provision of technical information on FMDV vaccine strains and antigenic matching/similitudes

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 predict efficacy of FMD vaccines and potential cross-protection vs circulating viruses	1.5 year	Study of strength, kinetic and duration of the immune response to field vaccination with multivalent vaccines used in the country, in order to acquire knowledge on vaccination effectiveness and optimize FMD control program	Institut de la Recherche Vétérinaire de Tunisie, Tunis, Tunisia; EUFMD; OIE	TUNISIA
Field vaccine trials to predict efficacy of FMD vaccines and potential cross-protection vs circulating viruses	1.5 year	Study of strength, kinetic and duration of the immune response to field vaccination with multivalent vaccines used in the country, in order to acquire knowledge on vaccination effectiveness and optimize FMD control program	Institut National de la Médecine Vétérinaire, El Harrach, Algiers, Algeria; EUFMD; OIE	ALGERIA
Field vaccine trials to predict efficacy of FMD vaccines and potential cross-protection vs circulating viruses	1.5 year	Study of strength, kinetic and duration of the immune response to field vaccination with multivalent vaccines used in the country, in order to acquire knowledge on vaccination effectiveness and optimize FMD control program	Ministry of Environmental Protection and Agriculture of Georgi; EUFMD	GEORGIA
Serological and virological surveillance in Northern Tanzania to inform predictive models of foot-and-mouth disease spread	1.5 year	a) To time outbreaks of specific serotypes and inform epidemiological models of disease spread. b) Exploitation and validation of IZSLER kits for use in East Africa c) Exploitation of realtime RT-PCR specific for FMDV topotypes circulating in East Africa region (virus pool n. 4)	University of Glasgow, UK	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:

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: 3
1. Pezzoni G, Bregoli A, Grazioli S, Barbieri I, Madani H, Omani A, Sadaoui H, Bouayed N, Wadsworth J, Bachanek-Bankowska K, Knowles NJ, King DP, Brocchi E. Foot-and-mouth disease outbreaks due to an exotic virus serotype A lineage (A/AFRICA/G-IV) in Algeria in 2017. Transbound Emerg Dis. 2019 Jan;66(1):7-13. doi: 10.1111/tbed.13017
2. Daniel Nthiwaa, Bernard Bett, David Odongo, Eucharia Kenya, Martin Wainaina, Santina Grazioli, Efrem Foglia, Emiliana Brocchi, Silvia Alonso. Seroprevalence of foot and mouth disease virus in cattle at a livestock-wildlife interface area in Kenya. Preventive Veterinary Medicine, 2019. Revision submitted.
3. 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. 2019. Revision requested

b) International conferences: 1
Brocchi E., Grazioli S., Pezzoni G. Ongoing activities on FMD and other TADS at IZSLER: National/FAO/OIE FMD Reference Laboratory. 43rd General Session of the European Commission for the Control of Foot-and-Mouth Disease; FAO Rome, 17-18 April 2019 (poster)

c) National conferences: 1
Anfossi L., Grazioli S., Russo A., Nogarol C., Rosati S., Brocchi E. Development of a multiplex pen-side rapid test for identification and serotyping of FMD viruses type O, A and Asia 1. XIX Congress of Italian Society for Veterinary Diagnostic Laboratories (SIDiLV); 23-25 October, 2019 Matera-Italy

d) Other:
(Provide website address or link to appropriate information) 5
1. Workshop on Post Vaccination Monitoring in North Africa (Algeria, Morocco and Tunisia). 19 March 2019 Tunisi (vcf) – Results of field trials to estimate the effectiveness of the vaccination program implemented in the Maghreb region. (Brocchi E.)

2. Management meeting EUFMD/FAO Rome - Regional cooperation between TransCaucasus and neighbouring countries for the prevention and control of Foot-and-Mouth disease (FMD) and similar Transboundary Animal Diseases - 16 September 2019, FAO/Roma (vcf): Results of field trials to estimate the effectiveness of the vaccination program implemented in Georgia (E. Foglia)

3. Annual meeting of National Reference Laboratories in EU for FMD, organized by EURL, ANSES-Maison-Alfort, France, 07-08 October 2019:
Experiences of field vaccine trials to predict efficacy of FMD vaccines and potential cross-protection vs circulating viruses. (E. Brocchi)
Performance of molecular tests (topotype-specific Real-time RT-PCR) applied to field samples from Africa and comparison with other diagnostic assays (VI and Ag-detection). (G. Pezzoni)

4. 14th Annual meeting of the Network of OIE/FAO Reference Laboratories for FMD, 3-5 December, South Korea
Report on activities conducted by the FMD Reference Laboratory during 2019 (S. Grazioli)

5. National Workshop on FMD updates for laboratory experts of Italian Regional laboratories and official veterinarians. 5th November, Ministry of health, Rome. Lessons provided:
a) Overview of FMD global epidemiology
b) Programs of the National/OIE/FAO reference centre for international cooperation
c) Laboratory Contingency Plan
d) Reports of Proficiency Tests and plans for future
e) Initiatives of international organization (OIE/FAO/EUFMD) for the global control of FMD and The Progressive Control Pathway
f) Presentation of the model EUFMDis

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: 10
b) Seminars: 0
c) Hands-on training courses: 5
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 a Russian delegation (5 scientists) to visit labs and reagents/kits production facilities and discuss subject of potential collaboration	Russia	5
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 other vesicular diseases	Argentina	5
c) Two-week training on Biosafety and Biosecurity provisions for BSL-3/4 facilities (Laboratories and Animal housing).	UAE	2
c) Two-week hands-on laboratory training on cultures and infection of BHK-38 cells in suspension for FMD vaccines production	Egypt	3

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
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	

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
Workshop on Post Vaccination Monitoring in North Africa (Algeria, Morocco and Tunisia)	03/2019	Tunis, Tunisia	speaker	Detailed results of field vaccine trials to estimate the effectiveness of the vaccination program implemented in the Maghreb region
14th OIE/FAO FMD Laboratory Network Meeting	12/2019	Busan, South Korea	short communication	Updates from the OIE/FAO reference lab-IZSLER
43rd General Session of the European Commission for the Control of Foot-and-Mouth Disease	04/2019	FAO, Rome, Italy	poster	Ongoing activities on FMD and other TADS at IZSLER: National/FAO/OIE FMD Reference Laboratory

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 2019, organized by the FMD-EURL. It aims to evaluate testing laboratory capability to early detection of FMD/SVD outbreaks using virological and serological methods. Panels 1-live viruses for FMDV/SVDV detection, typing and sequencing; Panel 3 for FMDV Serological investigation; Panel 4 for SVD serological investigation	participant	37	Participating Labs: 26 FMD National Reference Laboratories of EU member countries (which include 4 OIE Ref Labs), 5 EU candidate countries, 6 strategic countries supported by EUFMD./Organizer: ANSES, France, FMD EURL/OIE Ref Lab
Inter-laboratory exercise to compare the performance of two commercial kits based on competitive ELISA used for FMDV non-structural protein serology.	participoant	5	Participating Labs: IZSLER (Italy) and ANSES (France) OIE Ref Labs, Wageningen Bioveterinary research-Netherlands, Animal Plant & Health Agency, UK Organizing Lab: 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); Cross-reactivity of SP Ab-ELISAs Development of diagnostic tools for SAT3	1) IZSLER, Italy 2) The Pirbright Institute, UK
Research agreement to study the interaction between FMDV and host proteins during infection	Production and provision of mAbs suited for research studies	1) IZSLER, ITALY 2) USDA ARS PADC Foreign Animal Disease research, Plum Island NY, US

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 2019	see point 21	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
2) Organization of a national Proficiency Test for FMD serology, to maintain preparedness of regional laboratories to support the NRL in case of emergency	N. 10 Italian regional Laboratories	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
3) Organization of a Proficiency test for FMD diagnosis, focused on virological (Antigen detection ELISA and rtRT-PCR) and serological (NSP antibody detection) tests for the Laboratory of Turkish Cyprus	N. 1 (Turkish Cyprus)	☐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)	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: