OIE Reference Laboratory Reports Activities

Activities in 2017

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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):	Prof. Stefano Cinotti General Director IZSLER
Name (including Title and Position) of OIE Reference Expert:	Emiliana Brocchi, Dr. Head of National, OIE, FAO Reference Centre for FMD and for 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	1107	1519
Competitive ELISA – Ab to SP type A	yes	1107	1519
Competitive ELISA – Ab to SP type Asia 1	yes	1107	1519
Competitive ELISA – Ab to SP type SAT 2	yes	1107	1519
Competitive ELISA – Ab to SP type SAT 1	yes	0	799
NSP Ab ELISA (3ABC trapping ELISA)	yes	0	1519
Direct diagnostic tests		Nationally	Internationally
Virus Isolation (IB-RS2, BHK21, LFBK)	yes	0	9
Conventional RT-PCR (3D region)	yes	0	0
Real Time PCR-3D region	yes	0	10
Real Time PCR-5UTR region	yes	0	10
Ag detection and serotyping ELISA (MAbs-based)	yes	0	9
VP1 sequencing	yes	0	6
Full Genome Sequencing	no	0	4

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	No. 155 kits	34	☒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	0	No. 50 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	0	No. 1414 kits	21	☒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	0	No. 389 kits	23	☒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 Asia 1)	Produced and provided	0	No. 102 kits	16	☒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 SAT 2)	Produced and provided	0	No. 20 kits	8	☒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 SAT 1)	produced and provided	0	5	2	☒Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
Monoclonal Antibodies anti-FMDV NSP and anti-FMDV SP		Provided	0	N. 6 MAbs (70 ml)	4	☐Africa ☒Americas ☐Asia and Pacific ☒Europe ☐Middle East
BHK-38 cell line	FMD virus production	provided	0	1 frozen vial	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	April 2017	0	8 (epithelium samples in transport medium and/or lysis buffer)
KENYA	February 2017	N. 720 sera (vaccinated cattle tested for NSP and	
KENYA	March 2017	N. 799 sera (cattle from endemic setting, tested for NSP and	

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
KYRGYZSTAN	Tests on FMD vaccine (sterility, purity, efficacy, etc.)	Consultancy and advice by email exchange on standard prescribed tests, feasibility, and proposal of cooperation based on field trials; preliminary suggestions for a surveillance program finalized to Post-Vaccination Monitoring.
LIBYA	Refresh training for laboratory staff; provision of diagnostic kits; assistance in designing field activities to be carried out in the short term	Meeting on 16 February with Libyan Authorities and EUFMD, OIE, FAO, IZSLER representatives. Contribution to prepare an workplan for surveillance, to gain knowledge on FMDV distribution and serotypes circulating, through serological and virological assessment.

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
Evaluation of the immune response to vaccination	18 months	Kinetic and Evaluation of the immune response to field vaccination with locally produced tetravalent vaccines (types O, A, SAT 1 and SAT 2)	IZSLER and International Livestock Research Institute (ILRI)-Kenya	KENYA
Investigation on FMDV serotypes circulating in endemic settings through serological assessment	18 months	Investigation on FMDV serotypes circulating in endemic settings by end-point titration of SP-antibodies against FMDV serotypes circulating in pool 4	IZSLER and International Livestock Research Institute (ILRI)-Kenya	KENYA

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

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

Yes

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: 2
Fishbourne E, Ludi AB, Wilsden G, Hamblin P, Statham B, Bin-Tarif A, Brocchi E, Grazioli S, Dekker A, Eblé P, King DP. Efficacy of a high potency O1 Manisa foot-and-mouth disease vaccine in cattle against heterologous challenge with a field virus from the O/ME-SA/Ind-2001 lineage collected in North Africa.Vaccine. 2017 May 9;35(20):2761-2765. doi: 10.1016/j.vaccine.2017.02.047. Epub 2017 Apr 7.

Eldaghayes I, Dayhum A, Kammon A, Sharif M, Ferrari G, Bartels C, Sumption K, King DP, Grazioli S, Brocchi E. Exploiting serological data to understand the epidemiology of foot-and-mouth disease virus serotypes circulating in Libya. Open Vet J. 2017;7(1):1-11. doi: 10.4314/ovj.v7i1.1. Epub 2017 Jan 13.

b) International conferences: 0

c) National conferences: 0

d) Other:
(Provide website address or link to appropriate information) 10
Presentation given at OIE Workshop on “Atelier régional sur la procédure OIE pour la validation d’un programme national officiel de contrôle au regard de la fièvre aphteuse et de la peste des petits ruminants, 14-16 March

2017, Tunis:
“Spécificités pour la surveillance de la fièvre aphteuse dans la région” (Brocchi E.)
“Soutien des laboratoires de référence OIE pour la fièvre aphteuse aux Pays membres” (Brocchi E.)

Presentation given at the REMESA meeting organized on occasion of the 85th OIE General Session.
“Results of the phylogenetic analysis of the samples received from outbreaks occurred in Algeria in 2017, FMDV dynamics in Africa with co-occurrence of FMDV serotypes and topotypes” (Brocchi E.)

Presentation given at the Annual meeting of National Reference Laboratories in EU for FMD, 9-10 May 2017, Horsley, UK.
“Review of FMD laboratory simulation exercise in Balkan countries” (Grazioli S.)

Report on activities conducted by the FMD Reference Laboratory during 2017, presented at 12th Annual meeting of the Network of OIE/FAO Reference Laboratories for FMD, 29 Nov – 1st Dec 2017, Pretoria, South Africa” (Grazioli S.)

N. 6 theoric-practical courses on FMD for veterinarians on regional level in Italy: epidemiology, clinical signs and epidemiological investigation, diagnosis, legislation and outbreak management, outbreak simulation exercise.

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 certified according to an International Standard?

Yes

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

16. Is your laboratory accredited by an international accreditation body?

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

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
Atelier régional sur la procédure OIE pour la validation d'un programme national officiel de contrôle au regard de la fièvre aphteuse et de la peste des petits ruminants	03/17	Tunis, Tunisia	speaker	"Spécificités pour la surveillance de la fièvre aphteuse dans la région" "Soutien des laboratoires de référence OIE pour la fièvre aphteuse aux Pays membres"
REMESA meeting at the 85th OIE General Session	05/17	Paris, France	speaker	Results of the phylogenetic analysis of the samples received from outbreaks occurred in Algeria in 2017, FMDV dynamics in Africa with co-occurrence of FMDV serotypes and topotypes
14th REMESA meeting	07/17	Naples, Italy	speaker	Shipment of biological samples: rules and critical issues
12th OIE/FAO FMD Laboratory Network Annual Meeting	11/17	Pretoria, South Africa	communication	Update from IZSLER and Report of activities conducted in 2017 by the OIE/FAO reference lab-IZSLER

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.
2017 FMD Proficiency Testing Scheme, aimed at evaluating ability to diagnose FMD/SVD outbreaks and post-outbreak surveillance using an appropriate selection of virological and serological methods (including identification of agents by sequencing) and results interpretation on the basis of given scenarios. Panel 1-live virus, panel 2-non-infectious materials for genome/antigen detection/typing, panel 3-sera for FMD serology	participant	> 60	Participating Labs: all OIE Ref Labs + NRL of all EU member countries and several others. Organizing OIE Ref Lab: World FAO/OIE FMD Ref 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
On-going Research agreement between IZSLER and The Pirbright Institute for the development of new and improved diagnostic ELISAs and reagents	Continuous improvement and validation of ready-to-use ELISA kits, characterization of epitopes not involved in virus neutralization and study of their potential role in immunity, development of a universal test to quantitate protective antigen during FMD vaccines production, analysis of the inter-types cross-reactivity of SP-antibodies detected by ELISA kits, incorporation of integrin into kits as universal FMDV detector, etc	IZSLER, Italy The Pirbright Institute, UK
On-going Research agreement between IZSLER and USDA ARS PADC for production and provision of mAbs suited for research studies	Study of interaction between FMDV and host proteins during infection	IZSLER, Italy 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 2017	see point 21	☒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)
Lecture at REMESA meeting	Naples, Italy	Shipment of biological samples: rules and critical issues
Lecture at OIE workshop	OIE North Africa region, Tunis	Spécificités pour la surveillance de la fièvre aphteuse dans la région
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: