OIE Reference Laboratory Reports Activities

Activities in 2016

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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 Head of National Reference Centre for vesicular diseases and Biotechnology department
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 Structural Proteins	yes	N. 902 tests for the four serotypes O, A, Asia1 and SAT2	0
NSP Ab ELISA (3ABC trapping ELISA)	yes	23	0
Direct diagnostic tests		Nationally	Internationally
Virus Isolation (IB-RS2, BHK21)	yes	11	0
Conventional RT-PCR (3D region)	yes	5	0
Real Time PCR-3D region	yes	4	16
Real Time PCR-5UTR region	yes	4	0
Ag detection and serotyping ELISA (MAbs-based)	yes	4	0
VP1 sequencing	yes	0	16
Full Genome Sequencing	no	0	6

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. 167 kits	32	☒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. 33 kits	6	☒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. 503 kits	18	☒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. 280 kits	20	☒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	0	No. 142 kits	14	☐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	0	N. 27 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 SAT1)	produced and provided	0	N. 1 kit	1	☒Africa ☐Americas ☐Asia and Pacific ☐Europe ☐Middle East
Monoclonal Antibodies anti-FMDV NSP and anti-FMDV SP		produced and provided	0	N. 47 MAbs (48 ml)	3	☐Africa ☒Americas ☐Asia and Pacific ☒Europe ☐Middle East
Inactivated FMDV, 3 serotypes	Positive controls RT-PCR	produced and provided	0	12 ml (3 serotypes)	1	☐Africa ☐Americas ☐Asia and Pacific ☐Europe ☒Middle East
Proficiency test panel for FMDV antigen detection and RT-PCR composed by 10 samples	Ag-ELISA and RT-PCR	produced and provided	0	N. 3 panels (for 3 Algerian labs)	1	☒Africa ☐Americas ☐Asia and Pacific ☐Europe ☐Middle East
Proficiency test panel for FMDV Ab detection composed by 9 sera	NSP-ELISA SP-ELISA	produced and provided	0	N. 3 panels (for 3 Algerian labs)	1	☒Africa ☐Americas ☐Asia and Pacific ☐Europe ☐Middle East
Proficiency test panel for FMDV antigen detection and RT-PCR composed by 6 samples	Ag-ELISA and RT-PCR	produced and provided	0	N. 10 panels	10	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East

Proficiency test panel for FMDV Ab detection composed by 10 sera	NSP-ELISA SP-ELISA	produced and provided	0	N. 10 panels	10	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
LFBK cell line	Virus Isolation	provided	0	1	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?

Yes

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

No

Name of the new test or diagnostic method or vaccine developed	Description and References (Publication, website, etc.)
FMDV Antigen Detection ELISA and serotyping (O, A, Asia1, C, SAT1-2)	It is a new kit format derived from the combination of the previous two separate Ag-ELISA kits, each for 4 serotypes. This new format enables testing and serotyping of six FMDV serotypes pus a pan-FMDV detection in a unique microplate.

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
ALGERIA	“Mise à niveau des laboratoires de l’Institut national de la médecine vétérinaire aux standards européens et internationaux” (EU supported Italy-Algeria twinning)	Third mission of two IZSLER experts to Algeri and Tlemcen to evaluate implementation or improvement of lab diagnostic procedures for FMD and discuss the results of the proficiency test.
UNITED ARAB EMIRATES	Implementation of RT-PCR for diagnostic and sequencing applications	Sharing of protocols and advice
EGYPT	1) Improvement of FMD vaccines locally produced. 2)Immunohistochemistry for FMDV	1) Advice on process controls and trials for evaluation of vaccine efficacy. 2) Advice on IHC application

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 new and improvement of existing diagnostic assays and reagents	on going	Continuous improvement and validation of new-generation ELISAs (ready-to-use kits), substitution of FMDV inactivated antigens with VLP, production of anti-bovine IgA mAbs for assays measuring mucosal antibody	The Pirbright Institute-UK and IZSLER-Italy	UNITED KINGDOM
Study of interaction between FMDV and host proteins during infection	5 year (on going)	Characterization and selection of mAbs (anti-SP and anti-NSP) suited for the study	USDA ARS PADC Foreign Animal Disease research-US and IZSLER-Italy	UNITED STATES OF AMERICA
Evolutionary analysis of FMDV isolates from North Africa 2014-2015 epidemic	1.5 years (concluded)	genetic and antigenic characterization of FMD isolates from the 2014-2015 FMD epidemic in Maghreb by full genome sequencing and monoclonal antibodies profiling	ANSES-France, IZSLER-Italy, Institut de la Recherche Vétérinaire de Tunisie-Tunisia, Institut national de la Médecine vétérinaire, Algiers – Algeria	TUNISIA
Development of Nano-based Biosensor for FMDV	1 year	Evaluation of nanogold particles conjugated with oligonucleotides to improve diagnostic performances of FMDV realtime RT-PCR	AHRI-Egypt	EGYPT

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?

No

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
Knowles NJ, Bachanek-Bankowska K, Wadsworth J, Mioulet V, Valdazo-González B, Eldaghayes IM, Dayhum AS, Kammon AM, Sharif MA, Waight S, Shamia AM, Tenzin S, Wernery U, Grazioli S, Brocchi E, Subramaniam S,

Pattnaik B, King DP. Outbreaks of Foot-and-Mouth Disease in Libya and Saudi Arabia During 2013 Due to an Exotic O/ME-SA/Ind-2001 Lineage Virus. Transbound Emerg Dis. 2016 Oct;63(5): 431-5.

Shimmon G, Wood BA, Morris A, Mioulet V, Grazioli S, Brocchi E, Berryman S, Tuthill T, King DP, Burman A, Jackson T. Truncated Bovine Integrin Alpha-v/Beta-6 as a Universal Capture Ligand for FMD Diagnosis. PLoS One. 2016 Aug 5;11(8)

b) International conferences: 5
Pezzoni G., Calzolari M., Sghaier S., Madani H., Chiapponi C., Grazioli S., Relmy A., Bakkali L., Brocchi E. “Bayesian evolutionary analysis of FMD viruses collected from outbreaks that occurred in Maghreb regions during 2014-2015”, Pg.55. X° Annual Meeting Epizone, September 2016 – Madrid, Spain

Keynote: Brocchi E., King D. Foot-and-mouth disease viruses on the move: changing epidemiological patterns., X° Annual Meeting Epizone, September 2016 – Madrid, Spain

Pezzoni G., Calzolari M., Sghaier S., Madani H., Chiapponi C., Grazioli S., Relmy A., Bakkali L., Brocchi E. “Antigenic and evolutionary analysis of FMD viruses from the 2014-2015 outbreaks in the Maghreb region” pg.67, Open Session of the Standing Technical and Research Committees of the European Commission for the Control of Foot-and-Mouth Disease OS'16. Cascais, Portugal. 26th-28th October 2016

Brocchi E., Sghaier S., Grazioli S., Pezzoni G., Bugnetti M., “Estimate of cross-protection provided by an FMDV O-BFS vaccine in the Tunisian epidemiological context” pg.46, Open Session of the Standing Technical and Research Committees of the European Commission for the Control of Foot-and-Mouth Disease OS'16. Cascais, Portugal. 26th-28th October 2016

Ryan E., Zientara S., Bakkali Kassimib L., Brocchi E., King D., de Clercq K., “Encouraging the use of vaccination-to-live as a control strategy for FMD outbreaks: perspectives and issues” pg.31, Open Session of the Standing Technical and Research Committees of the European Commission for the Control of Foot-and-Mouth Disease OS'16. Cascais, Portugal. 26th-28th October 2016

c) National conferences: 0

d) Other:
(Provide website address or link to appropriate information) 6
Presentation given at OIE Workshop on Harmonization of the FMD vaccination strategy in North Africa. 30-31 marzo 2016, Tunis. “Activities conducted in the North Africa with focus on the vaccination trial with O-BFS vaccine in Tunisia and post vaccination monitoring in Libya” (Brocchi E.)

Presentations given at: Annual meeting of National Reference Laboratories in EU for FMD, 18-19 Maggio 2016, Ascot, UK.
“Update on the development and validation of ELISA kits for FMD diagnosis”. (Brocchi E.)
“Full genome analysis of FMD viruses collected from Tunisian outbreaks” (Pezzoni G.).

Report on activities conducted by the FMD Reference Laboratory during 2016 (Grazioli S.), presented at 11th Annual meeting of the Network of OIE/FAO Reference Laboratories for FMD, 30 Nov – 2 Dec 2016, ANSES, Maison Alfort, France

N. 2 theoric-practical courses for veterinarians on national level on FMD: epidemiology, clinical signs and epidemiological investigation, diagnosis, legislation and outbreak management.

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: 4
b) Seminars: 0
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: four-day technical visit of an EUFMD short term professional, based in FAO Rome, finalized to design an FMD Lab Proficiency Test for Balkan countries to test contingency plans and diagnostic capability, to observe testing flow. The visit included a practical training on ELISA kits and results interpretation to facilitate their implementation in Russian speaking countries	Ukraina (short tem professional at EUFMD/FAO)	1
a: three-day technical visit of an EUFMD short term professional, based in FAO Rome, finalized to discuss and elaborate the results of the Lab Proficiency Test organized for 10 Balkan countries and to familiarize with FMDV ELISA kits for antigen and antibodies serotyping and interpretation of serosurveillance results	Irland (short tem professional at EUFMD/FAO)	1
a: one week technical visit at Algeri and Tlemcen labs, to verify technical and organizational progress in FMD lab diagnosis in the framework of an EU supported twinning, aimed at “Mise à niveau des laboratoires de l’Institut national de la médecine vétérinaire aux standards européens et internationaux”.	Algeria	4
a: study visit of 1.5 months of an Egyptian researcher, in the framework of the Italy-Egypt cooperation project “Development of Nano-based Biosensor for FMDV”	Egypt	1
c: four-week hands-on training on reagents production and evaluation, ELISA assays development and calibration, cell cultures, theory and practice of FMD ELISAs for antigen and antibody detection and serotyping with results interpretation	UAE	2

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 ACCREDITAMENTO 20150928.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
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
VNT for SP-Ab detection against each of the 7 FMDV serotypes	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
Workshop on the harmonization of the FMD vaccination strategy in the North Africa - organized by OIE Tunis	03/16	Tunis	speaker	Activities conducted in the North Africa with focus on the vaccination trial with O-BFS vaccine in Tunisia and post vaccination monitoring in Libya
11th OIE/FAO FMD Laboratory Network Meeting	11/16	ANSES, Maison Alfort, France	communication	Report of activities conducted in 2016 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.
2016 FMD/SVD Proficiency Testing Scheme, aim: evaluate 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. N. 3 samples panels tested, respectively composed by 1) live virus, 2) non-infectious materials for genome/antigen detection/typing, and 3) sera for FMD serology	participant	all EU member countries and most OIE RL, plus several other countries	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, production of new monoclonal antibodies against new FMDV variants, validation of ELISA kits for post-vaccination monitoring, characterization of epitopes not involved in virus neutralization and study of their potential role in immunity, 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 and USDA ARS PADC Foreign Animal Disease research, Plum Island, US
Evolutionary analysis of FMDV isolates from North Africa 2014-2015 epidemic	Genetic and antigenic characterization of FMD isolates from the 2014-2015 FMD epidemic in Maghreb by full genome sequencing and monoclonal antibodies profiling	ANSES, France – IZSLER, Italy

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/SVD PTS 2016. see point 21	all EU member countries and most OIE RL, plus several other countries	☒Africa ☒Americas ☒Asia and Pacific ☒Europe ☒Middle East
Organization of a Proficiency test aimed at testing ability to rapidly generate accurate laboratory results with diagnostic interpretation in the context of a given epidemiological scenario. Two panels of samples (for virological and serological assays) and kits for Ag detection ELISA and for NSP/SP antibodies detection were provided, along with reagents for realtime RT-PCR prepared by ANSES	10	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
Organization of a Proficiency test aimed at evaluating laboratory performance in FMD virological and serological assays. Samples panels provided: 1) inactivated viruses for RT-PCR and antigen detection/serotyping ELISA, 2) sera for NSP and SP-ELISAs	3	☒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)
Two-day meeting	OIE North Africa region, Tunis	Harmonization of FMD vaccination strategy in North Africa
Collaboration for the design of field FMDV-vaccination trials in Maghreb Countries		Preliminary evaluation of vaccines selected for the regional vaccination campaign

25. Additional comments regarding your report:

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