OIE Reference Laboratory Reports Activities

Activities in 2013

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Name of disease (or topic) for which you are a designated OIE Reference Laboratory:	Foot and mouth disease
Address of laboratory:	Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna (IZSLER) Via A. Bianchi 7/9, 25124 Brescia, ITALY
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Name (including Title) of Head of Laboratory (Responsible Official):	Dr.Stefano Cinotti IZSLER General Director
Name (including Title and Position) of OIE Reference Expert:	Dr. Emiliana Brocchi - Head of the National Reference Center for vesicular diseases - Head of the Dpt. of Biotechnology
Which of the following defines your laboratory? Check all that apply:	Governmental

ToR: 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 for SP Ab types O, A, Asia1, SAT1 and 2	Yes	4200	18000
Virus neutralization Test (for 7 serotypes)	Yes		300
NSP Ab ELISA (3ABC trapping ELISA)	Yes		6000
Direct diagnostic tests		Nationally	Internationally
Virus Isolation (IB-RS2 and BHK21)	Yes		45
Conventional RT-PCR 3D gene	Yes	160	45
Real Time PCR-3D gene	Yes		45
Real Time PCR-5UTR region	Yes		45
Sandwich ELISA (mAbs-based)	yes		25

ToR: 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 ELISA kit for Antigen detection and serotyping of FMDV O, A, C, Asia1 (1 kit= 5 plates)	Antigen detection and serotyping ELISA	Produced and provided		No. 119 kits	10	☐Africa ☐Americas ☒Asia and Pacific ☒Europe ☒Middle East
Ready-to-use ELISA kit for Antigen detection and serotyping of FMDV O, A, SAT1 and SAT2 (1 kit= 5 plates)	Antigen detection and serotyping ELISA serotyping of FMDV O, A, SAT1 and SAT2 (1 kit= 5 plates)	Produced and provided		No. 12 kits	6	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☒Middle East
Ready-to-use ELISA kit for NSP antibodies (1 kit=5 plates)	3ABC trapping indirect ELISA	Produced and provided		No. 53 kits	6	☐Africa ☐Americas ☒Asia and Pacific ☒Europe ☒Middle East
Ready-to-use ELISA kit for SP-Ab FMDV serotype O	Solid-phase competitive ELISA (SP-Ab type O)	Produced and provided		No. 41 kits	9	☒Africa ☐Americas ☒Asia and Pacific ☒Europe ☒Middle East
KIT ELISA (ready-to-use)	competitive ELISA for Ab specific to FMDV type A	Produced and provided		No. 39 kits distributed	10	☒Africa ☐Americas ☒Asia and Pacific ☒Europe ☒Middle East
Ready-to-use ELISA kit for SP-Ab FMDV serotype Asia 1	Solid-phase competitive ELISA (SP Ab type Asia 1	Produced and provided		No. 34 kits	8	☐Africa ☐Americas ☒Asia and Pacific ☒Europe ☒Middle East
Ready-to-use ELISA kit for SP-Ab FMDV serotype SAT2	Solid-phase competitive ELISA (SP Ab type SAT2	Produced and provided		No. 7 kits	3	☒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: 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 KIT-Serotyping of FMDV O, A, Asia 1 and C	The test, validated with the collaboration of the "The Pirbright Institute", is a simple sandwich ELISA for detection and typing of FMD viruses of type O, A, Asia1 and C in homogenates of epithelium vesicles and in vesicles fluid. A pan-FMDV test, detecting any isolate of type O, A, C and Asia1 and some isolates of the SATs serotypes, is included in the kit. The kit is available ready-to-use, with plates pre-coated with type-specific mAbs and a unique pan-FMD conjugate; also positive controls antigens are pre-incorporated into plates. S. Grazioli, E. Brocchi, G. Dho, N.P. Ferris . A simple antigen detection ELISA kit for FMDV serotypes O, A, C and Asia 1. Report of EUFMD Open Session - Vienna, Austria, October 2010, EuFMD website.
FMDV ANTIGEN DETECTION ELISA KIT-Serotyping of FMDV O, A, SAT1 and SAT2	The kit, developed with the collaboration of "The Pirbright Institute", is based on the same concept as the previous one and was designed for detection and typing of African virus pools (serotypes O, A, SAT1 and SAT2). In addition to the pan-FMD detector mAb, a second conjugate (mAbs pool) is used for typing of SAT1 and 2 serotypes. IZSLER validation dossier Kit broshure S. Grazioli, N. Ferris, G. Dho, E. Spagnoli, E. Brocchi. Ready-to-use ELISA kit for FMDV diagnosis and serotyping tailored for Africa. Poster, lecture and abstract book of EUFMD Open Session – Jerez, Spain, October 2012.
ELISA KITS FOR SP-ANTIBODIES SPECIFIC TO FMDV SEROTYPES O, A, ASIA 1	Each assay is a solid phase competitive ELISA based on a peroxidase-conjugated, neutralizing monoclonal antibody (mAb), specific for one FMDV serotype. Its binding to the homologous FMDV serotype immobilized onto the solid-phase is inhibited by antibodies against that serotype present in sera. The test can be applied to measure antibodies in sera from FMDV infected or vaccinated animals of any susceptible species. The kit is available ready-to-use, with ELISA plates supplied pre-coated with inactivated FMDV antigens captured by homologous serotype-specific mAbs. E. Brocchi, E. Spagnoli, Y. Li, B. Haas, K. De Clercq, G. Dho, S. Grazioli, F. De Simone. Ready-to-use kits for detection of antibodies to FMDV serotypes O, A, Asia 1. Poster, poster, lecture and abstract book of EUFMD Open Session – Jerez, Spain, October 2012.
ELISA KIT FOR SP-ANTIBODIES SPECIFIC TO FMDV SEROTYPE SAT 2.	The assay is a solid phase competitive ELISA based on a peroxidase-conjugated, neutralizing monoclonal antibody (mAb), specific for FMDV SAT 2. The kit is available ready-to-use, with ELISA plates supplied pre-coated with inactivated FMDV-SAT 2 antigen captured by an homologous mAb. Validation dossier and kit broshure available at IZSLER.

ToR: 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
EGYPT	April 2013	1500 sera (large & small ruminants)	
LIBYA	June 2013	1150 (large & small ruminants)	
LIBYA	September 2013	3300 (large & small ruminants)	
LIBYA	September 2013	N. 13 whole blood samples, 5 epithelium swabs, 1 vesicular epith.; N. 41 sera collected in 10 suspect farms.	N. 6 ep. homogeneates
LIBYA	November 2013	N. 13 epithelium suspensions, 2 vesicle fluids, 6 whole blood samples; N. 70 sera	

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
LIBYA	Knowledge on the epidemiological situation, preparation of FMD surveillance programs and implementation of FMD control actions in Libya	Ad hoc meetings, remote assistance and in loco (at the OIE lab) for: assessing the level of FMD virus circulation by clinical investigations and by conducting country serosurvey, assessing the immune response of vaccinated animals, monitoring the level of vaccine immunity, train scientists on FMD laboratory diagnosis, provision of diagnostic kits and laboratory testing.
EGYPT	FMD serosurveillance, monitoring vaccine immunity and evaluation of different vaccines efficacy.	Assistance to EUFMD/FAO programs by conduction of tests at IZSLER and interpretation of the results of FMD serosurveillance, training of a lab scientist on FMD diagnostic strategies and tests.
IRAN	Interpretation of immune response to NSP and SP in experimentally vaccinated animals.	Remote assistance
IRAN	Assistance in elaboration and interpretation of results recorded with the diagnostic kits supplied for FMD diagnosis and serology.	Continuous remote assistance and advice
PAKISTAN	Assistance in elaboration and interpretation of results recorded with the diagnostic kits supplied for FMD diagnosis and serology.	Continuous remote assistance and advice
NIGERIA	Assistance in elaboration and interpretation of results recorded with the diagnostic kits supplied for FMD diagnosis and serology.	Continuous remote assistance and advice
IRAN	Consultation and provision of diagnostic protocols	Remote assistance
VIETNAM	Consultation and provision of diagnostic protocols	Remote assistance
IRAQ	Provision of a program for an hands-on training course on FMD laboratory diagnostic assays, with availability for organization in 2014.	Remote assistance through EuFMD

ToR: 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)
European Project : Development, enhancement and complementation of animal-sparing, foot-an--mouth disease vaccine-based control strategies for free and endemic regions" FMD-DISCONVAC "FMD-Disconvac"	4 years	WP2: development of vaccine quality test by in vitro methods (measurement of NSP, 146S particles, use of serology to estimate protection in vaccinated population). WP5: development of new generation ready-to-use ELISA kits for antigen and antibody detection and serotyping.	14 partner Institutions, distributed in Belgium, UK, The Netherlands, Germany, France, Denmark, Switzerland, Argentina, China, India, Israel and Italy.
Development of new and improvement of diagnostic assays and reagents	5 years	Stabilization of in-house assays in ready-to-use kits, substitution of FMDV inactivated antigens wit VLP, production of anti-bovine IgA for measurement of mucosal antibody	The Pirbright Institute, UK
Evaluation of 3ABC DIVA tests for Foot-and-mouth disease virus in the Southern Africa context	1 year	Development of a SAT-adapted DIVA test based on detection of anti-3ABC antibody and comparison with other existing 3ABC-ELISAs.	Onderstepoort Veterinary Institute, Agricultural Research Council, South Africa
Development of a ready-t--use ELISA kit for SAT2	1 year	Collaborative evaluation and validation of the kit developed by IZSLER OIE Reference Laboratory	Onderstepoort Veterinary Institute, Agricultural Research Council, South Africa - The Pirbright Institute, UK
Serology to estimate protection level in vaccinated populations: harmonization of results obtained with different tests in different labs.	1-2 years	Comparative analyses and harmonization of results of FMDV serology (ELISA and VNT) obtained in different laboratories when testing field sera.	CODA-CERVA-VAR, Belgium
Development of a competitive ELISA using mAbs for detection of anti-NSP antibody	2 years	Increase availability of DIVA tests based on anti-NSP antibodies	Central Veterinary Institute (CVI), Lelystad, The Netherlands
Study of interaction between FMDV and host proteins during infection	5 years	Provision of mAbs suited for the study	USDA ARS PADC Foreign Animal Disease research, Plum Island NY, US

ToR: 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?

Yes

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
Santina Grazioli, Francesca Fallacara and Emiliana Brocchi. Mapping of antigenic sites of Foot-and-Mouth Disease virus serotype Asia 1 and relationships with sites described in other serotypes. J Gen Virol. 2013 Mar; 94(Pt 3): 559-69

Gladue DP, O'Donnell V, Baker-Branstetter R, Holinka LG, Pacheco JM, Fernandez-Sainz I, Lu Z, Brocchi E, Baxt B, Piccone ME, Rodriguez L, Borca MV. Foot-and-mouth disease virus nonstructural protein 2C interacts with Beclin1, modulating virus replication. J Virol. 2012 Nov; 86(22): 12080-90

b) International conferences: 0

c) National conferences: 2
Spagnoli E., Grazioli S., Dho G., Brocchi E. a. Luminex technology for the simultaneous detection and serotyping of the FMD virus. National Congress of the Italian Society for Veterinary Diagnostic Laboratories (Italian Branch of WAVDL)) Palermo, Italy 23-25 October 2013.

Emiliana Brocchi, Giovanna Dho, Santina Grazioli, Nigel Ferris. Ready-to-use ELISA kits for diagnosis and serotyping of FMD viruses. National Congress of the Italian Society for Veterinary Diagnostic Laboratories (Italian Branch of WAVDL)) Palermo, Italy, 23-25 October 2013.

d) Other:
(Provide website address or link to appropriate information) 5
- Final meeting with representatives of the 14 partner Institutions of the FMD-Disconvac Project, Lyon May 2013; project reports and meeting presentations in project website.
- Annual meeting of the network of OIE Reference Laboratories for FMD, Bangkok, Nov. 2014; meeting report disseminated by the coordinating OIE Reference Laboratory, UK.
- Results of serosurveys conducted in Egypt and Libya submitted to local Authorities, EuFMD and FAO.
- Sequencing data submitted to GeneBank

ToR: 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: 3
b) Seminars:
c) Hands-on training courses: 6
d) Internships (>1 month):

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	Kazakhstan	2
a and c	US	1
c	Libya	4
c	Egypt	1

ToR: 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
ISO 170025

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

Yes

Test for which your laboratory is accredited	Accreditation body
Competitive ELISA for SP-Ab against each of FMDV serotype O, A, Asia1, SAT1, SAT2	Accredia
VNT fo SP-Ab detection against each of the 7 FMDV serotypes	Accredia
NSP Ab detection by IZSLER 3ABC trapping ELISA	Accredia
Antigen detection and serotyping ELISA	Accredia
Conventional RT-PCR (3D region)	Accredia
Real time RT-PCR (3D region)	planned for accreditation by Accredia
Real time RT-PCR (5'UTR region)	planned for accreditation by Accredia

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 2012, Chapter 1.1.3 or Manual of Diagnostic Tests for

Aquatic Animals 2012, Chapter 1.1.1)

ToR: 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
9th OIE/FAO FMD Laboratory Network Meeting	November 2013	Bangkok	speaker	Activities conducted in 2013 by the OIE/FAO FMD Reference Center-IZSLER
Annual meeting of the FMD Special Committee on Research and Program Development (EUFMD)	November 2013	Frascati, Rome	representative for FAO/OIE FMD reference Lab	Participation in working groups, mainly related to diagnostic needs for implementation of PCP.

ToR: 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 2013 Combined Proficiency Testing Scheme, aimed at evaluating capability for diagnosis of FMD and SVD outbreaks and carrying out post outbreak surveillance using virological and/or serological methods. All serological assays (VNT, SP- and NSP-ELISAs) and virological test (Virus Isolation, Antigen detection and serotyping ELISA, conventional and Realtime RT-PCRs) currently used in the lab are evaluated with proficiency panels of samples	Participant	about 60	World/OIE/FAO FMD Reference Laboratory, "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 the development of new and improvement of diagnostic assays and reagents	Stabilization of in-house assays in ready-t--use kits, substitution of FMDV inactivated antigens with safe recombinant virus like particles, production of anti-bovine IgA for measurement of mucosal antibody, production of new monoclonal antibodies against new FMDV variants.	The Pirbright Institute, UK
Identification, mapping and chracterization of epitopes not involved in Virus neutralization in vitro	Identification of epitopes not involved in virus neutralization by mapping of non-neutralizing monoclonal antibodies against epitopes either type-specific or inter-types cross-reactive, study of their potential role in inducing immune protection.	The Pirbright Institute, UK
Development of a SAT-adapted DIVA test based on detection of anti-3ABC antibody and comparison with other existing 3ABC-ELISAs	Evaluation of 3ABC DIVA tests for Foot-an--mouth disease virus in the Southern Africa context.	Onderstepoort Veterinary Institute, Agricultural Research Council, South Africa
Development of a ready-to-use ELISA kit for SAT2 Antibosy detection	Complete availability of a spectrum of user friendly and stable kits for the different FMD diagnostic needs. OIE reference Labs collaborate in evaluation and validation by testing experimental and field sera with known origin.	Onderstepoort Veterinary Institute, Agricultural Research Council – The Pirbright Institute
Serology to estimate protection level in vaccinated populations: harmonization of results obtained with different tests in different labs.	Comparative analyses and harmonization of results of FMDV serology (ELISA and VNT) obtained in different laboratories when testing field sera.	CODA-CERVA-VAR-Department of Virology, Epizootic Diseases Section, Belgium. OIE Collaborating Centre for Validation, Quality Assessment and Quality Control of Diagnostic Assays and Vaccine for Vesicular Diseases in Europe
Study of interaction between FMDV and host proteins during infection	Provision of mAbs suited for the study	USDA ARS PADC Foreign Animal Disease research, Plum Island NY, US

ToR: 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
Organization of the annual inter-laboratory test to maintain capability, monitor the harmonization of results and laboratories performance for the NSP-Ab detection by the 3ABC-ELISA kit produced and distributed by the reference laboratory	12 regional laboratories in Italy	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East

ToR: To place expert consultants at the disposal of the OIE

24. Did your laboratory place expert consultants at the disposal of the OIE?

No

25. Additional comments regarding your report:

There is an established, formal collaboration between IZSLER-OIE Reference Laboratory for FMD and Dr. Giancarlo Ferrari, who made available his expertise and competence for the implementaion and evaluation of FMD surveillance activities conducted in Libya during 2013. Dr. Ferrari is also a member of the "GF-TAD joint working group".