OIE Reference Laboratory Reports Activities

Activities in 2014

This report has been submitted : 2015-01-21 11:46:21

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 N. 9 25124 Brescia ITALY
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Name (including Title) of Head of Laboratory (Responsible Official):	Prof. Stefano Cinotti, General Director of IZSLER
Name (including Title and Position) of OIE Reference Expert:	Dr. Emiliana Brocchi, Head of Vesicular Diseases National Reference Centre and Dpt. Biotechnology
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 – Structural Proteins	yes	6392 (1598 x 4 serotypes O,A,Asia1,SAT2)	2370 (790x3 serotypes) + 360 (x 1 serotype)
Virus Neutralization Test	yes	0	720 (360 x 2 strains)
NSP Ab ELISA (3ABC trapping ELISA)	yes	0	1150
Direct diagnostic tests		Nationally	Internationally
Virus Isolation (IB-RS2, BHK21)	yes	1	9
Conventional RT-PCR (3D gene)	yes	1	9
Real Time PCR-3D gene	yes	1	9
Real Time PCR-5UTR region	yes	0	9
Ag detection and serotyping ELISA (MAbs-based)	yes	0	9
VP1 sequencing	yes	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 ELISA kit for Antigen detection and serotyping of FMDV O, A, C, Asia1 (1 kit= 5 plates)	Ag detection and serotyping ELISA (MAbs-based)	Produced and provided	0	No. 373 kits	18	☐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)	Ag detection and serotyping ELISA (MAbs-based)	Produced and provided		No. 75 kits	15	☒Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
Ready-to-use ELISA kit for NSP antibodies (1 kit=5 plates)	NSP Ab ELISA (3ABC trapping ELISA)	Produced and provided		No. 80 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		No. 68 kits	22	☒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		No. 60 kits	21	☒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		No. 47 kits	18	☐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		No. 17 kits	6	☒Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
IB-RS-2, BHK-21, LFBK cells		Provided			3 (Kenya, Sudan, Egypt)	☒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.)
ELISA KIT FOR SP-ANTIBODIES SPECIFIC TO FMDV SEROTYPE SAT 1	The assay is a solid phase competitive ELISA based on a peroxidase-conjugated, neutralizing monoclonal antibody (mAb), specific for FMDV SAT 1. The test was developed as a ready-to-use kit, available at a prototype level, with ELISA plates supplied pre-coated with inactivated FMDV-SAT 1 antigen captured by a monoclonal antibody. G. Dho, S. Grazioli, M. Bugnetti, G. Pezzoni, F.F. Maree, J. Esterhuysen, M. Chitray, K. Scott and E. Brocchi. “Ready-to-use kits for the detection of antibody to FMDV serotypes SAT1 and SAT2.” Open Session of the Standing Technical and Research Committees of EuFMD, Cavtat (Croatia), 29-31 October 2014.
New ready-to-use ELISA kits for FMDV antigen (serotypes O,A,Asia1, SAT1 and SAT2) and antibodies (serotypes O,A,Asia1, SAT2) detection were reported in 2014	

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
TUNISIA	May 2014	-	N. 5 epithelium homogenates
ALGERIA	August 2014		N. 4 epithelium
LIBYA	January 2014	N. 788 sera (large & small ruminants, tested for NSP and SP-O,A,SAT2 Ab)	

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	FMD surveillance and vaccination program and monitoring for 2014	Consultancy on surveillance and monitoring design, testing and interpretation of serological data
TUNISIA	Estimate of vaccine strain efficacy against circulating strain	Proposal and design of field vaccine trial and availability to test virus neutralizing antibodies.
SUDAN	Implementation of pilot FMDV vaccine production in suspension	Ad hoc training at IZSLER on BHK culture suspension technology, SOP for FMD virus inactivation and evaluation of inactivated antigens, IZSLER ELSA kits. Supply of cells.

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)
Development of new and improvement of diagnostic assays and reagents	5 years	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
Validation of ready-to-use ELISA kits for SAT2 and SAT1 Ab detection	1-2 years	Collaborative evaluation and validation of ELISA kits developed at IZSLER	Onderstepoort Veterinary Institute, Agricultural Research Council, South Africa
Study of interaction between FMDV and host proteins during infection	5 years	Selection and provision of mAbs suited for the study	USDA ARS PADC Foreign Animal Disease research, Plum Island NY, US
Estimate of vaccine strain efficacy against circulating strain	6 months	Evaluate, by a field vaccine trial in selected cattle and sheep groups in Tunisia, the kinetic and the level of virus neutralizing antibodies elicited by the vaccine strain and cross-neutralizing the different field virus.	Institut de la Recherche Vétérinaire de Tunisie, Tunis, Tunisia

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?

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: 3
Gladue DP, O'Donnell V, Baker-Branstetter R, Pacheco JM, Holinka LG, Arzt J., Pauszek S., Fernandez-Sainz I, Fletcher P., Brocchi E, , Lu Z, Rodriguez LL, Borca MV.
Interaction of Foot-and-Mouth Disease Virus Nonstructural Protein 3A with Host Protein DCTN3 is Important for Virus Virulence in Cattle. J Virol, 2014, 88(5): 2737-47.
Nick J. Knowles, Katarzyna Bachanek-Bankowska, Jemma Wadsworth, Valerie Mioulet1, Begoña Valdazo-González, Ibrahim M. Eldaghayes, Abdunaser S. Dayhum, Abdulwahab M. Kammon, Monier A. Sharif, Santina Grazioli, Emiliana Brocchi, Saravanan Subramaniam, Bramhadev Pattnaik and Donald P. King.
Outbreaks of foot-and-mouth disease virus in Libya and Saudi Arabia during 2013 due to an exotic O/ME-SA/Ind-2001 lineage. Transbound Emerg Dis. 2014 Dec 7. doi: 10.1111/tbed.12299. [Epub ahead of print]
Mahamat Ouagala, Emiliana Brocchi, Santina Grazioli, Ben Youssef Adel, Keith Sumption, Djibrine Kiram, Assandi Oussigu´er´, Pascal Hendrikx, Dirk Berkvens, Claude Saegerman
Evaluation of the sensitivity of the Chadian Animal Disease Epidemiosurveillance Network with respect to Foot-and-mouth Disease, Acta Tropica, submitted 2014.

b) International conferences: 6
Giovanna Dho, Santina Grazioli, Emiliana Brocchi. “Enhanced sensitivity of FMDV antigen detection by novel signal amplification systems.” Pg. 244-45, Open Session of the Standing Technical and research Committees of EuFMD, Cavtat (Croatia), 29-31 October 2014.

Emiliana Brocchi, Santina Grazioli, Giovanna Dho, Ibrahim Eldaghayes, Abdunaser Dayum, Abdulwahab Kammon, Monier Sharij and Giancarlo Ferrari. “Serological survey in Libya to assess FMD viruses circulation and vaccine immune response.” Pg. 162-63, Open Session of the Standing Technical and research Committees of EuFMD, Cavtat (Croatia), 29-31 October 2014.

G. Dho, S. Grazioli, M. Bugnetti, G. Pezzoni, F.F. Maree, J. Esterhuysen, M. Chitray, K. Scott and E. Brocchi. “Ready-to-use kits for the detection of antibody to FMDV serotypes SAT1 and SAT2.” Pg. 140-41, Open Session of the Standing Technical and research Committees of EuFMD, Cavtat (Croatia), 29-31 October 2014.

Ibrahim Eldaghayes, Abdunaser Dayum, Abdulwahab Kammon, Monier Sharij, Giancarlo Ferrari, Keith Sumption, Donald King, Santina Grazioli and Emiliana Brocchi. “FMD in Libya and the control strategy.” Pg. 166-67, Open Session of the Standing Technical and research Committees of EuFMD, Cavtat (Croatia), 29-31 October 2014.

C.van Maanen, A. Habashi, H. Ularamu, A. Sangula, S. grazioli and E. Brocchi. “Diagnostic observation with IZSLER antigen detection ELISA Kit for detection and serotyping of FMDV serotypes O, A, SAT1 and SAT2 in several African countries.” Pg. 150-51, Open Session of the Standing Technical and research Committees of EuFMD, Cavtat (Croatia), 29-31 October 2014.

Katarzyna Bachanek-Bankowka, Jemma Wadsworth, Valerie Mioulet, Begona Valdazo-Gonzalez, Ibrahim M. Eldaghayes, Abdunaser S. Dayhum, Abdulwahab M. Kammon, Monier A. Sharij. “Outbreaks of Foot-and-mouth disease virus in Libya and Saudi Arabia during 2013 due to an exotic O/ME-SA/IND-2001 lineage.” Pg. 154-55, Open Session of the Standing Technical and research Committees of EuFMD, Cavtat (Croatia), 29-31 October 2014.

c) National conferences: 0

d) Other:
(Provide website address or link to appropriate information) 6
N. 3 updating courses on FMD for veterinarians on national level
Report of diagnostic results submitted to local Authorities and International Organizations (OIE/FAO/EUFMD)
Report of results of serosurveillance and vaccine immune response conducted in Libya at international meetings (The FMD day, Tripoli March 2014 – FMD EU-NRL annual meeting, May Pirbright, UK)
Presentations given at OIE/REMESA meetings (September and November) on diagnostic results and isolates characterization referred to North African countries
Report of activities and outputs at the annual meeting of the network of OIE reference laboratories for FMD

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: 1
b) Seminars: 0
c) Hands-on training courses: 2
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
One One-week technical visit to transfer technologies for production of immunologicals used in diagnostic ELISA kits and kits manufacturing	United Kingdom	1
10 days hands-on training on BHK-38 suspension culture, FMD Virus culture and inactivation, FMDV antigen evaluation (quantification and serotyping), IZSLER ELISA kits	Sudan	1
One week hands-on training on FMD ELISAs for antigen and antibody detection and serotyping, concepts of FMD Lab Biosecurity	9 Balkan countries + Ukraine	10

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.pdf

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, C, 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
Virus Isolation	Planned for accreditation

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 2014, Chapter 1.1.3a)

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?

Yes

National/ International	Title of event	Co-organiser	Date (mm/yy)	Location	No. Participants
International	9th OIE/FAO FMD Laboratory Network Meeting	The Pirbright Institute, Network coordinator	11/2014	IZSLER, Brescia, Italy	36

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
Meeting on the evolution of the epidemic of FMD in North African countries	September 2014	OIE Tunis, Tunisia	Speaker	Analysis of results of the samples received from the countries of the Maghreb region (2013-2014)
Third Global Conference of OIE Reference Centres: "Challenges and expectations for the future	October 2014	Incheon (Seoul), Republic of Korea	Designated expert for OIE/FAO reference lab	//
9th Meeting of the Joint Permanent Committee REMESA	November 2014	Tunis, Tunisia	Speaker	Results of surveillance and diagnostic activities conducted by the OIE reference laboratory (IZSLER) in the Maghreb region
9th OIE/FAO FMD Laboratory Network Meeting	November 2014	IZSLER, Brescia, Italy	Speaker	Activities conducted in 2014 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.
Proficiency Testing Scheme 2014, aimed at evaluating capability for diagnosis of FMD outbreaks (with differential diagnosis for SVD) and carrying out post outbreak surveillance using virological and 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) regularly used in the lab are used to tests the proficiency panels of samples	Participant	About 60 (including OIE RL and NRL globally)	For participating OIE Ref Labs contact the Organiser / 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
Research agreement for the development of next-generation and improved diagnostic ELISAs and reagents	Stabilization of in-house assays in ready-to-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
Characterization of epitopes not involved in virus neutralization	Study the potential role of epitopes not involved in virus neutralization in inducing immune protection, by using non-neutralizing monoclonal antibodies directed against either type-specific or inter-types cross-reactive epitopes to identify and map such epitopes.	The Pirbright Institute, UK
Development and validation of a ready-to-use ELISA kit for SAT1 Antibody detection	Complete the 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, South Africa – The Pirbright Institute, UK
Research agreement for provision of mAbs suited for the research study	Study of interaction between FMDV and host proteins during infection	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
See answer at previous point 21	About 60 (including OIE ref Labs and NRLs globally)	☒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)
Answering an OIE questionnaire for the potential interest in a Biobank of veterinary biological products	-	-
Answering an OIE questionnaire for the potential interest in a database of genomic sequences connected to WAHIS		
Collaboration provided by IZSLER for the design and for the creation of a database of genomic sequences connected to WAHIS		

25. Additional comments regarding your report: