OIE Reference Laboratory Reports Activities

Activities in 2015

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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 No. 9 25124 Brescia ITALY
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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
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	type O 1149, Type A 1114, Type Asia 1 1133, Type SAT2 1068	Type O 450, Type A 450, Type SAT2 450
Virus Neutralization Test	yes	0	370 x 2 type O strains
NSP Ab ELISA (3ABC trapping ELISA)	yes	1	450
Direct diagnostic tests		Nationally	Internationally
Virus Isolation (IB-RS2, BHK21)	yes	1	0
Conventional RT-PCR (3D gene)	yes	5	10 x 3 cell lines
Real Time PCR-3D region	yes	5	0
Real Time PCR-5UTR region	yes	5	0
Ag detection and serotyping ELISA (MAbs-based)	yes	5	50 (to identify isolates)
VP1 sequencing	yes	0	27
Full Genome Sequencing	no	0	10

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		No. 143 kits	11	☐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. 52 kits	7	☒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		No. 120 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. 297 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		No. 143 kits	17	☒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. 69 kits	11	☐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. 22 kits	6	☒Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East
IB-RS-2, BHK-21 cells		Provided		N. 2 flasks each	3	☒Africa ☐Americas ☐Asia and Pacific ☐Europe ☐Middle East
Monoclonal antibodies anti-FMDV NSP and anti-FMDV SP		Produced and provided		N. 17 MAbs	2	☐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 kits for detection and serotyping of FMDV antigens and antibodies	The ready-to-use ELISA kits for detection and serotyping of FMDV antigens and antibodies (serotypes O, A, Asia1, C, SAT1 and SAT2), previously reported, are subject to continuous validation and improvement, based on extended validation on target species, design of new plates layout, evaluation of different antigens sources, different monoclonal antibodies, etc.

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	November 2014-January 2015	N. 370 sera (vaccinated large and small ruminants) titrated by SP-ELISA type O, VNT O BFS and O Tunisia14, NSP Abs	
ALGERIA	May 2015		N. 2 for sequencing
EGYPT	May 2015		N. 10 epithelium homogenates
EGYPT	April 2015		N. 180 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
TUNISIA	Estimate of vaccine efficacy against the heterologous circulating strain	Testing and results interpretation and reporting of a field vaccine trial designed to estimate cross-protection elicited by the vaccines used against the field-circulating virus, irrespective data from in-vitro matching
ALGERIA	“Mise à niveau des laboratoires de l’Institut national de la médecine vétérinaire aux standards européens et internationaux” (EU supported Italy-Algeria twinning)	Missions of IZSLER experts to Algeri and Tlemcen and implementation de novo (Tlemcen) or improvement (Algeri) of lab diagnostic procedures for FMD One-week hands on training of 4 Algerian experts at IZSLER labs
EGYPT	Assistance in elaboration and interpretation of results recorded with the diagnostic kits supplied for FMD diagnosis and serology	Continuous remote assistance and advice
IRAN	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

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	IZSLER-Italy and The Pirbright Institute-UK
Epitopes identification and mapping in SATs serotypes	1 year	Combine data from monoclonal antibodies, mutagenesis studies and sequencing studies to confirm identification and immunodominance of antigenic sites in SATs serotypes	OVI, Agricultural Research Council, South Africa and IZSLER-Italy
Study of interaction between FMDV and host proteins during infection	5 years	Selection and provision of mAbs suited for the study; production of a new MAbs panel specific to the 2B NSP	USDA ARS PADC Foreign Animal Disease research, Plum Island NY, US and IZSLER-Italy
Antigenic and genomic characterization of FMDV isolates	1.5 years	Genetic and antigenic characterization of FMD viruses isolated during the epidemic wave of FMD occurred in 2014 in Tunisia, in order to identify epidemiological relationships between outbreaks and major risk factors of disease spreading in the country, in addition to evaluating the degree of homology between the vaccine strains and field circulating viruses	ANSES-France, IZSLER-Italy, Institut de la Recherche Vétérinaire de Tunisie-Tunisia
Antigenic and genomic characterization of FMDV isolates	2 years	Genetic and antigenic characterization of SAT2 viruses circulating in different outbreaks in Egypt	IZSLER-Italy, AHRI-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?

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: 1
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, accepted under revision

b) International conferences: 2
Eldaghayes, I; Dayhum, A; Kammon, A; Sharif, M.2; Ferrari, G; Sumption, K; King, D; Grazioli, S and Brocchi, E. “Control Strategy Of FMD In Libya And Post-Vaccination Monitoring”. Global Foot-and-Mouth Disease Research Alliance (GFRA) meeting 2015, Hanoi 20-22 October 2015. Abstract book, page 49

Dayhum, A; Eldaghayes; Kammon, A; Sharif, M; Ferrari, G; Conchedda, G; Cinardi, G; Sumption, K; King, D.; Grazioli, S and Brocchi, E. “FMD Serological Survey In Libya And The Circulating Viruses”. Global Foot-and-Mouth Disease Research Alliance (GFRA) meeting 2015, Hanoi 20-22 October 2015. Abstract book, page 103

c) National conferences: 0

d) Other:
(Provide website address or link to appropriate information) 5
N. 1 updating course on FMD for veterinarians on national level

Reports of diagnostic results and isolates characterization submitted to local Authorities and International Organizations (OIE/FAO/EUFMD)

Presentations given at 10th JPC OIE/REMESA meeting (March) and FMD EU-NRL annual meeting (May) on “Results of the field study conducted in collaboration with Tunisia about the efficacy of the vaccination”

Presentation given at 90th EUFMD Executive Committee on activities and results of the OIE/FAO reference Laboratory for the REMESA region

Report of activities and outputs at the annual meeting of the network of OIE reference laboratories for FMD, Uccle-Brussels, November

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: 3
b) Seminars: 1
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
a: two-day technical visit to understand the FMDV diagnostic flow and SOPs in use at the IZSLER lab and for reciprocal exchange of expertise with discussion on potential collaborative projects (Dr. Alyssa Karin Van Dreumel)	Australia	1
a: two-day technical visit to understand the FMDV diagnostic flow and SOPs in use at the IZSLER lab and for reciprocal exchange of expertise with discussion on potential collaborative projects (Reinhold Kittelberger)	New Zealand	1
a: two-week technical visit of a Libyan expert, to show activities and technologies applied at IZSLER, with focus on the virology, including diagnosis and surveillance for FMD and other diseases, sequencing and phylogenetic analyses, strategies for use of monoclonal antibodies and recombinant antigens, organization of the diagnostic flow, LIMS	Libya	1
b: two-day seminars on FMD and FMDV, epidemiology, laboratory diagnosis, tests strategies and interpretation - hold in Algeri	Algeria	7
c: 10 days hands-on training on ELISAs for antibodies and antigen detection and serotyping, cell cultures and virus isolation, RT-PCR conventional and realtime, Virus Neutralization Test, lab results interpretation, core concepts of sequencing	Egypt	2
c: One-week hands-on training on FMD ELISAs for antigen and antibody detection and serotyping, RT-PCR conventional and realtime, results interpretation. Training conducted in Algeri and Tlemcen labs	Algeria	5
c: One week hands-on training on FMD ELISAs for antigen and antibody detection and serotyping, RT-PCR conventional and realtime, results interpretation, FMD Lab Biosecurity, concepts of sequence analysis. Traning organized and conducted at IZSLER OIE Ref Lab	Algeria	4

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
ompetitive 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 FMDV 3ABC-trapping ELISA	Accredia
FMDV Antigen detection and serotyping ELISA	Accredia
Conventional RT-PCR (3D region)	Accredia
Realtime RT-PCR (3D and 5'UTR)	planned for accreditation in 2016

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?

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
10th Meeting of the Joint Permanent Committee REMESA/OIE	03/15	Crete, Greece	speaker	Results of the field study conducted in collaboration with Tunisia to estimate the efficacy of heterologous vaccination against the circulating strain
“Implementation of the biosafety and biosecurity measures in the laboratories” Workshop organized by OIE Tunis for Countries of the RELABS network (REMESA framework)	09/15	Tunis, Tunisia	speaker	1)Biosecurity in the laboratory: Experience of the OIE Reference laboratory for FMD 2)Elements of a laboratory biosecurity plan
90th EUFMD Executive Committee	09/15	Monza, Italy	speaker	Activities and results of the OIE/FAO reference Laboratory-IZSLER for the REMESA region
10th OIE/FAO FMD Laboratory Network Meeting	11/15	CODA-CERVA, Uccle, Brussels	speaker	Report of activities conducted in 2015 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 2015, aim : complete a PTS for virology and serology diagnosis for FMD. 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 analyze three proficiency panels of samples	Participant	all EU member countries and all OIE RL, plus several other countries	Organizing 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 next-generation and improved diagnostic ELISAs and reagents	Production of ready-to-use kits, continuous and extended validation of new ELISA kit, evaluation of recombinant virus like particles, monoclonal antibodies specific to bovine IgA for measurement of mucosal antibody, production of new monoclonal antibodies against new FMDV variants, validation of ELISA kits for post-vaccination monitoring, etc	Italy UK
Joint BBSRC and DBT Farmed Animal Disease and Health (FADH) project “An effective vaccination programme for the eradication of foot-and-mouth disease from India”	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. Characterization of epitopes not involved in virus neutralization	UK Italy
On-going Research agreement between IZSLER and USDA ARS PADC for production and provision of mAbs suited for the research study	“Study of interaction between FMDV and host proteins during infection”	US Italy
Collaborative study	Combining and comparing data of epitopes mapping on SAT2 FMDV serotype using monoclonal antibodies (MAR-Mutants) and reverse genetics. Epitopes identification and mapping in SATs serotypes	South Africa Italy
ADECIA: Antigenic and genomic characterization of FMDV isolates from the FMD Tunisian outbreaks 2014.	Genetic and antigenic characterization of FMD viruses isolated during the epidemic wave of FMD occurred in 2014 in Tunisia, in order to identify epidemiological relationships between outbreaks and major risk factors of disease spreading in the country, in addition to evaluating the degree of homology between the vaccine strains and field circulating viruses	Itay France

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 point 21		☒Africa ☒Americas ☒Asia and Pacific ☒Europe ☒Middle East
Proficiency test organized as part of an FMD outbreak simulation exercise conducted in three Balkan countries with EUFMD support, to verify preparedness of NRL to recognize FMD. Panels of samples and kits for Ag detection ELISA and PCR and for NSP/SP antibodies detection were prepared and provided	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)
Provision of collaboration		Collaboration for the design and creation of a database of genomic sequences connected to WAHIS
OIE Working Group	OIE Headquarters – Paris	Implementation of FMD Vaccine Banks for North Africa
Meeting (13/04/2015) with the OIE regional representative for the Middle East OIE and a delegation of the Abu Dhabi Food Control Authority (ADFCA) Animal Health Center for diagnostic and research in Abu Dhabi – UAE (Candidate center of an OIE Collaborating Center on camel diseases) for outlining a twinning project plan	Brescia - IZSLER	Provision of suggestions and expert advice for the development of an OIE Collaborating Center on camel diseases
Referee for Plurithematic Issue of the OIE Scientific and Technical Review		
Opinion provided to OIE Biological Standards Commission		FMD sera to calibrate diagnostic tests
Comments on OIE Standards		Comments to Chapter OIE 2.1.19 Terrestrial Manual

25. Additional comments regarding your report: