# OIE Reference Laboratory Reports Activities

## *Activities in 2021*

### This report has been submitted : 2022-02-02 10:20:40

| | |
|---|---|
| **Name of disease (or topic) for which you are a designated OIE Reference Laboratory:** | Foot and mouth disease |
| **Address of laboratory:** | Via A. Bianchi No. 9 25124 Brescia ITALY |
| **Tel.:** | +390-30 229 03 10 |
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| **E-mail address:** | santina.grazioli@izsler.it |
| **Website:** | www.izsler.it |
| **Name (including Title) of Head of Laboratory (Responsible Official):** | Dr. Piero Frazzi General Director |
| **Name (including Title and Position) of OIE Reference Expert:** | OIE Reperence Expert: Tbd |
| **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 | 969 | 208 |
| Competitive ELISA – Ab to SP type A | yes | 969 | 208 |
| Competitive ELISA – Ab to SP type Asia 1 | yes | 969 | 208 |
| Competitive ELISA – Ab to SP type SAT 2 | yes | 969 | 208 |
| VNT – Ab to FMDV type O | yes | 0 | 204 |
| VNT – Ab to FMDV type A | yes | 0 | 750 |
| VNT – Ab to FMDV type Asia 1 | yes | 0 | 204 |
| NSP Ab ELISA (3ABC trapping ELISA) | yes | 2 | 204 |
| Direct diagnostic tests | | Nationally | Internationally |
| | | | |

### *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 | N. 135 kits | 27 | ☒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 | N. 35 kits | 8 | ☐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 | N. 87 kits | 20 | ☒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 | N. 81 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 | 0 | N. 55 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 | 0 | N. 16 kits | 7 | ☒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. 8 kit | 7 | ☒Africa<br>☐Americas<br>☐Asia and Pacific<br>☒Europe<br>☒Middle East |
| Ready-to-use Master Mix for FMDV rtRT-PCR | rtRT-PCR 3D region | Assembled and provided | 0 | N. 8 tubes, each tube for 50 reactions | 4 | ☐Africa<br>☐Americas<br>☐Asia and Pacific<br>☒Europe<br>☐Middle East |
| N. 24 different monoclonal antibodies specific for different FMDV serotypes | Varius test, research programms | Produced and provided | 0 | N. 9 tubes 2ml each, 15 tubes 1 ml each. 33 ml of concentrated MAbs | 2 | ☐Africa<br>☐Americas<br>☐Asia and Pacific<br>☒Europe<br>☐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?

No

9. Did your laboratory provide expert advice in technical consultancies on the request of an OIE Member Country?

No

### *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 |
|---|---|---|---|---|
| Field vaccine trials to estimate efficacy of FMD vaccines adopted in the country and to improve vaccination strategies | 1,5 years | Study of strength, kinetic and duration of the immune response to vaccination with the multivalent vaccines used in the country, in order to acquire knowledge on vaccination effectiveness and optimize FMD control program | AQTA-Food Safety Agency of the Republic of Azerbaijan | AZERBAIJAN |
| OIE twinning Project | 3 years | antigen profiling of the FMDV strains circulating in East Africa | The Pirbright Institute | UNITED KINGDOM |
| Development of a multiplex lateral flow device for on-field identification and serotyping of foot-and mouth disease virus | on going | development and validation of a multiplex LFD, based on well characterized monoclonal antibodies (MAbs), for FMD diagnosis and simultaneous serotyping of FMDV O, A and Asia 1 in a single strip | University of Turin (Italy); The Pirbright Institute, SAP Institute Turkey, Foot and Mouth Disease Laboratory, Kenya | UNITED KINGDOM |

## *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

| If the answer is no, please provide a brief explanation of the situation: |
| --- |
| The Laboratory does not cover a specific endemic region, it rather collaborates with individual countries, or other research institutes, or international organizations; however, as a member of the Network of OIE Reference Labs for FMD, it contributes to the collection of epizootological data by reporting the results of activities and studies conducted. This role is indeed more related to initiatives and programmes of international Organizations (ex. OIE, FAO, EUFMD, FMDWRL). |

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

Yes

| If the answer is yes, please provide details of the data collected: |
| --- |
| Diagnostic results and phylogenetic analyses for field samples collected in northern Tanzania during 2012-2018 |

**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: 4
1. Paton, David; Di Nardo, Antonello; Knowles, Nick; Wadsworth, Jemma; Pituco, Maristela; Cosivi, Ottorino; Rivera, Alejandro; Bakkali-Kassimi, Labib; Brocchi, Emiliana; de Clercq, Kris; Carrillo, Consuelo; Maree, Francois; Singh, Raj; Vosloo, Wilna; Park, Min; Sumption, Keith; Ludi, Anna; King, Donald.
The history of foot-and-mouth disease virus serotype C: the first known extinct serotype? Virus Evolution, 2021, 7 (1): veab009. doi: http://orcid.org/0000-0002-9097-2262

2. Foglia EA, Lembo T, Kazwala R, Ekwem D, Shirima G, Grazioli S, Brocchi E, Pezzoni G
Combining Multiple Assays Improves Detection and Serotyping of Foot-and-Mouth Disease Virus. A Practical Example with Field Samples from East Africa.
Viruses. 2021 Aug 10;13(8):1583. doi: 10.3390/v13081583

3. Richard Bradhurst, Graeme Garner, Mark Hovari, Maria de la Puente, Koen Mintiens, Shankar Yadav, Tiziano Federici, Ian Kopacka, Simon Stockreiter, Ivanka Kuzmanova, Samuil Paunov, Vladimir Cacinovic, Martina Rubin, Jusztina Szilagyi, Zsofia Szepesine, Kokany, Annalisa Santi, Marco Sordilli, Laura Sighinas, Mihaela Spiridon, Marko Potocnik, Keith Sumption.
Development of a transboundary model of livestock disease in Europe.
Transboundary and Emerging Diseases, 2021, 1–20. https://doi.org/10.1111/tbed.14201

4. Design of multiplexing lateral flow immunoassay for detection and typing of foot-and-mouse disease virus using pan-reactive and serotype-specific monoclonal antibodies: evidence of a new hook effect
Simone Cavalera, Alida Russo, Barbara Colitti, Sergio Rosati, Chiara Nogarol, Efrem Alessandro Foglia, Santina Grazioli, Giulia Pezzoni, Fabio Di Nardo, Thea Serra, Matteo Chiarella, Claudio Baggiani, Emiliana Brocchi and Laura Anfossi. Accepted to Talanta

b) International conferences: 4
1. A multiplex lateral flow device for on-field identification and serotyping of Foot-and-Mouth disease virus. Efrem

Alessandro Foglia, Santina Grazioli, Giulia Pezzoni, Laura Anfossi, Sergio Rosati, Emiliana Brocchi. DISCONTOOLS "Filling the knowledge gaps in animal disease control" – 20 October 2021, Bruxelles.
2. Preliminary experiments for the development of a new serotyping assay for Foot-and-Mouth disease virus. Efrem Alessandro Foglia, Giulia Pezzoni, Santina Grazioli, Emiliana Brocchi. EAVLD 2021 Virtual Meeting – 17 November 2021

3. Exploring Foot -and-mouth disease virus antibody interactions using bio-layer interferometry. Abrew shaw, Alison Burman, amin Asfor, Anna Ludi, Emiliana Brocchi, Santina Grazioli, Donald King. Scientific Meeting of the Global Foot-and-Mouth Disease Research Alliance 1-3 November 2021-Buenos Aires, Argentina - virtual event

4. A universal test for quality of conventional FMD vaccine: VP4 to distinguish between intact and dissociated antigen. Stephen Berryman, amin Asfor, Amina Yasmin, Santina Grazioli. Emiliana Brocchi, Tobias Tuthill. Scientific Meeting of the Global Foot-and-Mouth Disease Research Alliance 1-3 Novembre 2021-Buenos Aires, Argentina - virtual event

c) National conferences: 1
National workshop on FMD updates for laboratory expert of Italian Regional laboratories.
10 November – virtual event

d) Other:
(Provide website address or link to appropriate information) 2
1. Annual Meeting of National Reference Laboratories in EU for FMD, organized by EURL, ANSES-Maison Alfort France 14 October, online edition.
Combining multiplex assays improves detection and serotyping of foot-and-mouth Disease virus. A practical example with field samples from East Africa. (E. Foglia)
2. 16th Annual meeting of the Network of OIE/FAO Reference Laboratories for FMD, 23-24 November, online edition. Report on activities conducted by the FMD Reference Laboratory during 2021 www.foot-and-mouth.org

## *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?

Yes

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

16. Is your quality management system accredited?

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 |
| Realtime RT-PCR (3D and 5'UTR regions) | Accredia: Italy System Accreditation Service |
| Other assays (Virus Isolation, VP1 sequencing, Topotypes-specific realtime RT-PCR) are IZSLER-coded tests | 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 |
|---|---|---|---|---|
| Knoledge-sharing on official Recognition of foot and mouth disease-free status. Orgnised by by OIE, General Administration of customs of the peolìple's Republic of china (GACC) Asian Development bank in collaboration with Urumqi customs District of GACC and Harbin Veterinary Research Institute, Chinase Academy of Agricultural Sciences | 25-26 November 2021 | virtual event | OIE/FAO lab expert, speaker | Elements of foot and mouth Disease (FMD)-free status |
| 16th OIE/FAO FMD Laboratory Network Meeting | 23-24 November 2021 | virtual event | Lab expert, Short communication | Updates from the OIE/FAO reference lab-IZSLER |
| 5th virtual GF-TADs Foot-and-Mouth Disease roadmap meeting for the Middle East, combined with Epi and Lab networks meeting | 6-9 December 2021 | virtual event | Participant | Lab expert |

### *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. |
|---|---|---|---|
| FMD/SVD Proficiency Test 2021, organized by the FMD-EURL. It aimed evaluate the existing ability of each laboratory to diagnose FMD/SVD outbreaks using virological and serological methods, according to the given outbreak scenario. Panels 1-live viruses for FMDV/SVDV detection, typing and sequencing; Panel 3 for FMDV serological investigation and PVM; Panel 4 for SVD serological investigations. | participant | >30 | FMD National Reference Laboratories of EU member countries and laboratories from others European countries. Organizing Lab: EURL (ANSES/France) |
| Interlaboratory Method Validation Test (IMVT), organized by the FMD-EURL. It aimed to assess the reproducibility of a new one-step triplex real-time RT-PCR for FMD detection developed by FMD-EURL. | participant | 10 | 10 FMD National Reference Laboratories of EU member countries. Organizing Lab: EURL (ANSES/France) |
| FMD/SVD Proficiency Test 2021 (PHASE XXXIII: 2021), organized by the FMD-WRL, with the request to employ the test systems in use in each lab to address the scenarios that accompany the samples. Panels 1-live viruses for FMDV detection, typing and sequencing, with interpretation of the FMDV status for the individual samples and cases outlined in the scenario; Panel 2 for FMDV serological investigation with interpretation of the FMDV status and post-vaccination immunity. | participant | >25 | OIE/FAO Reference Laboratories for FMD and NRL of other OIE Member countries Organizing Lab: FMDWRL/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 to development of new and improved diagnostic ELISAs and reagents | Six different projects finalized to improve and apply new technology for FMD serology and antigen detection. | The Pirbright Institute, UK |
| Post- vaccination serology | Harmonisation and calibration of VNT mathods | the Pirbright Institute (UK), Sciensano (Belgium) , ANSES (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 |
|---|---|---|
| 1) Participation at the FMD Proficiency Test 2021 organized for EU NRLs and WRL. | see point 21 | ☐Africa<br>☐Americas<br>☐Asia and Pacific<br>☒Europe<br>☐Middle East |
| 2) Organization of a national Proficiency Test for FMD, to build and maintain preparedness of regional laboratories to support the NRL in case of emergency.The 2021 national PT included serological investigations and realtime RT-PCR for the 3D gene | 3) N. 10 Italian regional Laboratories | ☐Africa<br>☐Americas<br>☐Asia and Pacific<br>☒Europe<br>☐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) |
|---|---|---|
| Member of the Scientific Commission for Animal Diseases (SCAD) | Paris, OIE | Assistance in identifying the most appropriate strategies and measures for disease prevention and control. Evaluation of Member Country submissions regarding their animal health status |
| 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: