

WOAH Reference Laboratory Reports Activities 2024

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LABORATORY INFORMATION

*Name of disease (or topic) for which you are a designated WOAH Reference Laboratory:	Foot and mouth disease
*Address of laboratory:	Via Bianchi, 9 - 25124 Brescia - Italy
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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. Giorgio Varisco, General Director, IZSLER
*Name (including Title and Position) of WOAH Reference Expert:	Dr. Santina Grazioli Head of National/WOAH Reference Centre for FMD and SVD, Head of Biotechnology Lab
*Which of the following defines your laboratory? Check all that apply:	Governmental

TOR1: DIAGNOSTIC METHODS

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 WOAH Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
Indirect diagnostic tests			
Competitive ELISA – Ab to SP type O	Yes	10	0
Competitive ELISA – Ab to SP type A	Yes	10	0
Competitive ELISA – Ab to SP type Asia 1	Yes	10	0

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Competitive ELISA – Ab to SP type SAT 2	Yes	10	0
Competitive ELISA – Ab to SP type SAT 1	Yes	10	0
Direct diagnostic tests		Nationally	Internationally
Virus isolation	Yes	2	0
Antigen ELISA	Yes	1	0
Real Time RT-PCR	Yes	2	19
VP1 sequencing	Yes	0	1
Phylogenetic analyses	Yes	0	1

TOR2: REFERENCE MATERIAL

2. Did your laboratory produce or supply imported standard reference reagents officially recognised by WOA?H?

No

3. Did your laboratory supply standard reference reagents (nonWOAH-approved) and/or other diagnostic reagents to WOA?H Members?

Yes

Type of reagent available	Related diagnostic test	Produced/ provide	Amount supplied nationally (ml, mg)	Amount supplied internationally (ml, mg)	No. of recipient WOA?H Member Countries	Country 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	255	23	ALGERIA, ARMENIA, AUSTRALIA, AZERBAIJAN, BAHRAIN, EGYPT, FRANCE, GEORGIA, GREECE, HONG KONG, ISRAEL, KOREA (DEM. PEOPLE'S. REP. OF), LIBYA, MALTA, MONGOLIA, NEPAL, NIGERIA, ROMANIA, SAUDI ARABIA, SINGAPORE, SPAIN, TURKEY, UNITED ARAB EMIRATES,
						ALGERIA, AUSTRALIA, CHINA (PEOPLE'S REP. OF), EGYPT, GEORGIA, IRAQ, ISRAEL, JORDAN, KOREA

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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	169	23	(DEM. PEOPLE'S. REP. OF), KUWAIT, LATVIA, LIBYA, MALTA, MONGOLIA, MOROCCO, MOZAMBIQUE, NIGERIA, PAKISTAN, ROMANIA, SINGAPORE, SYRIA, TURKEY, UNITED ARAB EMIRATES,
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	133	21	ALGERIA, AUSTRALIA, CHINA (PEOPLE'S REP. OF), EGYPT, GEORGIA, IRAQ, ISRAEL, KOREA (DEM. PEOPLE'S. REP. OF), KUWAIT, LIBYA, MALTA, MONGOLIA, NEPAL, NIGERIA, ROMANIA, SINGAPORE, SPAIN, SWEDEN, SYRIA, TURKEY, UNITED ARAB EMIRATES,
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	66	16	ALGERIA, AUSTRALIA, EGYPT, GEORGIA, IRAQ, ISRAEL, LATVIA, LIBYA, MALTA, NIGERIA, PAKISTAN, ROMANIA, SINGAPORE, SYRIA, TURKEY, UNITED ARAB EMIRATES,
Ready-to-use ELISA kit for SPAb Type SAT2 (1 kit=5 plates)	Solid-phase competitive ELISA (SP Ab type SAT2)	Produced and provided	0	98	16	ALGERIA, ARMENIA, AUSTRALIA, EGYPT, IRAQ, ISRAEL, JORDAN, LATVIA, MOROCCO, NIGERIA, POLAND, SAUDI ARABIA,

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						SINGAPORE, SYRIA, TURKEY, UNITED ARAB EMIRATES,
Ready-to-use ELISA kit for SPAb Type SAT 1 (1 kit=5 plates)	Solid-phase competitive ELISA (SP Ab type SAT 1)	Produced and provided	0	34	7	ALGERIA, JORDAN, KOREA (DEM. PEOPLE'S. REP. OF), NIGERIA, SAUDI ARABIA, TURKEY, UNITED ARAB EMIRATES,
Ready-to-use ELISA kit for FMDV NSP antibodies (1 kit=5 plates)	FMDV NSP Ab ELISA (3ABC trapping ELISA)	Produced and provided	10	67	12	ALGERIA, BAHRAIN, COTE D'IVOIRE, EGYPT, JORDAN, MALTA, NIGERIA, ROMANIA, SYRIA, TURKEY, UGANDA, UNITED ARAB EMIRATES,
Lateral flow Device 1 (typing O, A , Asia 1 and Pan-FMD)	LFD1 (typing O, A , Asia 1 and Pan- FMD)	provide	0	14	3	EGYPT, JORDAN, KENYA,
Lateral flow Device 1 (typing SAT 1 and SAT 2, Pan-FMD)	LFD2 (typing SAT 1 and SAT 2, Pan- FMD)	provide	0	13	2	EGYPT, JORDAN,
Ready-to-use Master Mix for Real time PCR	rtRT-PCR 3D region	Assembled and provided	0	N. 7 tubes, each tube contains 50	1	KENYA,

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to WOA Members?

No

TOR3: NEW PROCEDURES

6. Did your laboratory develop new diagnostic methods for the designated pathogen or disease?

No

7. Did your laboratory validate diagnostic methods according to WOA Standards for the designated pathogen or disease?

No

8. Did your laboratory develop new vaccines for the designated pathogen or disease?

No

9. Did your laboratory validate vaccines according to WOA Standards for the designated pathogen or disease?

No

TOR4: DIAGNOSTIC TESTING FACILITIES

10. Did your laboratory carry out diagnostic testing for other WOAHH Members?

Yes

Name of WOAHH Member Country seeking assistance	Date	Which diagnostic test used	No. samples received for provision of diagnostic support	No. samples received for provision of confirmatory diagnoses
LIBYA	2024-03-26	rRT-PCR, VP1 sequencing on FTA cards	0	19

11. Did your laboratory provide expert advice in technical consultancies on the request of an WOAHH Member?

Yes

Name of the WOAHH Member Country receiving a technical consultancy	Purpose	How the advice was provided
SYRIA	Continuous remote assistance and advice are provided for elaboration and interpretation of results on PVM 2024 recorded with the diagnostic kits supplied for FMD diagnosis and serology.	On line training and remote assistance

TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

12. Did your laboratory participate in international scientific studies in collaboration with WOAHH Members other than the own?

Yes

Title of the study	Duration	Purpose of the study	Partners (Institutions)	WOAHH Member Countries involved other than your country
Research agreement between IZSLER and the Pirbright Institute	2021-2026	Research and development of assay for FMDV diagnosis	The Pirbright Institute	
International comparison Test FMD ELISA	2024	International comparison study on reproducibility and repeatability of the Test FMD ELISA for the detection of antibodies against non-structural protein 3ABC using the ELISA FMD gIII kit produced by PANAFITOSA.	WOAHH Reference Laboratory on Foot and Mouth Disease of the Pan American Centre for Foot-and-Mouth Disease and Veterinary Public Health (PANAFITOSA/VPH - PAHO/WHO)	

13. In exercising your activities, have you identified any regulatory research needs* relevant for WOAHH?

No

TOR6: EPIZOOLOGICAL DATA

14. Did your Laboratory collect epidemiological data relevant to international disease control?

Yes

If the answer is yes, please provide details of the data collected:

Confirmation the circulation of serotype O which belongs to the EA-3 topotype in Lybia.

15. Did your laboratory disseminate epidemiological data that had been processed and analysed?

Yes

If the answer is yes, please provide details of the data collected:

Data disseminated at the WOA/FAO FMD Laboratory Network Meeting

16. What method of dissemination of information is most often used by your laboratory? (Indicate in the appropriate box the number by category and list the details in the box)

a) Articles published in peer-reviewed journals:

3

1) Simone Cavallera, Eugenio Alladio, Efrem Alessandro Foglia, Santina Grazioli, Barbara Colitti, Sergio Rosati, Chiara Nogari, Fabio Di Nardo, Thea Serra, Valentina Testa, Claudio Baggiani, Giampietro Maccabiani, Emiliana Brocchi, Laura Anfossi

Experimental design for the development of a multiplex antigen lateral flow immunoassay detecting the Southern African Territory (SAT) serotypes of foot-and-mouth disease virus. *Microchimica Acta* (2024) 191:9 <https://doi.org/10.1007/s00604-023-06090-6>

2) Efrem Alessandro Foglia, Tengiz Chaligava, Tamilla Aliyeva, Satenik Kharatyan, Vito Tranquillo, Carsten Pötzsch, Cornelis van Maanen, Fabrizio Rosso, Santina Grazioli, Emiliana Brocchi

Evaluation of Two Vaccines against Foot-and-Mouth Disease Used in Transcaucasian Countries by Small-Scale Immunogenicity Studies Conducted in Georgia, Azerbaijan and Armenia

Vaccines (Basel). 2024 Mar 12;12(3):295 <https://doi.org/10.3390/vaccines12030295>

3. Urbinati C, Pezzoni G, Cavadini P, Giovanni VD, Capucci L, Rusnati M.

Validation of plasmonic-based biosensors for rapid and in depth characterization of monoclonal antibodies directed against rabbit haemorrhagic and foot-and-mouth disease viruses in biological samples. *Methods*. 2024 Dec 9;234:85-92. doi:

10.1016/j.ymeth.2024.12.003. Online ahead of print.

b) International conferences:

10

Title of event: Microbiology Society – Annual Conference 2024 OS24 – Open Session 2024 of the EuFMD Standing Technical Committee
Date and location: 8-11 April 2024, Edinburgh, UK

1. Abdelaziz Yassin, Santina Grazioli, Emiliana Brocchi, Daniel Horton, Anna Ludi, Donald King, Amin Asfor

Characterisation of a neutralising (D9-like) epitope within the G-H loop of Foot-and-mouth disease virus serotypes O, A and SAT1
FAO Reference Centre – Annual Report (Thematic areas) Page 9

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Title of event: OS24 – Open Session 2024 of the EuFMD Standing Technical Committee

Date and location: 29-31 Ottobre 2024, Alcalá de Henares, Spain

2. S Berryman, A Asfor, A Yasmin, C Grant, A Ludi, E Perez, E Benham, N Howe, A Burman, E Brocchi, S Grazioli, D King, T Tuthill

Foot-and-Mouth Disease vaccine quality: A universal test for intact antigen based on detection of VP4

3. A.B. Ludi, G., Wildsden, S. Grazioli, E.M. Pituco, L. Heath, P. Eble, A. Dekker, C. Browning, K. ParekhS. Metwally, C.V. Maanen, D.J. Paton, N. Knowles, A. Di Nardo, D.P. King

Regionally relevant reference FMD viruses for post vaccination studies

4. E. A. Foglia, G. Maccabiani, C. van Maanen, V. Tranquillo, T Trogu, E. M. Bennour, M. Hashem, N. A. Osman, M. Khalifeh, M. S. Al Ameer, M. S. F. Bintarif, S. A. Salah, S. Baiomy, F. Ambrosini, F. Rosso, S. Grazioli

Evaluation of the duration of the immune response induced by FMD vaccination in Jordan

5. T. Trogu, G. Ferrari, A. Abdulkader, M. Younan, D. Jaffan, E. A. Foglia, S. Baiomy, C. Van maanen, H. A. Mansour, A. A Yousif, E. Bennour, N. A. Osman, M. Khalifeh, F. Rosso, S. Grazioli

Post-vaccination monitoring in north-western Syria (2022)

6. Nb. Singanallur NB, M. Scaramuzza, S. Grazioli, P Eble, A. Dekker, AM. Lee, W. Vosloo

Validation of two commercial FMD NSP ELISA assays for use in small ruminants (sheep and goats)

7. A.Romey, E.A.Foglia, Al.Salomez, A.Relmy, C.Bernelin-Cottet, G.Girault, S.Grazioli, I. Bakkali Kassimi and S.Blaise-Boisseau

Safe cost-effective shipment of FMDV suspected samples to diagnostic laboratories: evaluation of the process on LFD produced by different manufacturers

8. Anna Castelli, Elena Facchini, Manuel Corsa, Efrem Alessandro Foglia, Giampietro Maccabiani, Tiziana Trogu, Santina Grazioli, Divine Ekwem, Tiziana Lembo, Giulia Pezzoni

Point-of-care diagnostics: evaluation of a rapid and cost-effective dipstick-based method for FMDV RNA purification

9. Ea Foglia, E Filippini, G Pezzoni

Development of a reverse transcription - recombinase polymerase amplification (rt-rpa) for the on-field detection of foot-and-mouth disease virus

10. Jozhel Baguisi Valérie Mioulet Elizabeth Henry, Harry Bull, Britta Wood, Amy Mccarron, Donald king, Efrem A. Foglia, Santina Grazioli, Andrew Bentham, Kerry Mitchell, Alison Wakeham

Lateral flow devices for the detection of fmdv and approaches for field preparation

c) National conferences:

1

Title of event: SCI 2024 XXVIII National congress Società chimica Italiana

Date and location: 26-30 August 2024, Milan Italy

Work presented:

S. Cavallera, E. A. Foglia, S. Grazioli, S. Rosati, A. Russo, B. Colitti, C. Nogarol, F. Di Nardo, T. Serra, C. Baggiani, E. Brocchi, L. Anfossi

Concerted development of Lateral Flow Immunoassays detecting infectious diseases: the case of the foot-and-mouth disease (FMD) virus diagnosis and serotyping

d) Other (Provide website address or link to appropriate information):

1

<https://www.izsler.it/chi-siamo/per-chi-e-con-chi-lavoriamo/centri-di-referenza/laboratorio-di-referenza-woah-foot-and-mouth-disease/>

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

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17. Did your laboratory provide scientific and technical training to laboratory personnel from other WOA Members?

Yes

a) Technical visit : 0

b) Seminars : 1

c) Hands-on training courses: 0

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
B	SYRIA	5

TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)	
UNI CEI EN ISO/IEC 17025:2018 UNI CEI EN ISO/IEC 17025:2018	pdf	Accreditatio Certificate_0148L rev6.pdf
UNI EN ISO 9001:2015	pdf	- Cert IQNET_ISO9001 n.144421 IZSLER 2023.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
Competitive ELISA – SP antibodies (FMDV	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, Topotypesspecific realtime RT-PCR) are IZSLER-coded tests	Accredia: Italy System Accreditation Service

20. Does your laboratory maintain a "biorisk management system" for the pathogen and the disease concerned?

Yes

Management system of high containment lab in compliance with "Minimum Biorisk Management standards for foot and mouth disease laboratories (MBRMS)"

TOR9: SCIENTIFIC MEETINGS

21. Did your laboratory organise scientific meetings related to the pathogen in question on behalf of WOA?

No

22. Did your laboratory participate in scientific meetings related to the pathogen in question on behalf of WOA?

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Yes

Title of event	Date	location	Role (speaker, presenting poster, short communications)	Title of the work presented
18th WOA/FAO FMD Laboratory Network Meeting	2024-09-24	Rome (HQ FAO)	Participant as Lab expert	Updates from the WOA/FAO reference lab-IZSLER

TOR10: NETWORK WITH WOA/FAO REFERENCE LABORATORIES

23. Did your laboratory exchange information with other WOA/FAO Reference Laboratories designated for the same pathogen or disease?

Yes

24. Do you network (collaborate or share information) with other WOA/FAO Reference Laboratories designated for the same pathogen?

Yes

NETWORK/DISEASE	ROLE OF YOUR LABORATORY (PARTICIPANT, ORGANISER, ETC)	NO. PARTICIPANTS	PARTICIPATING WOA/FAO REF. LABS
WOA/FAO Laboratory Network for FMD	participant	20	WOA/FAO designed experts for FMD

25. Did you organise or participate in inter-laboratory proficiency tests with WOA/FAO Reference Laboratories designated for the same pathogen during the past 2 years?

Yes

Purpose of the proficiency test:	Role of your Reference Laboratory (organiser/participant)	No. participating Laboratories	Participating WOA/FAO Ref. Labs/organising WOA/FAO Ref Lab
FMD/SVD Proficiency Test 2024, organized by the FMD-EURL, ANSES, France	Participant	unknown	ANSES, France
FMD Proficiency Test Scheme (PHASE XXXV: 2023), organized by the FMD-WRL	Participant	unknown	The Pirbright Institute , UK

26. Did your laboratory collaborate with other WOA/FAO 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 WOA/FAO 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

TOR11: OTHER INTERLABORATORY PROFICIENCY TESTING

27. Did your laboratory organise or participate in inter-laboratory proficiency tests with laboratories other than WOA/FAO Reference Laboratories for the same pathogen during the past 2 years?

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Yes

Purpose for inter-laboratory test comparisons ¹	Role of your reference laboratory (organizer/participant)	No. participating laboratories	Name of the test	WOAH Member Countries
Organization of a National Proficiency Test for FMD, to build and maintain preparedness of regional laboratories to support the NRL in case of emergency	Provider	10	NSP Ab ELISA (3ABC trapping ELISA)	

TOR12: EXPERT CONSULTANTS

28. Did your laboratory place expert consultants at the disposal of WOAH?

Yes

Kind of consultancy	Location	Subject (facultative)
consensus opinion from WOAH experts to Biological Standards Commission	e-mail	Including in the WOAH Terrestrial Manual chapter on FMD information on a novel FMD vaccine is based on recombinantly expressed virus-like particles

29. Additional comments regarding your report:

No