

WOAH Reference Laboratory Reports Activities 2023

Activities in 2023

Laboratory Information

Name of disease (or topic) for which you are a designated WOA Reference Laboratory:	Foot and mouth disease
Address of laboratory:	Via Bianchi, 9 - 25124 Brescia - Italy
Tel.:	+39 03022901
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 WOA Reference Expert:	Dr. Santina Grazioli Head of National/WOA 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 WOA Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
Indirect diagnostic tests			
Competitive ELISA – Ab to SP type O		5	2967
Competitive ELISA – Ab to SP type A		5	2967
Competitive ELISA – Ab to SP type Asia 1		5	2580
Competitive ELISA – Ab to SP type SAT 2		5	387

Competitive ELISA – Ab to SP type SAT 1		5	387
NSP-ELISA		0	2967
Direct diagnostic tests		Nationally	Internationally
Virus isolation		3	5
Antigen ELISA		0	5
Real Time RT-PCR		3	18
VP1 sequencing		0	5
Phylogenetic analyses		0	5

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, SAT 1-2) (1 kit= 5 plates)	Ag detection and serotyping ELISA	Produced and provided	0	171	43	ALBANIA, ALGERIA, ARGENTINA, ARMENIA, AUSTRALIA, AUSTRIA, AZERBAIJAN, BAHRAIN, BOTSWANA, BULGARIA, CROATIA, CYPRUS, CZECH REPUBLIC, EGYPT, FRANCE, GEORGIA, GREECE, IRAQ, IRELAND, JORDAN, KENYA, KOSOVO, KYRGYZSTAN, LATVIA, LEBANON, LIBYA, LITHUANIA, MALTA, MONGOLIA, MONTENEGRO, MOROCCO, NORTH MACEDONIA (REP. OF), PAKISTAN,

						POLAND, SAUDI ARABIA, SERBIA, SIERRA LEONE, SINGAPORE, SWEDEN, 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	0	69	16	ARMENIA, AUSTRIA, BAHRAIN, CZECH REPUBLIC, EGYPT, FRANCE, IRAQ, IRELAND, JORDAN, KYRGYZSTAN, LEBANON, NIGERIA, SAUDI ARABIA, SENEGAL, SIERRA LEONE, TURKEY,
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	178	30	ALBANIA, ARGENTINA, ARMENIA, AUSTRIA, BANGLADESH, BOTSWANA, BULGARIA, CROATIA, CZECH REPUBLIC, EGYPT, GEORGIA, GREECE, IRAQ, IRELAND, KOSOVO, KYRGYZSTAN, LITHUANIA, MALTA, MONGOLIA, MONTENEGRO, MOROCCO, NIGERIA, NORTH MACEDONIA (REP. OF), PAKISTAN, POLAND, SERBIA, TURKEY, UNITED ARAB EMIRATES,
						ALBANIA, ARGENTINA, ARMENIA, AUSTRIA, BANGLADESH, BOTSWANA, BULGARIA, CROATIA, CZECH REPUBLIC, EGYPT, GEORGIA, GREECE,

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	33	IRAQ, IRELAND, KOSOVO, KYRGYZSTAN, LITHUANIA, MALTA, MONGOLIA, MONTENEGRO, MOROCCO, NIGERIA, NORTH MACEDONIA (REP. OF), PAKISTAN, POLAND, SAUDI ARABIA, SERBIA, SWEDEN, 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	106	30	ALBANIA, ALGERIA, ARGENTINA, ARMENIA, AUSTRIA, BANGLADESH, BULGARIA, CROATIA, CZECH REPUBLIC, GEORGIA, GREECE, IRAQ, IRELAND, KOSOVO, KYRGYZSTAN, LITHUANIA, MALTA, MONGOLIA, MONTENEGRO, NEW ZEALAND, NORTH MACEDONIA (REP. OF), PAKISTAN, POLAND, SERBIA, SWEDEN, TURKEY, UNITED ARAB EMIRATES,
Ready-to-use ELISA kit for SPAb Type SAT2 (1	Solid-phase competitive ELISA	Produced and provided	0	123	27	ALGERIA, ARGENTINA, ARMENIA, AUSTRIA, AZERBAIJAN, BOTSWANA, BULGARIA, CROATIA, CZECH REPUBLIC, EGYPT, GEORGIA, GREECE, IRAQ, IRELAND,

kit=5 plates)	(SP Ab type SAT2)					JORDAN, MALTA, NEW ZEALAND, NIGERIA, PALESTINIAN AUTON. TERRITORIES, POLAND, SAUDI ARABIA, SWEDEN, TURKEY, UNITED ARAB EMIRATES,
Ready-to-use ELISA kit for SPAb Type SAT1 (1 kit=5 plates)	Solid-phase competitive ELISA (SP Ab type SAT1)	Produced and provided	0	44	12	ALGERIA, AUSTRIA, AZERBAIJAN, BOTSWANA, CROATIA, CZECH REPUBLIC, IRELAND, MALTA, POLAND, SWEDEN, 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	173	5	COMOROS, IRAQ, PAKISTAN, SYRIA, UGANDA,
Lateral flow Device 1 (typing SAT 1 and SAT 2, Pan-FMD)	LFD2 (typing SAT 1 and SAT 2, Pan-FMD)	provide	0	106	5	IRAN, IRAQ, JORDAN, SYRIA, UGANDA,
tissue extraction kits	tissue extraction kits	provide	0	110	6	COMOROS, IRAN, IRAQ, JORDAN, SYRIA, UGANDA,
Ready-to-use Master Mix for Real time PCR	rtRT-PCR 3D region	Assembled and provided	0	N. 20 tubes, each tube contains 50	10	ALBANIA, BOSNIA AND HERZEGOVINA, BULGARIA, GREECE, KOSOVO, MOLDOVA, MONTENEGRO, NORTH MACEDONIA (REP. OF), SERBIA,
Positive control for molecular tests consisting of inactivated FMD virus	BEI inactivated FMD virus	Produced and provided	0	N. 10 tubes, each tube contains 1 ml	10	ALBANIA, BOSNIA AND HERZEGOVINA, BULGARIA, GREECE, KOSOVO, MOLDOVA, MONTENEGRO, NORTH MACEDONIA (REP. OF), SERBIA,

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to WOAHA 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 WOAHA 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 WOAHA Standards for the designated pathogen or disease?

No

TOR4: DIAGNOSTIC TESTING FACILITIES

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

Yes

NAME OF WOAHA 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	2023-03-23	rRT-PCR, VP1 sequencing on FTA cards	0	13
LIBYA	2023-05-17	rRT-PCR, VI, Ag-ELISA, VP1 sequencing on clinical lesions	0	14

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

Yes

NAME OF THE WOAHA MEMBER COUNTRY RECEIVING A TECHNICAL CONSULTANCY	PURPOSE	HOW THE ADVICE WAS PROVIDED
JORDAN	Mission carried out the 8th-9th of March 2023 to visit the laboratories, following the incursion of the FMDV type SAT 2 in the country	Meeting with CA and laboratories staff. Recommendations and conclusions reported in a final report

TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

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

Yes

				WOAHA MEMBER

Title of the study	Duration	PURPOSE OF THE STUDY	PARTNERS (INSTITUTIONS)	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 Insitute	

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

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 toptype 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?H/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:

2

1) Jacquelyn Horsington, Elke Abbeloos, Labib Bakkali Kassimi, Kingkarn Boonsuya Seeyo, Alejandra V. Capozzo 6, Eunice Chepkwony, Phaedra Eblé, Sabrina Galdo-Novo, Daniel Gizaw, Lizelle Gouverneur, Santina Grazioli, Livio Heath, Pascal Hudelet, Joseph M. K. Hyera, Martin Illott, Alasdair King, David J. Lefebvre, David Mackay, Samia Metwally, Frank N. Mwiine, Charles K. Nfon, Min-Kyung Park, Edviges Maristela Pituco, Fabrizio Rosso, Francisco Simon, Hussaini G. Ularamu, Paul Vermeij, Wilna Vosloo and Donald P. King Application of the Nagoya Protocol to veterinary pathogens: concerns for the control of foot-and-mouth disease. *Frontiers in Veterinary Science* November 2023 Volume 10 - 2023 <https://doi.org/10.3389/fvets.2023.1271434>;

2) Simone Cavalera, Eugenio Alladio, Efre?m Alessandro Foglia, Santina Grazioli, Barbara Colitti, Sergio Rosati, Chiara Nogarol, 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>

b) International conferences:

4

Title of event: 2023 Scientific Meeting of the Global Foot and Mouth Disease Research Alliance (GFRA)

Date and location: 8– 10 November, Kampala, Uganda

Work presented:

1. Foglia EA, Maccabiani G, van Maanen C, Tranquillo V, Trogu T, Bennour EM, Hashem M, Osman NA, Khalifeh M, Al Ameer MS, Bintarif MSF, Salah SA, Baiomy S, Ambrosini F, Rosso F, Grazioli S. *Post Vaccination Monitoring (PVM) to assess the efficacy of the FMD vaccine used in Jordan.*

2. Mioulet V, Baguisi J, Henry E, Bull H, Wood B, McCarron A, King D, Foglia EA, Grazioli S, Bentham A, Mitchell K, Wakeham A. *Lateral flow devices for the rapid detection of FMDV.*

3. Paton D, Ludi A, King D, Wilsden G, Browning C, Belgrave S, Knowles N, Di Nardo A, Nwankpa N, Chitsungo E, Rahamatou C, Boukary M, Melesse GA, Bodjo SC, Grazioli S, Foglia EA, Brocchi E.

Selection and use of a reference antigen panel to assess the regional relevance of foot-and-mouth disease vaccines in East Africa.

4. Foglia EA, Mioulet V, Baguisi J, Bull H, Inel Turgut S, Sangula A, Anfossi L, Nogarol C, Cavalera S, Henry L, Pezzoni G, Rosati S, Bulut A, King D, Brocchi E, Grazioli S.

Preliminary validation of multiplex Lateral Flow Devices LFD1 and LFD2 for on-field identification and serotyping of Foot-and-Mouth Disease viruses.

c) National conferences:

3

Title of event: XXII National Congress organised by Sidilv – Italian Society of Veterinary laboratory diagnostic

Date and location: 11-13 September 2023, Brescia Italy

Work presented:

1. *Diagnostica point-of-care: valutazione di un metodo veloce ed economico basato su dipstick per la purificazione di RNA virale di afta epizootica.* Anna Castelli, Elena Facchini, Manuel Corsa, Roberto Benevenia, Giampietro Maccabiani, Santina Grazioli, Divine Ekwem, Tiziana Lembo, Giulia Pezzoni.

2. *Messa a punto di una reazione isoterma RT-RPA (Reverse Transcription - Recombinase Polymerase Amplification) per la rilevazione in campo del virus dell'afta epizootica.* E. Filippini, G. Pezzoni, E.A. Foglia

3. *Recupero del virus integro dell'afta epizootica e del suo genoma da test rapidi di campo di tipo Lateral Flow Devices (LFD).* E. A. Foglia, E. Filippini, G. Pezzoni, S. Grazioli

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

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

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

Yes

a) Technical visit : 2

b) Seminars : 0

c) Hands-on training courses: 1

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
C	JORDAN	2
C	IRAQ	2

A	KOSOVO	3
A	NORTH MACEDONIA (REP. OF)	3

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	pdf	certificato-148-L-rev.6.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 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, Topotypespecific 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

The Biorisk management system maintained in the lab is according the requirements of "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?H?

No

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

Yes

Title of event	Date (mm/yy)	Location	Role (speaker, presenting poster, short communications)	Title of the work presented
17th WOA?H/FAO FMD Laboratory Network Meeting	2023-10-10	Winnipeg (Canada)	Participant as Lab expert	Updates from the WOA?H/FAO reference lab- IZSLER
GF-TADs meeting, FAO/WOA?H (hybrid				

event). PPR Blueprint Consultation and FMD Roadmap meeting for Economic Cooperation Organisation (ECO)/West Eurasia countries	2023-04-25	Virtual	Observer	
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TOR10: NETWORK WITH WOAHA REFERENCE LABORATORIES

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

Yes

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

Yes

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

25. Did you organise or participate in inter-laboratory proficiency tests with WOAHA Reference Laboratories designated for the same pathogen?

Yes

PURPOSE OF THE PROFICIENCY TESTS: 1	ROLE OF YOUR REFERENCE LABORATORY (ORGANISER/PARTICIPANT)	NO. PARTICIPANTS	PARTICIPATING WOAHA REF. LABS/ ORGANISING WOAHA REF. LAB.
FMD/SVD Proficiency Test 2023, organized by the FMD-EURL, ANSES, France	Participant	unknown	ANSES, France
FMD Proficiency Test 2022 (PHASE XXXV: 2023), organized by the FMD-WRL,	Participant	unknown	The Pirbright Institute , UK

26. Did your laboratory collaborate with other WOAHA 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 WOAHA 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 WOAHA Reference Laboratories for the same pathogen?

Yes

Purpose for inter-	Role of your reference			

laboratory test comparisons ¹	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	Organiser	10	SP ELISA to detect the ab agist FMDv type A, NSP ELISA, Real Time RT-PCR (3D region)	

TOR12: EXPERT CONSULTANTS

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

Yes

KIND OF CONSULTANCY	Location	SUBJECT (FACULTATIVE)
Providing advice	virtual	Technical support to the IZSLER kits users

29. Additional comments regarding your report:

No