OIE Reference Laboratory Reports Activities Activities in 2021

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Name of disease (or topic) for which you are a designated OIE Reference Laboratory:	Foot and mouth disease
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Name (including Title) of Head of Laboratory (Responsible Official):	P.I.Kosyrev, Director of Federal State-Financed Institution «Federal Centre for Animal Health» of Federal Service for Veterinary and Phytosanitary Surveillance (FGBI "ARRIAH")
Name (including Title and Position) of OIE Reference Expert:	Valery Zakharov, ARRIAH expert, Doctor of Science (Veterinary Medicine), professor
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 yea	
Indirect diagnostic tests		Nationally	Internationally
Liquid phase blocking indirect ELISA (LPB	Yes	176188	0
Virus neutralization test	Yes	8051	0
Indirect ELISA (ELISA-NSP)	Yes	67996	0
Vaccine matching in VNT	Yes	18	0
Direct diagnostic tests		Nationally	Internationally
Virus isolation in cell culture	Yes	282	0
Indirect double sandwich ELISA	Yes	282	0
CFT	Yes	282	0
Real-time RT-PCR, 3D gene	Yes	1294	0
Real-time RT-PCR, 5'HTO gene	Yes	1294	0
RT-PCR, VP1 gene	Yes	2	0
VP1 gene sequencig	Yes	2	0

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
Kit for detection of FMD antibodies in animal sera by ELISA	LPB ELISA		2011 kits	43 kits	3	 □Africa □Americas □Asia and Pacific □Europe □Middle East
Kit for FMDV antigen detection by ELISA	Ag detection ELISA		6 kits	5 kits	1	 Africa Americas Asia and Pacific Europe Middle East
FMD NSP-ELISA kit	NSP-ELISA		65 kits	0	0	 □Africa □Americas □Asia and Pacific □Europe □Middle East
Test system for detecting FMD virus RNA by polymerase chain reaction in real time "FMD RT- PCRRT	FMD RTPCR- RT		10 kits	0	0	Africa Americas Asia and Pacific Europe Middle East

4. Did your laboratory produce vaccines?

Yes

5. Did your laboratory supply vaccines to OIE Member Countries?

Vaccine name	Amount supplied nationally (ml, mg) (including for own use)	Amount supplied to other countries (ml, mg)	Name of recipient OIE Member Countries
Sorbat, mono- and polyvalent FMD vaccine (based on the virus grown in BHK-21 cells)	contract	contract	AFGHANISTAN ARMENIA BANGLADESH EGYPT GEORGIA IRAN JORDAN KAZAKHSTAN KUWAIT KYRGYZSTAN LEBANON PAKISTAN SAUDI ARABIA SYRIA
Emulsion ARRIAH-VAC, mono- and polyvalent FMD vaccine (based on the virus grown in BHK-21 cells	contract	contract	IRAN KAZAKHSTAN KOREA (REP. OF) MONGOLIA PAKISTAN

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?

Name of the new test or diagnostic method or vaccine developed	Description and References (Publication, website, etc.)
Inactivated emulsion vaccine for early protection against Asia 1 FMD mouth disease (FMD)	RF Patent No. 2 741 639, 05.06.2020 Inactivated emulsion vaccine for early protection against Asia 1 FMD // Application No. 2020449505. Bul. No. 4 / V. A. Starikov, D. V. Mikhalishin, D. A. Lozovoy [et al.]05.06.2020 Russian Federation, MPK A61K 39/135 / V.A. Starikov, D.A. Lozovoy, D.V. Mikhalishin [et al.]; FGBI ARRIAH Applied 25.12.2017; published 04.09.2018.
Preparation of immunogenic components of cultured type A, O, Asia-1 FMDV using serum-free media Cellvento BHK-200 for the production of FMD vaccines	RF Patent No. 2 751 664, 31.08.2020 Preparation of immunogenic components of cultured type A, O, Asia-1 FMDV using serum-free media for Cellvento BHK-200 for the production of FMD vaccines // Application 2020128797, Bul. No. 20 29 p./ Doronin M.I., Mikhalishin D.V., Guseva M.N. [et al.]
Indirect determination of FMDV antigen inactivation completeness in the vaccine raw materials using real-time reverse- transcription polymerase chain reaction with large-size fragment amplification	RF Patent No. 2 753 969, 05.04.2021 Indirect determination of FMDV antigen inactivation completeness in the vaccine raw materials using real-time reverse-transcription polymerase chain reaction with large-size fragment amplification // Application 2021109435, Bul No. 24 / Doronin M.I., Mikhalishin D.V., Borisov A.V., Kozlov A.A.

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
RUSSIA	December	2	0

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

Name of the OIE Member Country receiving a technical consultancy	Purpose	How the advice was provided
PAKISTAN	Analysis of causes of FMD outbreak occurrence in Pakistan and ways of addressing the issues related to the FMD outbreaks in the region	Recommendations on the selection of the vaccine strains and use of monovalent vaccines (immunogenicity at least 6,5 PD50)

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
Assessment of immunity level in animals vacinated against FMD and detection of possible virus circulation in zones where vaccination is practiced (at the stage of signing)	2020-2022	Eradication of highly dangerous diseases including FMD in Mongolian livestock	State Central Veterinary Laboratory, Ulan Bator	MONGOLIA
Agreement on crossborder trade and TADs risk reduction between China, Mongolia and Russia	Not defined	Interactions in case of emrgencies associated with dangerous animal diseases including FMD	Veterinary Service Department of the Ministry of Agriculture, PRC; Veterinary and Animal Breeding Agency, Governmental Executive Authority, Mongolia	CHINA (PEOPLE'S REP. OF) MONGOLIA
Cooperation on the prevention and control of foot and mouth disease and other transboundary animal diseases between the countries of the Caucasus, Russia and Iran (GF-TADs)	Not defined	Exchange of information on outbreaks of diseases, vaccination of animals	EuFMD	ARMENIA AZERBAIJAN GEORGIA IRAN TURKEY
Joint CIS measures for FMD prevention and contro	to 2025	FMD prevention and control		ARMENIA AZERBAIJAN BELARUS KAZAKHSTAN KYRGYZSTAN MOLDOVA TAJIKISTAN TURKMENISTAN UKRAINE UZBEKISTAN

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

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

The information is maintained online on the Rosselkhoznadzor website in the "Epizootic Situation" section, subsections "Russia" and Foreign Countries "http://www.fsvps.ru/fsvps/ya/, http://www.fsvps.ru/fsvps/ iac / foreign.html

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:

The information is maintained online on the Rosselkhoznadzor website in the "Epizootic Situation" section, subsections "Russia" and Foreign Countries "http://www.fsvps.ru/fsvps/ya/, http://www.fsvps.ru/fsvps/ iac / foreign.html

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: 7

1. Evolutionary and Ecological Drivers Shape the Emergence and Extinction of Foot-and-Mouth Disease Virus Lineages / Antonello Di Nardo , Luca Ferretti, Jemma Wadsworth, Valerie Mioulet, Boris Gelman, Sharon Karniely, Alexey Scherbakov, Ghulam Ziay, Fuat Ozyoruk, Unal Parlak, Pelin Tuncer-Goktuna, Reza Hassanzadeh, Mehdi Khalaj, Seyed Mohsen Dastoor, Darab Abdollahi, Ehtisham-ul-Haq Khan, Muhammad Afzal, Manzoor Hussain, Nick J. Knowles, and Donald P. King // Mol. Biol. Evol.. -2021. – V.38. - N10/ - P. 4346-4361

2. The level of humoral immunity, determined in the reaction of enzyme immunoassay and neutralization, and the degree of protection against infection with a homologous FMD virus when monitoring the effectiveness of FMD vaccines / M.I. Doronin, D.V. Mihalishin, N.N. Lugovskaya, V.V. Mihalishin // Polish Journal of Science. – 2021. – V. 40. – P. 4-9.

3. Using spectrometric analysis for indirect estimation of 146S component concentration while measuring FMDV RNA amount / M. I. Doronin, D. V. Mikhalishin, N. Ye. Kamalova, A. V. Borisov / Veterinary Science Today/ - 2021. - N 1 -P. 7-14.

4. The use of specialised Sheff-Vax ACF supplements for BHK-21/SUSP/ARRIAH cell cultivation and FMDV reproduction M. N. Guseva, M. I. Doronin, A. A. Shishkova, D. V. Mikhalishin, M. A. Shevchenko, B. L. Manin / Veterinary Science Today - 2021. – N 1 –P. 15-21.

5. Studies of biological properties of continuous suspension BHK-21/SUSP/ARRIAH cell line / M. I. Doronin , M. N. Guseva , D. V. Mikhalishin A. S. Sharypov , N. S. Mudrak , N. Ye. Kamalova , B. L. Manin / Veterinary Science Today - 2021. - N 3 -P. 230-238.

6. Role of meat and meat products in foot and mouth disease spread /A. V. Mischenko, V. A. Mischenko, V. Yu. Chernykh [et al.] // Agrarnaya nauka, 2021. Vol. 1.-P.20-23

7. Analysis of SAT-1, -2, -3 FMD outbreaks in Africa in 2017-2019

M. V. Sidorovskaya, S. N. Fomina, S. R. Kremenchugskaya / Veterinary Science Today - 2021. - N 2 - P. 113-120.

b) International conferences: 0

c) National conferences: 0

d) Other:

(Provide website address or link to appropriate information) 2

1.Mikhalishin D.V. Development of production technology of emulsion FMD vaccine for livestock animals /Mikhalishin Dmitry V. - 2021 - 38 p.

2.http://www.fsvps.ru/fsvps/iac

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: 7
c) Hands-on training courses: 3
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
а	Uganda	3
а	The Democratic People's Republic of Korea (North Korea)	4
b	Pakistan (3)	150
b	Russia (4)	200
с	Pakistan	3
с	Russia (2)	4
а	Iraq	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?

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)
ISO 9001:2015	Сертификат СМК 2019-2022.pdf
ISO 17025	аттестат_ЛДЦ.pdf

16. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
virus isolation	National accreditation system "Federal accreditation service"
FMDV antigen detection ELISA	National accreditation system "Federal accreditation service"
FMDV antigen detection CFT	National accreditation system "Federal accreditation service"
RNA detection in RT-PCR	National accreditation system "Federal accreditation service"
FMD antibody detection LPB ELISA	National accreditation system "Federal accreditation service"
FMD NSP antibody detection ELISA	National accreditation system "Federal 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?

Title of event	Date (mm/yy)	Location	Role (speaker, presenting poster, short communications)	Title of the work presented
International conference "Food safety in the context of COVID-19 pandemic".	March 29-31, 2021	Ural State Agrarian University, Yekaterinburg	speaker	Examination of immunogenic and protective properties of emulsion FMD vaccine based on strain O/Korea/14 (O/SEA/ Mya-98)
Xth International Veterinary Congress	April 20-22, 2021	Moscow	speaker	Epidemic situation in Russia and in Central, East and Southeast Asian countries in 2020-2021
44th General Session of the European Commission for the Control of Foot-and- Mouth Disease	April 21-23, 2021	online	participants	-
3d online meeting of the FMD Epidemiology and Laboratory Network in the West Eurasia	August 17-18, 2021	online	speaker	Vaccines and choice of vaccines for FMD prevention and control programs
16th meeting of the FAO/OIE FMD Reference Laboratory Network	November 23-24, 2021.	Pirbright, UK (online)	speaker	Progress report of the OIE Regional Reference Laboratory for Foot and Mouth Disease (FGBI "ARRIAH") for 2021

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?

Purpose of the proficiency tests: ¹	Role of your Reference Laboratory (organiser/ participant)	No. participants	Participating OIE Ref. Labs/ organising OIE Ref. Lab.
specify the tests for FMD and SVD	paticipant	4	The French Agency for Food, Environmental and Occupational Health & Safety (ANSES)

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
Molecular epidemiology of FMD outbreaks	Exchange genomic sequences of FMDV, accoding to Memorandum of understanding for OIE/FAO Network for FMD Reference Laboratories	FMD WRL (Pirbright, UK)

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: <u>http://www.oie.int/en/our-scientific-expertise/reference-laboratories/proficiency-testing</u> see point 1.3

Purpose for inter-laboratory test	No. participating	Region(s) of participating OIE
comparisons ¹	laboratories	Member Countries
Harmonization of methods for diagnostic FMD	8	■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?

No

25. Additional comments regarding your report: