Food and Agriculture Organization of the United Nations

eufmd
european commission for the control of foot-and-mouth disease

Shipment of lateral flow devices

The joint opinion of the Standing Technical Committee (STC) and the Special Committee for Biorisk Management (SCBRM) of the European Commission for the Control (EuFMD) on the shipment of lateral flow devices positive for foot-and-mouth disease (FMD) virus to Tier D FMD laboratories in the European region after proper inactivation in 0.2% citric acid.

European Commission for the Control of Foot-and-Mouth Disease

EuFMD's programme, tools and initiatives

FAST
Foot-and-mputh And Similar Transboudary animal diseases

Pillars
eufmd activities

Dt
eufmd digital transformation

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vlearning
eufmd virtual learning centre

microLearning
eufmd virtual learning

vlc EA
virtual learning centre for East Africa

Tom
eufmd training management system

SimExOn
simulation exercises online

KnowBank
eufmd knowledge bank

GetPrepared
emergency preparedness toolbox

RiskComms
risk communications

SQRA
a method for spatial qualitative risk analysis applied to fmd.

Pragmatist
prioritization of antigen management with international surveillance tool

EuFMDiS
european foot-and-mouth disease spread model

Impact
impact calculator

Vademos
fmd vaccine demand estimation model

GVS
global vaccine security

PQv
vaccine prequalification

PCP
progressive control pathway

PSO
pcp practicioner officers

VPP
veterinary paraprofessionals

PPP
public private partnership

Sustainable development goals, UN-SDGs. EuFMD's programme has a focus on

Together agains wasting resources, think twice before printing.

Thinking of the environmental footprint

The joint opinion of the EuFMD STC and the EuFMD SCBRM on the shipment of lateral flow devices positive for FMDV to Tier D FMD laboratories in the European region after proper inactivation in 0.2% citric acid

The Standing Technical Committee (STC) and the Special Committee for Biorisk Management (SCBRM) of the EuFMD have reviewed data provided by ANSES, France, on one specific lateral flow device (LFD) for detection of foot-and-mouth disease (FMD) virus antigen, its inactivation by submersion in 0.2% citric acid (pH ≤ 2.6 for 15 minutes), and attempts to subsequently recover FMD virus by cell culture inoculation and chemical transfection (Romey *et al.*, 2018).

It is noted that other LFD designs for FMDV detection must be evaluated individually by the STC and SCBRM, who decide whether the exception from the IATA rules described below can apply to these designs or if a new inactivation study is required.

On the basis of the data provided by ANSES, **it is the joint opinion of the members of EuFMD STC and SCBRM that:**

- The FMD virus on this LFD is fully inactivated by the treatment with 0.2% citric acid for a minimum of 15 minutes at room temperature (RT) according to the presented protocol, and thus no longer infectious.

The members of the STC and the SCBRM recognize that:

- FMD virus can be recovered from inactivated LFDs using special techniques (chemical transfection or electroporation), but not by simple inoculation of cell cultures;
- In the field, LFDs are handled in a contaminated environment, and infectious FMD virus can be present on parts of the LFDs and other materials (e.g. tubes, wrappers) that are not submerged in 0.2% citric acid;
- The efficacy of the citric acid treatment depends on the pH of the solution (pH ≤ 2.6). FMD virus is rapidly inactivated at pH 6 or lower. At pH 4, infectivity is completely abolished within seconds (*Bachrach et al.*, 1957).

It is the joint recommendation of the members of the EuFMD STC and SCBRM that:

- The LFD in question treated as described falls under the exception listed in section 3.6.2.2.3.3[1] of the *IATA Dangerous Goods Regulations (DGR), 62nd edition, January 1st, 2021.* Therefore, the IATA DGR do not apply and this LFD in this form can be shipped without UN markings to Tier D laboratories in the European region, provided that:
    a. The LFD is placed in a solution of 0.2% (w/v) citric acid monohydrate in water in a receptacle designed to ensure that the entire LFD will be completely submerged in this solution for at least 15 minutes.

    b. The LFD includes an indicator to ascertain the correct pH of the 0.2% citric acid solution (≤ 2.6).

    c. The LFD will only be shipped internationally by national reference laboratories (NRLs), or by other capable laboratories with authorization from the national competent authorities, and by personnel trained in packaging and shipping of the LFD in question:
        i. those collecting the samples must be trained in national requirements on how to handle, inactivate, pack and transfer the LFD in question to an appropriate laboratory for international shipment.
        ii. the international shipment must be accompanied by a dated and signed statement confirming that the LFD has been inactivated as per requirements.
        iii. the LFD in question should be placed in a sealed airtight plastic bag within a sturdy outer packing (e.g. cardboard box or padded envelope).
        iv. the international shipment must be done in a manner that ascertains that the receiving laboratory can track the shipment and will be notified of any issues that may arise in transit, in particular diversion or destruction of the shipment. It is the duty of the sending laboratory to notify the receiving Tier D laboratory of the shipment including the tracking information.

    d. The LFD and inactivation receptacle are delivered with a pamphlet with clear instructions regarding
        i. how the inactivation solution is to be prepared and verified.
        ii. how the LFD must be put into the inactivation receptacle, and how long it must be fully immersed in the inactivation solution.
        iii. how the inactivated LFD must be disinfected and packed, and that it must be shipped with tracking by recognized courier company.
        iv. how the shipment must be arranged and carried out.

[1] "3.6.2.2.3.3 Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subjected to these Regulations unless they meet the criteria for inclusion in another class."

This opinion only applies up to the point of the reception of the LFDs by Tier D laboratories in the European region. Onward shipment is guided by the respective national law.

On behalf of the EuFMD STC and SCBRM

Date:	Date:
___6 October 2021_____	6 October 2021_____
Stéphan Zientara, Chair STC	Kirsten Tjørnehøj, Chair SCBRM

References:

- Romey, A., Relmy, A., Gorna, K., Laloy, E., Zientara, S., Blaise-Boisseau, S., Bakkali Kassimi, L. (2018). Safe and cost-effective protocol for shipment of samples from Foot-and-Mouth Disease suspected cases for laboratory diagnostic. Transbound Emerg Dis, 65 (1): 197-204.
- Bachrach, H.L., Breese, S.S., Callis, J.J., Hess, W.R., Patty, R.E. (1957). Inactivation of foot-and-mouth disease virus by pH and temperature changes and by formaldehyde. Proc Soc Exp Biol Med 95(1):147-52.

EuFMD Committees

Executive Committee, Standing Technical Committee (STC), Special Committee for Surveillance and Applied Research (SCSAR), Special Committee on Biorisk Management (SCBRM), Tripartite Groups.

Hold-FAST tools

AESOP. Assured emergency supply options; **EuFMDiS**, FMD spread model; **GET PREPARED** toolbox. Emergency preparedness; **GVS**. Global Vaccine Security; **Impact Risk Calculator**; **Online Simulation Exercises**; **Outbreak Investigation application**; **Pragmatist**. Prioritization of antigen management with international surveillance management tool; **PCP-FMD**. Progressive Control Pathway for foot-and-mouth disease. **PCP-Support Officers**; **SAT**. PCP Self-Assessment Tool; **RTT**. Real Time Training; **SMS Disease reporting**; **SQRA toolkit**. A method for spatial qualitative risk analysis applied to FMD; **Telegram**; **TOM**. EuFMD training management system; **Global Monthly reports**; **VADEMOS**. Vaccine Demand Estimation Model; **VLC**. Virtual Learning Center. Microlearning.

United Nations Sustainable Development Goals (UN-SDGs)

EuFMD's programme has a main focus on

Funded by the European Union

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Thinking of the environmental footprint

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