Diagnostics

Effective and appropriate sample collection, diagnostic testing, surge capacity, and reporting are critical in an effective FMD response. These tools are needed for surveillance during an outbreak to determine the extent of disease spread and continue to be used after the outbreak to determine when transmission has stopped. Additionally, diagnostic surveillance serves as the basis for declaring freedom from FMD.

Goals

During a suspected or actual FMD outbreak, the key goals of response are the following:

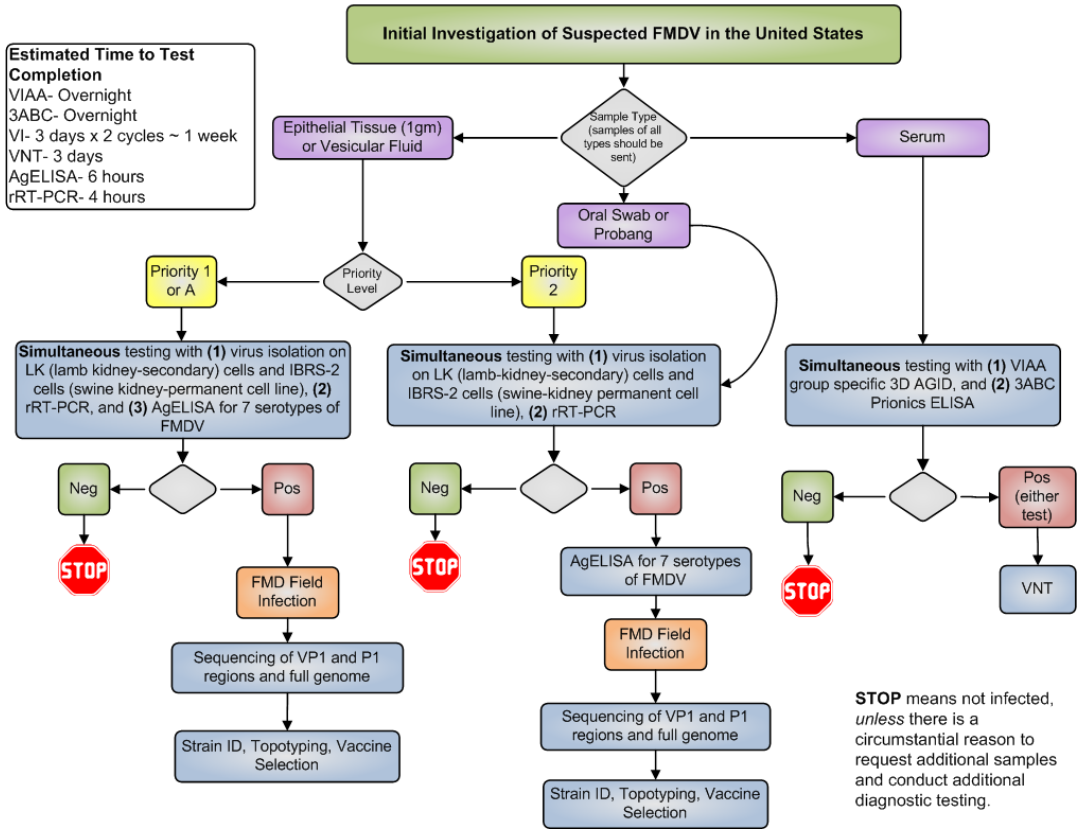
- Meet the surge requirements for diagnostic testing at specific intervals, starting at time zero and at 24-hour intervals as the response escalates, and
- Report all diagnostic test results to appropriate personnel and information management systems as soon as possible or within 12 hours of diagnostic test completion.

Foreign Animal Disease Investigations Policy and Procedures

For information regarding FMD (or other foreign animal diseases) investigation policy and procedures see *Veterinary Services (VS) Guidance Document 12001* (which replaced *VS Memo 580.4*) and the *Foreign Animal Disease Investigation Manual* (FAD PReP Manual 4-0).

Testing for suspect FMD virus in the United States is done at the National Veterinary Services Laboratories—Foreign Animal Disease Diagnostic Laboratory (NVSL FADDL) at Plum Island, NY. Preliminary testing may be ongoing at a National Animal Health Laboratory Network (NAHLN) lab, but confirmation is only done by NVSL FADDL. If FMD virus (FMDV) is detected, then sequencing will be completed to reveal the strain, topotype, and to conduct vaccine matching.

Diagnostic Flowchart for Initial Investigation of FMD



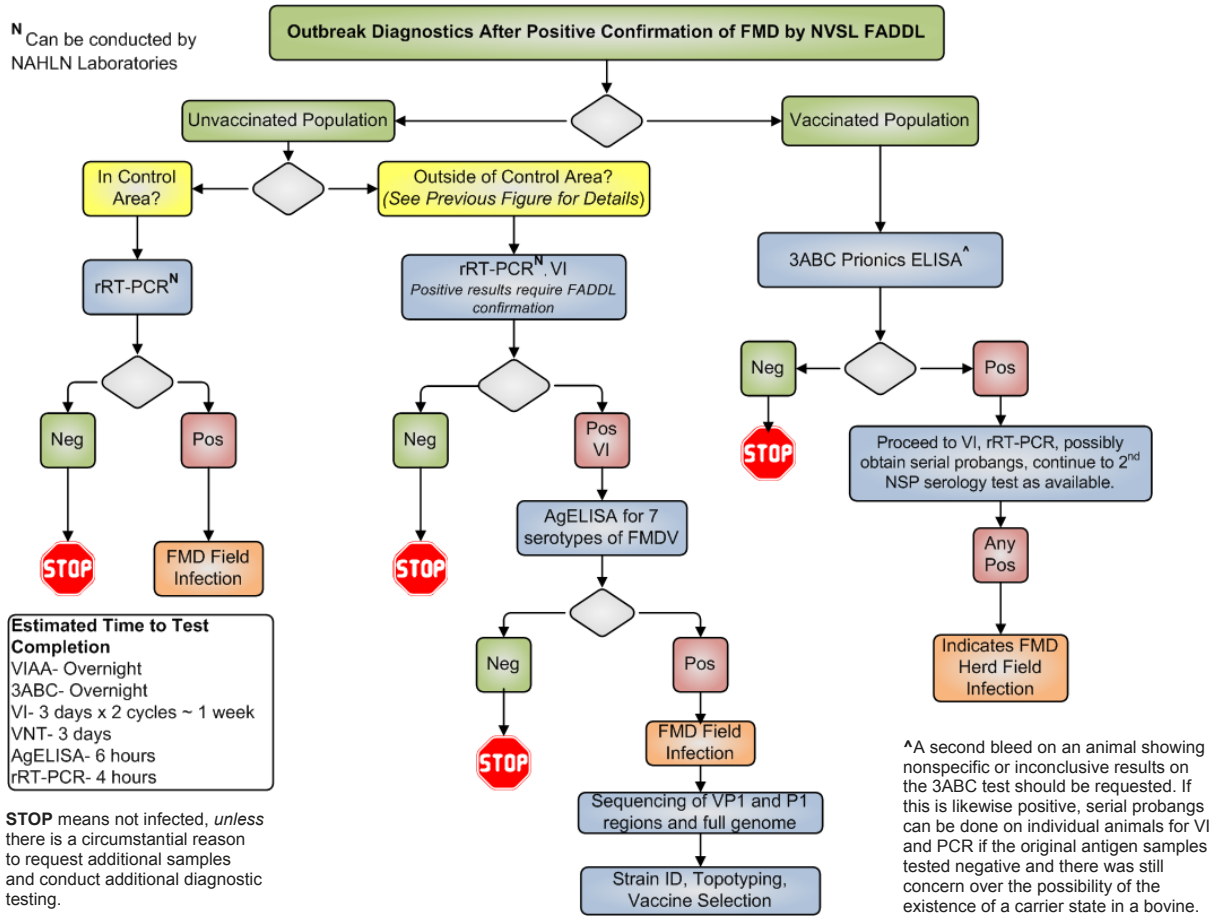
Abbreviations

Ag: antigen
AGID: agar-gel immunodiffusion
ELISA: enzyme-linked immunosorbant assay
rRT-PCR: real-time reverse transcriptase polymerase chain reaction
VI: virus isolation
VIAA: virus infection association antigen
VNT: virus neutralization test

Diagnostics During an FMD Outbreak

After NVSL FADDL confirmation of FMD on a premises (index case), subsequent swab samples for rRT-PCR may be sent to NAHLN laboratories. Incident Command will provide specific instructions regarding the direction and collection of samples, which is likely to change as the outbreak evolves. In all cases 1) NVSL FADDL will confirm the index case, 2) presumptive positive samples (on a rRT-PCR) from outside an established Control Area will be tested and confirmed by NVSL FADDL, and 3) NVSL FADDL will receive samples routinely from inside the Control Area to monitor for changes in the FMDV.

Diagnostic Flowchart after Positive Confirmation of FMD in the United States



Diagnostic Surge Capacity

In an FMD outbreak, additional resources—such as personnel and materials—may be needed for sample collection. Additional capacity may also be required for laboratory sample testing. NAHLN labs have the capability to conduct rRT-PCR tests. Ideally, NAHLN laboratories will also have the capability to conduct 3ABC ELISA serology testing and to differentiate between infected and vaccinated animals (DIVA testing) on a herd basis if required in the outbreak. Surge capacity can help facilitate a rapid response as well as continuity of business for non-infected premises. Should NVSL FADDL or the State NAHLN laboratory become overwhelmed by diagnostic testing requirements, NAHLN labs from across the country may provide surge capacity. Individual laboratories have independent protocols on how to manage personnel if a surge is required. See the NAHLN website for list of approved NAHLN labs.

Reporting & Notification

- Cases of clinical illness that are found to be presumptive positive by NVSL-FADDL, based on the current case definition, will be reported to the affected States, other States, Tribal Nations, industry, other Federal agencies, trading partners, and the World Organization for Animal Health (OIE).
- Appropriate Federal-State-Tribal-industry response and containment measures will be initiated during FMD investigations.
- For more information reporting and notification, see APHIS VS Guidance Document 12001 and the *FAD Investigation Manual (FAD PReP Manual 4-0)* which can be found at http://www.aphis.usda.gov/fadprep.