

**Diagnostics**

Effective and appropriate sample collection, diagnostic testing, surge capacity, and reporting are critical in an effective HPAI 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 HPAI.

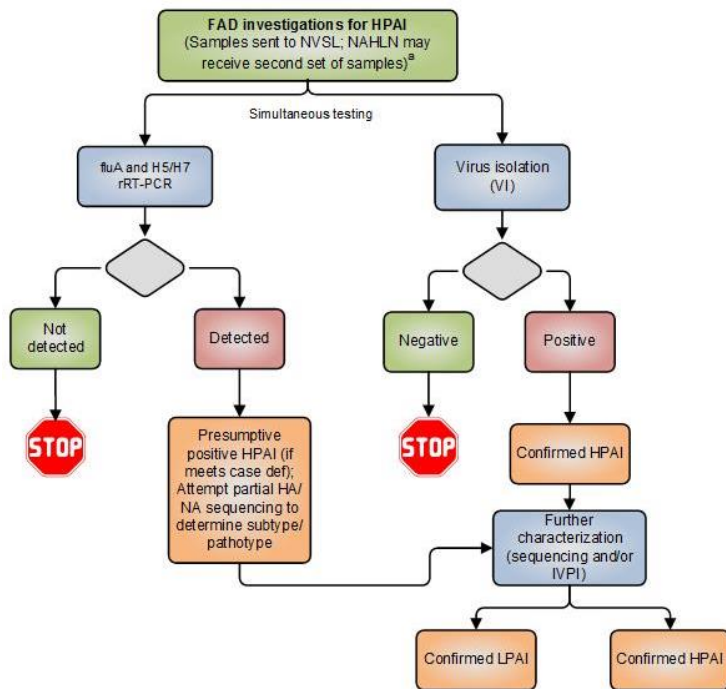
**Goals**

- During a suspected or actual HPAI outbreak, the key goals for diagnostics are to
1. provide clear direction to responders on sample collection and processing procedures, if modification from routine standards is required,
  2. meet the surge requirements for diagnostic testing at specific intervals, starting at time zero and at 24-hour intervals as the response escalates, and
  3. report all diagnostic test results to appropriate personnel *and* information management systems (Emergency Management Response System 2.0) as soon as possible and within 4 hours of diagnostic test completion.

**Diagnostic Flow for Initial HPAI Detection**

For information regarding HPAI (or other foreign animal diseases) investigation policy and procedures see *Veterinary Services (VS) Guidance Document 12001* and the *Foreign Animal Disease Investigation Manual (FAD PReP Manual 4-0)*. Figure 1 illustrates the typical diagnostic flow for suspected HPAI via an FAD investigation. Confirmation of HPAI is only made at the National Veterinary Services Laboratories (NVSL) in Ames. In the event that HPAI is suspected as part of routinely conducted surveillance, samples should be forwarded to NVSL for confirmation and sequencing immediately.

**Figure 1. Diagnostic Flow for FAD Investigations Suspected of HPAI**



**Abbreviations**

<b>fluA</b>	influenza A virus
<b>IVPI</b>	intravenous pathogenicity index
<b>NAHLN</b>	National Animal Health Laboratory Network
<b>rRT-PCR</b>	real-time reverse transcriptase polymerase chain reaction
<b>VI</b>	virus isolation

<sup>a</sup>See VS Guidance Document 12001. The first or best set of samples must be sent to NVSL. A second set may be sent to an approved NAHLN laboratory. This figure describes NVSL testing.

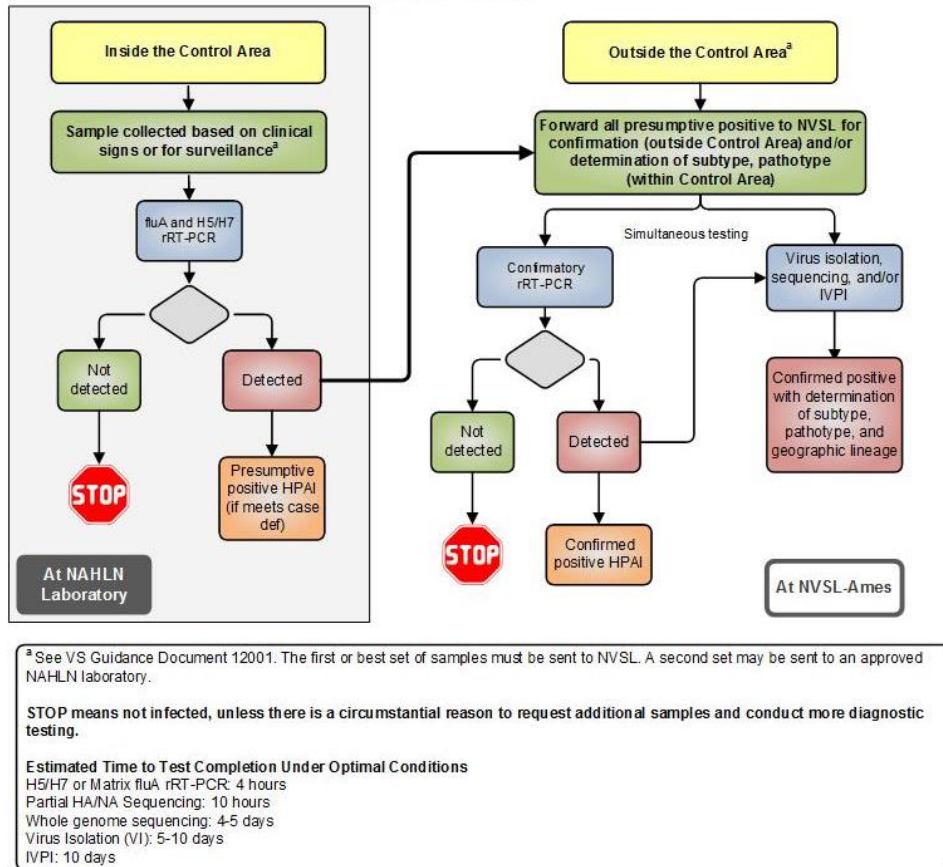
**STOP** means not infected, unless there is a circumstantial reason to request additional samples and conduct more diagnostic testing.

**Estimated Time to Test Completion Under Optimal Conditions**  
 H5/H7 or Matrix fluA rRT-PCR: 4 hours  
 Partial HA/NA Sequencing: 10 hours  
 Whole genome sequencing: 4-5 days  
 Virus Isolation (VI): 5-10 days  
 IVPI: 10 days

**Diagnostics Flow during an HPAI Outbreak**

In all cases, (1) NVSL confirms the index case, (2) presumptive positive samples based upon rRT-PCR results from outside an established Control Area are tested and confirmed by NVSL, and (3) NVSL receives samples routinely from *inside* the Control Area to monitor for changes in the HPAI virus. Based on the recommendation of the Incident Command and Incident Coordination Group, *all* presumptive positive samples from National Animal Health Laboratory Network (NAHLN) laboratories may be forwarded to NVSL for confirmation and subtyping. The unified Incident Command provides any specific instructions regarding the direction and collection of samples, which may evolve as the outbreak changes in size or scope. Figure 2 illustrates the diagnostic flow after HPAI has been detected.

**Figure 2. Diagnostic Flow During an HPAI Outbreak**



**Diagnostic Surge Capacity**

In an HPAI outbreak, additional resources, such as personnel and materials, will be needed for sample collection. Additional capacity may also be required for laboratory sample testing. Surge capacity can help to ensure a rapid response and continuity of business for uninfected premises. In the event that the State NAHLN laboratory and NVSL-Ames are overwhelmed by the diagnostic testing requirements, NAHLN labs from neighboring States will provide surge capacity for diagnostic testing. For more information on surge capacity, please visit <http://www.aphis.usda.gov/fadprep>. Individual laboratories have independent protocols on how to manage personnel if a surge is required.

**Reporting & Notification**

- ◆ Cases considered a presumptive positive for HPAI, based on the current case definition, are reported to the affected States, other States, Tribal nations, industry, other Federal agencies, trading partners, and the World Organization for Animal Health.
- ◆ This includes breeder and commercial poultry flocks, domestic waterfowl and upland game birds, backyard flocks, and the live bird marketing system.
- ◆ Appropriate Federal-State-Tribal-industry response and containment measures are initiated during HPAI investigations.