



**Potentially Actionable Suspect Sample (PASS) System  
and Initiation of Regulatory Response  
for *Phytophthora ramorum***

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## **PURPOSE**

The purpose of this document is to create a submission guideline for APHIS provisionally approved laboratories or laboratories with identification authority and provide guidance to field personnel regarding regulatory response. This system will reduce the time needed for a final determination by limiting the required number of samples requiring APHIS confirmation. This document provides guidelines on which samples need to be submitted for APHIS confirmation and which determinations require a regulatory response.

## **INTRODUCTION**

The establishment of provisionally approved laboratories for PCR diagnostics and the issuing of identification authority for cultures are intended to significantly reduce the time needed for a final determination for *P. ramorum* samples. The Potentially Actionable Suspect Sample System (PASS) **further facilitates the timely final determination of samples by** eliminating the need to submit presumptive positive cultures or DNA from redundant samples, reducing the number of samples requiring confirmation by APHIS/PPQ laboratories, thereby reducing the time interval between sampling and final identification. Additionally, this system ensures that key samples be forwarded for Federal determination

Not all determinations result (or immediately result) in a regulatory response. This document clarifies for field personnel the triggers for a regulatory response. *P. ramorum* diagnostic policy can be located at [http://www.aphis.usda.gov/plant\\_health/plant\\_pest\\_info/pram/](http://www.aphis.usda.gov/plant_health/plant_pest_info/pram/)

## **DEFINITIONS**

### **Confirmed positive:**

The test result on a presumptive positive that *P. ramorum* is present based on DNA testing or culture morphology. This confirmation would be conducted by APHIS in the case of PASS samples or by the provisionally approved lab or diagnosticians with identification authority in the case of non-PASS samples.

<b>Identification authority:</b>	Authority to confirm the presence of <i>P. ramorum</i> issued by the APHIS National Identification Services – National Mycologist, Beltsville to diagnosticians that have demonstrated proficiency in identifying <i>P. ramorum</i> in culture.
<b>Provisional approval:</b>	Authority to perform approved PCR diagnostics for <i>P. ramorum</i> issued by the APHIS National Plant Germplasm and Biotechnology Laboratory, Beltsville to laboratories that have demonstrated proficiency in detecting and identifying <i>P. ramorum</i> DNA.
<b>Potentially Actionable Suspect Sample (PASS):</b>	A presumptive positive <i>P. ramorum</i> sample diagnosed or identified by a provisionally approved laboratory or diagnostician with identification authority that would require confirmatory testing by an official APHIS Laboratory due to the nature of the sample and its regulatory implications (For more information see: “PASS System Policy” at <a href="http://www.aphis.usda.gov/plant_health/plant_pest_in fo/pram/protocols.shtml">http://www.aphis.usda.gov/plant_health/plant_pest_in fo/pram/protocols.shtml</a> )
<b>Presumptive positive:</b>	A preliminary diagnostic test result from a laboratory indicating <i>P. ramorum</i> is present.
<b>Trace Forward (TF) plants:</b>	Plants identified on a trace forward list as being potentially infected with <i>P. ramorum</i> .
<b>Trace Forward (TF) site:</b>	Any location that received potentially infected plants from a confirmed infested source nursery; including residential or commercial landscapes.
<b>Trace Back (TB) plants:</b>	Plants identified on a trace back list as being potentially infected with <i>P. ramorum</i> .
<b>Trace Back (TB) site:</b>	Any source location, including residential or commercial landscapes, which shipped presumptive, confirmed or potentially infected plants.

## ROUTING FOR SAMPLES

<b>If the sample is an Initial Presumptive Positive from a:</b>	<b>Then the sample is a:</b>
Nursery survey site (generally under CAPS)	PASS Sample and must be sent to an APHIS Laboratory for confirmation within 2 weeks.  <b>Go to Table A</b>
Compliance Inspection site	
Cleanliness Inspection site	
Certification Inspection site	
TF plant at a TF site that ships interstate	
TF plant at a TF site in a state other than the source site	
TB site	
Any unusual or unexpected detection or one not otherwise covered above (*see below)	
<b>If the sample is an Initial Presumptive Positive or any other Presumptive Positive from:</b>	
Any TF site where the sample is from any plant not part of the TF shipments(s)	PASS Sample and must be sent to an APHIS Laboratory for confirmation within two weeks.  <b>Go to Table A</b>
Any sample that will require Federal regulatory action	
Any previously undescribed or unknown host(s) (*see below)	
Any new host or host not previously reported found in the US (*see below)	
Any environmental location outside the current quarantined counties, including home owner's yards, natural landscape or forest location(s) whether or not associated with a positive nursery (*see below)	
<b>If the sample is other than the Initial Presumptive Positive from:</b>	
Nursery survey site (generally under CAPS)	Not a PASS sample if the initial presumptive positive PASS sample was confirmed positive by APHIS.  <b>Go to Table B</b>
Compliance Inspection site	
Cleanliness Inspection site	
Certification Inspection site	
TF plant at a TF site that does not ship interstate and is in the same state as the source site	
TB site (originating source)	

**\*Do to the potential impact and importance of these samples, a second official sample must be collected, processed, and Federally confirmed. Inconsistent results may require additional sampling and testing, to be determined on a case-by-case basis.**

## REGULATORY DECISIONS

**Table A**

<b>Sample is a PASS sample, and</b>	<b>Regulatory Action</b>
The positive sample was a culture, then:	Invoke appropriate regulatory response
Site is not a TF site and one sample is PCR positive, then.	Wait for result of second sample if in process, or if none, hold only the lot containing the positive sample and re-sample and retest remainder of lot before plants are destroyed
Site is a TF site; a single PCR positive is sufficient to:	Invoke appropriate regulatory response
Site has two or more PCR samples confirmed positive from the site for this sampling, then:	Invoke appropriate regulatory response
Site is not a TF site and despite re-sampling and retesting site has only one PCR sample determined positive for this sampling then:	This is not a result that invokes a regulatory response. Either re-inspect and resample site or discontinue regulatory activities at this site

**Table B**

<b>Sample is not a PASS sample, and</b>	<b>Regulatory Action</b>
Appropriate regulatory action has been taken, then:	Continue to invoke appropriate regulatory response
Appropriate regulatory action has not been taken, then:	Invoke appropriate regulatory response

The PASS sample may be a single sample or may be several samples collected at the same time. In any instance where a culture of *P. ramorum* has been obtained, confirmatory testing of DNA extracted from regulatory samples is not required, although confirmation of the ID of the culture is required.

This process applies to each nursery certification, e.g., if a nursery was determined to be positive, mitigation measures were undertaken as specified in the APHIS protocols, and the nursery is again seeking certification, the PASS process begins again. The above decision tables are for provisionally approved laboratories or diagnosticians with identification authority.

Samples from laboratories that are not provisionally approved or to which identification authority has not been granted must be treated in the manner described in the Federal Regulations and all DNA extractions and cultures must be submitted to APHIS for final and official determination.