

Regulation in the shipping of samples for ASF diagnosis

Guidance for shipping suspect ASF samples to the
USDA NVSL Foreign Animal Disease Diagnostic Lab

Travis McCarthy Ph.D., RBP

Biosafety Manager

National Centers for Animal Health

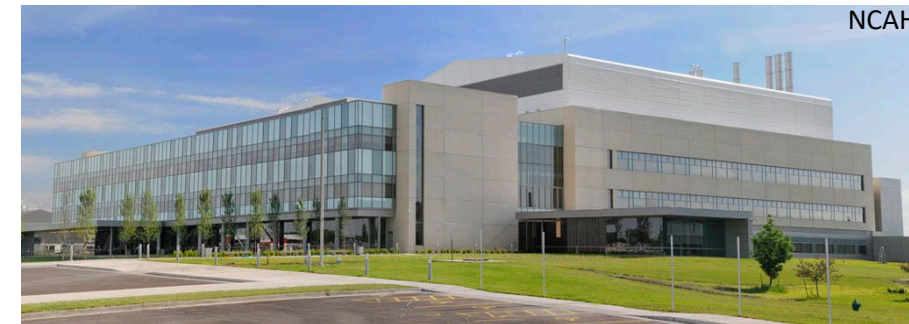
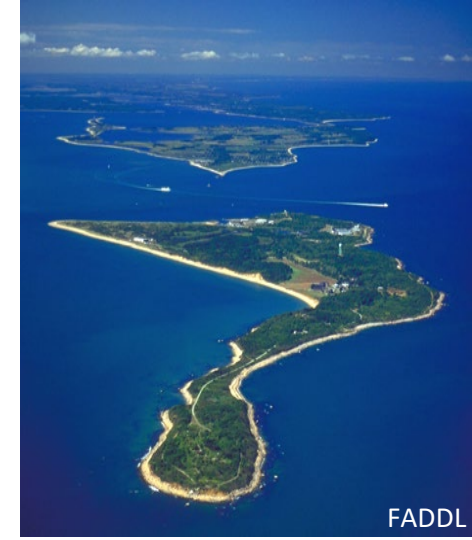
USDA | APHIS | VS | D&B | CVB | SSU

Ames, IA USA



USDA APHIS National Veterinary Services Laboratory

- The NVSL provides diagnostic support to foreign animal disease investigations at:
 - National Centers for Animal Health (NCAH) in Ames, IA
 - Foreign animal Disease Diagnostic Laboratory (FADDL) on Plum Island, NY
- NVSL performs nearly 500,000 diagnostic tests annually from almost 50,000 accessions received.
- ASF samples are all addressed to FADDL



Overview – Getting samples to FADDL

- Sample Collection
- Packaging
- Notification and pre-shipment communication
- Submission Paperwork
- Permit Requirements
- Shipping
- Contact Information

Sample Preparation

- Samples must be packaged securely so they don't break in transit
- Label samples clearly
 - **Printed labels**
 - Permanent marker
- Document samples on a spreadsheet
 - Send the electronic version with the advance notification

African Swine Fever		
Swine	Serum	Red Top Tube (10ml)
	Whole Blood	Green Top Tube (10 ml) Purple Top Tube (10 ml)
	Fresh Tissue: Tonsil, Gastrohepatic LN, Renal LN, Spleen	Separate Whirlpak Bag Per Tissue Type
	Set of Tissues	Formalin (10:1)

Supplies

Sample collection supplies

- serum separator (red top) tubes
- EDTA (purple top) tubes
- sterile needles & syringes

Sample Collection



Dispense blood into blood tubes. Gently invert purple top blood tubes to mix with anticoagulant.



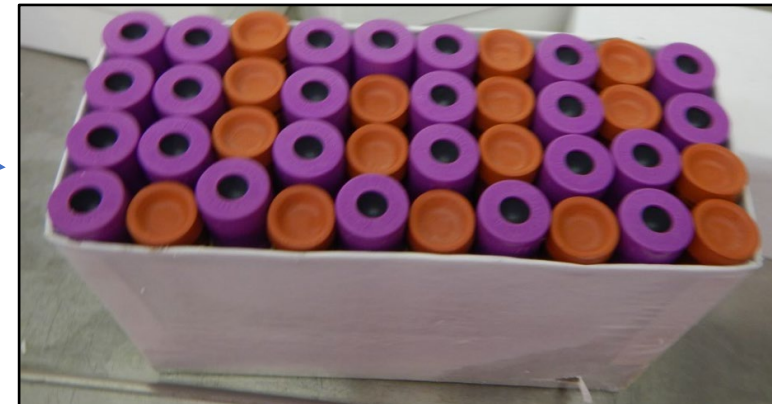
Label tubes with animal and sample identification, date of collection, and other relevant information.

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Boxes with tube separators

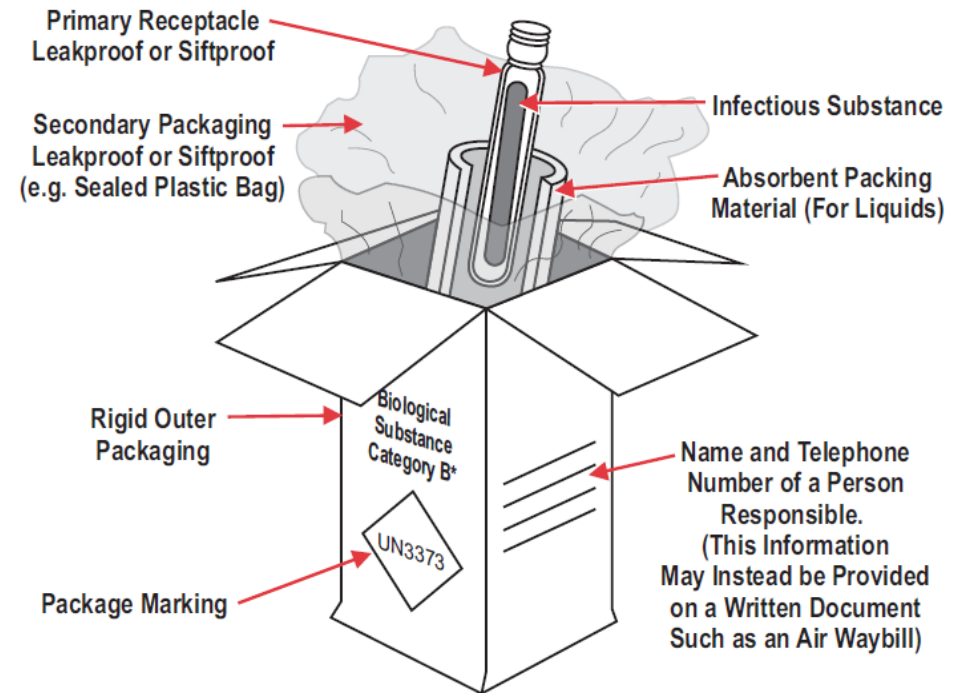


Additional information is available on the NVSL webpage under “Diagnostic Testing at NVSL”

Sample Packaging

- Follow all applicable guidelines for packaging and shipment of **Category B Infectious Materials**
 - UN3373 Infectious Substance Cat B
- 3x Layers:
 - Inner primary package is sealed and leakproof
 - Secondary sealed package containing absorbent material
 - Rigid outer packaging with labels
- NVSL has packaging available
 - Sample package can be requested.

DIAGRAM OF CATEGORY B PACKAGE



TC-34 Large Diagnostic Kit

Shipping and packing materials

- Examples of materials are available on the USDA NVSL website.

The screenshot shows the USDA Animal and Plant Health Inspection Service (APHIS) website. At the top, the USDA logo and the text "Animal and Plant Health Inspection Service U.S. DEPARTMENT OF AGRICULTURE" are visible. Navigation links include "Home", "Our Focus", "Resources", "Newsroom", "Pet Travel", and "Blog". A search bar labeled "Search APHIS" is on the right. A green banner below the navigation contains a warning icon and the text "USDA FAQ's and resources about coronavirus (COVID-19). LEARN MORE".

The main content area is titled "Reagents and Proficiency Testing Available from the NVSL". Below the title, it says "Last Modified: Sep 16, 2020" and has a "Print" button. The text describes that diagnostic reagents are produced by the National Veterinary Services Laboratories (NVSL) for veterinary diagnostic use when commercial sources are not available or not fulfilling needs. It also mentions that proficiency testing is offered for diagnostics associated with USDA program diseases and other diseases requiring APHIS laboratory approval.

On the left side, there is a vertical navigation menu under the heading "Animal Health". The menu items are: "Contact Us", "Program Overview", "News and Announcements", "Animal Disease Information", "Emergency Management", "Export from the U.S.", "Import into the U.S.", "Epidemiology", "Laboratory Information and Services", "Frequently Asked Questions", "Lab-Related Forms", "General NVSL Information", "Diagnostic Testing at NVSL", "Reagents and Proficiency Tests from NVSL", "APHIS-Approved Testing Laboratories", and "National Animal Health Laboratory Network (NAHLN)". Two orange arrows point to "Laboratory Information and Services" and "Reagents and Proficiency Tests from NVSL". The "Reagents and Proficiency Tests from NVSL" item is circled in orange.

Below the main text, there is a "Quick Links" section with two buttons: "NVSL Reagent Catalog" and "Reagent Request Form VS 4-9". Below that, another section asks "Questions about ordering? First-time customer? Visit our Ordering page" and has two buttons: "Kit/Instrument Catalog" and "Kit/Instrument Request Form". Both "Kit/Instrument Catalog" and "Reagent Request Form VS 4-9" are circled in orange.

On the right side, there is a "Related Links" section with several links: "National Veterinary Services Laboratories", "General NVSL Information", "Diagnostic Testing at the NVSL", "NCAH Portal Guidance for NVSL Submitters", and "Lab-Related Forms (NVSL)".

At the bottom of the page, there is a "Reagents" section with the text "Catalog of reagents" and a note: "Text in the PDF-format reagent catalog is fully".

Shipping and packing materials

- Examples of materials are available on the USDA NVSL website.
- Kits are only available to USDA labs but you may request a sample kit to be sent to your country for reference.

NVSL KIT & INSTRUMENT CATALOG

For use by authorized federal personnel only

For use with [VS Form 4-12](#)

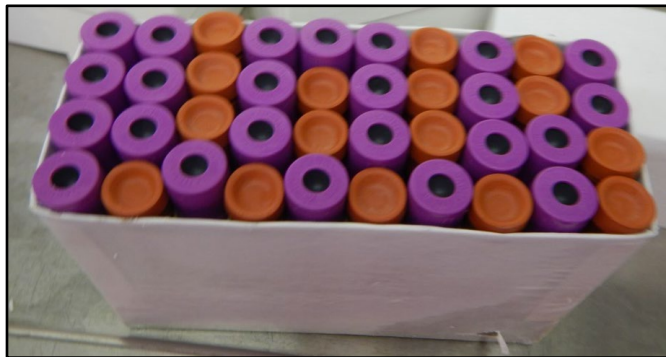
Click on hyperlink to view image of item

ITEM	ITEM
BSE FRESH TISSUE:	DIAGNOSTIC KITS:
KIT # 5 (5 Red-Top Tubes)	LARGE (TC-34)
KIT # 10 (10 Red-Top Tubes)	SMALL (307)
KIT # 25 (25 Red-Top Tubes)	
	INSTRUMENTS:
	SMALL SPOONS
SCRAPIE (formalin):	LARGE SPOONS
KIT # 1 (2-180 ml jars)	FORCEPS (rat tooth)
KIT # 2 (12-180 ml jars)	METZENBAUM SCISSORS (curved nose)
KIT #3 (2-90 ml jars)	BSE DRESSING SCISSORS
KIT #4 (12-90 ml jars)	SCALPELS /Box
	RECTAL SPECULUM
TB KITS:	
SLAUGHTER (Black/Yellow)	
DEER (Orange)	MISC KITS:
	FADD REPLENISHMENT
MEDIA:	AI KITS
BHI Broth (3 mL media, 40 tubes/box OR 5.5 mL media-500 tube minimum)	BLOOD COLLECTION KIT (STP 210)
TBTB (10/box)	
	MISC ITEMS:
FORMALIN CASE SIZE:	AI BAR CODES (4/SET)
	BSE BAR CODES (8/SET)
90ml (96/CS)	TISSUE CASSETTE
180ml (64/CS)	BIOPSY SPONGES

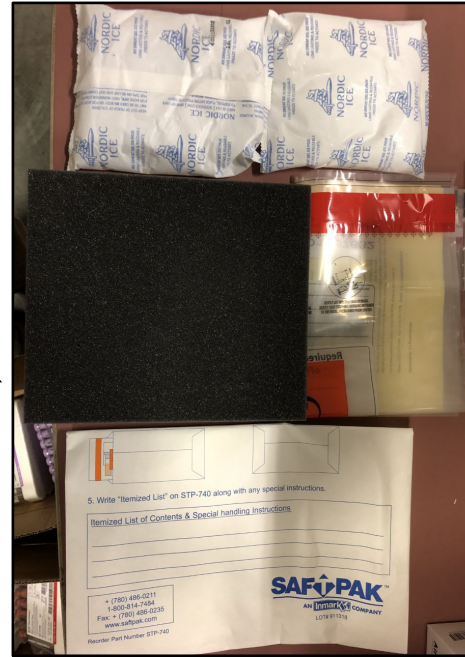


FAX Orders to the NVSL Shipping Dept. @ 515-337-7378
 The NVSL Shipping Dept. may be reached by phone @ 515-337-7530 or e-mail @ NVSLShipping@usda.gov.
 MSDS sheets may be obtained at
http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth/sa_lab_information_services/sa_reagents/ct_safety

Preparation for shipment



Place labeled blood tubes
in slotted cardboard box



Place samples in plastic biohazardous
specimen bag, then place into SaftPak
envelope, then place in insulated box
with cold packs.



Submission Form: https://www.aphis.usda.gov/library/forms/pdf/VS_Form10_4.pdf

VS 10-4

- All shipments must include a VS 10-4 Specimen Submission Form
- Include an electronic version with the pre-notification and printed version in the final package.

Animal Health
Contact Us
Program Overview
News and Announcements
Animal Disease Information
Emergency Management
Export from the U.S.
Import into the U.S.
Epidemiology
Laboratory Information and Services
Frequently Asked Questions
Lab-Related Forms
General NVSL Information
Diagnostic Testing at NVSL
Reagents and Proficiency Tests from NVSL
APHIS-Approved Testing Laboratories
National Animal Health Laboratory Network (NAHLN)
Training at the NVSL
Monitoring and Surveillance
Veterinary Services Applications
One Health
OIE International Standards
Traceability
Training and Development
Veterinary Accreditation
Veterinary Biologics
Site Map

Diagnostic Testing at the NVSL

Last Modified: Sep 16, 2020



The National Veterinary Services Laboratories (NVSL) has laboratories in two locations: Ames, Iowa and the Foreign Animal Disease Diagnostic Laboratory (FADDL) at Plum Island, New York. Diagnostic test services range from a single laboratory test to comprehensive laboratory services covering many pathogens for a suspected disease outbreak. Click the links below to view the services conducted at each location.

[General Specimen Submission Form VS 10-4](#)

Text in the following PDF-format catalogs is fully searchable. When the catalog displays, click the Search feature (binoculars icon) in the Adobe Acrobat toolbar or CTRL + F to type in keywords.

Items requested from the National Veterinary Services Laboratories catalog may not be available or may be limited in quantity at any time due to domestic testing or production priorities.

- [Ames, IA Diagnostic Catalog](#)
- [Plum Island, NY \(FADDL\) Diagnostic Catalog](#)
- [Current user fee rates](#) (9CFR 130.14-19)
- [Animal Disease Information](#), Iowa State University

Unfamiliar with an abbreviation or acronym in the catalogs? Click here for [catalog definitions](#) (PDF, 20K)

Unfamiliar with an abbreviation used in a diagnostic test report? Click here for [report definitions](#) (PDF, 7K)

Submitting Diagnostic Samples to the NVSL

- [Veterinary Services Notice 10-07](#), Diagnostic Submissions to the National Veterinary Services Laboratories (226K)
- [Specimen Submission Form VS 10-4](#)
- [Other submission forms](#)
- [Authorization for Submitting Specimens](#)
 - o Domestic submissions
 - o **Samples originating outside the US**
 - o **Suspected exotic diseases**
 - o Primate samples
- [Information for the proper collection of specimens](#)
 - o Sampling materials and shipping kits for Program diseases (authorized personnel only):
 - [Request Form](#)
 - [Catalog](#)

Related Links

[National Veterinary Services Laboratories](#)

[General NVSL Information](#)

[Reagents and Proficiency Testing Available from the NVSL](#)

[NCAH Portal Guidance for NVSL Submitters](#)

[Lab-Related Forms \(NVSL\)](#)

[National Bio and Agro-Defense Facility \(NBAF\) Scientist Training Program](#)

The form is titled 'SPECIMEN SUBMISSION' and includes the following sections:

- 1. SUBMITTER NAME** (including business name)
- 2. NVSL SUBMITTER ID**
- 3. NAME OF OWNER** (Check if wildlife (No owner))
- 4. LOCATION OF ANIMALS**
- 5. PAYMENT METHOD** (User Fee Account No., Check/Money Order, Credit Card Number)
- 6. HERDFLOCK SIZE**
- 7. NUMBER IN HERDFLOCK AFFECTED**
- 8. NUMBER IN HERDFLOCK DEAD**
- 9. EXAMINATIONS REQUESTED**
- 10. COLLECTED BY**
- 11. DATE COLLECTED**
- 12. AUTHORIZED BY**
- 13. PURPOSE OF SUBMISSION** (Interstate Movement, Export, Pre-import, Import, FADIEP Diagnostic, Surveillance, TB, General Diagnostic, Reagent Evaluation, NVSL Intraab, Developmental Research)
- 14. COUNTRY OF ORIGIN / DESTINATION**
- 15. REFERRAL NUMBER**
- 16. PRESERVATION** (None, Ice Pack, Dry Ice, Formalin, Borax, Alcohol, Other)
- 17. SPECIMENS SUBMITTED** (Blood, Culture, Extract, Feces, Feed, Milk, Parasite, Plant, Semen, Serum, Swab, Tissue, Urine, Whole Animal, Other)
- 18. TOTAL NUMBER OF SPECIMENS SUBMITTED**
- 19. SPECIES OR SOURCE** (Cattle, Swine, Sheep, Goat, Horse, Donkey, Chicken, Turkey, Other PHS, Bison, Turkey, Deer, Pig, Fish, Environment, Reagent, Other)
- 20. NUMBER OF ANIMALS SAMPLED**
- 21. IDENTIFICATION** (Table with columns for Sample ID, Animal ID, Breed, Age, Sex)
- 22. ADDITIONAL DATA** (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions)
- 23. SIGNATURE OF SUBMITTER AND DATE**

Organisms and Vectors Import Permit

- All samples originating outside of the United States must be accompanied by a valid VS 16-6 Permit
 - You can apply for a 16-6 Permit by completing Form 16-3 through the VS Permitting Assistant:
 - efile.aphis.usda.gov/s/vs-permitting-assistant
- **NVSL will assist with acquisition of the permit. Notify them of the shipment before initiating the permit process so they can assist.**

The screenshot displays the USDA Animal and Plant Health Inspection Service (APHIS) VS Permitting Assistant web application. The page is titled "Veterinary Services Permitting Assistant" and includes a navigation bar with "HOME" and "GUIDE ME" links. The main content area is divided into three steps:

- Step 1: Select a Category Tab to Enter a Commodity's Details**: This step includes tabs for "Animal Products & Byproducts", "Live Animals", and "Organisms & Vectors". Below the tabs, there are several dropdown menus and a search bar: "Movement Type" (Select a Movement type), "Intended Use" (Select an Intended Use), "Materials" (Search Materials), and "Animal Origin" (Select an animal origin). A "Search" button is located at the bottom right of this section.
- Step 2: Select Attributes**: This step shows "0 filters applied" and a "Clear All" button. Below this, it states "No filters available. Use the search bar above to search for a material, and generate applicable filter options."
- Step 3: Select Your Material**: This step shows "Showing 0 of 0 Materials" and a "Search" button. Below this, it states "No results available. Use the search bar above to search for a material, and generate applicable result options."

Organisms and Vectors Import Permit

- FADDL has permits to receive diagnostic ASF samples (i.e. not select agents) and confirmatory samples (i.e. select agents) from a broad range of international sources

- Before seeking a permit contact FADDL to initiate and complete a risk assessment for the samples

Dr. Meng Deng

ming.y.deng@usda.gov

Dr. Joseph Chung

chungwon.chung@usda.gov

- FADDL Representatives will respond with further shipping instructions



Pre-Shipment Notification

- It is essential that you notify NVSL in advance that the sample is being shipped:
 - We will support the shipment as it transits customs
 - We will assist with permit acquisition and shipping
 - We will prepare to receive the sample
 - Send the notification directly to the NVSL and FADDL Director
- Include in the notification:
 - FedEx Number of the package (if known)
 - An electronic copy of the shipping manifest
 - Electronic copies of any additional available information (sample records, preliminary results)
- The Chief Veterinary Officer (CVO) from the originating country must authorize the NVSL to test any sample submitted
 - Blanket authorizations are available. Contact the NVSL Director for more information.



Who do you notify?

- Send email notification to:

fad.submissions@usda.gov

suelee.robbe-austerman@usda.gov

- Include all available information including:

- 10-4 Specimen Submission form
- Spreadsheet of samples
- CVO letter
- Import permit
- FedEx tracking number

- Send the email the same day the sample is shipped



Where do you ship the package?

- FedEx Address: FADDL Lab Director
USDA/APHIS/NVSL/FADDL
Plum Island Animal Disease Center
40550 Route 25
Orient Point, NY 11957
United States, US
(718) 553-3570 or 3577

Include printed copies of all materials sent electronically.



Guidelines

- Information and examples can be found on the NVSL website.
- Send notification before shipment!
 - Send all available information in the notification (electronic documents, spread sheets, FedEx #)
 - Send directly to the NVSL FADDL Director
- Careful and appropriate packaging is essential for safe and efficient receipt
- Don't forget:
 - VS 16-6 Permit
 - VS 10-4 Sample Submission Form
 - National Veterinarian Approval



Any questions?

- Contact information:

- NVSL Director:

- Suelee Robbe-Austerman

suelee.robbe-austerman@usda.gov

- FADDL Associate Director:

- Muzafar Makhdoomi

muzafar.makhdoomi@usda.gov

- FADDL Diagnostic Services Section Head

- Robin Holland

robin.holland@usda.gov

- NCAH Biosafety Manager

- Travis McCarthy

travis.mccarthy@usda.gov

- Links:

- Diagnostic Testing at the NVSL:

- https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/sa_diagnostic_tests/ct_diagnostic_tests

- Shipping Specimens to NVSL-FADDL

- https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/sa_diagnostic_tests/ct_shipping_specimens_to_faddl

