

## Biologics Sample Submissions - (APHIS 2020) "Special Request"

### Where were changes made in the 10/21/2020 version?

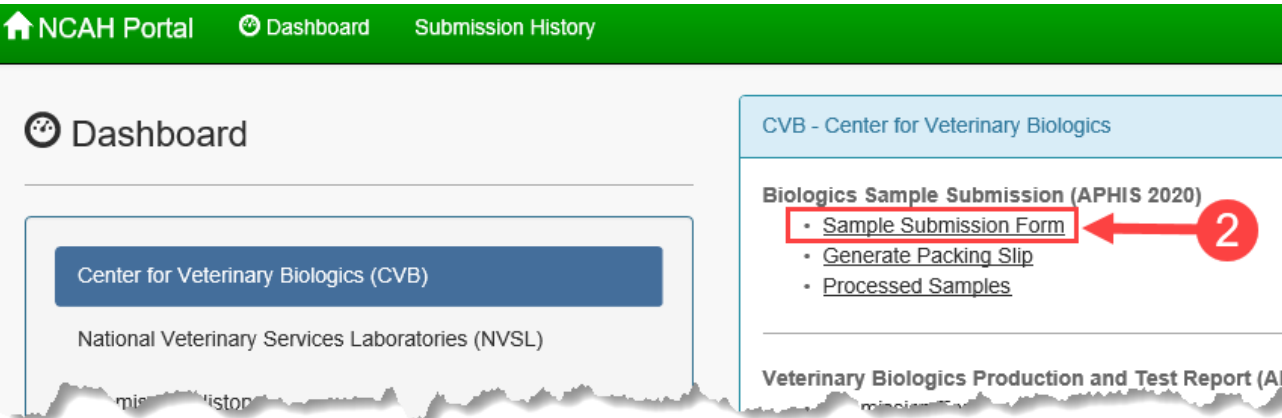
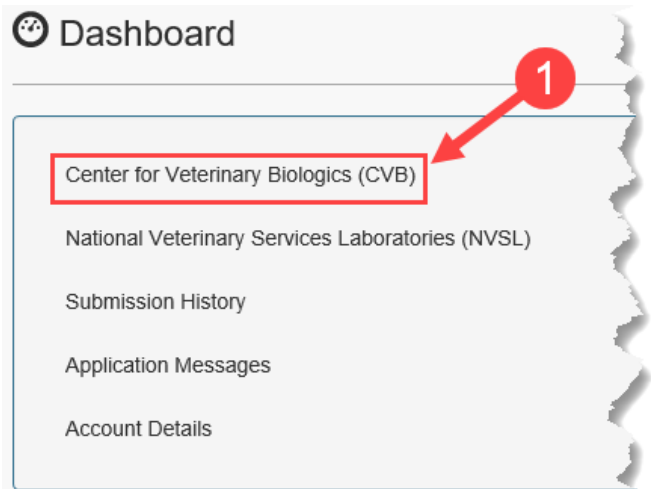
1. Updated screenshots were added and the [sample code field is now a required field when the Purpose is "Resubmission"](#)

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\* **Special Test Request (STR)** applies to samples pre-authorized by the CVB, such as those for prelicense testing, or testing of Master Seeds or Master Cells.

Only users with the **Sampler Role** can enter sample information and generate Packing Slips to be shipped with samples.

For all types of sample submissions, start by entering the CVB section of the Portal and then navigating to the Sample Submission Form.



You will be taken to the Biologics Sample Submission Form.

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SERIAL INFORMATION

Fields with a red asterisk (\*) are required.

Create - Shipment and Receipt of Biologics Samples (APHIS 2020)

[CVB Home](#) / Submission Form (APHIS 2020)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to provide an answer to this information if it does not affect your legal rights. The time required to complete this information collection is estimated to average 15 minutes per response, including reviewing the collection of information, gathering the data needed, and completing and reviewing the collection of information.

### Serial Information

<b>Auth Number</b>	3187	<input type="button" value="✕ Reset"/>	<b>Enter the Authorization Number/Special Test Request (STR) Number provided by the CVB</b>
<b>Establishment*</b>	999 - Your Firm, Inc.		
<b>Site Address*</b>	<input type="text" value="125 1st Street, Ames, IA 50010"/>		<b>Select appropriate address from the drop down list</b>
<b>Product Code*</b>	142120		
<b>Product Name</b>	Canine Parainfluenza Vaccine, Modified Live Virus		
<b>Serial Number*</b>	1234		
<b>Purpose*</b>	Resubmission		
<b>Sample Code*</b>	<input type="text"/>		

**Enter the Sample Code provided by the CVB**

**Auth Number** - Upon entry of the authorization number provided by CVB, fields will autopopulate based on the information entered by CVB upon creation of the Special Test Request\*

**For Serial or Subserial samples** - The Establishment number, name, Product Code, Product name, Serial Number, and Purpose will be 'Resubmission' or 'Prelicense'.

**For Master Seed samples** - The Establishment number and Establishment name, Master Seed identification, and Purpose will be 'Master Seed'.

**For Master Cell samples** - The Establishment number and Establishment name, Master Cell identification, and Purpose will be 'Master Cell'.

*\*If it appears that any of the information autopopulated is incorrect, contact the Reviewer assigned to your firm prior to submission.*

**Site Address** - Default is the manufacturer’s mailing address. All licensed sites will appear in the drop down list.

**Sample Code** - Required field that appears when Purpose is Resubmission. Only valid Sample Codes assigned by CVB for the specified Product Code and Serial Number can be entered.

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SAMPLE INFORMATION

Sample Information

Subserial?  Check the box if serial is considered by the manufacturer

Package Shipped With\* Type\*  
 Ice Pack Select from drop down menu ▼

Size\* Number of Containers\* Amount Per Container\* Type\*  
  Doses ▼

Sample Type\* Select from drop down menu  
 Final Bulk or Final ▼ Select from drop down menu

Contains Thimerosal?  Check the box if sample has Thimerosal (Merthiolate)

**Packaged Shipped With** - Samples shall be kept under refrigeration at 35°- 45°F (2° - 7°C) unless otherwise specified in the approved Outline of Production (9 CFR 114.11).

**Size -**

**Number of Containers** - See VSM 800.59 for guidance (9 CFR 113.3)

**Amount Per Container** - The number of doses/mLs/Units per container.

If more than one sample size is submitted, use the smallest volume for entry. However, multiple dose sizes submitted should be entered into the Remark Section.

If the volume is less than 1 unit, round the number up to 1. If the volume is not a whole number, but is greater than 1 (i.e. 10.5 mL), round down to the nearest whole number.

**Type** - Doses, mL Units. For diagnostic test kits, use units.

**Sample Type** - Final samples should be submitted in most cases, unless directed by the CVB.

**Contains Thimerosal?** - Utilize this check box if the product contains Thimerosal.

MISC.

Misc

Remarks Enter remarks if you have any.

Check box once complete  I agree that I've looked over this information and everything entered is true to my knowledge.

Click on Save button when done

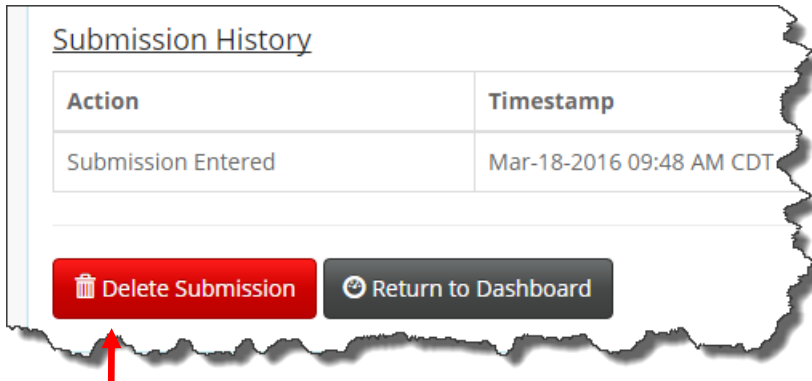
**Remarks** - Enter any applicable information not contained in the above fields, such as reagents that are being included in the shipment for testing. This information will be included in the packing slip as "Comments".

**Save** - Upon saving, the record must be printed and submitted to the CVB with the sample packaging to be submitted to the CVB (see [User Guide #8 - How to Generate Packing Slips for Biologics Samples](#) for details on this).

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### WHAT IF I MADE A MISTAKE?

If a record needs any corrections, it must be deleted and re-entered completely. The record may be deleted until it has been received by the CVB.



*Select to Delete the submitted form.*