Biologic Sample Submissions – (APHIS 2020) “Special Request”

Where were changes made in the July 15, 2025, version?

1. Updated screenshots were added and the sample code field now auto-populates for “Resubmissions” once the Special Test Request number provided by CVB is entered.

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

2. Updated screenshots were added and the sample code field is now a required field when the Purpose is "Resubmission"

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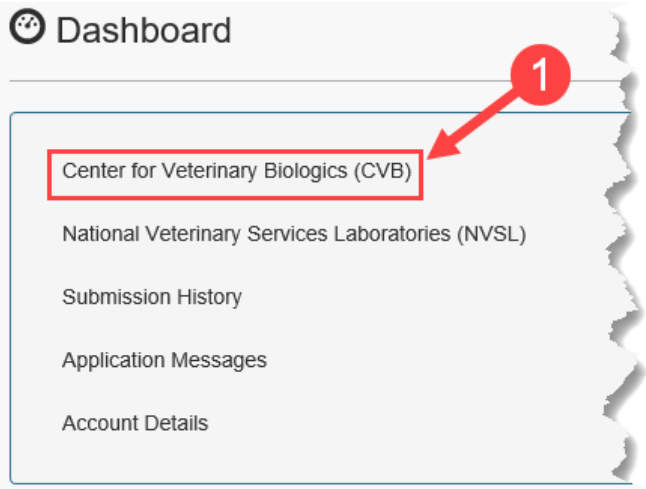
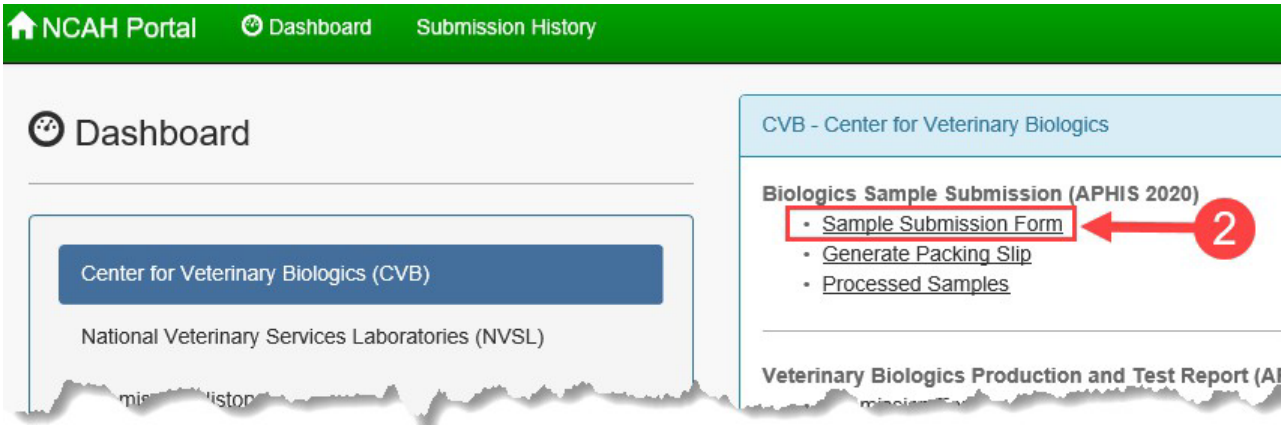
Special Test Request (STR) *applies to samples pre-authorized by the CVB, such as those for prelicense testing, or testing of Master Seeds or Master Cells.*

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 Center for Veterinary Biologics (CVB) section of the NCAH Portal and then navigate to the Biologics Sample Submission (APHIS 2020) section.



Click to open 'Sample Submission Form'



You will be taken to the Biologics Sample Submission Form.

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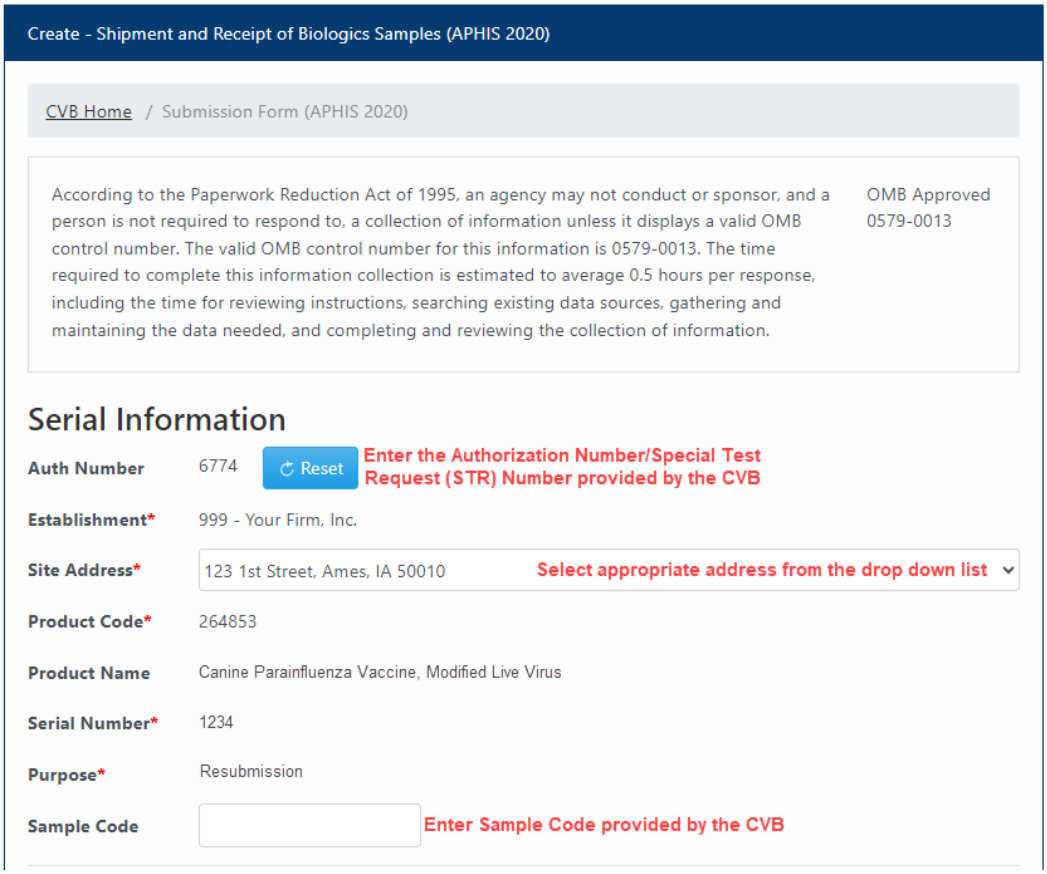
SERIAL INFORMATION

Fields with a red asterisk (*) are required.



Auth Number - Upon entry of the authorization number (STR number) provided by CVB, fields will auto-populate 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 any of the auto-populated information appears to be 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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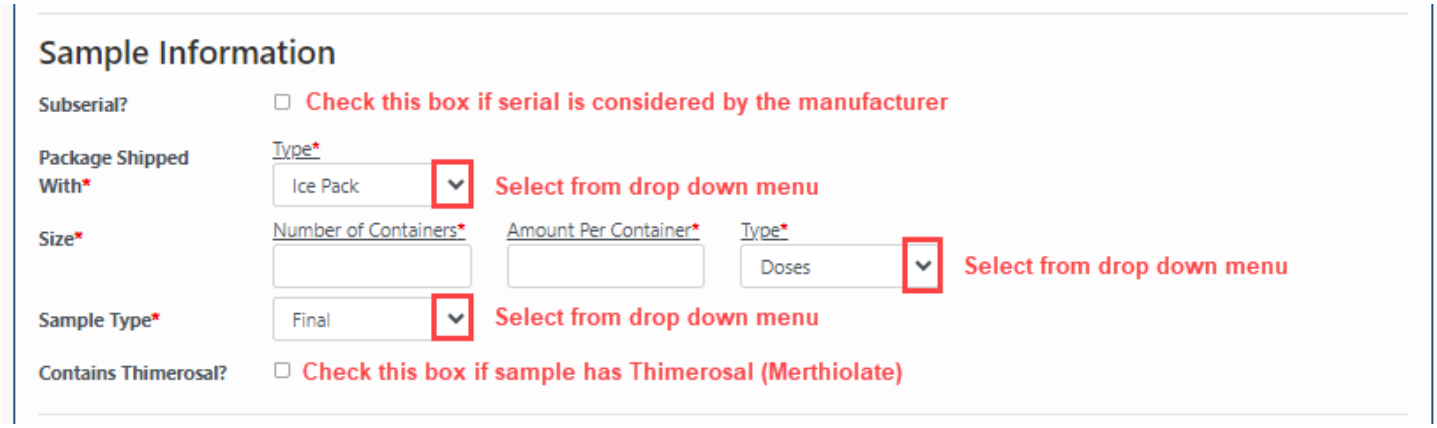
SAMPLE INFORMATION



Subserial? - Utilize this check box if serial is considered by the manufacturer.

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 (Merthiolate).

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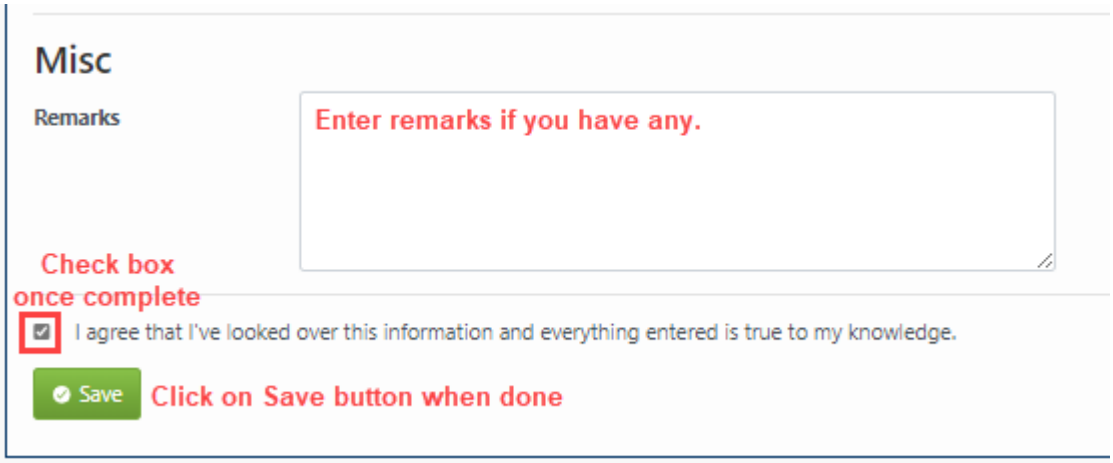
MISC.



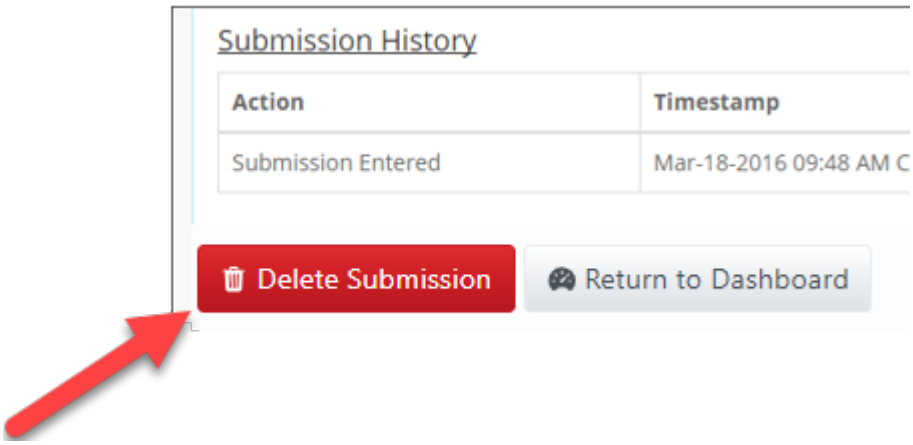
Remarks - Enter any applicable information not contained in the above fields, such as reagents that are being included in the shipment for testing. This information will be included in the packing slip as "Comments".

Utilize the check box to acknowledge "I agree that I've looked over this information and everything entered is true to my knowledge."

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).

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.



Click the 'Delete Submission' button to delete.