

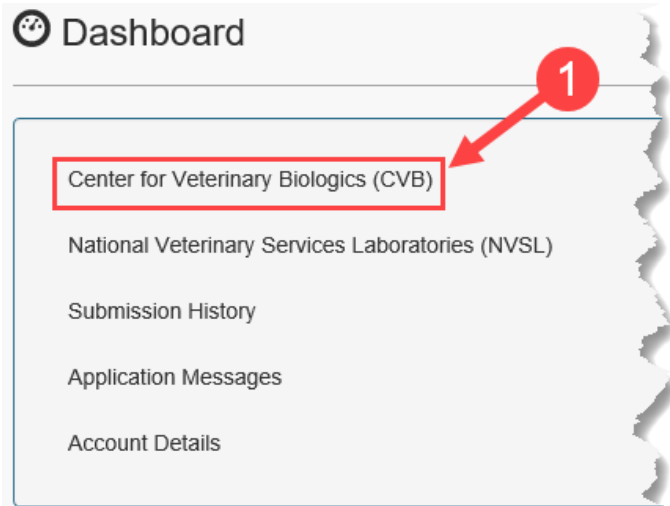
Biologics Sample Submissions - (APHIS 2020) "Routine Samples"

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

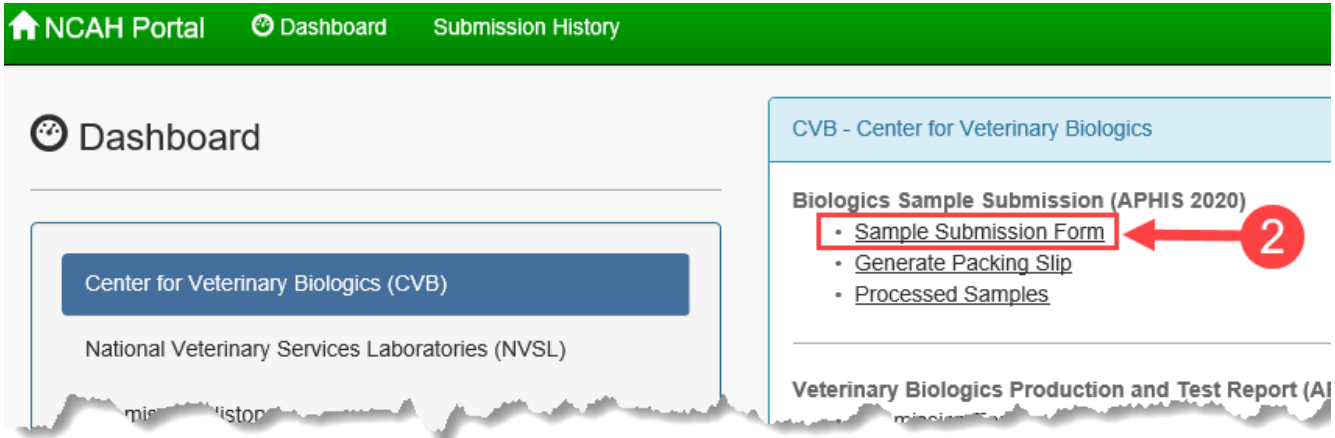
1. [Page 4, when "Resubmission" is selected for the Purpose, the Sample Code field is now required to be filled](#)

Biologics Sample Submissions - (APHIS 2020) "Routine Samples"

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



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



You will be taken to the Biologics Sample Submission Form.

Biologics Sample Submissions - (APHIS 2020) "Routine Samples"

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

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

Fields with a red asterisk (*) are required.

Serial Information

Auth Number	<input type="text"/>	- - - - -> Not needed for Routine Samples.
Establishment*	123 - Establishment Example ▼	->Select from drop-down menu, if different from default.
Site Address*	1234 - Site Address Example ▼	->Select from drop-down menu, if different from default.
Product Code*	123456 ▼	- - - - -> Select from drop-down menu.
Product Name	Product Name Example	- - - - -> This field will be auto-populated based on the selected Product Code.
Serial Number*	123ABC	- - -> Enter Serial Number, 20 alphanumeric characters only—NO SYMBOLS.

Serial Information

Establishment – This list is populated by the active manufacturers the user is assigned to within the CVB database.

Site Address – Defaulted to manufacturer's mailing address; however, this can be the address from where the samples are being shipped. All licensed sites will appear in the drop down list for domestic manufacturers.

Product Code – Select from the list of all available product codes for the manufacturer if not auto-populated.
 NOTE: Any product code, ever assigned to your firm will be listed here in an effort to make the system flexible to users' needs and situations (like information needed on a Destroyed serial for one that was recently terminated, or if there was a firm merger).

Product Name – This field will auto-populate based upon the selected product code.

Serial Number – This field is free text, however, the serial number listed here must match the Form 2008 submission exactly, or the records will not match up. Do not enter symbols.

Auth Number – This field is for the STR (Special Request authorization number) assigned by the CVB. For entry of samples for STR Auth Numbers, see the User Manual for [Sample Entry for a Special Test Request](#).

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Sample Information

Purpose* Type*

Subserial? -----> Check the box if applicable.

Package Shipped With* Type*
 -----> Select from drop-down menu.

Size* Number of Containers* Amount Per Container* Type*

 -----> Enter Number of Containers and Amount Per Container. -----> Select from drop-down menu.

Sample Type* -----> Enter if the sample is either Bulk or Final.

Contains Thimerosal? -----> Check the box if the sample has Thimerosal or Merthiolate.

Sample Information - Routine

Purpose –

- Select "Routine" when submitting routine post-license samples to the CVB that will be eligible to be selected for confirmatory (check) testing. Also, use this purpose when submitting samples that had previously been rejected by CVB.
- Select "Resubmission" when submitting samples of any serial or master seed or cell that has previously been submitted to the CVB for any reason.
- Select "Pre-license" when submitting samples for pre-license testing.

Sample Code – this field will only appear when "Resubmission" is selected for the Purpose. You will be required to enter a sample code when using this purpose; contact the CVB if you don't know the sample code to use. If testing was initiated by the CVB on routine testing, but more samples are needed to finish the testing, the CVB will contact the firm to request more samples to be resubmitted.

Subserial – Indicate if the serial is considered a subserial 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 (FILLED in each container) or Units (number of test kits). If the manufacturer has authorization for partial-fills (see VSM 800.206), a final container label used on the retention samples may not match the actual fill volume. In these cases, notate in the Remarks section the volume and doses/tests.

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

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Misc.

Misc

Remarks

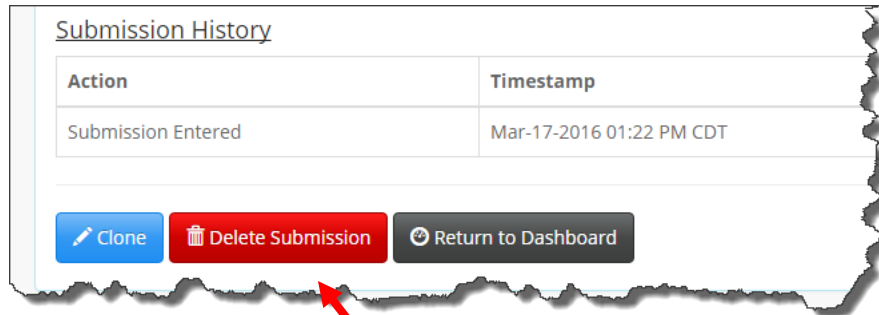
I agree that I've looked over this information and everything entered is true to my knowledge. —> *Check box once complete.*

—> *Select button to Save form.*

Remarks – Enter any applicable information not contained in the above fields. (i.e. who requested the resubmission of samples, additional doses sizes submitted to CVB).

Save—Upon saving, the record must be printed as a Packing Slip and submitted to the CVB with the sample packaging.

After saving the submission, you will be directed to the Shipment and Receipt Page.



Select to Clone the submitted form.

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

CLONING

Cloning - Cloning allows the user to copy fields from the submission form. Fields that are copied include: Product Code, Purpose, Shipment with Type, Number of Containers, Amount Per Container, Dose Type, Sample Type, Containing Thimerosal, and Remarks.

SUBMITTING THE SAMPLES TO CVB

For guidance on submitting the sample to CVB, see the User Manual for [Generating a Packing Slip for Shipment of Samples.](#)