

Section V testing at Alternate Locations

In general, it is expected that preparation of a licensed biologic, including Section V testing, be completed by the manufacturer in licensed facilities. In certain instances, however, unlicensed third party vendors may be approved to perform specific tests, or testing may be performed at sites other than the manufacturing site. Products for use in minor species may be tested at an alternate location. For example, if a manufacturer does not have the facilities or expertise to conduct Section VB safety testing in fish, Section VB safety testing may be done by a third party vendor.

Third party vendors may be considered when the primary Section V test is conducted by the firm, but a secondary, confirmatory test is also allowed that is beyond the expertise of the firm.

[REDACTED] . It may also be considered for tests with special requirements, such as the handling of human pathogens. This would be on a case by case basis.

Guidance and Regulations regarding testing are included in:

Veterinary Services Memorandum 800.115, Potency Testing by Unlicensed Facilities
9CFR 113.5, 114.3, 114.7, 115.1, 116

Location of testing

See VSM 800.115 for guidance regarding potency testing by unlicensed facilities under “contract testing” It should be noted that in lieu of a testing laboratory being listed on the Establishment License, the product being potency tested will carry a restriction on the product license. A product licensing plan is required.

[REDACTED]

[REDACTED]

It is also possible to consider performing a test at a licensed facility location other than the manufacturing site. This location may be a research laboratory at the firm, or at a University. This site does not necessarily have to be owned by the firm, but may be considered a licensed facility and listed on the establishment license. The location must be disclosed prior to approval. Facility documents of the site must be submitted, as well as a permission letter from the location allowing Center for Veterinary Biologics Inspection and Compliance (CVB IC) to inspect the facilities, to be in compliance with 9 CFR 115.1(a). In performing Section V testing in the same facility as research, the biggest issue is that the firm may put their product at risk for failure, possibly due to cross contamination.

During the inspection of the site, IC would look for appropriate means of mitigating cross contamination, proper treatment of effluent, personnel training, and operations.

Also, the organisms being used at the facility must be disclosed. This could be a part of the facility document. Currently it is understood all licensed facilities need to have permission to bring in organisms from their reviewer under 103.1. For testing sites at alternate locations, you may consider allowing the site to provide a quarterly list of organisms that they are working with to PEL, and annual updates to the facility documents filed in IC.

If the site is deemed acceptable, it will be added to the establishment license of the firm manufacturing the biologic. Copies of the test results from the site must be maintained at the manufacturing site and be available upon inspection, in compliance with 9 CFR 113.5(c) and 113.6. Alternate testing sites should be located within the regulatory jurisdiction of the United States

[REDACTED]. Alternate testing sites to be included on the establishment license (ie not "contract testing") should only serve one licensed establishment, to be in compliance with 9 CFR 114.3. An exemption to 9 CFR 114.3 must be granted before allowing a third party vendor to serve as a testing site for more than one establishment. Check LSRTIS to see if the third party vendor is conducting similar testing for another firm. APHIS Forms 2007 for employees at the alternate site that will be involved in testing licensed product must be reviewed and approved by the CVB. The alternate site must store samples and perform testing according to the processes in the Outline of Production.

Information to be included in the Outline of Production when Section V testing is performed at a site other than the manufacturing location

The Outline of Production should include the following information.

- Testing facility Name and Address
- Conditions for shipment of product to testing site including number of samples per test, volume, mode of transportation, and environmental conditions (temperature, insulated package, etc).
- Detailed description of test method (this information may be described in a Special Outline and the Outline of Production may refer to the Special Outline)
- Approval date of CVB to allow testing at the alternate site

[REDACTED]

