

Diagnostic Test Kits & Reagents Derived from Bovine Brain

Japan does not require APHIS certification for diagnostic test kits derived from bovine brain.

Prior to export, the importer should demonstrate (via commercial documents) to the relevant AQS* authorities that the products to be imported to Japan are both:

1. Either (one of the following):

- packaged box kits; or
- packaged growth media; or
- positive/negative controls that are already dispensed as a single dose

AND

2. Either (one of the following is true)

- Falls under the category of pharmaceuticals, quasi-drugs or cosmetics in accordance with the act on securing quality, efficacy and safety of pharmaceuticals, medical devices, regenerative and cellular therapy products, gene therapy products, and cosmetics (Law No. 145 of 1960)

OR

- Is in circulation as a commodity in the country of origin, and the processing steps are obvious with the catalogue etc.,- if this option is chosen the commercial documentation such as instruction manual and product catalog or other commercial documentation (such as manufacturer's statement), must confirm:
 - That the product for diagnostic testing is packaged in a way to preclude use as feed or fertilizers; AND
 - That the product for diagnostic testing is distributed for sale to laboratories and research centers such as universities in the country of production; AND
 - The manufacturing process of the product for diagnostic testing (must be clearly shown).

When certification is required: If the discussion between the importer and the AQS station cannot demonstrate one of the items under number 2 above, then a VS Form 16-4 certificate from APHIS is required, but may only contain the following text (noted in blue) in the "ADDITIONAL DECLARATION" area of the VS Form 16-4:

This office has on file a notarized affidavit from [insert name of company here] verifying the accuracy of the statements below. I, the endorsing official listed below, have read the notarized affidavit referenced above, and to the best of my knowledge and belief these statements are true.

The product described below was produced through the following processing steps: [insert processing steps- limited to verifiable critical limits].

*To find contact information for Japanese AQS authorities, please go back to the previous page and select:

When a consignment is on hold in Japan [Steps to follow](#) (includes contact information for Japanese Animal Quarantine Service offices)