

## **Diagnostic Test Kits Containing Bovine Serum and Bovine Brain**

Bovine brain components must be sourced from countries that Japan considers free of BSE. In these cases, export certificates from the government of the country of origin must be provided- and these export certificates must include all applicable statements. Each facility that handles each animal origin component in the United States must provide notarized affidavits.

The following statements only should appear 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.*

*The product has been produced under sanitary conditions.*

*All bovine- origin ingredients were collected from clinically healthy cattle. The bovine origin pituitary glands from which the product is derived were imported from [insert country] a country that has no record of BSE occurrence, and not commingled with any other ruminant products other than bovine serum.*

NOTE- in cases where bovine brain components other than the pituitary gland are utilized, the name of those components may substitute for “pituitary glands.”