



USDA-licensed products

Help improve efficiency and confidence in results

The USDA Animal and Plant Health Inspection Service (APHIS) regulates veterinary biologics (vaccines, bacterins, antisera, diagnostic kits and other products of biological origin) to help ensure that the veterinary biologics available for the diagnosis, prevention and treatment of animal diseases are pure, safe, potent and effective. The APHIS Center for Veterinary Biologics (CVB) carries out this work focusing on enforcement of the Virus-Serum-Toxin Act (VSTA).

USDA-licensed products are:

- Manufactured by qualified operators in a controlled environment from an inspected, approved facility
- Manufactured with qualified raw materials using validated processes, and monitored for consistent serial-to-serial performance
- Validated in the laboratory and in the field, and found to be suitable for the intended purpose
- Reviewed by CVB prior to serial release
- Reviewed by CVB for approval of material/process changes
- Subject to post-market surveillance

Benefits

- USDA-licensed test kits help simplify the effort to comply with accreditation requirements
- Stringent standards help ensure quality of product and confidence in results
- We are partnering with laboratories to utilize our USDA-licensed tests in standardized workflows

USDA-licensed products

- VetMAX-Gold BVDV PI Detection Kit
- VetMAX-Gold SIV Detection Kit
- VetMAX-Gold SIV Subtyping Kit
- VetMAX-Gold Trich Detection Kit
- VetMAX-Gold AIV Detection Kit

What are the criteria for the approval of a USDA-licensed product?

Focus areas for USDA approval for veterinary diagnostics

- Production facility
- Test kit performance
- Test kit production and commercialization

Facility requirements

- Plot plans, blueprints and legends
- Fraction list/risk assessment
- Personnel qualifications
- Serial release
- Adverse event reporting
- Facility inspections

Performance requirements

- Field sensitivity and specificity
- Field repeatability and reproducibility
- Analytical studies (e.g., limit of detection, inclusivity, exclusivity)
- Stability

Production and commercialization

- Intended use, limitations
- Raw materials produced in-house or sourced from qualified suppliers
- Standardized/validated manufacturing processes
- Serial release criteria
- Test kit configuration
- Product labeling

How we have worked with the USDA

Thermo Fisher Scientific implemented a process with the USDA to provide additional products to help meet the increased demand during AIV outbreaks. In case of an AIV outbreak, we can repackage existing kits of Applied Biosystems™ VetMAX™-Gold SIV Detection Kit into Applied Biosystems™ VetMAX™-Gold AIV Detection Kits to meet the increased demand.

Ordering information

Product	Type	Quantity	Cat. No.
VetMAX-Gold BVDV PI Detection Kit	Real-time PCR	100 reactions	4413938
VetMAX-Gold SIV Detection Kit	Real-time PCR	100 reactions	4415200
VetMAX-Gold SIV Subtyping Kit Real-time PCR	Real-time PCR	100 reactions	4485541
VetMAX-Gold Trich Detection Kit	Real-time PCR	100 reactions	4483869
VetMAX-Gold AIV Detection Kit	Real-time PCR	100 reactions	4485261

Find out more at thermofisher.com/animalhealth