United States Department of Agriculture
Marketing and Regulatory Programs
Animal and Plant Health Inspection Service
Veterinary Services

VS Guidance 15200.2

Approval of Laboratories to Conduct Competitive Enzyme-Linked Immunosorbent Assay (cELISA) Testing for Equine Piroplasmosis

1. Purpose and Background

This document describes the criteria and process to approve laboratories to conduct cELISA testing for *Theileria* (formerly *Babesia) equi* and *Babesia caballi*, the etiologic agents of equine piroplasmosis (EP).

In October 2009, State and Federal veterinarians identified *T. equi* infection in 413 horses epidemiologically linked to a Texas ranch where the veterinarians confirmed the detection of natural tick-borne transmission over many years. Since 2009, subsequent movement and surveillance testing identified at least 456 EP-positive horses unrelated to the Texas ranch outbreak. These horses are confined mainly to the Quarter Horse racing population and horses imported from other countries before 2005 using the complement fixation test for EP. As a result of these findings, industry-driven movement and surveillance testing for EP is continuing nationwide with more than 390,000 U.S. equids tested to date.

In response to these EP-positive findings, many States and equine events established EP testing requirements for inter- and intrastate movement. The recommended test to identify EP infection in nonclinical equids is the cELISA for *T. equi* and *B. caballi.*

In 2010, the Animal and Plant Health Inspection Service (APHIS) Veterinary Services unit (VS) approved laboratories other than the National Veterinary Services Laboratories (NVSL) to conduct the cELISA for inter- and intrastate movement purposes only. Previously, only the NVSL could conduct the cELISA for *T. equi* and *B. caballi* for export purposes. However, in response to requests from approved laboratories, VS allows them to conduct export testing using the cELISA for countries that will accept results from a laboratory other than the NVSL.

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2. Document Status

A. Review date: 2/20/2023.

B. This document replaces Veterinary Services Guidance No 15200.1, which is cancelled. The substantive content of the document is the same as that of the former memorandum.

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3. Reason for Reissuance

VS is reissuing this guidance to update internal structuring and responsibility changes.

4. Authority and References

A. Authorities (*Code of Federal Regulations* (CFR) and U.S. Code (U.S.C.)):
- 7 CFR 371.4
- 7 U.S.C 8301-8317
- Homeland Security Presidential Directive-7 (HSPD-7)
- Homeland Security Presidential Directive-9 (HSPD-9)

B. Definitions

Equid: Animals of all equine species, including horses, donkeys, mules, zebras, and hybrids.

5. Audience

VS employees, other Federal and State agencies, laboratories, and members of the public.

6. Guidance

A. Criteria for Laboratory Approval and Maintenance of Approval

1) VS will only consider laboratories currently approved as part of the National Animal Health Laboratory Network (NAHLN). Approval will authorize the laboratory to conduct the cELISA on nonclinical equids for inter- or intrastate movement. Approved laboratories may also test horses for export to countries not requiring the NVSL to conduct the testing and that require only the cELISA. Laboratories must also follow the procedures below to maintain approval.

a. Any equine serum sample identified as non-negative at an approved laboratory must be forwarded within one (1) business day to the NVSL for confirmatory testing.

b. Any sample submitted from an equid with reported compatible clinical signs of EP must be forwarded within one (1) business day of receipt to the NVSL for testing. The sample will not be tested at the NAHLN laboratory.

c. Any sample submitted from a known EP-positive or EP-suspect equid or from equids under State or Federal investigation for possible exposure to an EP-positive or EP-suspect equid must be forwarded to the NVSL for testing within one (1) business day of receipt. The sample will not be tested at the NAHLN laboratory.

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d. The laboratory will report summaries of all EP tests conducted at the NAHLN's request.

2) Approval will require specific training and proficiency tests as the NVSL directs. The NVSL will also base laboratory approval consideration on the State's need for cELISA testing. The NVSL will consider each of the following circumstances in assessing need:

a. The presence of an ongoing EP outbreak in the State.

b. The existence of an active EP surveillance program in the State.

c. The existence of a region within the State with documented natural transmission of EP (either current or former).

d. An upcoming significant international equestrian event in the State for which APHIS has approved temporary import of EP-positive horses and for which U.S. horses may be tested before participating.

3) The NVSL will review approved laboratories annually. Laboratories maintain approval as long as they meet the criteria above or complete a sufficient amount of testing (approximately more than 1,000 tests per year).

B. Approval Process

1) The NAHLN laboratory director makes initial laboratory approval requests to the Area Veterinarian in Charge (AVIC) in the requesting laboratory's State.

2) The AVIC, with the State animal health official's concurrence, forwards the request to the NVSL for consideration.

3) If the laboratory meets at least one of the criteria in 6.A.2), the NAHLN coordinator, as well as personnel from the NVSL, the Equine Health Team, and the relevant District Office, will agree to approve it for cELISA testing.

4) The laboratory must complete personnel training, proficiency testing, laboratory inspection, and other preparation as the NVSL requires as part of the approval process before it can begin testing. The AVIC gives all requirements to the laboratory upon initial approval. These activities are also necessary to maintain approved status.

7. Inquiries

Please direct any inquiries to the NVSL at (515) 337-7568 or to the Equine Health Team at (970) 494-7391.

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