Equine Health Team, Fall 2019

Outline: Laboratory Approval to Conduct EIA testing - VSG 15201.1

Guidance is Effective upon release 11 OCT 2019

This is a summary; please consult the guidance document itself!

1. **What are the general requirements to be an approved EIA testing laboratory?**
    a. Provide and maintain adequate and appropriate facilities.
    b. Provide NVSL trained, technical personnel, who have successfully completed individual proficiency test(s), to perform official EIA testing.
    c. Accept only samples submitted by a Category II Federally accredited veterinarian, authorized in the State where the sample was obtained, or a State or Federal official.
    d. Accept only submissions with an accurate and complete official test form (VS 10-11).
    e. Conduct all testing according to protocol: NVSL, test kit literature or VSG 15201.1.
    f. Use only diagnostic test kits that have been approved by the USDA.
    g. Submit all non-negative samples to NVSL for confirmation (those testing positive, suspect, discrepant, or equivocal).
    h. Conduct all EIA testing as official testing; no screening, preliminary or retesting.
    i. Meet annual laboratory proficiency (check) test requirements, per NVSL protocols and deadlines.
    j. Expect to perform at least 500 EIA tests per year.
    k. Promptly report test results to State and Federal officials.
    l. Submit monthly summary data & provide adequate record keeping.
    m. Pass an annual inspection - required to maintain approval.
    n. Maintain current contact information and respond to official requests and inquiries.
    o. Have a signed, up-to-date, Director's Agreement (VS 10-15) on file with VS.

2. **What is the process to apply to become an approved EIA lab?**
    a. The applicant submits "*Application to Conduct EIA Testing*" (VS 10-16) to AVIC.
    b. AVIC/SAHO make consensus decision to deny, or approve and proceed (as below).
    c. AVIC/SAHO review the applicant Lab Director's responsibilities, Director acknowledges regulatory responsibilities and signs "*Agreement to Conduct EIA Testing*" (VS 10-15).
    d. AVIC/SAHO inspect applicant lab facilities and complete the checklist (Attachment 1).
    e. AVIC/SAHO must concur and submit to Director, NVSL a joint "*Memo of Recommendation and Justification*", and include the VS 10-15, 10-16 and Attachment 1.
    f. The applicant is then eligible to submit: "*Application for Training"* (VS 4-11) to the AVIC for review and joint AVIC/SAHO approval of the **individual** designated for training.
    g. Applicants/AVIC contact NVSL to schedule training; NVSL will inform when slots are available.
    h. Applicant attends & completes NVSL training, passes individual proficiency test (PT) after which NVSL issues a certificate authorizing the **individual** to conduct EIA testing.
    i. Follow up laboratory inspection (as needed, depending on which test kit was chosen by lab and what additional equipment is needed and purchased by lab), complete checklist.

j. Applicant lab orders one EIA test kit from manufacturer and a PT kit from NVSL.
k. **Laboratory** wide Proficiency Test – conducted at applicant lab and submitted to NVSL.
l. Once **laboratory** PT is passed, NVSL grants final approval and lab can begin EIA testing.
m. NVSL informs the EIA kit manufacturers the new lab is authorized to purchase EIA kits.

3. What are the laboratory's test reporting requirements?

a. All non-negative samples (i.e. positive, discrepant or equivocal) must be referred to NVSL for confirmation.
b. The samples being referred to NVSL must be reported to the AVIC & SAHO immediately.

4. What are the laboratory's monthly data submission requirements?

a. Summary monthly data must be submitted and must include:
    i. State of sample origin
    ii. Result NEG/POS
    iii. Test type: ELISA/AGID
b. Must be sent electronically to SAHO and Equine Health Team (EHT) (equine.health@usda.gov) on Excel spreadsheet provided by EHT.

5. What defines an official EIA test form?

a. The VS Form 10-11 is the official Federal EIA test form and serves as the reference standard for all other official, VS approved, EIA test forms.
b. All other official EIA test forms must be approved by USDA VS.
c. Approved EIA forms must have identical information and data fields to the VS 10-11.

6. How should an animal be identified on an EIA test form?

a. All EIA test forms must include a written description: name, age, breed, color, gender, markings (e.g., brands, tattoos, scars, etc.)
b. All unique and permanent forms of identification that are present must be recorded on the form: including, but not limited to brands, tattoos, scars, whorls, electronic identification/microchip number(s) and biometric identifiers.
c. Additional Identifiers:
    i. Line drawings/diagrams.
    ii. High quality photographs.
    iii. Breed registration number.

7. Who can submit an EIA sample to an approved lab?

a. Only a Category II USDA accredited veterinarian, who is authorized to perform accredited duties in the State where the animal was sampled, or a State or Federal animal health official.

8. How do I become Category II accredited and authorized in a particular state?

a. National Veterinary Accreditation Program webpage: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap .
b. Contact your APHIS-VS District office: https://www.aphis.usda.gov/animal_health/contacts/field-operations-districts.pdf .
a. Contact your State Animal Health official: https://www.usaha.org/saho .

9. Where can I obtain more information about EIA?

a. APHIS's EIA webpage: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/horse-disease-information/eia/equine-infectious-anemia .
b. Equine Disease Communication Center: http://www.equinediseasecc.org .
c. Your local veterinarian https://aaep.org/horse-owners/get-dvm .

10. Who can I contact if I have further questions?

a. Your State Animal Health Official and/or your APHIS-VS District office
b. Direct questions on the laboratory approval process to the NVSL Diagnostic Virology Laboratory NVSL.Coggins@usda.gov, (515) 337-7551, FAX (515) 337-6508.
c. Other questions can be directed to rory.o.carolan@usda.gov, (301) 851-3558 or angela.m.pelzel-mccluskey@usda.gov, (970) 494-7391.