Attachment 1
Inspection Checklist

Laboratory Name:	
Date of Inspection:	
Name and Title/Affiliation of Inspector:	
State Representative (if present):	
Laboratory Director:	
Director's Representative (if applicable):	
Physical Address of Laboratory (street, city, State, and ZIP code (not P.O. box):	
Mailing Address of Laboratory (if different):	
Shipping Address of Laboratory (if different):	
Laboratory Phone #:	
Laboratory Fax #:	
Laboratory Director's Email Address:	
Laboratory/Alternate Email Address:	

List or attach a list of all NVSL-trained personnel currently conducting EIA tests at the laboratory and the date on which NVSL authorized each person.

Name	Date Authorized

List or attach a list of all in-house trained personnel currently conducting EIA tests at the laboratory and the date on which NVSL authorized each person (applies to State, Federal, university, or military laboratories ONLY).

Name	Date Authorized

Laboratory Inspection Checklist for Equine Infectious Anemia (EIA) Testing

Section	Item	Yes	No	Notes
Building Facility	The building is in good repair and provides a professional appearance inside and outside.	Y	N	
	The building has adequate and functional doors, windows, and screens that maintain a clean and climate-controlled environment appropriate for a laboratory.	Y	N	
	The building has clean, functional restrooms.	Y	N	
	The building appears free of rodents, insects, and other pests.	Y	N	
	Refuse is properly contained, removed and is handled in accordance with local ordinances.	Y	N	
Laboratory Facility	There is a separate and dedicated room reserved for laboratory use where the EIA testing is conducted, with floor-to-ceiling walls and doors delineating that room. The public is denied access to the laboratory space. The laboratory space may also be used to store pharmaceuticals, biologics, or clean medical supplies, for example, but cannot be used for any animal use, eating meals, or other use that could create dust, dirt or excessive traffic; however all other standards will be maintained. While EIA testing is being conducted there will be no non-laboratory concurrent use.	Y	N	
	Adequate open, clutter-free bench space (at least 5 feet) is evident. There is hot and cold running water with a sink in the laboratory area.	Y	N	
	Bright white light is available to the bench space. For AGID testing the facility must be capable of dimming or restricting ambient/daylight to properly read the results.	Y	N	

Section	Item	Yes	No	Notes
	Laboratory temperature is maintained at all times between 68° and 77 °F (20° and 25 °C) and/or an incubator is available to maintain these temperatures for the testing, when required. The laboratory facility is capable of preventing reagents and supplies from cold damage or overheating in accordance with label instructions.	Y	N	Laboratory temperature at time of inspection: ___°F
	Mobile and satellite laboratories: When operating or supplied with reagents, are equipped with a thermometer capable of high/low temperature memory/recording. A weekly high/low temperature record/log is kept.	Y	N	Attach or copy the temperature log.
	Laboratory and laboratory equipment is clean, functional, and properly stored; records indicate it is properly maintained in accordance with manual of operations.	Y	N	
	Refrigerator is functional, properly maintained, and equipped or supplemented with a thermometer capable of high/low temperature memory/recording, and is labeled for lab use only; no food or drink. A weekly high/low temperature record/log is kept.	Y	N	Attach or copy the refrigerator temperature log.
	Clean laboratory clothes (coats) are available and required to be worn.	Y	N	
	There is no evidence of prohibited activities in the laboratory area, such as: eating, drinking, applying cosmetics, handling contact lenses, or storage of food. Appropriate signage is clearly visible.	Y	N	
Laboratory Supplies and Equipment	**The following equipment must be available and functioning properly for the agar gel immunodiffusion (AGID) test:**			
	High intensity laboratory light that can be focused for reading AGID plates.	Y	N	

Section	Item	Yes	No	Notes
	Blinds on windows or separate room so light can be reduced to read AGID plates.	Y	N	
	Medium seven-well immunodiffusion template cutter, a center well surrounded by six evenly spaced wells. Wells are 5.3 mm in diameter and 2.4 mm apart.	Y	N	
	A balance designed and functioning to read with accuracy to plus or minus 0.1 gram; maintained and calibrated in accordance with operations manual.	Y	N	
	Method to remove agar plug (such as a vacuum pump).	Y	N	
	Equipment to make agar: Graduate measures, flasks, and additional appropriate glassware.	Y	N	
	Source of heat for agar preparation (microwave, hot plate, autoclave).	Y	N	
	Method for protecting from disturbance and incubating AGID plates on test (a room temperature incubator will suffice).	Y	N	
	Clean or new pipettes for delivery of reagents to wells.	Y	N	
	Distilled water and chemicals for buffer (sodium bicarbonate, boric acid, distilled water).	Y	N	
	Noble agar.	Y	N	
	Disposable 60 mm or 100 mm petri dishes.	Y	N	
	Materials or equipment to accurately measure pH within 0.2 pH unit.	Y	N	
	The following equipment must be available and functioning properly for the enzyme-linked immunosorbent assay (ELISA) test:			
	Incubator (if 37 °C incubation is required for the ELISA test used), functioning and properly maintained in accordance with operations manual.	Y	N	
	Wash bottles, pipetting devices, and plate holders.	Y	N	
	ELISA washer and reader (optional).	Y	N	

Section	Item	Yes	No	Notes
	Clean or new micropipettes and appropriate tips to deliver reagents to wells.	Y	N	
	Pipettes must be properly calibrated a minimum of every 12 months, preferably every 6 months.	Y	N	
	Maintain pipette calibration records.	Y	N	Attach calibration record log.
Control of Specimens and Reporting	**(Only applicable for approved laboratories)**			
	Laboratory should not be accessible to the general public during testing.	Y	N	
	Records indicate the laboratory assigns an accession number with unique identification (animal name) to each sample. The specimen identity is maintained on the sample, worksheets, on the petri dish and ELISA plates/strips. The accession number is recorded on the official EIA reporting form.	Y	N	Inspector will trace a recent random sample through entire process and verify accountability and document sample number and compliance.
	Test worksheets include appropriate and complete information, including accession number, animal and sample identification, lot numbers and expiration dates of reagents used in the test, date/time of test start, identity of technicians setting up and completing test, and date/time of test completion.	Y	N	
	Maintenance of test worksheets and accession paperwork for a minimum of 24 months. The lab must provide the worksheets at inspection or NVSL request.	Y	N	
	Specimens not appropriately identified are not tested.	Y	N	

Section	Item	Yes	No	Notes
	Records indicate only specimens with properly filled official EIA submission forms (with name of the owner, name, address, and accreditation number of the submitting veterinarian, location of animal at the time the test sample was obtained, complete animal identification, and signed by the submitting veterinarian) are tested/processed. A minimum of 1 random accession per month for the previous 12 months will be reviewed for completeness and compliance and accession numbers recorded.	Y	N	
	The test results for each sample are recorded on a worksheet which should be made available for review.	Y	N	
	The results are recorded on the reporting form with a copy kept in the laboratory. Results are reported only as negative, positive, or no test.	Y	N	
	Records indicate all positive, equivocal, or discrepant samples are forwarded to NVSL. If a non-negative result was found since the last inspection, the inspector will trace a sample and document NVSL confirmation and appropriate notifications to Federal and State officials.	Y	N	
	Records indicate all tests are reported regardless of results. No unofficial EIA tests are performed to determine the status of the animals before the "official" test is performed. **Each and every EIA test is an official test.**	Y	N	

Section	Item	Yes	No	Notes
	On a review of reports of test results they include the name, city, and State of the laboratory, the type of test performed, and the handwritten signature (or secure electronic signature) of the technician who performed the test. Stamped or perforated signatures are not in use. The technician's initials unequivocally identify that person. All laboratory information and signature/initials are legible on all copies of the official test form. A minimum of 1 random accession per month for the previous 12 months will be reviewed and documented for compliance.	Y	N	

	Records indicate official test results and summary data are reported to the State and/or Federal animal health officials within the time specified by these officials.
	• Non-negative test results were reported within 24 hours to:
	  ○ SAHO where the animals were sampled and where laboratory is located.
	  ○ AVIC where the animals were sampled.
	  ○ VS Equine Health Team via email.
	• Negative test results were reported monthly to the SAHO where the laboratory is located (as requested or required) and the SAHO where the animals were sampled (as requested or required).
	• Negative test results were reported monthly to the SAHO in the State where the animals were located.
	• Monthly summary data is being reported to the SAHO and the VS Equine Health Team.
		Y	N	

	Records or inspection indicate specimens are held for at least 30 days after results are reported; either refrigerated whole blood or frozen serum with clot removed.	Y	N	Document the dates on a representative number of samples currently stored.

Section	Item	Yes	No	Notes
EIA Reagents	**(Only available to approved laboratories)**			
	Only reagents licensed by APHIS or supplied by NVSL are to be used. Both unopened and open/partially used reagents must demonstrate current expiration dates and be properly stored/refrigerated in accordance with label directions.	Y	N	Record lot numbers and expiration dates on current reagents or a representative sample.
	Unused or outdated reagents, other chemicals and supplies, and the inoculated EIA AGID or ELISA plates must be appropriately discarded according to local rules and regulations.	Y	N	
Test Procedure	Appropriate SOPs are available in the lab.	Y	N	
	Records indicate the procedures outlined in the appropriate test protocol are being followed.	Y	N	

ADDITIONAL REMARKS

Laboratory is: ☐ Satisfactory ☐ Unsatisfactory (check one)

Inspector's Name, Signature, and Date

Laboratory Director's Name, Signature, and Date

Laboratory Director's Representative Name (if not same), Signature, and Date

Inspector/Federal VMO: Inspection copies to the following; check when completed:

- ☐ Laboratory Director/Representative
- ☐ Diagnostic Virology Laboratory, NVSL, Ames, Iowa
- ☐ State Animal Health Official
- ☐ Federal District Office
- ☐ Copy uploaded to EMRS

Estimated date of next laboratory inspection: _____