

Identification of Select Agents in Diagnostic Labs

Purpose

This Standard Operating Procedure (SOP) describes the process that personnel working in diagnostic labs must follow if they identify Select Agents and Toxins as a part of their diagnostic activities. The use of Select Agents and Toxins is highly regulated because of the threat to human, animal and/or plant health.

1. General Information

- 1.1 The select agents and toxins that must be reported are listed in Appendix A.
- 1.2 Identification of the following agents require direct reporting to State Veterinarian's Office and/or USDA Area Veterinarian in Charge (AVIC) when diagnosed or suspected:
 - African Horse Sickness
 - African Swine Fever
 - Anthrax
 - Avian Infectious Laryngotracheitis
 - Babesiosis (*Babesia bovis*, *B. bigemina*)
 - Brucellosis
 - Cattle Tick Fever
 - Contagious Equine Metritis
 - Dourine (*Trypanosoma equiperdum*)
 - Eastern Equine Encephalomyelitis (EEE)
 - Equine Infectious Anemia (EIA)
 - Equine Viral Arteritis
 - Erysipelas
 - Foot and Mouth Disease
 - Glanders - *Burkholderia mallei* (formerly *Pseudomonas mallei*)
 - Heartwater (*Cowdria ruminantium*)
 - Highly Pathogenic Avian Influenza (Fowl Plague)
 - Hog Cholera (Classical Swine Fever)
 - Newcastle Disease (Exotic)
 - Paratuberculosis - Johne's Disease
 - Pseudorabies
 - Pullorum - Fowl Typhoid
 - Q Fever (*Coxiella burnetii*)
 - Rabies - coordinated with DHEC
 - Rinderpest
 - Scrapie
 - Screwworm (*Cochliomyia hominivorax*)
 - Tuberculosis
 - Venezuelan Equine Encephalomyelitis (VEE)
 - Vesicular Exanthema
 - Vesicular Stomatitis
 - West Nile (WNV) Encephalitis

Western Equine Encephalomyelitis (WEE)
OIE Listed Diseases (formerly A & B lists; found here:
<http://www.oie.int/animal-health-in-the-world/oie-listed-diseases-2013/>)

All foreign and exotic diseases and parasites of animals,
including birds

- 1.2.1 The State Veterinarian may declare other diseases as reportable.
 - 1.2.2 Reporting of agents in section 1.2 shall supersede reporting in section 1.3 so long as the state agency is in contact with the federal agencies.
 - 1.2.3 The person reporting the identification of the select agent must confirm 1.2.2 and the time and date must be noted.
- 1.3 Identification of the following select agents and toxins from a clinical or diagnostic specimen must be reported immediately by telephone, facsimile or email to the United State Department of Agriculture/Animal Plant Health Inspection Service (USDA/APHIS) or the Centers for Disease Control and Prevention (CDC):
- Botulinum neurotoxins
 - Bovine spongiform encephalopathy agent
 - Brucella melitensis*
 - Ebola virus
 - Francisella tularensis*
 - Hendra virus
 - Lassa fever virus
 - Marburg virus
 - Nipah virus
 - Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)
 - Phoma glycinicola* (formerly *Pyrenochaeta glycines*)
 - Ralstonia solanacearum* race 3, biovar 2
 - Rathayibacter toxicus*
 - Rift Valley fever virus
 - Rinderpest virus
 - Sclerophthora rayssiae var zae*
 - South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
 - Synchytrium endobioticum*
 - Variola major virus (Smallpox virus)
 - Variola minor (Alastrim)
 - Xanthomonas oryzae*
 - Xylella fastidiosa* (citrus variegated chlorosis strain)
 - Yersinia pestis*

- 1.3.1 Note that reporting of agents in section 1.2 to the State Veterinarian or the USDA AVIC supersedes reporting of agents in section 1.3 so long as the state agency is in contact with the federal agencies.
- 1.3.2 The person reporting the identification of the select agent must confirm 1.3.1 and the time and date must be noted.
- 1.4 In addition to the immediate notification of agents in section 1.2 and 1.3, submission of APHIS/CDC form 4 within seven calendar days after identification is required.
- 1.5 For all other select agents and toxins, submit APHIS/CDC form 4 within seven calendar days after identification (no immediate notification required).
 - 1.5.1 A list of all select agents can be found here:
<http://www.selectagents.gov/select%20agents%20and%20toxins%20list.html>
- 1.6 Clinical and diagnostic labs at Clemson University are exempt from registration as a select agent facility provided that;
 - 1.6.1 Within seven calendar days the select agent or toxin is transferred to a registered facility or destroyed on site (see section 3.3 and 3.4 below)
 - 1.6.2 The select agent or toxin is secured against theft, loss or release during the period between identification and transfer or destruction.
 - 1.6.3 Identification is reported to the USDA/APHIS or CDC
- 1.7 Direct all communication concerning select agents and toxins to the Clemson University Biological Safety Officer (BSO). The contact information is:
 - 1.7.1 Kerri Kwist, Biological Safety Officer
 - 1.7.1.1 Work phone: 656-7686
 - 1.7.1.3 Email: kkwist@clemson.edu
 - 1.7.1.4 Campus address: 120 Long Hall, Clemson University, Clemson, SC 29634
 - 1.7.1.5 Fax: 864-656-3599
 - 1.7.2 The BSO may designate someone to answer questions regarding select agents and toxins when necessary

2 Identification of a Select Agent or Toxin

- 2.1 If any select agent or toxin is isolated and identified, the Clemson University BSO or his designee must be contacted to initiate communication to the appropriate federal and/or state authorities. Provide the following issues:
 - 2.1.1 Name of the agent or toxin
 - 2.1.2 Description of the clinical or diagnostic case

- 2.1.3 When and how it was identified
- 2.2 If a select agent or toxin is identified, the BSO or his designee will immediately contact:
 - 2.2.1 The State Veterinarian (803-788-2260) or the USDA AVIC (803-788-1919) for agents in section 1.2
 - 2.2.2 USDA/APHIS (telephone: 301-734-5960, fax: 301-734-3652, email: ASAP@aphis.usda.gov) for agents in section 1.3
 - 2.2.3 CDC (telephone: 404-718-2000, fax: 404-718-2096, email: lrsat@cdc.gov) for agents in section 1.3
 - 2.2.4 Immediate contact required only for agents listed in section 1.2 and/or 1.3 above
- 2.3 The BSO or his designee will assist the diagnostic lab in completing APHIS/CDC Form 4, "Report of the Identification of a Select Agent in a Clinical or Diagnostic Laboratory", within seven calendar days after identification.
- 2.4 The BSO or his designee will provide a copy of APHIS/CDC Form 4 to the lab and mail or fax the original to:
 - 2.4.1 Animal and Plant Health Inspection Service, Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737. FAX: 301-734-3652.
 - 2.4.2 Centers for Disease Control and Prevention, Division of Select Agents and Toxins, 1600 Clifton Road NE, Mailstop A-46, Atlanta, GA 30333 (if applicable). FAX: 404-718-2096.
 - 2.4.3 The diagnostic lab and the BSO must maintain all records for a minimum of three years.

3 Inactivation or Transfer of a Select Agent or Toxin

- 3.1 The diagnostic lab will coordinate with the BSO or his designee to inactivate or transfer the select agent or toxin to a registered facility within seven calendar days of identification.
- 3.2 The diagnostic lab must document its actions by completing the attached form, "Inactivation or Transfer of Select Agents and Toxins".
- 3.3 **Inactivation:** If the select agent or toxin is inactivated on site, the diagnostic lab must:
 - 3.3.1 Describe the means of inactivation and provide a witness as listed on the attached form.
 - 3.3.2 Contact the BSO or his designee if using a means of inactivation other than an autoclave or if Bovine spongiform encephalopathy agent is the select agent identified.
 - 3.3.2.1 If an autoclave is used for inactivation, it must be operated by the standards set forth in Chapter 9 of the Clemson University Biosafety Manual.

- 3.3.3 Process the inactivated material through the Clemson University Infectious Waste program.
 - 3.3.3.1 The date and time of removal of the inactivated select agent or toxin must be noted and reported to the BSO.
 - 3.3.3.2 A copy of the manifest for removal of the inactivated select agent or toxin must be provided to the BSO if it is removed from the site by a third party infectious waste handler in accordance with the Clemson University Infectious Waste Program.
- 3.4 **Transfer:** Clemson University is not a registered site for select agents and toxins. Transfer of select agents or toxins to any laboratory of Clemson University is prohibited. If the agent will transferred to a registered facility:
 - 3.4.1 The BSO or his designee and the diagnostic lab will identify and contact a registered facility. The recipient facility must have a certificate of registration that includes the select agent or toxin to be transferred.
 - 3.4.2 The recipient Responsible Official (RO) must initiate the transfer process by completing the applicable sections of APHIS/CDC Form 2 "[Request to Transfer Select Agents and Toxins](#)" and forwarding the form to the Clemson University BSO.
 - 3.4.3 The BSO and the diagnostic lab will assess the need for permits to transfer the select agent or toxin.
 - 3.4.4 The BSO or his designee will complete the applicable sections of APHIS/CDC Form 2 and submit the form via facsimile to USDA/APHIS or CDC for authorization.
 - 3.4.4.1 USDA/APHIS at 301-734-3652.
 - 3.4.4.2 CDC at 404-718-2096.
 - 3.4.5 If authorization is granted, USDA/APHIS will return the approved form to the BSO or his designee. This form must be submitted with the shipment of select agent or toxin to the registered, recipient facility.
 - 3.4.6 The BSO and the diagnostic lab will request that the recipient RO provide notification of receipt of the select agent or toxin.
 - 3.4.7 The diagnostic lab will ship the select agent or toxin to the registered, recipient facility, while complying with applicable domestic and international laws governing packaging and shipping (42 CFR 171, IATA DGR).
- 3.5 The diagnostic lab and the BSO must maintain all records for a minimum of three (3) years.

