REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN FROM A CLINICAL/DIAGNOSTIC SPECIMEN (APHIS/CDC FORM 4A)

FORM APPROVED
OMB NO. ####-####
OMB NO. ####-####
EXP DATE ##/##/20##

INSTRUCTIONS

Detailed instructions are available at http://www.selectagents.gov/form4.html. Answer all items completely and type or print in ink. This report must be signed and submitted to either APHIS or CDC at:

Animal and Plant Health Inspection Service
Agriculture Select Agent Services
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
Email: AgSAS@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30329
FAX: (404) 471-8469
Email: CDCForm4@cdc.gov

Submit completed form only once by either email, fax, or mail

SECTION A – REFERENCE LABORATORY INFORMATION

1. Name of individual completing Sections A and B: First: MI: Last:	2. Email address:	3. Telephone #:
4. ☐ Registered Entity (APHIS or CDC Registration #: _____) ☐ Clinical or Diagnostic Laboratory [non-registered entity (NRE)] (NRE # (provided by APHIS or CDC): _____)	9. Entity name:	
5. Responsible Official or Laboratory Supervisor name (if same as field 1 then skip to field 9: First: MI: Last:	10. Address (NOT a post office address):	

6. Email address:	7. Telephone #:	8. Fax #:	11. City:	12. State:	13. Zip Code:

SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)

1. Select Agent or Toxin Identified:		2. Date identified:
1a. If Botulinum neurotoxins identified in Block #1, will you attempt to isolate Botulinum neurotoxin producing species of *Clostridium?* ☐ Yes (if yes, an update answering questions 18 and 19 is required within 7 days of identification) ☐ No	1b. Date identified:	1c. Dispositions of select agent or toxin by entity listed in field 8 (complete all that apply): ☐ Transferred (Provide entity name and date of transfer. Entity: _____ Date:_____) ☐ Destroyed (Provide destruction method and date. Method: _____ Date:_____) ☐ Retained (Provide name of Principal Investigator retaining sample. Name:_____)

3. Case/patient/sample ID #(s):	4. # of samples received:	5. Sample type received:	6. Case/patient origin (zip code):

7. Type of test performed (e.g., PCR, mouse bioassay, ELISA)

8. Dispositions of select agent or toxin by entity listed in field 8 (complete all that apply):
☐ Transferred (Provide entity name and date of transfer. Entity: _____ Date:_____)
☐ Destroyed (Provide destruction method and date. Method: _____ Date:_____)
☐ Retained (Provide name of Principal Investigator retaining sample. Name:_____)

9. Were any of the samples containing a select agent or toxin handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin?
☐ No ☐ Yes (If Yes, you are required under 7 CFR Part 331.19, 9 CFR Part 121.19, and 42 CFR Part 73.19 to complete and submit an APHIS/CDC Form 3)

10. Do you anticipate receiving additional samples/specimens for this case/patient that originate from the initial case (e.g. patient, environmental sample)?
☐ No ☐ Yes (If Yes, please refer to the guidance instructions at www.selectagents.gov for further directions.)

11. Has the sender(s) (i.e., sample provider(s)) of the specimen(s) been notified of the identification of the select agent or toxin? ☐ No ☐ Yes ☐ N/A
NOTE: Please request completed and signed Sections C & D from each facility that was in possession of the specimen(s).

12. Sample Provider Entity Name:	13. Sample Provider Point of Contact: (First, MI, and Last Name)	14. Sample Provider Email Address:	15 Sample Provider Contact Number:

16. Comments / Notes:

I hereby certify that the information contained in Sections A and B of this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, or 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Responsible Official/Laboratory Supervisor: _____ Date Signed: _____

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FORM APPROVED
OMB NO. ####-####
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EXP DATE ##/##/20##

INSTRUCTIONS

Detailed instructions are available at http://www.selectagents.gov/CDForm.html. Answer all items completely and type or print in black ink. This report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Services
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
Email: AgSAS@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30329
FAX: (404) 471-8469
Email: CDCForm4@cdc.gov

Submit completed form only once by either email, fax, or mail

SECTION C – SAMPLE PROVIDER INFORMATION

1. Name of individual completing Sections C and D: First: MI: Last:	2. Email address:	3. Telephone #:
4. ☐ Registered Entity (APHIS or CDC Registration #: _____) ☐ Clinical or Diagnostic Laboratory [non-registered entity (NRE)] (NRE # (provided by APHIS or CDC): _____)	9. Entity name:	
5. Responsible Official or Laboratory Supervisor name (if same as field 1 then skip to field 9): First: MI: Last:	10. Address (NOT a post office address):	

6. Email address:	7. Telephone #:	8. Fax #:	11. City:	12. State:	13. Zip Code:

SECTION D – SPECIMEN(S) CONTAINING SELECT AGENT OR TOXIN PROVIDED TO REFERENCE LABORATORY

1. Select Agent or Toxin Identified:	2. Date notified of select agent or toxin identification:	3. Case/patient/sample ID #(s):
4. # of samples shipped:	5. Sample type provided:	6. Case/patient/sample origin (zip code):
7. Date sample(s) shipped to Reference Laboratory:	8. Name of Reference Laboratory:	

9. Disposition of any remaining select agent or toxin by entity listed in field 8:
- ☐ Destroyed (Provide destruction method and date. Method: _____ Date:_____)
- ☐ Retained (Provide name of Principal Investigator retaining sample. Name:_____)
- ☐ Not applicable, the entire specimen was transferred to the Reference Laboratory.

10. Were any of the samples containing a select agent or toxin handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin?
☐ No ☐ Yes (If Yes, you are required under 7 CFR Part 331.19, 9 CFR Part 121.19, and 42 CFR Part 73.19 to complete and submit an APHIS/CDC Form 3)

11. Was your entity the source of the sample(s)? ☐ No ☐ Yes (If Yes, skip to field 18)

12. Do you anticipate receiving additional samples/specimens for this case/patient that originate from the initial case (e.g. patient, environmental sample)?
☐ No ☐ Yes (If Yes, please refer to the guidance instructions at www.selectagents.gov for further directions.)

13. Has the sender(s) (i.e. sample provider(s)) of the specimen(s) been notified of the identification of the select agent or toxin? ☐ No ☐ Yes ☐ N/A
NOTE: Please request completed and signed Sections C & D from each facility that was in possession of the specimen(s).

14. Sample Provider Entity Name:	15. Sample Provider Point of Contact: (First, MI, and Last Name)	16. Sample Provider Email Address:	17. Sample Provider Contact Number:

18. Comments / Notes:

I hereby certify that the information contained in Sections C and D of this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, or 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Responsible Official/Laboratory Supervisor: _____ Date Signed: _____