



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. <input type="checkbox"/> Registered Entity (APHIS or CDC Registration #: _____) <input type="checkbox"/> 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 <i>Clostridium</i> ? <input type="checkbox"/> Yes (if yes, an update answering questions 18 and 19 is required within 7 days of identification) <input type="checkbox"/> No		1b. Date identified: _____	1c. Dispositions of select agent or toxin by entity listed in field 8 (complete all that apply): <input type="checkbox"/> Transferred (Provide entity name and date of transfer. Entity: _____ Date: _____) <input type="checkbox"/> Destroyed (Provide destruction method and date. Method: _____ Date: _____) <input type="checkbox"/> 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): <input type="checkbox"/> Transferred (Provide entity name and date of transfer. Entity: _____ Date: _____) <input type="checkbox"/> Destroyed (Provide destruction method and date. Method: _____ Date: _____) <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> 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)? <input type="checkbox"/> No <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 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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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
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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. <input type="checkbox"/> Registered Entity (APHIS or CDC Registration #: _____) <input type="checkbox"/> 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: <input type="checkbox"/> Destroyed (Provide destruction method and date. Method: _____ Date: _____) <input type="checkbox"/> Retained (Provide name of Principal Investigator retaining sample. Name: _____) <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> 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)? <input type="checkbox"/> No <input type="checkbox"/> 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)? <input type="checkbox"/> No <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 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: _____

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D74, Atlanta, Georgia 30329; ATTN: PRA (0920-0576).