



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

FORM APPROVED  
OMB NO. 0579-0213  
OMB NO. 0920-0576  
EXP DATE 11/30/2015

**INSTRUCTIONS**

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

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  
Email: [Agricultural.Select.Agent.Program@aphis.usda.gov](mailto:Agricultural.Select.Agent.Program@aphis.usda.gov)

Centers for Disease Control and Prevention  
Division of Select Agents and Toxins  
1600 Clifton Road NE, Mailstop A-46  
Atlanta, GA 30333  
FAX: (404) 471-8469  
Email: [CDCForm4@cdc.gov](mailto:CDCForm4@cdc.gov)

Accession Number:
(For Program Use ONLY)

**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: First: _____ MI: _____ Last: _____		10. Address (NOT a post office address): _____			
6. Telephone #: _____	7. Fax #: _____	8. Email address: _____	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: _____		
3. Case/patient/sample ID #(s): _____	4. # of samples received: _____	5. Sample type(s) received: _____	6. Case/patient origin (zip code): _____		
7. Dispositions of select agent or toxin (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 person retaining sample. Name: _____)					
8. 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)					
9. 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 <a href="http://www.selectagents.gov">www.selectagents.gov</a> for further directions.)					
10. 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 laboratory that was in possession of the specimen(s).					
11. Sample Provider Entity Name: _____	12. Sample Provider Point of Contact: (First, MI, and Last Name)	13. Sample Provider Email Address: _____	14. Sample Provider Contact Number: _____		
15. 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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Reference ID Number:
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**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: First: _____ MI: _____ Last: _____			10. Address (NOT a post office address): _____			
6. Telephone #: _____	7. Fax #: _____	8. Email address: _____		11. City: _____	12. State: _____	13. Zip Code: _____

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

1. Date specimens(s) shipped to Reference Laboratory: _____		2. # of specimens provided: _____		3. Case/patient/sample ID #(s): _____	
4. Sample type(s) provided: _____				5. Case/patient/sample origin (zip code): _____	
6. Date notified by Reference Laboratory of select agent or toxin identification: _____			7. Select agent or toxin identified by Reference Laboratory: _____		
8. Dispositions of select agent or toxin (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 person 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 <a href="http://www.selectagents.gov">www.selectagents.gov</a> 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 laboratory 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:   
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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 30333; ATTN: PRA (0920-0576).