



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

FORM APPROVED
OMB NO. 0920-0576
EXP DATE: 01/31/20XX

Detailed instructions are available at <http://www.selectagents.gov/form4.html>. This report must be submitted to either DASAT or DRSC.

Animal and Plant Health Inspection Service
Division of Agricultural Select Agents and Toxins
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
E-mail: DASAT@usda.gov

Centers for Disease Control and Prevention
Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4 Atlanta, GA 30329
FAX: (404) 471-8469
E-mail: CDCForm4@cdc.gov

Submit completed form only once by either eFSAP, e-mail, or fax

PART 1 – REPORT OF IDENTIFICATION			
SECTION A – REFERENCE LABORATORY INFORMATION			
1. Name of individual completing Sections A and B (First, MI, Last):		2. E-mail address:	
3. Telephone #:			
4. Entity name or Name of Clinical/Diagnostic Laboratory:			
5. Responsible Official or Laboratory Supervisor name (First, MI, Last):		6. E-mail address:	
7. Telephone #:			
8. Address (NOT a post office address):		9. City:	
		10. State:	11. Zip Code:
SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)			
1. Select Agent or Toxin Identified:	2. Date identified:	3. Date of Immediate Notification for Tier 1 agents or N/A for non-Tier 1 agent to APHIS or CDC:	4. Type of notification to APHIS or CDC: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> Telephone <input type="checkbox"/> eFSAP <input type="checkbox"/> N/A
5. # of select agent/toxin samples received:	6. Sample type received:		7. Zip code for case/patient/sample origin:
8. Type of test performed:			
<input type="checkbox"/> Biochemical	<input type="checkbox"/> Immunochemistry	<input type="checkbox"/> PCR	
<input type="checkbox"/> Culture	<input type="checkbox"/> Mass Spectrometry (e.g., MALDI)	<input type="checkbox"/> Sequencing	
<input type="checkbox"/> DFA/IFA	<input type="checkbox"/> Microscopy	<input type="checkbox"/> Other: _____	
<input type="checkbox"/> ELISA/EIA/RIA	<input type="checkbox"/> Mouse Bioassay		
9. Dispositions of select agent or toxin listed by entity (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. Must be onsite. Method: _____ Date: _____)			
<input type="checkbox"/> Retained (Provide name of Principal Investigator retaining sample. _____)			
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 §331.19, 9 CFR §121.19, and 42 CFR §73.19 to complete and submit an APHIS/CDC Form 3)			
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 Date of Notification: _____ NOTE: Please request completed and signed Part 2 from each facility that was in possession of the specimen(s).			
12. Was your entity the source of the sample(s)? No Yes (If Yes, skip to #22 if you have any additional comments.)			
13. Is the sample provider located outside the United States? <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, provide country: _____			
14. Sample Provider Entity Name:			
15. Address (NOT a post office address):		16. City:	17. State:
			18. Zip Code:
19. Sample Provider Point of Contact (First, MI, Last):		20. Sample Provider E-mail Address:	21. Sample Provider Contact Number:
22. Comments / Notes:			

I hereby certify that the information contained in Part 1 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 Part 331, 9 CFR Part 121, or 42 CFR Part 73 may result in Civil or criminal penalties, including imprisonment.

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



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

FORM APPROVED
OMB NO. 0920-0576
EXP DATE: 01/31/20XX

Detailed instructions are available at <http://www.selectagents.gov/form4.html>. This report must be submitted to either DASAT or DRSC:

Animal and Plant Health Inspection Service
Division of Agricultural Select Agents and Toxins
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
E-mail: DASAT@usda.gov

Centers for Disease Control and Prevention
Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4 Atlanta, GA 30329
FAX: (404) 471-8469
E-mail: CDCForm4@cdc.gov

Submit completed form only once by either eFSAP, e-mail, or fax

PART 2 – REPORT OF IDENTIFICATION

SECTION C – SAMPLE PROVIDER INFORMATION

1. Name of individual completing Sections C and D (First, MI, Last):		2. E-mail address:		3. Telephone #:		
4. Your facility name:						
5. Responsible Official or Laboratory Supervisor name ((First, MI, Last):			6. E-mail address:		7. Telephone #:	
8. Address (NOT a post office address):			9. City:		10. State: 11. Zip Code:	

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

1. Select Agent or Toxin Identified:		2. Date notified by reference laboratory of select agent or toxin identification:			
3. # of select agent/toxin samples shipped:		4. Sample type provided:		5. Zip code for case/patient/sample origin:	
6. Date sample(s) shipped to Reference Laboratory:			7. Name of Reference Laboratory:		
8. Disposition of any remaining select agent or toxin listed by entity: <input type="checkbox"/> Destroyed (Provide destruction method and date. Must be onsite. 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.					
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 §331.19, 9 CFR §121.19, and 42 CFR §73.19 to complete and submit an APHIS/CDC Form 3)					
10. Was your entity the source of the sample(s)? <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, skip to #21 if you have any additional comments.)					
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 NOTE: Please request completed and signed Part 2 from each facility that was in possession of the specimen(s).					
12. Is the sample provider located outside the United States? <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, provide country: _____					
13. Sample Provider Entity Name:					
14. Address (NOT a post office address):		15. City:		16. State: 17. Zip Code:	
18. Sample Provider Point of Contact (First, MI, Last):			19. Sample Provider E-mail Address:		20. Sample Provider Contact Number:
21. Comments / Notes:					

I hereby certify that the information contained in Part 2 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 Part 331, 9 CFR Part 121, or 42 CFR Part 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).



**REPORTING THE IDENTIFICATION OF A SELECT AGENT
OR TOXIN: PROFICIENCY TESTING REPORT
(APHIS/CDC FORM 4B)**

FORM APPROVED
OMB NO. 0920-0576
EXP DATE 1/31/2024

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:

Animal and Plant Health Inspection Service
Division of Agricultural Select Agents and Toxins
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07,
Riverdale, MD 20737
FAX: (301) 734-3652
E-mail: DASAT@usda.gov

Centers for Disease Control and Prevention
Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4,
Atlanta, GA 30329
FAX: (404) 471-8469
E-mail: CDCForm4@cdc.gov

Submit completed form only once by either e-mail or fax

SECTION A – INFORMATION FOR LABORATORY THAT RECEIVED PROFICIENCY TESTING SAMPLE(S)					
1. Name of individual completing the form: First: _____ MI: _____ Last: _____		2. E-mail address: _____		3. Telephone #: _____	
4. <input type="checkbox"/> Registered Entity <input type="checkbox"/> Clinical or Diagnostic Laboratory [non-registered entity (NRE)]		5. Entity name: _____			
6. Responsible Official or Laboratory Supervisor name: First: _____ MI: _____ Last: _____		7. Address (NOT a post office address): _____			
8. Telephone #: _____	9. E-mail address: _____		10. City: _____	11. State: _____	12. Zip Code: _____
13. Sponsor/entity that you received select agent or toxin from: Entity name: _____ Entity address: _____ Telephone #: _____ E-mail: _____					
SECTION B – SELECT AGENTS AND TOXINS IDENTIFIED FROM PROFICIENCY TESTING					
1. Select Agent or Toxin Identified		2. Date obtained from sponsor		3. Date identified	
4. Dispositions of select agents or toxins (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. Must be on-site. Method: _____ Date: _____) <input type="checkbox"/> Retained (Provide name of person retaining sample. Name: _____)					
5. 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 §331.19, 9 CFR §121.19, and 42 CFR §73.19 to complete and submit an APHIS/CDC Form 3)					

I hereby certify that the information contained on 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 Part 331, 9 CFR Part 121, or 42 CFR Part 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)



**REPORTING THE IDENTIFICATION OF A SELECT AGENT
OR TOXIN: FEDERAL LAW ENFORCEMENT SEIZURE
REPORT (APHIS/CDC FORM 4C)**

FORM APPROVED
OMB NO. 0920-0576
EXP DATE 1/31/2024

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:

Animal and Plant Health Inspection Service
Division of Agricultural Select Agents and Toxins
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07,
Riverdale, MD 20737
FAX: (301) 734-3652
E-mail: DASAT@usda.gov

Centers for Disease Control and Prevention
Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4,
Atlanta, GA 30329
FAX: (404) 471-8469
E-mail: CDCForm4@cdc.gov

Submit completed form only once by either e-mail or fax

SECTION A – FEDERAL LAW ENFORCEMENT INFORMATION		
1. Name of federal law enforcement agency:	2. Name of federal law enforcement agent: First: _____ MI: _____ Last: _____	
3. Telephone #:	4. E-mail address:	
SECTION B – SELECT AGENTS AND TOXINS SEIZED		
1. Name of entity select agent or toxin seized from:	2. Entity Address (NOT a post office address):	
3. Select agent or toxin seized	4. Amount seized	5. Disposition of seized select agent or toxin
6. Were any of the seized select agents or toxins 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 §331.19, 9 CFR §121.19, and 42 CFR §73.19 to complete and submit an APHIS/CDC Form 3)		
7. Comments / Notes:		

I hereby certify that the information contained on 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 Part 331, 9 CFR Part 121, or 42 CFR Part 73 may result in civil or criminal penalties, including imprisonment.

Signature of Agent: _____ 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).