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: {Select} / 11. Zip Code:

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

1. Select Agent or Toxin Identified: {Select}	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: ☐ E-mail ☐ Fax ☐ Telephone ☐ eFSAP ☐ N/A
5. # of select agent/toxin samples received:	6. Sample type received: {Select}	7. Zip code for case/patient/sample origin:	

8. Type of test performed:

☐ Biochemical	☐ Immunochemistry	☐ PCR
☐ Culture	☐ Mass Spectrometry (e.g., MALDI)	☐ Sequencing
☐ DFA/IFA	☐ Microscopy	☐ Other: _____
☐ ELISA/EIA/RIA	☐ Mouse Bioassay	

9. Dispositions of select agent or toxin listed by entity (complete all that apply):
☐ Transferred (Provide entity name and date of transfer. Entity: _____ Date: _____)
☐ Destroyed (Provide destruction method and date. Must be onsite. Method: _____ Date: _____)
☐ 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?
☐ No ☐ 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? ☐ No ☐ 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? ☐ No ☐ Yes If Yes, provide country: {Select}

14. Sample Provider Entity Name:

15. Address (NOT a post office address):	16. City:	17. State: {Select}	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: {Select} / 11. Zip Code:

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

1. Select Agent or Toxin Identified: {Select}	2. Date notified by reference laboratory of select agent or toxin identification:	
3. # of select agent/toxin samples shipped:	4. Sample type provided: {Select}	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:
- ☐ Destroyed (Provide destruction method and date. Must be onsite. Method: _____ Date: _____)
- ☐ Retained (Provide name of Principal Investigator retaining sample. Name: _____)
- ☐ 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?
☐ No ☐ 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)? ☐ No ☐ 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? ☐ No ☐ 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? ☐ No ☐ Yes If Yes, provide country: {Select}

13. Sample Provider Entity Name:

14. Address (NOT a post office address):	15. City:	16. State: {Select}	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: _____

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. ☐ Registered Entity ☐ 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):
☐ Transferred (Provide entity name and date of transfer. Entity: _____ Date:_____)
☐ Destroyed (Provide destruction method and date. Must be on-site. Method: _____ Date:_____)
☐ 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?
☐ No ☐ 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: _____

Reset Form | Save Form | Print | CDC E-mail Form | APHIS E-mail Form

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?
☐ No ☐ 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: _____

Print | Save Data | CDC E-mail Form | APHIS E-mail Form