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: 01/31/2024

INSTRUCTIONS

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

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 Select Agents and Toxins
1600 Clifton Road NE, Mailstop H21-7
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:	4. Type of notification: ☐ E-mail ☐ Fax ☐ Telephone ☐ eFSAP ☐ N/A
5. # of samples received:	6. Sample type received: {Select}	7. Case/patient/sample origin (zip code):	

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. Method:_____Date:_____)
☐ Retained (Provide name of Principal Investigator retaining sample. Name:_____)

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:_____

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

1. Select Agent or Toxin Identified: {Select}		2. Date notified of select agent or toxin identification:
3. # of samples shipped:	4. Sample type provided: {Select}	5. Case/patient/sample origin (zip code):
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. 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:_____