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 10/31/2014

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

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: (404) 718-2096
Email: 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. ☐ Registered Entity (APHIS or CDC Registration #: _____) ☐ 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):
☐ Transferred (Provide entity name and date of transfer. Entity: _____ Date:_____)
☐ Destroyed (Provide destruction method and date. Method: _____ Date:_____)
☐ 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?
☐ No ☐ 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)?
☐ No ☐ Yes (If Yes, please refer to the guidance instructions at www.selectagents.gov 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? ☐ No ☐ Yes ☐ N/A
NOTE: Please request completed and signed Sections C & D from each laboratory that was in possession of the specimen(s).

11. 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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Accession Number:

(For Program Use ONLY)

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SECTION C – SAMPLE PROVIDER INFORMATION

1. Name of individual completing Sections C and D: First: MI: Last:	2. Email address:	3. Telephone #:

4. ☐ Registered Entity (APHIS or CDC Registration #: _____) ☐ 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 specimen(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):
☐ Transferred (Provide entity name and date of transfer. Entity: _____ Date:_____)
☐ Destroyed (Provide destruction method and date. Method: _____ Date:_____)
☐ 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?
☐ No ☐ 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)?
☐ No ☐ Yes (If Yes, please refer to the guidance instructions at www.selectagents.gov for further directions.)

11. 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 30333; ATTN: PRA (0920-0576).

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