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| HHS Logo300 | USDALOGO | **reporting the identification of A SELECT AGENT or TOXIN FROM A CLINICAL/DIAGNOSTIC SPECIMEN****(APHIS/CDC Form 4a)** | FORM APPROVEDOMB NO. ####-####OMB NO. ####-####EXP DATE ##/##/20## |

**INSTRUCTIONS**

**Detailed instructions are available at** [**http://www.selectagents.gov/form4.html**](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 at:**

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| Animal and Plant Health Inspection ServiceAgriculture Select Agent Services4700 River Road Unit 2, Mailstop 22, Cubicle 1A07Riverdale, MD 20737FAX: (301) 734-3652Email: AgSAS@aphis.usda.gov | Centers for Disease Control and PreventionDivision of Select Agents and Toxins1600 Clifton Road NE, Mailstop A-46Atlanta, GA 30329FAX: (404) 471-8469Email: CDCForm4@cdc.gov  |

***Submit completed form only once by either email, fax, or mail***

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| 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 (if same as field 1 then skip to field 9:First: MI: Last:  | 10. Address (NOT a post office address): |
| 6. Email address: | 7. Telephone #: | 8. Fax #: | 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: |
| 1a. If Botulinum neurotoxins identified in Block #1, will you attempt to isolate Botulinum neurotoxin producing species of *Clostridium?* Yes (if yes, an update answering questions 18 and 19 is required within 7 days of identification) No | 1b. Date identified: | 1c. Dispositions of select agent or toxin by entity listed in field 8 (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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |
| 3. Case/patient/sample ID #(s): | 4. # of samples received: | 5. Sample type received: | 6. Case/patient origin (zip code): |
| 7. Type of test performed (e.g., PCR, mouse bioassay, ELISA) |
| 8. Dispositions of select agent or toxin by entity listed in field 8 (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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |
| 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](http://www.selectagents.gov) 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?  No  Yes  N/A **NOTE:** Please request completed and signed Sections C & D from each facility 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: |

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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**INSTRUCTIONS**

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

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| Animal and Plant Health Inspection ServiceAgricultural Select Agent Services4700 River Road Unit 2, Mailstop 22, Cubicle 1A07Riverdale, MD 20737FAX: (301) 734-3652Email: AgSAS@aphis.usda.gov | Centers for Disease Control and PreventionDivision of Select Agents and Toxins1600 Clifton Road NE, Mailstop A-46Atlanta, GA 30329FAX: (404) 471-8469Email: CDCForm4@cdc.gov  |

***Submit completed form only once by either email, fax, or mail***

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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 (if same as field 1 then skip to field 9):First: MI: Last:  |  10. Address (NOT a post office address): |
| 6. Email address: | 7. Telephone #: | 8. Fax #: | 11. City: | 12. State: | 13. Zip Code: |
| SECTION D – SPECIMEN(S) CONTAINING SELECT AGENT OR TOXIN PROVIDED TO REFERENCE LABORATORY |
| 1. Select Agent or Toxin Identified: | 2. Date notified of select agent or toxin identification: | 3. Case/patient/sample ID #(s): |
| 4. # of samples shipped: | 5. Sample type provided: | 6. Case/patient/sample origin (zip code): |
| 7. Date sample(s) shipped to Reference Laboratory: | 8. Name of Reference Laboratory: |
| 9. Disposition of any remaining select agent or toxin by entity listed in field 8: 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. |
| 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 Part 331.19, 9 CFR Part 121.19, and 42 CFR Part 73.19 to complete and submit an APHIS/CDC Form 3) |
| 11. Was your entity the source of the sample(s)?  No  Yes (If Yes, skip to field 18) |
| 12. 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](http://www.selectagents.gov) for further directions.) |
| 13. 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 facility that was in possession of the specimen(s). |
| 14. Sample Provider Entity Name: | 15. Sample Provider Point of Contact: (First, MI, and Last Name) | 16. Sample Provider Email Address: | 17. Sample Provider Contact Number: |
| 18. 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 30329; ATTN: PRA (0920-0576).