

APHIS/CDC Form 4: Report of the Identification of a Select Agent or Toxin

Outside the entity information and select agent identified, data for the APHIS/CDC Form 4 were not collected in NSAR. The pdf of the form was scanned into the system. The below screen prints show what will be collected in eFSAP.

SECTION A – REFERENCE LABORATORY INFORMATION

1. Name of individual completing Sections C and D: First MI Last 2. E-mail address: 3. Telephone #: () - - ext.

4. APHIS or CDC Registration #: Registered Entity

5. Responsible Official or Laboratory Supervisor name (if same as field 1 then skip to field 9): First MI Last

6. E-mail address: 7. Telephone #: () - - ext. 8. Fax #: () - - ext.

9. Entity name:

10. Address (NOT a post office address):

11. City: 12. State: -- Select an option-- 13. Zip Code:

For the below screen print, this is found in Section B of the form.

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

1. Select Agent or Toxin Identified: 2. Date identified: mm/dd/yyyy

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 Block A9 (complete all that apply):

Transferred
 Destroyed
 Retained

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

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

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

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:

14. Sample Provider E-mail Address:

15. Sample Provider Contact Number:

16. Comments / Notes:

This is a required field

Signature

Certification: 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.

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).

Signature of Respondent:

Date Signed:

For the below screen print, this is found in Section C of the form.

SECTION C – SAMPLE PROVIDER INFORMATION

1. Name of individual completing Sections C and D: 2. E-mail Address: 3. Telephone #:

4.

Registered Entity APHIS or CDC Registration #:

Clinical or Diagnostic Laboratory (NRE # (provided by APHIS or CDC):

5. Responsible Official or Laboratory Supervisor name (if same as field 1 then skip to field 9):

6. E-mail address: 7. Telephone #: 8. Fax #:

9. Entity Name:

10. Address (NOT a post office address):

11. City: 12. State: 13. Zip Code:

For the below screen prints, this is found in Section D of the form.

SECTION D – SPECIMENS CONTAINING SELECT AGENT OR TOXIN PROVIDED TO REFERENCE LABORATORY

1. Select Agent or Toxin Identified: <input type="text"/>	2. Date notified of select agent or toxin identification: <input type="text" value="mm/dd/yyyy"/>
3. Case/patient/sample ID #(s): <input type="text"/>	4. # of samples shipped: <input type="text"/>
5. Sample type provided: <input type="text"/>	6. Case/patient/sample origin (zip code): <input type="text"/>
7. Date sample(s) shipped to Reference Laboratory: <input type="text" value="mm/dd/yyyy"/>	8. Name of Reference Laboratory: <input type="text"/>

9. Disposition of any remaining select agent or toxin by entity listed in Block C9:

<input type="checkbox"/> Destroyed	Method: <input type="text"/>	Date: <input type="text" value="mm/dd/yyyy"/>
<input type="checkbox"/> Retained	Name: <input type="text"/>	
<input type="checkbox"/> 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

Information
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

Information
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

Information
If Yes, please refer to the guidance instructions at 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

Note
Please notify senders about Section C & D requirements that are a prerequisite of the exemption.

14. Sample Provider Entity Name:

15. Sample Provider Point of Contact:	16. Sample Provider E-mail Address:	17. Sample Provider Contact Number:
<input type="text" value="First"/> <input type="text" value="MI"/> <input type="text" value="Last"/>	<input type="text"/>	<input type="text"/>

18. Comments / Notes:

Signature

Certification: 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.

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 CDCIATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D74, Atlanta, Georgia 30329; ATTN: PRA (0920-0576).

Signature of Respondent: <input type="text"/>	Date Signed: <input type="text"/>
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APHIS/CDC Form 5: Request for Exemption of Select Agents and Toxins for an Investigational Product

Similar to NSAR, the form will not be available in the new system. Applicants will still complete the pdf available on the Federal Select Agent Program website.