



Electronic Federal Select Agent Program (eFSAP) Information System - Updates

APHIS/CDC Form 4

Report of the Identification of a Select Agent or Toxin





APHIS/CDC FORM 4

Report of the Identification of a Select Agent or Toxin



APHIS/CDC Form 4A – Identification of BSAT

Create Form 4A - Section A&B

Create Form 4B

Create Form 4C

Form 4 Section ABs

Id	Select Agent	Status	Date Created
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No Section A & B's have been created

Form 4A- Section CD's

Id	Select Agent	Status	Date Created
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No Section C & D's have been assigned to this entity

Form 4B

Id	Select Agent	Status	Date Created
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No 4B's have been created

Form 4C

Id	Law Enforcement Agency	Status	Date Created
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No 4C's have been created



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APHIS/CDC Form 4A – Section A

SECTION A – REFERENCE LABORATORY INFORMATION		
1. Name of individual completing Sections A and B	2. E-mail address:	3. Telephone #:
<input type="text" value="First M Last"/>	<input type="text"/>	<input type="text" value="() - ext."/>

Complete section A questions 1-3.



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APHIS/CDC Form 4A – Section A

4. Registered Entity APHIS or CDC Registration #:

Clinical or Diagnostic Laboratory [non-registered entity (NRE)]

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

243 of 255 characters left

6. E-mail address: 40 of 50 characters left

7. Telephone #:

8. Fax #:

9. Entity name:

228 of 255 characters left

10. Address (NOT a post office address):

237 of 255 characters left

11. City: 39 of 50 characters left

12. State: ▼

13. Zip Code:

For registered entities, information on this page is automatically pulled from your Form 1.



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APHIS/CDC Form 4A – Section B

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

1. Select Agent or Toxin Identified: <input type="text"/>	2. Date identified: <input type="text" value="mm/dd/yyyy"/>
3. Case/patient/sample ID #(s): <input type="text"/>	4. # of samples received: <input type="text"/>
5. Sample type received: <input type="text" value="--Select an option--"/>	6. Case/patient origin (zip code): <input type="text" value="____-____"/>
7. Type of test performed (e.g., PCR, mouse bioassay, ELISA): <input type="text"/>	

Submitter completes section B questions 1-7.



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APHIS/CDC Form 4A – Section B

8. Dispositions of select agent or toxin by entity listed in Block A9 (complete all that apply):

Must answer at least one of the below

Select the correct disposition of the agent/toxin

- Transferred
- Destroyed
- Retained

If retained, select the correct PI from the pre-populated choices based on the list of approved PIs at the entity.

Retained

Retained by:

–Select an option–

Tier 1

- Michael Adams
- Marranda Ayers
- Janice James
- Louis Pasteur

Non Tier 1

- Clint Carson

9. Were any of the sample unintentional release and



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APHIS/CDC Form 4A – Section B

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?

Yes No

10. Do you anticipate receiving additional samples/specimens for this case/patient that originate from the initial case (e.g., patient, environmental sample)?

Yes No

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?

Yes No 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:

Clear

+ Add Row

Complete
section B
questions 9-15



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APHIS/CDC Form 4A – Section B

16. Comments / Notes:

Signature of Responsible Official or Laboratory Supervisor:

responsible official

Please type name as above.

Date Signed:

Choose the desired action

- **Immediate notification** – as required by the regulations (must submit name of select agent or toxin, date identified, and whether there was a theft, loss, or release).
- **Save – Draft only.** This does not fulfill the requirements of the regulations. The Form 4A **will not be reviewed** by FSAP staff.
- **Submit** – This option will activate once the Form is filled out in its entirety. Once submitted, the Form 4A will be reviewed by FSAP.



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APHIS/CDC Form 4A – Section C/D

After submission by the identifying lab:

- **FSAP staff will assign the Section C/D to the supplying laboratory identified in Section A/B for completion.**
 - **If the supplying laboratory is registered with FSAP then they will receive a notification on their eFSAP homepage.**
 - **If the supplying laboratory is unregistered, FSAP will contact the entity and they will use the forms on the FSAP website and continue to use current practices to submit.**



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APHIS/CDC Form 4A – Section C/D

If your entity was the supplying lab:

- A notification will appear in your notification center informing you that a Form 4A is required.

From Janet Wilson on Form4A [Link](#) 🔔 Form4A was modified (State: Required) by Janet Wilson on 10/26/2017 11:11:07 AM. 🕒 10/26/2017 11:11:07 AM

Forms **Form 1** **Form 2** **Form 3** **Form 4**

To see all required Form 4As you can use your Form 4 tab.

Form 4A- Section CD's

Id	Select Agent	Status	Date Created	
CID-F4-010073	Peronosclerospora philippinensis (Peronosclerospora sacchari)	Required	10/26/2017	View
CID-F4-010074	Peronosclerospora philippinensis (Peronosclerospora sacchari)	Required	10/26/2017	View



APHIS/CDC FORM 4

Report of the Identification of a Select Agent or Toxin



APHIS/CDC Form 4A – Section C/D

To enter the information for this Form 4A, click the View button.

Form 4A- Section CD's				
Id	Select Agent	Status	Date Created	
CID-F4-010073	Peronosclerospora philippinensis (Peronosclerospora sacchari)	Required	10/26/2017	View
CID-F4-010074	Peronosclerospora philippinensis (Peronosclerospora sacchari)	Required	10/26/2017	View



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Report of the Identification of a Select Agent or Toxin



APHIS/CDC Form 4A – Section C

Complete section C
questions 1-3.

SECTION C – SAMPLE PROVIDER INFORMATION

1. Name of individual completing Sections C and D:

2. E-mail Address:

3. Telephone #:



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APHIS/CDC Form 4A – Section C

For registered entities, this information is automatically pulled from your Form 1.

4.

Registered Entity APHIS or CDC Registration #:

Clinical or Diagnostic Laboratory

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 #:

40 of 50 characters left

9. Entity Name:

228 of 255 characters left

10. Address (NOT a post office address):

237 of 255 characters left

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

39 of 50 characters left



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APHIS/CDC Form 4A – Section D

Question 1 is pre-populated with the agent indicated by the identifying laboratory that filled out section B.

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

<p>1. Select Agent or Toxin Identified:</p> <p>Peronosclerospora philippinensis (Peronosclerospora saccc ▼)</p>	<p>2. Date notified of select agent or toxin identification:</p> <p>mm/dd/yyyy</p>
<p>3. Case/patient/sample ID #(s):</p> <p></p>	<p>4. # of samples shipped:</p> <p></p>
<p>5. Sample type provided:</p> <p>--Select an option-- ▼</p>	<p>6. Case/patient/sample origin (zip code):</p> <p>____-____</p>
<p>7. Date sample(s) shipped to Reference Laboratory:</p> <p>mm/dd/yyyy</p>	<p>8. Name of Reference Laboratory:</p> <p></p>

Complete the remaining fields 2-8.



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APHIS/CDC Form 4A – Section D

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

Must answer at least one of the below

Destroyed

Retained

Not applicable, the entire specimen was transferred to the Reference Laboratory.

Retained

Retained by:

--Select an option--

Tier 1

- Michael Adams
- Marranda Ayers
- Janice James
- Louis Pasteur

Non Tier 1

- Clint Carson

Were any of the sample unintentional release and

This is a list of approved PIs at the entity.



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APHIS/CDC Form 4A – Section D

Complete questions 10-17.

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?

Yes No

11. Was your entity the source of the sample(s)?

Yes No

12. Do you anticipate receiving additional samples/specimens for this case/patient that originate from the initial case (e.g., patient, environmental sample)?

Yes No

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?

Yes No

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:

16. Sample Provider E-mail Address:

17. Sample Provider Contact Number:



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APHIS/CDC Form 4A – Section D

Signature of Respondent:

Date Signed:

responsible official

i Please type name as above.

Choose the desired action →

- **Save – Draft only.** The completed Form 4A **will not be** reviewed by FSAP staff.
- **Submit** – This option will activate once the Form is filled out in its entirety. Once submitted, the Form 4A **will be** reviewed by the FSAP.