APHIS/CDC Form 4A – Reporting the Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen

Multi-Agency Informational Meeting (webinars) to Discuss Select Agent and Toxin Reporting Requirements
October 6 and November 3, 2021

Federal Select Agent Program
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Program Services Branch
APHIS/CDC Form 4 Team
### APHIS/CDC Form 4A Part 1 Updates

#### Section B: Select agent or toxin identification by Reference Laboratory:
- Question B3: Immediate notification date
- Question B4: Type of notification made
- Question B8: Type of tests
- Question B11: Date sample provider notified
- Question B12: Source of the sample
- Question B13: Country for sample provider
- Questions B15-18: Sample provider address

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<table>
<thead>
<tr>
<th>Section B – Select Agent or Toxin Identified from Clinical/Diagnostic Specimen(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select Agent or Toxin Identified.</td>
</tr>
<tr>
<td>(Select)</td>
</tr>
<tr>
<td>5. # of samples received:</td>
</tr>
<tr>
<td>8. Type of test performed:</td>
</tr>
<tr>
<td>[ ] Biochemical</td>
</tr>
<tr>
<td>[ ] Culture</td>
</tr>
<tr>
<td>[ ] DFA/IFA</td>
</tr>
<tr>
<td>[ ] ELISA/EIA/RIA</td>
</tr>
<tr>
<td>[ ] PCR</td>
</tr>
<tr>
<td>[ ] Other:</td>
</tr>
<tr>
<td>9. Dispositions of select agent or toxin listed by entity (complete all that apply):</td>
</tr>
<tr>
<td>[ ] Transferred (Provide entity name and date of transfer. Entity:</td>
</tr>
<tr>
<td>[ ] Destroyed (Provide destruction method and date. Method:</td>
</tr>
<tr>
<td>[ ] Retained (Provide name of Principal Investigator retaining sample. Name:</td>
</tr>
<tr>
<td>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?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>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?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Date of Notification:</td>
</tr>
<tr>
<td>NOTE: Please request completed and signed Part 2 from each facility that was in possession of the specimen(s).</td>
</tr>
<tr>
<td>12. Was your entity the source of the sample(s)? Yes</td>
</tr>
<tr>
<td>(If Yes, skip to #22 if you have any additional comments.)</td>
</tr>
<tr>
<td>13. Is the sample provider located outside the United States? Yes</td>
</tr>
<tr>
<td>If Yes, provide country (Select):</td>
</tr>
<tr>
<td>14. Sample Provider Entity Name:</td>
</tr>
<tr>
<td>15. Address (NOT a post office address):</td>
</tr>
<tr>
<td>17. State: (Select)</td>
</tr>
<tr>
<td>19. Sample Provider E-mail Address:</td>
</tr>
<tr>
<td>20. Sample Provider Contact Number:</td>
</tr>
<tr>
<td>21. Sample Provider Point of Contact (First, MI, Last):</td>
</tr>
<tr>
<td>22. Comments / Notes:</td>
</tr>
</tbody>
</table>
APHIS/CDC Form 4A Part 2 Updates

- Section D: Specimen(s) containing select agent or toxin – **Sample Provider**:
  - Question D12: Provide the country where sample provider is located
  - Questions D14-17: Address, city, state, and zip for sample provider

```markdown
<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>D12</td>
<td>Provide the country where sample provider is located</td>
</tr>
<tr>
<td>D14-17</td>
<td>Address, city, state, and zip for sample provider</td>
</tr>
</tbody>
</table>
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### SECTION D – SPECIMEN(S) CONTAINING SELECT AGENT OR TOXIN PROVIDED TO REFERENCE LABORATORY

- **Select Agent or Toxin Identified:**
- **Date notified of select agent or toxin identification:**
- **# of samples shipped:**
- **Sample type provided:**
- **Case/patient/sample origin (zip code):**
- **Date sample(s) shipped to Reference Laboratory:**
- **Name of Reference Laboratory:**
- **Disposition of any remaining select agent or toxin listed by entity:**
  - Destroyed (Provide destruction method and date):
  - Retained (Provide name of Principal Investigator retaining sample):
  - Not applicable, the entire specimen was transferred to the Reference Laboratory.
- **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?**
- **Was your entity the source of the sample(s)?**
- **Has the sender(s) (i.e., sample provider(s)) of the specimen(s) been notified of the identification of the select agent or toxin?**
- **Is the sample provider located outside the United States?**
- **Sample Provider Entity Name:**
- **Address (NOT a post office address):**
- **City:**
- **State:**
- **Zip Code:**
- **Sample Provider Point of Contact (First, M, Last):**
- **Sample Provider E-mail Address:**
- **Sample Provider Contact Number:**
- **Comments / Notes:**
• Notification of the identification
  o Date the reference laboratory informed of the final identification
  o How notified
    ▪ Telephone call
    ▪ Email
    ▪ Laboratory information system
    ▪ Fax
**SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)**

1. Select Agent or Toxin Identified: [Select]
2. Date identified: [Select]
3. Date of immediate notification for Tier 1 agents or N/A for non-Tier 1 agent: [Select]
4. Type of notification: Email, Fax, Telephone
5. No. of samples received: [Select]
6. Sample type received: [Select]
7. Case/patient/sample origin (zip code): [Select]
8. Type of test performed:
   - Immunochrome
   - Mass Spectrometry (e.g., MALDI
   - Microscopy
   - Other:
9. Dispositions of select agent or toxin listed by entity (complete all that apply):
   - Transferred: Provide entity name and date of transfer. Entity: [Select], Date: [Select]
   - Destroyed: Provide destruction method and date. Method: [Select], Date: [Select]
   - Retained: Provide name of principal investigator retaining sample. Name: [Select]
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, are you 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: [Select]
   - Additional comments:
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
14. Sample Provider Entity Name:
15. Address (NOT a post office address): [Select]
16. City:
17. State: [Select]
18. Zip Code:
19. Sample Provider Point of Contact (First, M., Last):
20. Sample Provider E-mail Address:
21. Comments/Notes:

**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: [Select]
3. No. of samples shipped: [Select]
4. Sample type provided: [Select]
5. Case/patient/sample origin (zip code): [Select]
6. Date samples shipped to Reference Laboratory: [Select]
7. Name of Reference Laboratory:
8. Disposition of any remaining select agent or toxin listed by entity:
   - Destroyed: Provide destruction method and date. Method: [Select], Date: [Select]
   - Retained: Provide name of principal investigator retaining sample. Name: [Select]
   - 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, are you 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 #22 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
   - Date of notification: [Select]
   - Additional comments:
12. Is the sample provider located outside the United States? No/Yes
13. Sample Provider Entity Name:
14. Address (NOT a post office address): [Select]
15. City:
16. State: [Select]
17. Zip Code:
18. Sample Provider Point of Contact (First, M., Last):
19. Sample Provider E-mail Address:
20. Sample Provider Contact Number:
21. Comments/Notes:
**SECTION A – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)**

1. Select Agent or Toxin Identified: [ ]
2. Date identified: [ ]
3. Date of immediate notification for Tier 1 agents or N/A for non-Tier 1 agent: [ ]
4. Type of notification: [ ] Email [ ] Fax [ ] Telephone [ ] eGAP [ ] N/A
5. No. of samples received [ ]
6. Sample type received: [ ]
7. Case/patient/sample origin (zip code): [ ]
8. Type of test performed:
   - [ ] Biochemical
   - [ ] Culture
   - [ ] Mass Spectrometry (e.g., MALDI)
   - [ ] Microscopy
   - [ ] ELISA/IEA/RIA
   - [ ] Other: [ ]
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 §351.19, 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)?
   - [ ] Yes (If Yes, skip to #21 if you have any additional comments.)
   - [ ] No
13. Is the sample provider located outside the United States?
   - [ ] Yes
   - [ ] No

**SECTION B – SAMPLE(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. No. of samples shipped: [ ]
4. Sample type provided: [ ]
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 §351.19, 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)?
    - [ ] 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?
    - [ ] Yes
    - [ ] No

**SECTION C – ADDITIONAL INFORMATION**

13. Sample Provider Entity Name: [ ]
14. Address (NOT a post office address): [ ]
15. City: [ ]
16. State: [ ]
17. Zip Code: [ ]
18. Sample Provider Point of Contact (First, M., Last): [ ]
19. Sample Provider E-Mail Address: [ ]
20. Sample Provider Contact Number: [ ]
21. Comments / Notes: [ ]
APHIS/CDC Form 4 Statistical Information

Agents and Toxins

<table>
<thead>
<tr>
<th>Year</th>
<th>Toxins</th>
<th>Bacteria</th>
<th>Virus</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>236</td>
<td>630</td>
<td>315</td>
</tr>
<tr>
<td>2019</td>
<td>233</td>
<td>569</td>
<td>502</td>
</tr>
<tr>
<td>2020</td>
<td>226</td>
<td>489</td>
<td>150</td>
</tr>
</tbody>
</table>