

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

SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)			
1. Select Agent or Toxin Identified: {Select}	2. Date identified:	3. Date of Immediate Notification for Tier 1 agents or N/A for non-Tier 1 agent:	4. Type of notification: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> Telephone <input type="checkbox"/> eFSAP <input type="checkbox"/> N/A
5. # of samples received:	6. Sample type received: {Select}	7. Case/patient/sample origin (zip code):	
8. Type of test performed:			
<input type="checkbox"/> Biochemical	<input type="checkbox"/> Immunochemistry	<input type="checkbox"/> PCR	
<input type="checkbox"/> Culture	<input type="checkbox"/> Mass Spectrometry (e.g., MALDI)	<input type="checkbox"/> Sequencing	
<input type="checkbox"/> DFA/IFA	<input type="checkbox"/> Microscopy	<input type="checkbox"/> Other: _____	
<input type="checkbox"/> ELISA/EIA/RIA	<input type="checkbox"/> Mouse Bioassay		
9. Dispositions of select agent or toxin listed by entity (complete all that apply):			
<input type="checkbox"/> Transferred (Provide entity name and date of transfer. Entity: _____ Date: _____)			
<input type="checkbox"/> Destroyed (Provide destruction method and date. Method: _____ Date: _____)			
<input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, you are 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? <input type="checkbox"/> No <input type="checkbox"/> 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)? <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, skip to #22 if you have any additional comments.)			
13. Is the sample provider located outside the United States? <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, provide country: {Select}			
14. Sample Provider Entity Name:			
15. Address (NOT a post office address):	16. City:	17. State: {Select}	18. Zip Code:
19. Sample Provider Point of Contact (First, MI, Last):		20. Sample Provider E-mail Address:	21. Sample Provider Contact Number:
22. Comments / Notes:			



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

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:	
3. # of samples shipped:	4. Sample type provided: {Select}	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: <input type="checkbox"/> Destroyed (Provide destruction method and date. Method: _____ Date: _____) <input type="checkbox"/> Retained (Provide name of Principal Investigator retaining sample. Name: _____) <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, you are 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) <input type="checkbox"/> No <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, provide country: {Select}			
13. Sample Provider Entity Name:			
14. Address (NOT a post office address):	15. City:	16. State: {Select}	17. Zip Code:
18. Sample Provider Point of Contact (First, Mi, Last):		19. Sample Provider E-mail Address:	20. Sample Provider Contact Number:
21. Comments / Notes:			



APHIS/CDC Form 4 Helpful Information

- Notification of the identification
 - Date the reference laboratory informed of the final identification
 - How notified
 - Telephone call
 - Email
 - Laboratory information system
 - Fax

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3. # of samples shipped:	4. Sample type provided: {Select}	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: <input type="checkbox"/> Destroyed (Provide destruction method and date. Method: _____ Date: _____) <input type="checkbox"/> Retained (Provide name of Principal Investigator retaining sample. Name: _____) <input type="checkbox"/> Not applicable, the entire specimen was transferred to the Reference Laboratory.			
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14. Address (NOT a post office address):		15. City:	16. State: {Select}
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18. Sample Provider Point of Contact (First, MI, Last):		19. Sample Provider E-mail Address:	20. Sample Provider Contact Number:
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APHIS/CDC Form 4 Helpful Information

SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)			
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5. # of samples received:	6. Sample type received: {Select}	7. Case/patient/sample origin (zip code):	
8. Type of test performed: <input type="checkbox"/> Biochemical <input type="checkbox"/> Immunochemistry <input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Mass Spectrometry (e.g., MALDI) <input type="checkbox"/> Sequencing <input type="checkbox"/> DFA/IFA <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____ <input type="checkbox"/> ELISA/EIA/RIA <input type="checkbox"/> Mouse Bioassay			
9. Dispositions of select agent or toxin listed by entity (complete all that apply): <input type="checkbox"/> Transferred (Provide entity name and date of transfer. Entity: _____ Date: _____) <input type="checkbox"/> Destroyed (Provide destruction method and date. Method: _____ Date: _____) <input type="checkbox"/> Retained (Provide name of Principal Investigator retaining sample. Name: _____)			
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14. Sample Provider Entity Name: _____			
15. Address (NOT a post office address):	16. City:	17. State: {Select}	18. Zip Code:
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8. Disposition of any remaining select agent or toxin listed by entity: <input type="checkbox"/> Destroyed (Provide destruction method and date. Method: _____ Date: _____) <input type="checkbox"/> Retained (Provide name of Principal Investigator retaining sample. Name: _____) <input type="checkbox"/> Not applicable, the entire specimen was transferred to the Reference Laboratory.			
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APHIS/CDC Form 4 Helpful Information

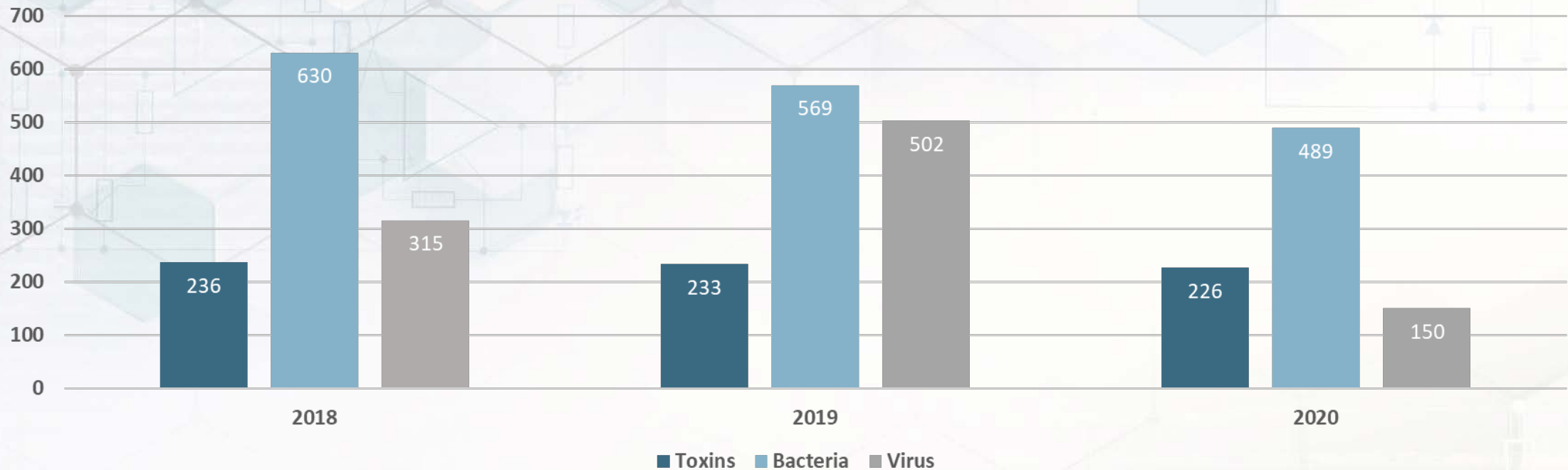
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8. Type of test performed: <input type="checkbox"/> Biochemical <input type="checkbox"/> Culture <input type="checkbox"/> DFA/IFA <input type="checkbox"/> ELISA/EIA/RIA <input type="checkbox"/> Immunochemistry <input type="checkbox"/> Mass Spectrometry (e.g., MALDI) <input type="checkbox"/> Microscopy <input type="checkbox"/> Mouse Bioassay <input type="checkbox"/> PCR <input type="checkbox"/> Sequencing <input type="checkbox"/> Other: _____			
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18. Sample Provider Point of Contact (First, MI, Last):		19. Sample Provider E-mail Address: 20. Sample Provider Contact Number:
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APHIS/CDC Form 4 Statistical Information

Agents and Toxins



www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
lrsat@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
DASAT@usda.gov
301- 851-2070

