# 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 T	OXIN IDENTIFIED FROM CLINICA	AL/DIAGNOSTIC SPECIMEN(S)
Select Agent or Toxin Identified:     Select}	2. Date identified:	3. Date of Immediate Notification f	
5. # of samples received:	6. Sample type received: {S	relect}	7. Case/patient/sample origin (zip code):
8. Type of test performed:  Biochemical Culture DFA/IFA ELISA/EIA/RIA	0000	Immunochemistry Mass Spectrometry (e.g., MALDI) Microscopy Mouse Bioassay	PCR Sequencing Other:
the select agent or toxin?	and date of transfer. Entity: nethod and date. Method: pal Investigator retaining samp ng a select agent or toxin handl	Date: le. Name:	Date:) hay have led to an unintentional release and/or exposure
11. Has the sender(s) (i.e., sample pro Date of Notification:	ovider(s)) of the specimen(s) be NOTE: Please request	een notified of the identification of the selec completed and signed Part 2 from each fa	t agent or toxin? No Yes cility that was in possession of the specimen(s).
		s, skip to <mark>#22 if</mark> you have any additional co	·
13. Is the sample provider located out	side the United States? No	Yes If Yes, provide country: {Select	ct}
14. Sample Provider Entity Name:			_
15. Address (NOT a post office addres	16. City:	17	State: {Select}
19: Sample Provider Point of Contact	(First, MI, Last):	20. Sample Provider E-mail Addre	
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

Date sample(s) shipped to Reference  Disposition of any remaining select at Destroyed (Provide destruction median Retained (Provide name of Princip Not applicable, the entire specime	agent or toxin listed by ent ethod and date. Method:_ pal Investigator retaining so n was transferred to the Re	tity: ample. N	7. Name of Reference Lal	boratory:		toxin identification: patient/sample origin (zip code):
# of samples shipped:  Date sample(s) shipped to Reference  Disposition of any remaining select at Destroyed (Provide destruction median Retained (Provide name of Princip Not applicable, the entire specime	e Laboratory:  agent or toxin listed by enti- ethod and date. Method:_ oal Investigator retaining so n was transferred to the Re	tity: ample. N	7. Name of Reference Lal	,	5. Case/p	patient/sample origin (zip code):
Date sample(s) shipped to Reference  Disposition of any remaining select at Destroyed (Provide destruction median Retained (Provide name of Princip Not applicable, the entire specime	e Laboratory:  agent or toxin listed by enti- ethod and date. Method:_ oal Investigator retaining so n was transferred to the Re	tity: ample. N	7. Name of Reference Lal	,	5. Case/p	patient/sample origin (zip code):
Disposition of any remaining select and Destroyed (Provide destruction management of Princip Not applicable, the entire specime	agent or toxin listed by ent ethod and date. Method:_ pal Investigator retaining so n was transferred to the Re	ample. N	Dat	,	)	
Destroyed (Provide destruction me Retained (Provide name of Princip Not applicable, the entire specime	ethod and date. Method:_ oal Investigator retainingsa n was transferred to the Re	ample. N	Name:	te:	)	
Retained (Provide name of Princip Not applicable, the entire specime	oal Investigator retaining sa n was transferred to the Re	ample. Neference	Name:	te:		
Not applicable, the entire specime	n was transferred to the Re	eference				
			and the second s			)
Were any of the samples containing	a select agent or toxin ha		Laboratory.			
		ındled ou	tside of primary containmer	nt which may h	ave led to an uninte	entional release and/or exposure to the
elect agent or toxin?						
No Yes (If Yes, you are requi				•		S/CDC Form 3)
D. Was your entity the source of the sa	ample(s)1NoYe	es (If Ye	s, skip to <mark>#21 if</mark> you have ar	ny additional co	omments.)	
<ol> <li>Has the sender(s) (i.e., sample protection of the sender)</li> </ol>	alamand Dank O frame analy for				_	Yes
2. Is the sample provider located outs	ide the United States?	No	Yes If Yes, provide coun	try: {Select}		·
3. Sample Provider Entity Name:						
4. Address (NOT a post office address	s):	15. City	<i>y</i> :	16. State: {S	elect}	17. Zip Code:
b. Sample Provider Point of Contact (	First, Wii, Last).		i 9. Sample Provider E-ma	all Address.	20. Sample Provi	der Contact Number.
1. 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

Select Agent or Toxin Identified:		Date notified of select agent or toxin identification:						
{Select}	I		<u> </u>			1		
3. # of samples shipped:	4. Sample type provided: {Select}  5. Case/patient/sample origin (z						atient/sample origin (zip code	e):
6. Date sample(s) shipped to Refer	ence Laboratory:	7	7. Name of Reference La	aboratory:				
B. Disposition of any remaining sele	ect agent or toxin listed by entity	y:						
<ul> <li>Destroyed (Provide destruction)</li> </ul>	n method and date. Method:		Da	ite:		)		
<ul> <li>Retained (Provide name of Pr</li> </ul>	ncipal Investigator retaining sar	mple. Nai	me:					
<ul> <li>Not applicable, the entire spec</li> </ul>	imen was transferred to the Ref	ference La	aboratory.					
. Were any of the samples contain	ing a select agent or toxin hand	dled outsi	de of primary containme	nt which may	have led	to an uninten	tional release and/or exposu	ire to t
elect agent or toxin?								
No Yes (If Yes, you are re	equired under 7 CFR §331.19, 9	OFR §12	21.19, and 42 CFR §73.1	9 to complete	and subr	nit an APHIS	(CDC Form 3)	
10. Was your entity the source of the	ne sample(s) No Yes	s (If Yes,	skip to <mark>#21 if</mark> you have a	ny additional	comment	s.)		
11. Has the sender(s) (i.e., sample		. ma m r .			•	xin? No	Yes	
12. Is the sample provider located	outside the United States?	No 🔲	Yes If Yes, provide cou	ntry:{Selec	t}		·	
13. Sample Provider Entity Name:								
14. Address (NOT a post office add	lress):	15. City:		16. State: {	Select}		17. Zip Code:	
		1	19. Sample Provider E-n	nail Address:	20. S	ample Provid	er Contact Number:	
8: Sample Provider Point of Conta	ct (First, MI, Last):							
18: Sample Provider Point of Conta	ıct (First, MI, Last):							
·	ct (First, MI, Last):							











# APHIS/CDC Form 4 Helpful Information

SECTION B -	SELECT AGENT OR TO	XIN IDENTIFIED FROM CLINI	CAL/DIAGNOSTIC SPECIMEN(S)			
Select Agent or Toxin Identified:	2. Date identified:	Date of Immediate Notification				
{Select}		Tier 1 agents or N/A for non-	Tier 1 agent: E-mail Fax Telephone eFSAP N/A			
5. # of samples received:	6. Sample type received: {Sel	ect}	7. Case/patient/sample origin (zip code):			
8. Type of test performed:						
☐ Biochemical		nmunochemistry	■ PCR			
□ Culture		lass Spectrometry (e.g., MALDI)	Sequencing			
□ DFA/IFA		licroscopy	Other:			
□ ELISA/EIA/RIA	N	louse Bioassay				
9. Dispositions of select agent or toxin lis						
☐ Transferred (Provide entity name ar	· ·		)			
□ 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 §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 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 sar			•			
13. Is the sample provider located outsid	e the United States? No	Yes If Yes, provide country: {Se	lect}			
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 (Fi	rst_ML_last):	20. Sample Provider E-mail Add	dress: 21. Sample Provider Contact Number:			
, and the second	,,	·	21. Sample i Tovider Contact Hamber.			
22. Comments / Notes:		•				

SECTION D - SPE	CIMEN(S) CONTAINING	G SEL	ECT AGENT OR TOX	IN PROVID	ED TO F	REFEREN	NCE LABORA	TORY
Select Agent or Toxin Identified:     {Select}			·	2. Date notifi	ed of selec	ct agent or t	toxin identification	:
3. # of samples shipped:	4. Sample type provided: {Select}					5. Case/pa	atient/sample origi	n (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:								
<ul> <li>Destroyed (Provide destruction</li> </ul>	method and date. Method:_		Da	te:		)		
Retained (Provide name of Pri	ncipal Investigator retaining sa	mple. 1	Name:					
Not applicable, the entire speci	men was transferred to the Re	eference	Laboratory.					
9. Were any of the samples contain	ing a select agent or toxin har	ndled ou	itside of primary containme	nt which may l	have led to	an uninter	ntional release and	d/or exposure to the
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 re	quired under 7 CFR §331.19,	9 CFR §	§121.19, and 42 CFR §73.1	9 to complete	and submi	t 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.)								
NOTE: Discussional secondated 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							
12. Is the sample provider located outside the United States? No Yes If Yes, provide country:  [Select]								
13. Sample Provider Entity Name:								
14. Address (NOT a post office add	ress):	15. Cit	y:	16. State: {S	Select}		17. Zip Code:	
18: Sample Provider Point of Conta	ct (First, MI, Last):		19. Sample Provider E-m	ail Address:	20. Sar	nple Provid	er Contact Number	er:
21. Comments / Notes:								









# APHIS/CDC Form 4 Helpful Information

SECTION B - S	SELECT AGENT OR TOX	N IDENTIFIED FROM CLINICAL/DIA	GNOSTIC SPECIMEN(S)			
Select Agent or Toxin Identified:	2. Date identified:	3. Date of Immediate Notification for	4. Type of notification:			
{Select}		Tier 1 agents or N/A for non-Tier 1 ager	nt:			
5. # of samples received:	6. Sample type received: {Selec		/patient/sample origin (zip code):			
8. Type of test performed:						
☐ Biochemical	□ Imn	nunochemistry	■ PCR			
□ Culture	■ Mas	s Spectrometry (e.g., MALDI)	Sequencing			
□ DFA/IFA	■ Mic	roscopy	Other:			
□ ELISA/EIA/RIA	☐ Mou	ise Bioassay				
9. Dispositions of select agent or toxin lis	ted by entity (complete all that a	oply):				
□ Transferred (Provide entity name an	d date of transfer. Entity:		Date:)			
□ Destroyed (Provide destruction method and date. Method:						
□ 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 §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 provided Date of Notification:	der(s)) of the specimen(s) been r NOTE: Please request com	otified of the identification of the select agent pleted and signed Part 2 from each facility tha	or toxin? No Yes t was in possession of the specimen(s).			
12. Was your entity the source of the san		ip to <mark>#22 if</mark> you have any additional comments	.)			
13. Is the sample provider located outside	e the United States? No	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 (Fin	rst, MI, Last):	20. Sample Provider E-mail Address:	21. Sample Provider Contact Number:			
22. Comments / Notes:						

SECTION D - SPE	CIMEN(S) CONTAINING	G SEL	ECT AGENT OR TOX	IN PROVIDE	D TO	REFERENCE LABORATORY	
Select Agent or Toxin Identified:				2. Date notifie	d of sele	ect agent or toxin identification:	
{Select}			<u> </u>				
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:							
<ul> <li>Destroyed (Provide destruction</li> </ul>	method and date. Method:		Da	te:			
Retained (Provide name of Principal Investigator retaining sample. Name:							
■ Not applicable, the entire speci	•						
			<u> </u>	nt which may h	ave led t	to an unintentional release and/or exposure to the	
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?							
	quired under 7 CFR 8331 19	9 CFR	8121 19 and 42 CFR 873 1	9 to complete a	nd suhm	nit an APHIS/CDC Form 3)	
No 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) No Yes (If Yes, skip to #21 if you have any additional comments.)							
11. Has the sender(s) (i.e., sample   NOTE: Please request completed a					ent orto	xin?NoYes	
12. Is the sample provider located of							
13. Sample Provider Entity Name:							
14. Address (NOT a post office add	ress):	15. Cit	y:	16. State: {S	elect}	17. Zip Code:	
18: Sample Provider Point of Conta	ct (First, MI, Last):		19. Sample Provider E-m	ail Address:	20. Sa	ample Provider Contact Number:	
21. Comments / Notes:							

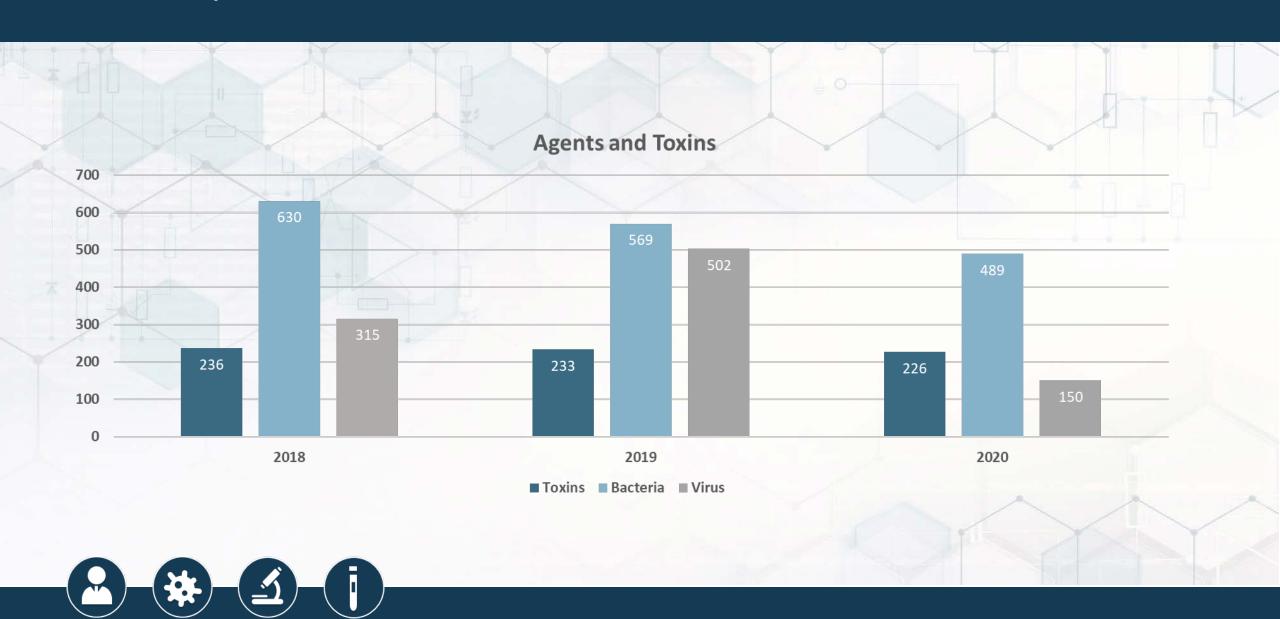








### APHIS/CDC Form 4 Statistical Information



**CDC Contact Information** Division of Select Agents and Toxins 404-718-2000

**APHIS Contact Information** Division of Agricultural **Select Agents and Toxins** 301-851-2070









