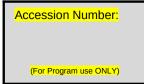


## REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN FROM A CLINICAL/DIAGNOSTIC SPECIMEN (APHIS/CDC FORM 4A)

#### INSTRUCTIONS

Read guidance instructions at <u>www.selectagents.gov</u> before completing this form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC by email attachment, fax, or mail:

Animal and Plant Health Inspection Service Agricultural Select Agent Program 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737 FAX: (301) 734-3652 E-mail: <u>Agricultural.Select.Agent.Program@aphis.usda.gov</u> Centers for Disease Control and Prevention Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop A46 Atlanta, GA 30333 FAX: (404) 718-2096 Email: <u>CDCForm4@cdc.gov</u>



# Submit completed form only once by either email, fax, or mail

SECTION A – REFERENCE LABORATORY INFORMATION								
1. Name of individual completing Sections A and B:			2. E	2. Email address:		3. Telephone #:		
First:	MI:	Last:						
4.   Registered Entity	4.  Registered Entity (APHIS or CDC Registration #:							
Clinical or Diagno	ostic Laboratory [	non-registered entity (NRE)]						
	d by APHIS or CD		)					
	5. Responsible Official or Laboratory Supervisor name:			10. Address (NOT a post office address):				
First: MI: Last:								
6. Telephone #:	7. Fax #:	8. Email address:		11. City:	12. State:	13. Zip Code:		
				III Only.				
SE	CTION B - SE	ELECT AGENT OR TOXIN I		I ROM CLINICAL/D	AGNOSTIC SPECIM	MEN(S)		
1. Select Agent or Toxin I					2. Date identified:	1211(0)		
3. Case/patient/sample IE		4. # of samples received:	E Comple tu	pe(s) received:		patient origin (zip code):		
3. Case/patient/sample il	J #(S).	4. # Of Samples received.	5. Sample ty	pe(s) received.	o. Case/p	alient origin (zip code).		
7. Dispositions of select a	gent or toxin (cor	mplete all that apply):						
□ Transferred (Provide	entity name and	date of transfer. Entity:			Date:	)		
		od and date. Method:		Date:	)			
		aining sample. Name:			)			
8. 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? Ves (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)								
9. Do you anticipate receiving additional samples/specimens for this case/patient that originate from the initial case (e.g. patient, environmental sample)?								
$\square$ No $\square$ Yes (If Yes, please refer to the guidance instructions at <u>www.selectagents.gov</u> for further directions.)								
10. 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 laboratory that was in possession of the specimen(s).								
11. Comments / Notes:								

I hereby certify that the information contained in Sections A and B 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.

Signature of Responsible Official/Laboratory Supervisor: \_



# REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN FROM A CLINICAL/DIAGNOSTIC SPECIMEN (APHIS/CDC FORM 4A)

FORM APPROVED OMB NO. ####-#### EXP DATE ##/##/20##

SECTION C – SAMPLE PROVIDER INFORMATION							
1. Name of individual completing Sections C and D: First: MI: Last:				Email address: 3. Telephone #:			#:
4. □ Registered Entity (APHIS or CDC Registration #:) □ Clinical or Diagnostic Laboratory [non-registered entity (NRE)] (NRE # (provided by APHIS or CDC):)				y name:			
5. Responsible Official or Laboratory Supervisor name: First: MI: Last:			10. Ad	10. Address (NOT a post office address):			
6. Telephone #:	7. Fax #:	8. Email address:	11. City	:		12. State:	13. Zip Code:
SECTION D	- SPECIMEN(S) CONT	AINING SELECT AGENT	OR TOXIN	PROVID	DED TO RE	FERENCE L	ABORATORY
1. Date specimens (s) shi	pped to Reference Laboratory	2. # of specimens provided:		3. Case	e/patient /sam	ple ID #(s):	
4. Sample type(s) provide	d:				5. Case/patie	ent/sample origi	in (zip code):
6. Date notified by Reference Laboratory of select agent or toxin identification:       7. Select agent or toxin identified by Reference Laboratory:							
Transferred (Provide	8. Dispositions of select agent or toxin (complete all that apply):  Transferred (Provide entity name and date of transfer. Entity: Date:)						
<ul> <li>Destroyed (Provide destruction method and date. Method: Date:)</li> <li>Retained (Provide name of person retaining sample. Name:)</li> </ul>							
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?							
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 (If Yes, please refer to the guidance instructions at <u>www.selectagents.gov</u> for further directions.)							
11. Comments / Notes:							

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.

Signature of Responsible Official/Laboratory Supervisor: \_

Date Signed:

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 30333; ATTN: PRA (0920-0576).



#### REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN: PROFICIENCY TESTING REPORT (APHIS/CDC FORM 4B)

#### INSTRUCTIONS

Read guidance instructions at <u>www.selectagents.gov</u> before completing this form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC by email attachment, fax, or mail:

Animal and Plant Health Inspection Service Agricultural Select Agent Program 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737 FAX: (301) 734-3652 E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov Centers for Disease Control and Prevention Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop A46 Atlanta, GA 30333 FAX: (404) 718-2096 Email: <u>CDCForm4@cdc.gov</u>



(For Program use ONLY)

# Submit completed form only once by either email, fax, or mail

SECTION A – INFORMATION FOR LABORATORY THAT RECEIVED PROFICIENCY TESTING SAMPLE(S)								
1. Name of individual com First:	pleting the form: MI:	Last:	2. Email address:	3. Telephone #:				
Ginical or Diagnostic Laboratory [non-registered entity (NRE)]     (NRE # (provided by APHIS or CDC):)			) 5. Entity name:	5. Entity name:				
6. Responsible Official or Laboratory Supervisor name: First: MI: Last:			7. Address (NOT a post of	7. Address (NOT a post office address):				
8. Telephone #:	9. Fax #:	10. Email address:	11 .City:	11 .City: 12. State: 13. Zip				
14. Sponsor/entity that you	received select agent o	r toxin from:						
Entity name:      Registration #:        Entity address:          Telephone #:      Email:								
SE	SECTION B – SELECT AGENTS AND TOXINS IDENTIFIED FROM PROFICIENCY TESTING							
	1. Select Agent or Toxin Identified         2. Date obtained from sponsor         3. Date identified							
4. Dispositions of select age								
<ul> <li>Transferred (Provide entity name and date of transfer. Entity:</li> <li>Destroyed (Provide destruction method and date. Method:</li> </ul>			Date:	_ Date:	)			
			Date:	)				
<ul> <li>Retained (Provide name of person retaining sample. Name:)</li> <li>Were any of the samples containing a select agent or toxin, listed in the table above, handled outside of primary containment which may have led to an</li> </ul>								
unintentional release and/or exposure to the select agent or toxin?								
🗆 No 🛛 Yes (If Yes, you	Laro required under 7 C	D Dort 221 10 0 CED Dort 1	21.10 and 42 CED Dart 72.10 to com	n lata and automit an AF				
	alle lequileu ulluei 7 Cr	-R Pail 331.19, 9 CFR Pail 1	21.19, and 42 CFR Part 73.19 to com	ipiete and submit an AF	PHIS/CDC Form 3)			

I hereby certify that the information contained on 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.

Date:

Signature of Responsible Official/Laboratory Supervisor:\_

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 30333; ATTN: PRA (0920-0576)

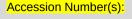


### REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN: FEDERAL LAW ENFORCEMENTSEIZURE REPORT (APHIS/CDC FORM 4C)

#### INSTRUCTIONS

Read guidance instructions at <u>www.selectagents.gov</u> before completing this form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC by email attachment, fax, or mail:

Animal and Plant Health Inspection Service Agricultural Select Agent Program 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737 FAX: (301) 734-3652 E-mail: <u>Agricultural.Select.Agent.Program@aphis.usda.gov</u> Centers for Disease Control and Prevention Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop A46 Atlanta, GA 30333 FAX: (404) 718-2096 Email: <u>CDCForm4@cdc.gov</u>



(For Program use ONLY)

## Submit completed form only once by either email, fax, or mail

SECTION A – FEDERAL LAW EMFORCEMENT INFORMATION							
1. Name of federal law enforcement agency	<i>r</i> .		First:	deral law enforceme	nt agent: MI:	Last:	
3.Telephone #:	4.Fax #:		5.Email addre	ess:			
	SECTION B - SEL	ECT AGEN	ITS AND TO	XINS SEIZED			
1.Name of entity select agent or toxin seize	d from:						
2.Select agent or toxin seized		3.Amoun	t seized	4.Dispos	ition of seized	select agent or toxin	
5.Were any of the seized select agents or toxins handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin?							
6.Comments / Notes:			,				

I hereby certify that the information contained on 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.

Signature of Agent:

Date Signed:

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 30333; ATTN: PRA (0920-0576).