

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

## INSTRUCTIONS

Detailed instructions are available at <u>http://www.selectagents.gov/form4.html</u>. Answer all items completely and type or print in ink. This report must be signed and submitted to either APHIS or CDC at:

Animal and Plant Health Inspection Service Agriculture Select Agent Services 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737 FAX: (301) 734-3652 Email: <u>AgSAS@aphis.usda.gov</u> Centers for Disease Control and Prevention Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop A-46 Atlanta, GA 30329 FAX: (404) 471-8469 Email: <u>CDCForm4@cdc.gov</u>

Accession Number:

(For Program Use ONLY)

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

		SECTION A – REFEREN	ICE LABO	ORATO	<b>RY INFORMA</b>	TION					
1. Name of individual com First:	npleting Sections MI:	A and B: Last:	2. Email a	address:			3. Telephone #:				
(NRE # (provided	ostic Laboratory [i d by APHIS or CD	non-registered entity (NRE)] C):		9. Entity name:							
5. Responsible Official or First:	Laboratory Supe MI:	rvisor name (if same as field 1 then s Last:	9: 10. /	10. Address (NOT a post office address):							
6. Email address:	7. Telephone #	#: 8. Fax #:		11. (	11. City:		12. State:	13. Zip Code:			
SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)											
1. Select Agent or Toxin I	dentified:			2. Date identified:							
3. Case/patient/sample ID #(s):		4. # of samples received:	5. Sample	e type rec	eived:		6. Case/patient origin (zip code)				
7. Type of test performed (e.g., PCR, mouse bioassay, ELISA)											
8. Dispositions of select agent or toxin by entity listed in field 8 (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:)											
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)?											
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 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 Entit	2. Sample Provider Entity Name: (First, MI, and Last Nam		act: 14.	. Sample	ample Provider Email Address:		15 Sample Number:	e Provider Contact			
16. Comments / Notes:		ctions A and B of this form is true and co									

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:

Date Signed:



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FORM APPROVED OMB NO. 0920-0576 OMB NO. 0920-0213 EXP DATE ##/##/20##

## INSTRUCTIONS

Detailed instructions are available at <a href="http://www.selectagents.gov/CDForm.html">http://www.selectagents.gov/CDForm.html</a>. Answer all items completely and type or print in black ink. This report must be signed and submitted to either APHIS or CDC:

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

Animal and Plant Health Inspection Service Agricultural Select Agent Services 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737 FAX: (301) 734-3652 Email: <u>AgSAS@aphis.usda.gov</u> Centers for Disease Control and Preven Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop A-46 Atlanta, GA 30329 FAX: (404) 471-8469 Email: <u>CDCForm4@cdc.gov</u>

Reference ID Number:

SECTION C – SAMPLE PROVIDER INFORMATION													
. Name of individual completing Sections C and D:						2. E	. Email address:				3. Telephone #:		
-irst:	MI:	Las	st:										
<ol> <li>□□Registered Entity (A</li> </ol>	PHIS or CDC F	Registration #:				)	9. Entity	/ name:					
Clinical or Diagnostic			enti	ty (NRE)]									
(NRE # (provided			_		)								
5. Responsible Official or Laboratory Supervisor name (if same as field 1 then skip to field 9):						field	10. Address (NOT a post office address):						
irst: MI: Last:													
6. Email address:	7. Telephone #	#: 8. Fax #:					11. City: 12. S					.3. Zip Code:	
SECTION D – SPECIMEN(S) CONTAINING SELECT AGENT OR TOXIN PROVIDED TO REFERENCE LABORATORY													
1. Select Agent or Toxin Identified:				2. Date not identification	toxin 3. Case/patient/sample ID #(s):								
4. # of samples shipped:				5. Sample type provided:				6. Case/patient/samp			le origin (zip code):		
7. Date sample(s) shipped to Reference Laboratory: 8. Name of Reference							nce Laboratory:						
<ol> <li>Disposition of any remaining</li> </ol>													
Destroyed (Provide de							Date:			)			
Retained (Provide name of Principal Investigator retaining sample. Name:)													
Not applicable, the en					,							·	
LO. Were any of the sample		select agent c	or to	oxin handled	l outside of prir	nary co	ntainment	which ma	ay have led to a	in unintenti	onal re	lease and/or ex	cposure
o the select agent or toxin' ] No □ ∏ Yes (If Yes, yo		under 7 CFR	Par	t 331.19. 9 (	CFR Part 121.1	19. and	42 CFR Pa	art 73.19	to complete an	d submit ar	n APHI	S/CDC Form 3	)
No Yes (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)											<u>'</u>		
L2. 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.)													
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? NO Yes N/A NOTE: Please request completed and signed Sections C & D from each facility that was in possession of the specimen(s).													
4. Sample Provider Entity Name: 15. Sample P (First, MI, and							Sample Provider Email Address:				17. Sample Provider Contact Number:		
L8. 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 30329; ATTN: PRA (0920-0576).