

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

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

## **INSTRUCTIONS**

Detailed instructions are available at http://www.selectagents.gov/form4.html. 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: AgSAS@aphis.usda.gov

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: CDCForm4@cdc.gov

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

	SECT	ION A - REFERENCE	LABORATOR	RY INFORMATI	ON						
Name of individual con First:	npleting Sections A and B: MI: La	st:	2. Email ad	dress:		3. Telephone #:					
4. □□Registered Entity (A	APHIS or CDC Registration #:		) 9. En	9. Entity name:							
	ostic Laboratory [non-registered by APHIS or CDC):	· ·									
5. Responsible Official or First:	d by APHIS or CDC): Laboratory Supervisor name MI: La		o field 9: 10. Ad	10. Address (NOT a post office address):							
6. Email address:	7. Telephone #:	8. Fax #:	11. Ci	ity:	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:				ype received:  6. Case/patient origin							
7. Type of test performed	(e.g., PCR, mouse bioassay,	ELISA)			•						
	gent or toxin by entity listed in				Date <sup>.</sup>	)					
Transferred (Provide entity name and date of transfer. Entity: Date:											
Retained (Provide name of Principal Investigator retaining sample. Name:											
the select agent or toxin?				,		·					
	ou are required under 7 CFR eiving additional samples/spec										
□ No □ Yes (If Ye	es, please refer to the guidanc	e instructions at <u>www.selecta</u>	agents.gov for fur	ther directions.)							
11. Has the sender(s) (i.e NOTE: Please reque	., sample provider(s)) of the s st completed and signed Sect	pecimen(s) been notified of the ions C & D from each facility	ne identification o that was in posse	of the select agent of ession of the specin	or toxin? $\ \square$ No $\ \square$ men(s).	] Yes 🔲 N/A					
12. Sample Provider Entit	er Entity Name:  13. Sample Provider Poir Contact: (First, MI, and L			14. Sample Prov Email Address:	vider 15 Samp Number:	ple Provider Contact :					
16. Comments / Notes:				1	1						
I hereby certify that the inform part of this form, or its attachn criminal penalties, including in	ation contained in Sections A and nents, I may be subject to crimina norisonment.	B of this form is true and correct fines and/or imprisonment. I furt	t to the best of my k her understand tha	knowledge. I understa It violations of 7 CFR	and that if I knowingly p 331, 9 CFR 121, or 42	rovide a false statement on any CFR 73 may result in civil or					
	cial/Laboratory Supervisor:			Date Signe	ed:						
BE USE	A REPORTING	THE IDENTIFICATION	ON OF A SEI	LECT AGENT	<b>OR</b> FO	RM APPROVED 3 NO. ####-####					



(APHIS/CDC FORM 4A)

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

## **INSTRUCTIONS**

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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>

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

			TION C - S	SAMPLE PE	ROVIDE	RINFO	RMAT	ION			
1. Name of individual completing Sections C and D:				2. E	2. Email address:				3. Telephone #:		
First:	MI: Last:										
1 □□Registered Entity (/	ADHIS or CDC Danie	stration #			<u> </u>	9 Entity	name.				
4. □□Registered Entity (APHIS or CDC Registration #:) □□Clinical or Diagnostic Laboratory [non-registered entity (NRE)]						9. Entity name:					
(NRE # (provided by APHIS or CDC):											
			same as field	1 then skin to	field	10. Address (NOT a post office address):					
9):	i. Responsible Official or Laboratory Supervisor name (if same as field 1 then skip to field					10. Address (NOT a post office address).					
First:	MI:	Last:	ast:								
6. Email address:	7. Telephone #:	8	B. Fax #:			11. City:			12. State:	13. Zip Code:	
						,				·	
CECTION D	CDECIMENI(C)	CONTAI	NINO CEL	FOT A OFN	T 0D T	OVIND	DO\ ((D	ED TO DEEL	DENOE L	DOD ATORY	
SECTION D – SPECIMEN(S) CONTAINING SELECT AGENT OR TOXIN PROVIDED TO REFERENCE LABORATORY											
Select Agent or Toxin Identified:			<ol><li>Date notified of select agent o identification:</li></ol>			3. Case/patient/sample ID #(s):					
4. # of samples shipped:			5. Sample type provided:			6. Case/patient/samp			nt/sample origi	ole origin (zip code):	
7. Date sample(s) shipped to Reference Laboratory:  8. Name of Reference Laboratory:											
9. Disposition of any remaining select agent or toxin by entity listed in field 8:											
Destroyed (Provide destruction method and date. Method:											
Retained (Provide na				Name:						)	
					/.						
Not applicable, the entire specimen was transferred to the Reference Laboratory.  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 Part 331.19, 9 CFR Part 121.19, and 42 CFR Part 73.19 to complete and submit an APHIS/CDC Form 3)											
11. Was your entity the source of the sample(s)? \[ \] No \[ \] Yes (If Yes, skip to field 18)											
12. 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 <a href="https://www.selectagents.gov">www.selectagents.gov</a> for further directions.)											
13. Has the sender(s) (i.e.	sample provider(s))	of the spec	imen(s) been	notified of the	e identifica	ation of th	e select	agent or toxin?	□ No □ Y	es N/A	
NOTE: Please reques										00 <u> </u>	
14. Sample Provider Entity Name: 15. Sample I						mple Provider Em		ail Address:		Provider Contact	
(First, MI, ar		rst, MI, and	d Last Name)						Number:		
18. Comments / Notes:											
I hereby certify that the informa	ation contained in Socti	one C and D	of this form is	true and correct	to the hos	t of my kno	wledne I	understand that it	I knowinaly pro	vide a false statement on any	
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 im	prisonment.									•	
Signature of Responsible Official/Laboratory Supervisor: Date Signed:											
Signature of receptional continual action of the conti											

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).