

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

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576 EXP DATE XX/XXXXXX

INSTRUCTIONS

Detailed instructions are available at http://www.selectagents.gov/form4.html. This report must be submitted to either AgSAS or DSAT.

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

E-mail: AgSAS@aphis.usda.gov

Centers for Disease Control and Prevention Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop H21-7 Atlanta, GA 30329 FAX: (404) 471-8469

E-mail: CDCForm4@cdc.gov

Submit completed form only once by either eFSAP, e-mail, fax, or mail											
PART 1 – REPORT OF IDENTIFICATION											
SECTION A - REFERENCE LABORATORY INFORMATION											
1. Name of individual completing Sections A and B (First, MI, Last):			2. E-mail address:			;	3. Telephone #:				
4. Entity name or Name of Clinical/Diagnos	stic Laboratory:										
5. Responsible Official or Laboratory Supervisor name (First, MI, Last):			6. E-mail address:			7. Telephone #:					
8. Address (NOT a post office address):			9. City:			0. State:	11. Zip Code:				
SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)											
Select Agent or Toxin Identified:	2. Date identified:	3. Dat	te of Immediate Notification r 1 agents or N/A for non-Ti	4. Type of	• •						
5. # of samples received: 6	Sample type received:	ample type received:			e/patient/sample origin (zip code):						
8. Type of test performed: □ Biochemical □ Culture □ DFA/IFA □ ELISA/EIA/RIA	☐ Mas ☐ Micr	☐ Mass Spectrometry (e.g., MALDI)☐ Microscopy				□ PCR □ Sequencing □ Other:					
9. Dispositions of select agent or toxin liste ☐ Transferred (Provide entity name and ☐ Destroyed (Provide destruction metho ☐ Retained (Provide name of Principal I)					
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 Source 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)? \square No \square Yes (If Yes, skip to #23 if you have any additional comments.)											
13. Is the sample provider located outside	the United States? No	Yes If Ye	es, provide country:								
14. Sample Provider Entity Name:											
15. Address (NOT a post office address): 16. City:			17. State:			18. Zip Code:					
19: Sample Provider Point of Contact (First, MI, Last):			20. Sample Provider E-mail Address: 2			21. Sample Provider Contact Number:					
22. Comments / Notes:					<u> </u>						
hereby certify that the information contained in I	Part 1 of this form is true and correc	ct to the be	st of my knowledge. I understa	ınd that if I kn	owingly prov	ide a false s	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 Part 331, 9 CFR Part 121, or 42 CFR Part 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. 0579-0213 OMB NO. 0920-0576 EXP DATE 11/30/2018

INSTRUCTIONS

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PART 2 – REPORT OF IDENTIFICATION										
SECTION C - SAMPLE PROVIDER INFORMATION										
Name of individual completing Sections C and D (First, MI, Last):				2. E-mail address:			3. Telephone #:			
4. Entity name or Name of Clinical/	Diagnostic Laboratory:									
5. Responsible Official or Laborato		6. E-mail address:			7. Telephone #:					
8. Address (NOT a post office address):				9. City:			10. State:	11. Zip Code:		
SECTION D - SPE	ECIMEN(S) CONTAININ	G SEL	ECT AGENT OR TOX	(IN PROVIDE	D TO F	REFERENC	CE LABO	RATORY		
1. Select Agent or Toxin Identified:					2. Date notified of select agent or toxin identification:					
3. # of samples shipped:	4. Sample type provided:				origin (zip code):					
6. Date sample(s) shipped to Reference Laboratory: 7. Name of Reference Laboratory:										
	n method and date. Method:_ incipal Investigator retaining s cimen was transferred to the F ning a select agent or toxin ha equired under 7 CFR §331.19,	ample. Referenc ndled ou	Name:e Laboratory. utside of primary containmes §121.19, and 42 CFR §73.	19 to complete a	ave led to	an unintenti		•		
10. Was your entity the source of the sample(s)? No Yes (If Yes, skip to #22 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? No 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? NO Yes If Yes, provide country:										
13. Sample Provider Entity Name:										
14. Address (NOT a post office address):		15. City:		16. State:		17. Zip Code:		le:		
18: Sample Provider Point of Contact (First, MI, Last):			19. Sample Provider E-n	nail Address: 20. Sample Provide		er Contact Number:				
21. Comments / Notes: I hereby certify that the information contains form, or its attachments, I may be sucivil or criminal penalties, including imprison.	ubject to criminal fines and/or impi									
Signature of Responsible Official/Labora			Signed:							
Public reporting burden: Public reporting	ng burden of providing this inform	ation is e	stimated to average 1 hour pe	er response, includ	ling the tim	ne for reviewing	instructions,	searching existing		

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).