



Submitting Select Agents to Orange County Public Health Laboratory

**Karen McLean, MPH, PHM
Supervising Public Health Microbiologist**

OBJECTIVES

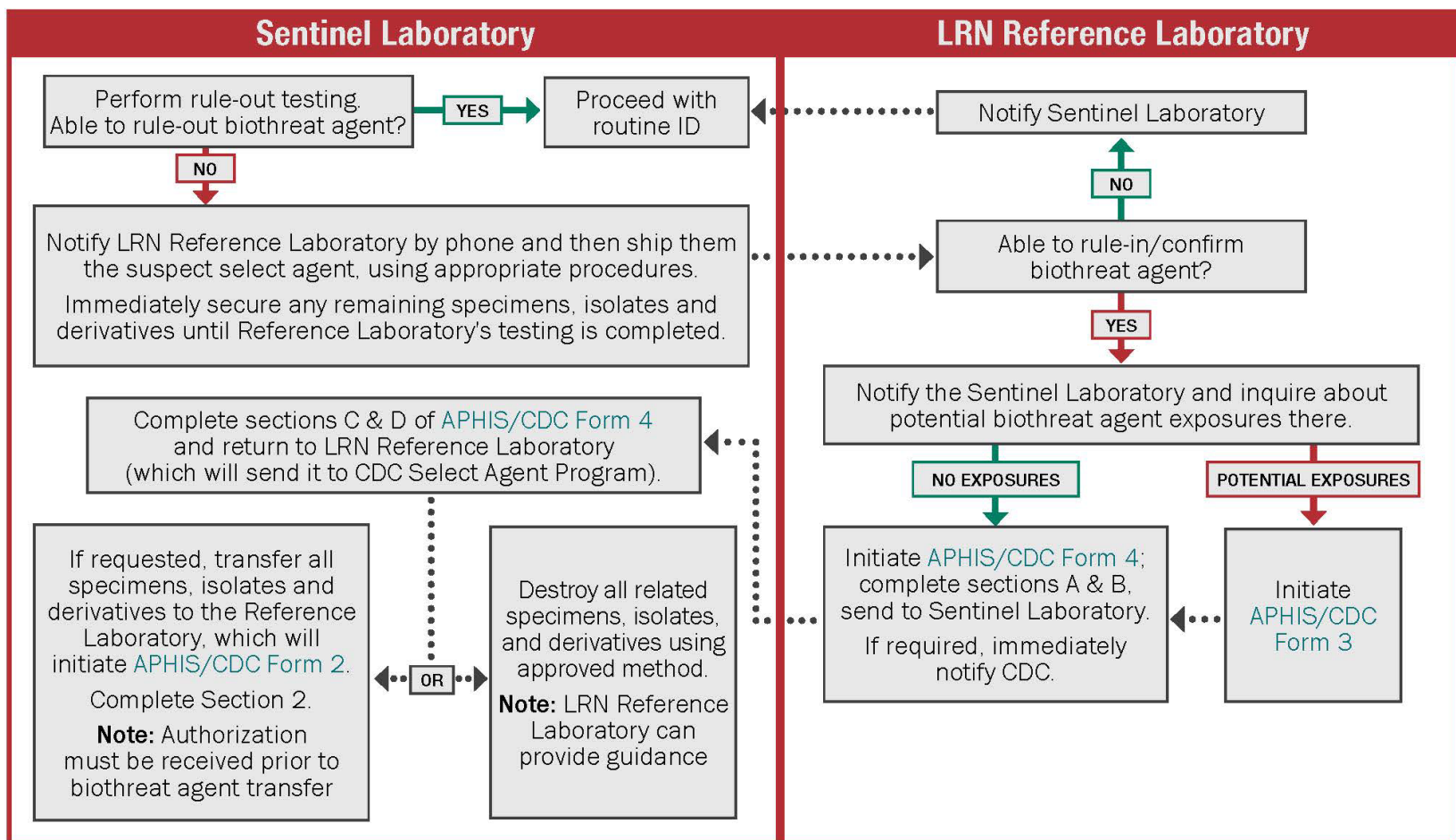
- What to do when a Select Agent is suspected
- How to complete OCPHL Supplemental Isolate Submission Form for Select Agents
- Describe Federal Select Agent Program
- Find and complete APHIS/CDC Form 4 and Form 3 if necessary



Biothreat Agent Response Algorithm

RESPONDING TO A BIOTHREAT AGENT

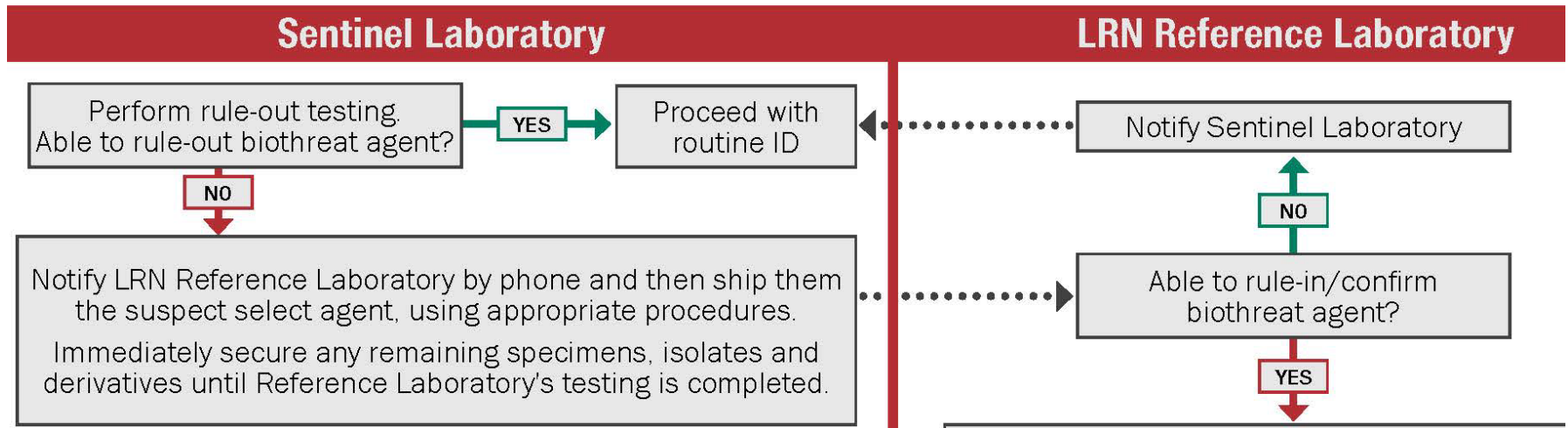
Biothreat Agent Response Algorithm



Biothreat Agent Response Algorithm

RESPONDING TO A BIOTHREAT AGENT

Biothreat Agent Response Algorithm



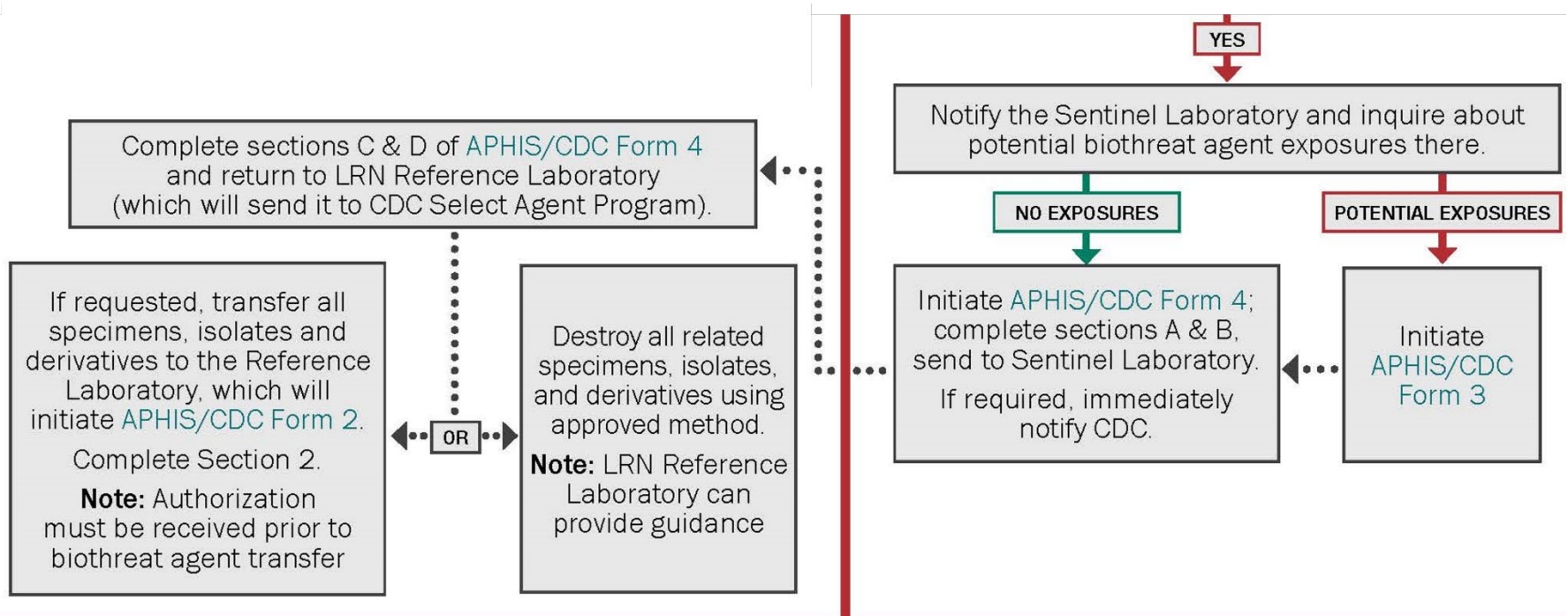
Biothreat Agent Response Algorithm

RESPONDING TO A BIOTHREAT AGENT

Biothreat Agent Response Algorithm

Sentinel Laboratory

LRN Reference Laboratory



DESTRUCTION

Non-registered clinical labs must destroy or transfer a **confirmed** select agent within 7 days

- **Suspected** select agent cultures may be retained until confirmed.
 - Select agent ruled out: follow your laboratory procedure for disposal
- **Confirmed** select agent cultures must be transferred or destroyed onsite

DESTRUCTION

Non-registered clinical labs must destroy or transfer a **confirmed** select agent within **7 days**

- **Transfer:** Must obtain permission prior to transfer (APHIS/CDC Form 2)
- **Destruction:** must inactivate using on-site autoclave or chemical decontamination method before disposal or transfer of select agent
 - Record date, amount/quantity, method of destruction and laboratory personnel destroying

DESTRUCTION

Decontamination of Select Agents Isolated in the Clinical Laboratory

September 2024



- Chemical Inactivation Decontamination Process for Samples and Cultures
- Chemical Inactivation Decontamination Process for Blood Culture Bottles
- Toxin Inactivation
- Decontamination of Material that may contain Select Agent Spores

<https://www.aphl.org/aboutAPHL/publications/Documents/PHPR-Select-Agent-Decontamination.pdf>

Is it a Select Agent?

You have an unusual isolate and you are unable to rule it out using the ASM protocols.


What do you do?

SUSPECT A SELECT AGENT? NOTIFY OCPHL

- **Call OCPHL**
 - Notify the Bacteriology Department before sending an isolate to OCPHL
- **Call laboratory general number at (714) 834-8385**
 - Specify that you have a select agent isolate to rule out
 - Ask to speak to the Bacteriology Department
 - After hours: contact on-call Public Health Officer at (714) 628-7008

PAPERWORK

- OCPHL Laboratory Requisition Form or Laboratory Web Portal Submission
- Supplemental Isolate Submission Form for Select Agents
- Please use one form per isolate
- ochealthinfo.com/ocphl



Public Health Laboratory
1729 West 17th Street Santa Ana, CA 92706
Phone (714) 834-8385 • Fax (714) 834-7968
Supplemental Isolate Submission Form For Select Agents

INSTRUCTIONS: Isolates submitted for Select Agent testing must include this supplemental form and a laboratory requisition form. You must receive verbal authorization from the Public Health Lab prior to sending any isolates. Use one form per isolate. Please print or type your answers.

PATIENT NAME:		CALL TO OCPHL DATE: <small>mm/dd/yy</small>	CALL RECEIVED BY:
<input type="checkbox"/> HUMAN	<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE <input type="checkbox"/> UNKNOWN	SUBMITTING LABORATORY:	
<input type="checkbox"/> ANIMAL	Type of animal:	SUBMITTING LAB CONTACT NAME:	
DOB: <small>mm/dd/yy</small>	AGE: <small>mm/dd/yy</small> COUNTY OF RESIDENCE or ZIP CODE:	SUBMITTING LAB PHONE NUMBER:	
SPECIMEN SOURCE:		TRAVEL HISTORY: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
PATIENT STATUS: <input type="checkbox"/> Inpatient <input type="checkbox"/> Outpatient <input type="checkbox"/> Discharged <input type="checkbox"/> Deceased <input type="checkbox"/> Unknown <input type="checkbox"/> Other:		Travel Date: <small>mm/dd/yy</small> Location:	
DESCRIPTION OF CLINICAL SYMPTOMS:		CONTACT WITH ANIMAL: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Describe the Animal Contact:	
PHYSICIAN:		PHYSICIAN PHONE NUMBER:	

DATE SPECIMEN COLLECTED: <small>mm/dd/yy</small>	DATE SPECIMEN INOCULATED: <small>mm/dd/yy</small>	DATE VISIBLE GROWTH SEEN: <small>mm/dd/yy</small>
SUSPECTED ORGANISM(S) TO RULE OUT:		LAB EXPOSURES: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
MEDIA GROWTH: BAP: <input type="checkbox"/> CHOC: <input type="checkbox"/> MAC: <input type="checkbox"/> Other:	GRAM STAIN: <input type="checkbox"/> GNCB <input type="checkbox"/> GPC <input type="checkbox"/> GNR <input type="checkbox"/> GPR <input type="checkbox"/> Variable <input type="checkbox"/> Pleomorphic <input type="checkbox"/> Other:	SPORES: <input type="checkbox"/> Oval <input type="checkbox"/> Spherical <input type="checkbox"/> Central <input type="checkbox"/> Terminal <input type="checkbox"/> Subterminal <input type="checkbox"/> None <input type="checkbox"/> Swelling <input type="checkbox"/> No Swelling
COLONY MORPHOLOGY DESCRIPTION:		ID METHOD: <input type="checkbox"/> Automated ID <input type="checkbox"/> Conventional biochemicals <input type="checkbox"/> SATELLITE: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> X <input type="checkbox"/> V <input type="checkbox"/> XV <input type="checkbox"/> NA <input type="checkbox"/> MALDI-TOF <input type="checkbox"/> Susceptibility TEMPERATURE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA <input type="checkbox"/> Sequencing <input type="checkbox"/> Commercial kit ATMOSPHERE: <input type="checkbox"/> Other:
HEMOLYSIS: <input type="checkbox"/> Alpha <input type="checkbox"/> Beta <input type="checkbox"/> Gamma		TSI Result: <small>mm/dd/yy</small>
MOTILITY: <input type="checkbox"/> Motile <input type="checkbox"/> Non-Motile METHOD: <input type="checkbox"/> Wet-Mount <input type="checkbox"/> Semi-Solid <input type="checkbox"/> NA		B-LACTAMASE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA
CATALASE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA	OXIDASE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA	COLISTIN: <input type="checkbox"/> Sensitive <input type="checkbox"/> Resistant <input type="checkbox"/> NA
UREA: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA	INDOLE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA	POLYMYXIN B: <input type="checkbox"/> Sensitive <input type="checkbox"/> Resistant <input type="checkbox"/> NA
NITRATE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA	ARGININE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA	
ADDITIONAL NOTES:		

Supplemental Isolate Submission Form Instructions

- Electronically fill out form, using drop downs where available
- Data can be saved at any time
- Print and include a copy with isolate
- Select Reset Form to clear the form



The form is a rectangular document with a white background. It is framed by a decorative border consisting of a top row of teal squares and a bottom row of red squares. On the left side, there is a logo for 'OC health CARE AGENCY' featuring an orange 'OC' and a circular seal with a landscape. To the right of the logo, a dark blue rectangular box contains white text for the 'Public Health Laboratory', including its address (1729 West 17th Street Santa Ana, CA 92706), phone number (714) 834-8385, fax number (714) 834-7968, and the title 'Supplemental Isolate Submission Form For Select Agents'. Below this box, a horizontal line separates the header from the instructions. The instructions, in blue text, state: 'INSTRUCTIONS: Isolates submitted for Select Agent testing must include this supplemental form and a laboratory requisition form. You must receive verbal authorization from the Public Health Lab prior to sending any isolates. Use one form per isolate. Please print or type your answers.'

 **Public Health Laboratory**
1729 West 17th Street Santa Ana, CA 92706
Phone (714) 834-8385 • Fax (714) 834-7968
Supplemental Isolate Submission Form For Select Agents

INSTRUCTIONS: Isolates submitted for Select Agent testing must include this supplemental form and a laboratory requisition form. You must receive verbal authorization from the Public Health Lab prior to sending any isolates. Use one form per isolate. Please print or type your answers.

Supplemental Isolate Submission Form Instructions

Please provide as much information as possible

PATIENT NAME:		CALL TO OCPHL DATE: <small>mm/dd/yy</small>	CALL RECEIVED BY:
<input type="checkbox"/> HUMAN	<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE <input type="checkbox"/> UNKNOWN	SUBMITTING LABORATORY:	
<input type="checkbox"/> ANIMAL	Type of animal:		
DOB: <small>mm/dd/yy</small>	AGE:	COUNTY OF RESIDENCE or ZIPCODE:	SUBMITTING LAB CONTACT NAME:
SPECIMEN SOURCE:		SUBMITTING LAB PHONE NUMBER:	
PATIENT STATUS: <input type="checkbox"/> Inpatient <input type="checkbox"/> Outpatient <input type="checkbox"/> Discharged <input type="checkbox"/> Deceased <input type="checkbox"/> Unknown <input type="checkbox"/> Other:		TRAVEL HISTORY: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Travel Date: <small>mm/dd/yy</small> Location:	
DESCRIPTION OF CLINICAL SYMPTOMS:		CONTACT WITH ANIMAL: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Describe the Animal Contact:	
PHYSICIAN:		PHYSICIAN PHONE NUMBER:	

Supplemental Isolate Submission Form Instructions

Please provide as much information as possible

DATE SPECIMEN COLLECTED: <input type="text"/> mm/dd/yy		DATE SPECIMEN INOCULATED: <input type="text"/> mm/dd/yy		DATE VISIBLE GROWTH SEEN: <input type="text"/> mm/dd/yy	
SUSPECTED ORGANISM(S) TO RULE OUT: <input type="text"/>			LAB EXPOSURES: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
<div> <i>Bacillus anthracis</i> <i>Brucella species</i> <i>Burkholderia mallei/pseudomallei</i> <i>Francisella tularensis</i> <i>Yersinia pestis</i> </div>			IN: <input type="checkbox"/> GNGB <input type="checkbox"/> GPC <input type="checkbox"/> GNR <input type="checkbox"/> GPR		
			<input type="checkbox"/> Variable <input type="checkbox"/> Pleomorphic		
			<input type="checkbox"/> Other: <input type="text"/>		
			SPORES: <input type="checkbox"/> Oval <input type="checkbox"/> Spherical <input type="checkbox"/> Central <input type="checkbox"/> Terminal <input type="checkbox"/> Subterminal <input type="checkbox"/> None <input type="checkbox"/> Swelling <input type="checkbox"/> No Swelling		
SATELLITE: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> X <input type="checkbox"/> V <input type="checkbox"/> XV <input type="checkbox"/> NA			ID METHOD: <input type="checkbox"/> Automated ID <input type="checkbox"/> Conventional biochemicals		
TEMPERATURE: <input type="text"/>		ATMOSPHERE: <input type="text"/>		<input type="checkbox"/> MALDI-TOF <input type="checkbox"/> Susceptibility	
MOTILITY: <input type="checkbox"/> Motile <input type="checkbox"/> Non-Motile				<input type="checkbox"/> Sequencing <input type="checkbox"/> Commercial kit	
METHOD: <input type="checkbox"/> Wet-Mount <input type="checkbox"/> Semi-Solid <input type="checkbox"/> NA				<input type="checkbox"/> Other: <input type="text"/>	
CATALASE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA		TSI Result: <input type="text"/>		B-LACTAMASE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA	
OXIDASE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA				COLISTIN: <input type="checkbox"/> Sensitive <input type="checkbox"/> Resistant <input type="checkbox"/> NA	
UREA: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA				POLYMYXIN B: <input type="checkbox"/> Sensitive <input type="checkbox"/> Resistant <input type="checkbox"/> NA	
INDOLE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA					
NITRATE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA					
ARGININE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA					
ADDITIONAL NOTES: <input type="text"/>					

Supplemental Isolate Submission Form Instructions

Please provide as much information as possible

DATE SPECIMEN COLLECTED: <small>mm/dd/yy</small>		DATE SPECIMEN INOCULATED: <small>mm/dd/yy</small>		DATE VISIBLE GROWTH SEEN: <small>mm/dd/yy</small>	
SUSPECTED ORGANISM(S) TO RULE OUT: <input type="text"/>			LAB EXPOSURES: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
MEDIA GROWTH: BAP: <input type="text"/> CHOC: <input type="text"/> MAC: <input type="text"/> <input type="checkbox"/> Other: <input type="text"/>		GRAM STAIN: <input type="checkbox"/> GNGB <input type="checkbox"/> GPC <input type="checkbox"/> GNR <input type="checkbox"/> GPR <input type="checkbox"/> Variable <input type="checkbox"/> Pleomorphic <input type="checkbox"/> Other: <input type="text"/>			
COLONY MORPHOLOGY DESCRIPTION: <input type="text"/>			SPORES: <input type="checkbox"/> Oval <input type="checkbox"/> Spherical <input type="checkbox"/> Central <input type="checkbox"/> Terminal <input type="checkbox"/> Subterminal <input type="checkbox"/> None <input type="checkbox"/> Swelling <input type="checkbox"/> No Swelling		
HEMOLYSIS: <input type="checkbox"/> Alpha <input type="checkbox"/> Beta <input type="checkbox"/> Gamma			ID METHOD: <input type="checkbox"/> Automated ID <input type="checkbox"/> Conventional biochemicals		
SATELLITE: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> X <input type="checkbox"/> V <input type="checkbox"/> XV <input type="checkbox"/> NA			<input type="checkbox"/> MALDI-TOF <input type="checkbox"/> Susceptibility		
TEMPERATURE: <input type="text"/>		ATMOSPHERE: <input type="text"/>		<input type="checkbox"/> Sequencing <input type="checkbox"/> Commercial kit	
MOTILITY: <input type="checkbox"/> Motile <input type="checkbox"/> Non-Motile			TSI Result: <input type="text"/>		
METHOD: <input type="checkbox"/> Wet-Mount <input type="checkbox"/> Semi-Solid <input type="checkbox"/> NA					
CATALASE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA			B-LACTAMASE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA		
OXIDASE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA					
UREA: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA			COLISTIN: <input type="checkbox"/> Sensitive <input type="checkbox"/> Resistant <input type="checkbox"/> NA		
INDOLE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA					
NITRATE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA			POLYMYXIN B: <input type="checkbox"/> Sensitive <input type="checkbox"/> Resistant <input type="checkbox"/> NA		
ARGININE: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> NA					
ADDITIONAL NOTES: <input type="text"/>					

Packing and Shipping

1. Identify

2. Classify

3. Pack

4. Mark

5. Label

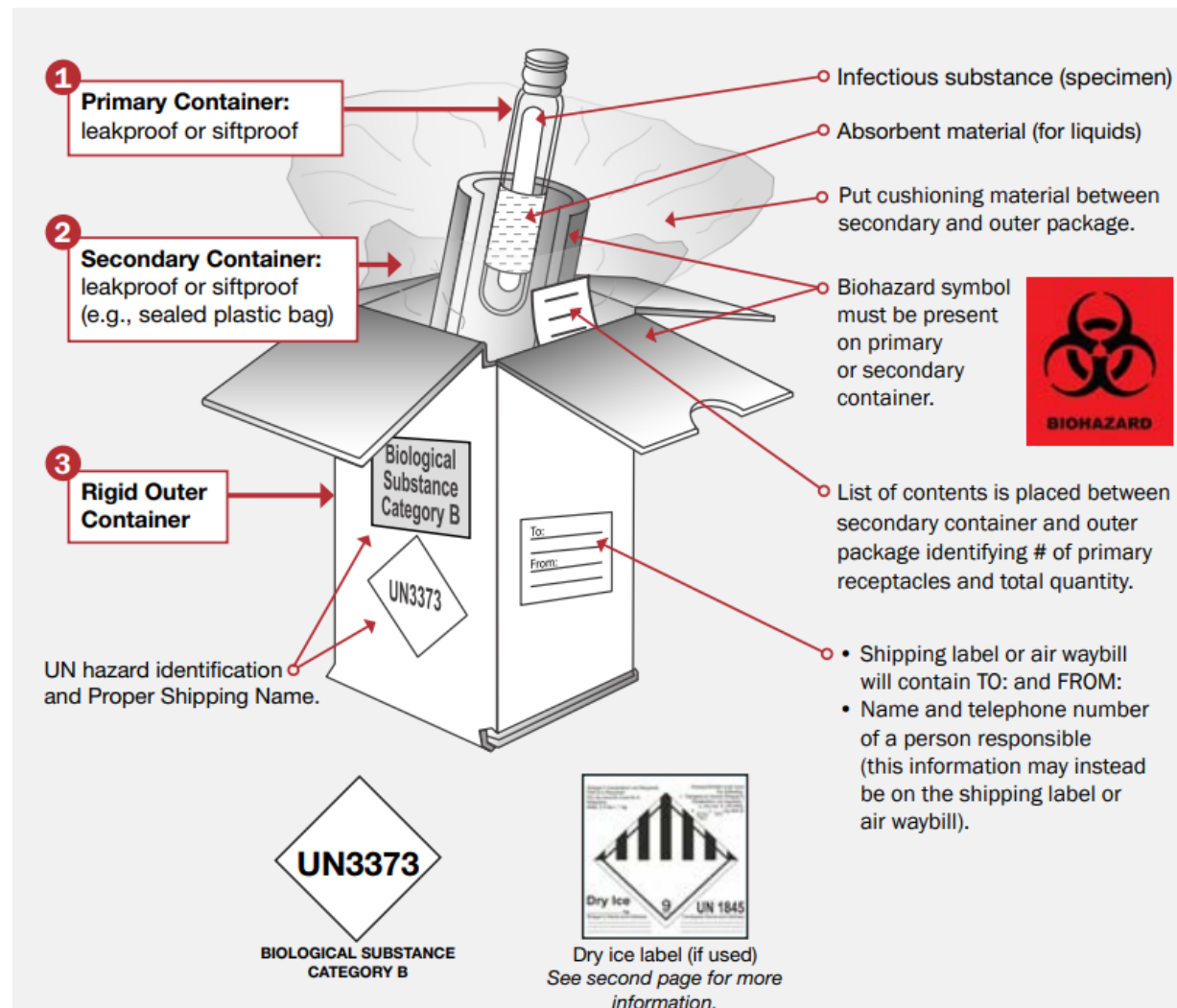
6. Document



Packing and Shipping

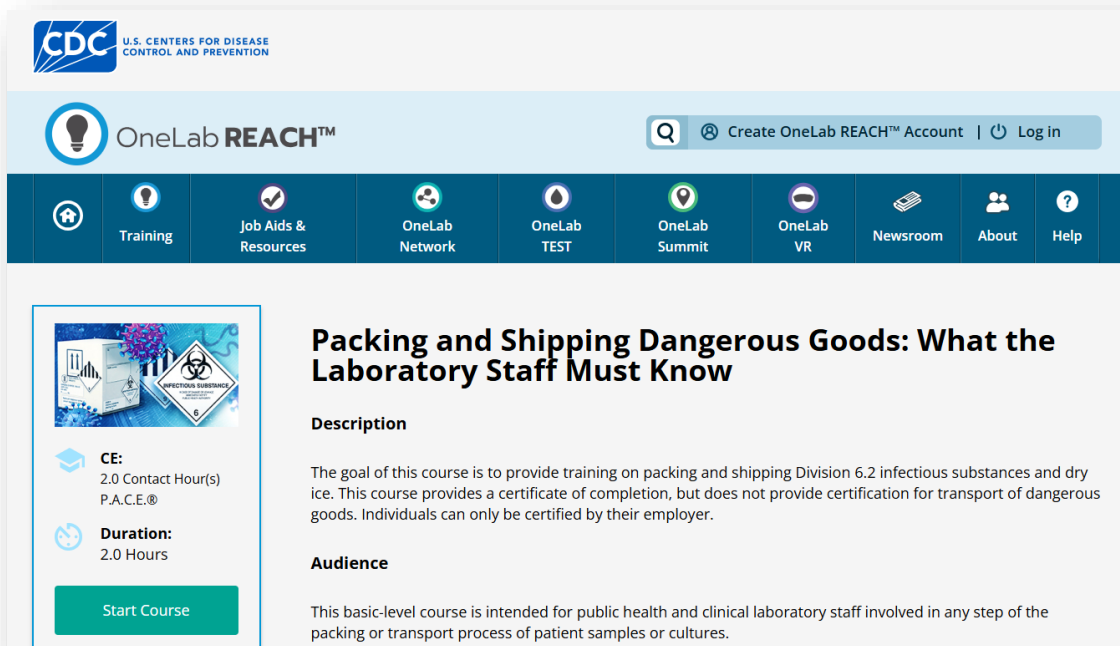
CATEGORY B

1. Primary Leakproof container
2. Absorbent material
3. Sealed leakproof secondary container
4. Rigid outer container
5. Proper labeling



Packing and Shipping

Department of Transportation (DOT) and the International Air Transport Association (IATA) require packing and shipping training every 2 years



The screenshot shows the CDC OneLab REACH website interface. At the top is the CDC logo and the text 'U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION'. Below this is the 'OneLab REACH™' header with a search bar and links for 'Create OneLab REACH™ Account' and 'Log in'. A navigation bar contains icons and labels for Training, Job Aids & Resources, OneLab Network, OneLab TEST, OneLab Summit, OneLab VR, Newsroom, About, and Help. The main content area features a course card for 'Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know'. The card includes a biohazard icon, a 'CE' (Continuing Education) badge, and a 'Start Course' button.

CDC U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

OneLab REACH™

Create OneLab REACH™ Account | Log in

Training Job Aids & Resources OneLab Network OneLab TEST OneLab Summit OneLab VR Newsroom About Help

Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know

Description

The goal of this course is to provide training on packing and shipping Division 6.2 infectious substances and dry ice. This course provides a certificate of completion, but does not provide certification for transport of dangerous goods. Individuals can only be certified by their employer.

Audience

This basic-level course is intended for public health and clinical laboratory staff involved in any step of the packing or transport process of patient samples or cultures.

CE:
2.0 Contact Hour(s)
P.A.C.E.®

Duration:
2.0 Hours

Start Course

CDC OneLab REACH offers a free online course (2.0 CEU)

[Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know | OneLab REACH](#)

OCPHL will test isolate and phone results to submitter.

If a Select Agent is identified, we must follow guidelines of Federal Select Agent Program.



FEDERAL SELECT AGENT PROGRAM

FEDERAL SELECT AGENT PROGRAM (FSAP)

- Regulates facilities that possess, use and transfer biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products.
- Requires registration of facilities that work with select agents and toxins (research, academic, non-federal government, federal government, commercial, and private non-profit laboratories)

FEDERAL SELECT AGENT PROGRAM (FSAP)

- 2001 – USA PATRIOT Act
- 2002 – Public Health Security and Bioterrorism Preparedness and Response Act
- Currently, regulating 63 select agents and toxins

FEDERAL SELECT AGENT PROGRAM (FSAP)

HHS and USDA Select Agents and Toxins

7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the regulations.

More information can be found at <https://www.selectagents.gov/sat/list.htm>

HHS Select Agents and Toxins

- 1) Abrin
- 2) *Bacillus cereus* Biovar *anthracis**
- 3) Botulinum neurotoxins*
- 4) Botulinum neurotoxin producing species of *Clostridium**
- 5) Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X₁CCX₂PACGX₃X₄X₅CX₆)
- 6) *Coxiella burnetii*
- 7) Crimean-Congo haemorrhagic fever virus
- 8) Diacetoxyscirpenol
- 9) Eastern equine encephalitis virus
- 10) *Ebolavirus**
- 11) *Francisella tularensis**
- 12) Lassa fever virus
- 13) Lujo virus
- 14) Marburg virus*
- 15) Monkeypox virus
- 16) Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)

- 17) Ricin
- 18) *Rickettsia prowazekii*
- 19) Severe acute respiratory syndrome coronavirus (SARS-CoV)
- 20) SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors
- 21) Saxitoxin

South American Haemorrhagic Fever viruses:

- 22) Chapare
- 23) Guanarito
- 24) Junin
- 25) Machupo
- 26) Sabia
- 27) Staphylococcal enterotoxins (subtypes A,B,C,D,E)
- 28) T-2 toxin
- 29) Tetrodotoxin



1

CS027006-A 01/04/2025

Tick-borne encephalitis complex (flavi) viruses:

- 30) Far Eastern subtype
- 31) Siberian subtype
- 32) Kyasanur Forest disease virus
- 33) Omsk hemorrhagic fever virus
- 34) Variola major virus (Smallpox virus)*
- 35) Variola minor virus (Alastrim)*
- 36) *Yersinia pestis**

Overlap Select Agents and Toxins

- 37) *Bacillus anthracis**
- 38) *Bacillus anthracis* Pasteur strain
- 39) *Burkholderia mallei**
- 40) *Burkholderia pseudomallei**
- 41) Hendra virus
- 42) Nipah virus*
- 43) Rift Valley fever virus
- 44) Venezuelan equine encephalitis virus

USDA Select Agents and Toxins

- 45) African swine fever virus
- 46) Avian influenza virus
- 47) Classical swine fever virus
- 48) Foot-and-mouth disease virus*
- 49) Goat pox virus
- 50) Lumpy skin disease virus
- 51) *Mycoplasma capricolum*
- 52) *Mycoplasma mycoides*
- 53) Newcastle disease virus
- 54) Peste des petits ruminants virus
- 55) Rinderpest virus*
- 56) Sheep pox virus
- 57) Swine vesicular disease virus

USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins

- 58) *Coniothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)
- 59) *Ralstonia solanacearum*
- 60) *Rathayibacter toxicus*
- 61) *Sclerophthora rayssiae*
- 62) *Synchytrium endobioticum*
- 63) *Xanthomonas oryzae*

* Denotes Tier 1 Agent

2

CS-257006-A 01/04/2025

www.selectagents.gov

Tier 1 Select Agents

HHS Agents and Toxins

- *Bacillus cereus* Biovar *anthracis*
- Botulinum neurotoxins
- Botulinum neurotoxin producing species of *Clostridium*
- *Ebolavirus*
- *Francisella tularensis*
- Marburg virus
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- *Yersinia pestis*

USDA Agents

- Foot-And-Mouth Disease virus
- Rinderpest virus

Overlap Agents

- *Bacillus anthracis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*

Information for Clinical/Diagnostic Laboratories

[Information for Clinical/Diagnostic Laboratories, Healthcare Facilities, and Other Entities Not Registered with the Federal Select Agent Program | Resources | Federal Select Agent Program](#)

- Diagnostic Specimen Exemption
- Medical Waste Exclusion
- Reporting Requirements
- Tier 1 Select Agents and Toxins
- Non-Tier 1 Select Agents and Toxins
- Select Agent and Toxin Exclusions
- Reporting the Identification of a Select Agent or Toxin

CDC/APHIS Forms



FEDERAL SELECT AGENT PROGRAM

- **Form 1-** Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins
- **Form 2-** Request to Transfer Select Agents and Toxins
- **Form 3-** Incident Notification and Reporting (Theft, Loss, or Release)
- **Form 4-** Reporting the Identification of a Select Agent or Toxin
- **Form 5-** Request for Exemption of Select Agents and Toxins for Investigational Product

FORM 4: REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN

- Used by clinical or diagnostic laboratories and other entities
- Notify the FSAP of the identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin.
- Tier 1 Select Agents or toxins require immediate notification to FSAP, followed by Form 4 within 7 calendar days

<https://www.selectagents.gov/forms/form4.htm>

FORM 4: REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN

- Form 4A-AB (Part 1)
 - Section A – Reference Laboratory Information
 - Section B – Select Agent or Toxin Identified from Clinical/Diagnostic Specimen(s)
- Form 4A-CD (Part 2)
 - Section C – Sample Provider Information
 - Section D- Specimen(s) Containing Select Agent or Toxin Provided to reference Laboratory

FORM 4: REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN

<https://www.selectagents.gov/forms/form4.htm>

Form 4 Downloads

For assistance in the completion of APHIS/CDC Form 4, please refer to the guidance document below. This guidance document provides detailed information and direction on how to complete all sections of APHIS/CDC Form 4.

Please only hand write if using print only form and do not adjust the formatting and text on the form.

- **APHIS/CDC Form 4A – Reporting the Identification from a Clinical/Diagnostic Specimen**
 - **Form 4A-AB**
 - Fillable PDF: [APHIS/CDC Form 4A-AB](#)  [PDF – 159 KB]
 - Print Only PDF: [APHIS/CDC Form 4A-AB](#)  [PDF – 129 KB]
 - [Guidance Document for the Completion of APHIS/CDC Form 4A-AB](#)  [PDF – 168 KB]
 - **Form 4A-CD**
 - Fillable PDF: [APHIS/CDC Form 4A-CD](#)  [PDF – 362 KB]
 - Print Only PDF: [APHIS/CDC Form 4A-CD](#)  [PDF – 119 KB]
 - [Guidance Document for the Completion of APHIS/CDC Form 4A-CD](#)  [PDF – 196 KB]
- **APHIS/CDC Form 4B – Reporting the Identification from a Proficiency Test**
 - Fillable PDF: [APHIS/CDC Form 4B](#)  [PDF – 234 KB]
 - Print Only PDF: [APHIS/CDC Form 4B](#)  [PDF – 184 KB]
- **APHIS/CDC Form 4C – Federal Law Enforcement Reporting Seizure of Select Agent or Toxin**
 - Fillable PDF: [APHIS/CDC Form 4C](#)  [PDF – 261 KB]
 - Print Only PDF: [APHIS/CDC Form 4C](#)  [PDF – 199 KB]

FORM 4: REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN



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

FORM APPROVED
OMB NO. 0920-0576
EXP DATE: 02/28/2027

Detailed instructions are available at <http://www.selectagents.gov/form4.html>. This report must be submitted to either DASAT or DRSC:

Animal and Plant Health Inspection Service
Division of Agricultural Select Agents and Toxins
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
E-mail: DASAT@usda.gov

Centers for Disease Control and Prevention
Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4 Atlanta,
GA 30329
FAX: (404) 471-8469
E-mail: CDCForm4@cdc.gov

Submit completed form only once by either eFSAP, e-mail, or fax

PART 2 – REPORT OF IDENTIFICATION			
SECTION C – SAMPLE PROVIDER INFORMATION			
1. Name of individual completing Sections C and D (First, MI, Last):		2. E-mail address:	
		3. Telephone #:	
4. Your facility name:			
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:	
		10. State: {Select}	
		11. Zip Code:	

SECTION D – SPECIMEN(S) CONTAINING SELECT AGENT OR TOXIN PROVIDED TO REFERENCE LABORATORY

FORM 4: REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN

SECTION D – SPECIMEN(S) CONTAINING SELECT AGENT OR TOXIN PROVIDED TO REFERENCE LABORATORY			
1. Select Agent or Toxin Identified: {Select}		2. Date notified by reference laboratory of select agent or toxin identification:	
3. # of select agent/toxin samples shipped:	4. Sample type provided: {Select}		5. Zip code for case/patient/sample origin:
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: <input type="checkbox"/> Destroyed (Provide destruction method and date. Must be onsite. Method: _____ Date: _____) <input type="checkbox"/> Retained (Provide name of Principal Investigator retaining sample. Name: _____) <input type="checkbox"/> Not applicable, the entire specimen was transferred to the Reference Laboratory.			
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? <input type="checkbox"/> No <input type="checkbox"/> 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)? <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, skip to #21 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? <input type="checkbox"/> No <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, provide country: {Select}			
13. Sample Provider Entity Name:			
14. Address (NOT a post office address):	15. City:	16. State: {Select}	17. Zip Code:
18. Sample Provider Point of Contact (First, MI, Last):	19. Sample Provider E-mail Address:	20. Sample Provider Contact Number:	
21. Comments / Notes:			

FORM 4: REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN

I hereby certify that the information contained in Part 2 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 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: _____

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).

Animal and Plant Health Inspection Service

Division of Agricultural Select Agents and Toxins

4700 River Road, Unit 2, Mailstop 22, Cubicle
1A07

Riverdale, MD 20737

Fax: 301-734-3652

Email: DASAT@usda.gov

Centers for Disease Control and Prevention

Division of Regulatory Science and Compliance

1600 Clifton Road, NE, Mailstop H21-4

Atlanta, GA 30329


Fax: 404-471-8375

Email: CDCForm4@cdc.gov

FORM 3: REPORTING OF A RELEASE/LOSS/THEFT

- Used to report a theft, loss, or release (including occupational exposure or release outside of the primary barriers of the biocontainment area) of a select agent or toxin
- Required to report immediately

<https://www.selectagents.gov/forms/form3.htm>

[Guidance Document for the Completion of APHIS/CDC Form 3](#)  [PDF – 505 KB]

- Fillable PDF: [APHIS/CDC Form 3](#)  [PDF – 291 KB]
- Print Only PDF: [APHIS/CDC Form 3](#)  [PDF – 297 KB]

Please only hand write if using print only form and do not adjust the formatting and text on the form.

FORM 3: REPORTING OF A RELEASE/LOSS/THEFT



REPORT OF A RELEASE/LOSS/THEFT OF A SELECT AGENT OR TOXIN APHIS/CDC FORM 3

FORM APPROVED
OMB NO. 0920-0576
EXP DATE: 02/28/2027

Detailed instructions are available at <http://www.selectagents.gov/form3.html>.
This report must be signed and submitted to either DASAT or DRSC:

Animal and Plant Health Inspection Service
Division of Agricultural Select Agents and Toxins
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
Email: DASAT@usda.gov

Centers for Disease Control and Prevention
Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4
Atlanta, GA 30329
FAX: (404) 471-8375
Email: form3@cdc.gov

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

SECTION A – ENTITY INFORMATION

1. Name of Entity:			
2. Physical Address (NOT a post office box):		3. City:	4. State: {Select}
5. Zip Code:			
6. Name of Responsible Official or Laboratory Supervisor:		7. Name of Principal Investigator:	
8. Telephone Number of Responsible Official:		9. Email address of Responsible Official:	

FORM 3: REPORTING OF A RELEASE/LOSS/THEFT

SECTION B – INCIDENT INFORMATION			
1. Date and Time of Incident: _____	2. Date of Immediate Notification to CDC or APHIS: _____	3. Type of notification to CDC or APHIS: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> Telephone <input type="checkbox"/> eFSAP	4. Location of Incident (bldg., room, equipment, etc.): _____
5. Name of Select Agent or Toxin: {Select}	6. Strain designation of Select Agent or Toxin: <input type="checkbox"/> Recombinant Agent <input type="checkbox"/> Unknown		7. Quantity (Unit (vial, plates, etc.)):
{Select}	<input type="checkbox"/> Recombinant Agent <input type="checkbox"/> Unknown		
{Select}	<input type="checkbox"/> Recombinant Agent <input type="checkbox"/> Unknown		
8. Type of Incident: <input type="checkbox"/> Release/ Potential Exposure (After completing Section B. Go to Section C) <input type="checkbox"/> Loss (After completing Section B. Go to Section D) <input type="checkbox"/> Theft (After completing Section B. Go to Section E) Note: Please complete Appendix 1, event timeline, to provide details on the theft/loss/release incident		9. Severity of the incident: <input type="checkbox"/> Negligible <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High	10. What Biosafety Level did the incident occur? <input type="checkbox"/> BSL2 <input type="checkbox"/> ABSL2 <input type="checkbox"/> BSL3 <input type="checkbox"/> ABSL3 <input type="checkbox"/> BSL4 <input type="checkbox"/> ABSL4 <input type="checkbox"/> ACL 2 <input type="checkbox"/> ABSL3Ag <input type="checkbox"/> ACL 3 <input type="checkbox"/> Storage area <input type="checkbox"/> ACL 4 <input type="checkbox"/> Other _____
11. Is this incident associated with an APHIS/CDC Form 2 (Transfer): <input type="checkbox"/> Yes, APHIS/CDC Form 2 transfer #: _____ <input type="checkbox"/> No		12. Is this incident associated with an APHIS/CDC Form 4 (Identification): <input type="checkbox"/> Yes, APHIS/CDC Form 4 clinical ID#: _____ <input type="checkbox"/> No	

FORM 3: REPORTING OF A RELEASE/LOSS/THEFT

- Section C – Report of Release
- Section D – Report of Loss
- Section E – Report of Theft

<https://www.selectagents.gov/forms/form3.htm>

FORM 3: REPORTING OF A RELEASE/LOSS/THEFT

APPENDIX 1 EVENTS TIMELINE

Provide a detailed summary of events, including a timeline of what occurred. Do not include personal identifiable information (PII).

**Do not include names, just number of people,
summary of medical surveillance, i.e. prophylaxis or
fever watch**

FORM 3: REPORTING OF A RELEASE/LOSS/THEFT

Certification: 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 the select agent regulations may result in civil or criminal penalties, including imprisonment, of 7 CFR Part 331, 9 CFR Part 121, or 42 CFR Part 73.

Signature of Respondent: _____ Title: _____

Typed or printed name of Respondent: _____ Date: _____

Animal and Plant Health Inspection Service

Division of Agricultural Select Agents and Toxins
4700 River Road, Unit 2, Mailstop 22, Cubicle
1A07
Riverdale, MD 20737
Fax: 301-734-3652
Email: DASAT@usda.gov

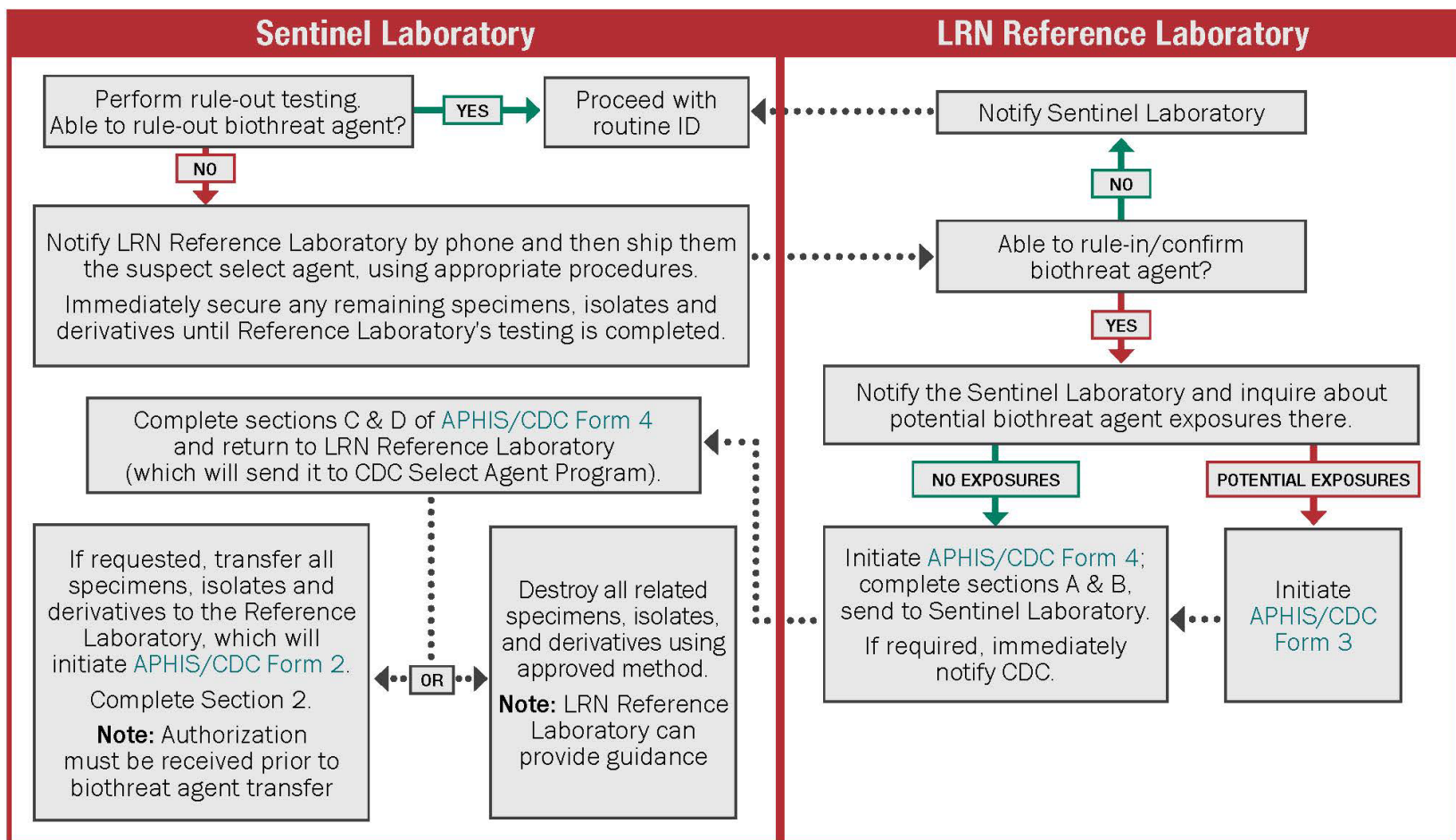
Centers for Disease Control and Prevention

Division of Regulatory Science and Compliance
1600 Clifton Road, NE, Mailstop H21-4
Atlanta, GA 30329
Fax: 404-471-8375
Email: CDCForm4@cdc.gov

Biothreat Agent Response Algorithm

RESPONDING TO A BIOTHREAT AGENT

Biothreat Agent Response Algorithm



OCPHL Select Agent Reference Website

ochealthinfo.com/ocphl

[Test Directory](#)

[Water Quality Laboratory
\(WQL\)](#)

[Select Agent Resources](#)

OCPHL SELECT AGENT RESOURCES

OCPHL Resources

[Supplemental_Isolate_Submission_Form_For_Select_Agents.pdf](#)

[Brucella Removal from Select Agent List Memo 2025](#)

Rule In/Rule Out Resources

[LRN Sentinel Level Clinical Laboratory Protocols](#) ^{cf}

[Clinical Laboratory Preparedness and Response Guide](#) ^{cf}

[Biothreat Agents Identification Bench Cards for Sentinel Laboratories](#) ^{cf}

[LABORATORY RESPONSE NETWORK \(LRN\) SENTINEL LEVEL CLINICAL LABORATORY PROTOCOLS FOR SUSPECTED BIOLOGICAL THREAT AGENTS AND EMERGING INFECTIOUS DISEASES](#) ^{cf}

Other Resources

[Lab Decon Job Aid](#) ^{cf}

[Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know | OneLab REACH](#) ^{cf}

[Federal Select Agent Program](#) ^{cf}

How to submit to the LRN B Lab



QUESTIONS?

Resources

- ochealthinfo.com/ocphl
- <https://www.aphl.org/aboutAPHL/publications/Documents/PHPR-Select-Agent-Decontamination.pdf>
- <https://www.selectagents.gov/forms/form3.htm>
- <https://www.selectagents.gov/forms/form4.htm>
- [Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know | OneLab REACH](#)
- [Information for Clinical/Diagnostic Laboratories, Healthcare Facilities, and Other Entities Not Registered with the Federal Select Agent Program | Resources | Federal Select Agent Program](#)

KAHOOT!

Kahoot!

How to submit to the LRN B Lab



QUESTIONS?

Continuing Education Units



THANK YOU!

Complete Survey for 3.5 hours of CEU

https://ochca.sjc1.qualtrics.com/jfe/form/SV_3aazQfrikAo4ltY

Complete by March 26, 2025