Instructions

Answer all items completely and type or print in ink. Questions concerning the completion of this form can be directed to the respective agency below:

Division of Agricultural Select Agents and Toxins
Telephone: (301) 851-2070
Email: DASAT@usda.gov

Division of Regulatory Science and Compliance
Telephone: (404) 718-2000
Email: cdcform4@cdc.gov

This form must be signed and submitted to either:

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

Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4
Atlanta, GA 30329
FAX: (404) 471-8469
Email: cdcform4@cdc.gov

Part 1 – Report of Identification

Section A – Reference Laboratory Information

Blocks A1-A3:

- □ Enter the name of individual, email address and telephone number completing the form.

Block A4 – Entity Name or Name of Clinical Diagnostic Laboratory:

- □ Please provide the legal name of your entity. Please do not abbreviate the entity name (e.g., International Business Machine Corporation instead of IBM).

Blocks A5-A7 – RO/Lab Supervisor Information:

- □ Responsible Official or Laboratory Supervisor Name:
  - ➢ For entities registered with APHIS or CDC, please provide the complete name of your entity's Responsible Official (RO), exactly as it appears on the current certificate of registration. If the RO is listed in Block A1, please skip to Block A8.
  - ➢ For non-registered entities, please provide the full legal name of your entity's Facility or Laboratory Supervisor or the individual who supervises the laboratory that handled or manipulated the identified select agent or toxin (e.g., Microbiology Supervisor).
- □ Enter the email address and telephone number of the Responsible Official or Laboratory Supervisor.

Blocks A8-11 – Entity's Address:

- □ Enter the address of the entity listed in block A4.

Section B – Select Agents and Toxins Identified from Clinical/Diagnostic Specimens

Block B1-B2 – Select Agent or Toxin Identified:

- □ Select only one select agent or toxin identified in specimen.
- □ Enter the date that the select agent or toxin was identified.

Block B3-B4 – Immediate Notification:

- □ Enter the date of Immediate Notification for Tier 1 agents to APHIS or CDC.
  - ➢ N/A for non-Tier 1 agents.
- □ Indicate how immediate notification was made to APHIS or CDC; via email, fax, telephone, eFSAP.
  - ➢ Select N/A if no immediate notification was made.

Instructions

Block B5 – Number of Samples:

- Enter the number of select agent/toxin samples that were produced and tested for the patient or animal. If more samples are anticipated, see Block B11 for more information.

Block B6 – Sample Type:

- When selecting clinical/diagnostic specimen or isolate, **indicate where the sample type originated from: human, animal, or plant.** Refer to the description of the terms listed in the Frequently Asked Questions.

Block B7 – Zip Code for Case/Patient/Sample Origin:

- Enter the zip code from which the patient, animal or plant is located. If the zip code is unknown enter the city and state.

Block B8 – Type of Test Performed:

- Select the type of test that was performed to identify the select agent or toxin.
- If multiple tests were performed, select all that apply.

Block B9 – Disposition of Select Agent or Toxins (Check All That Apply):

- Refer to the description of the terms listed in the Frequently Asked Questions.

Transferred:

- Check the 'Transferred' box if all or part of the identified select agent or toxin was transferred to another entity.

Destroyed:

- Check the 'Destroyed on site' box only if the entire identified select agent or toxin was destroyed on site. Must be onsite.

Retained:

- Check the 'Retained' box if all or part of the identified select agent or toxin was retained by your entity.

Block B10 – Exposure Outside Primary Containment:

- If there is any possibility that personnel handled the sample containing a select agent or toxin outside primary containment (e.g., working with culture on open bench), this box should be checked 'Yes' and an APHIS/CDC Form 3 must be submitted.

Block B11 – Sample Provider Notified:

- Please select 'Yes' if the facility that provided the specimen has been notified of the identification of the select agent or toxin.

Block B12 – Source of the Samples:

- Indicate whether your facility was the source of the original samples. If 'Yes', then skip to field B22. If 'No', continue to field B13.

Block B13 – International Sample Providers:

- If the sample provider is international, select 'Yes' and provide the country of origin.

Block B14 – Sample Provider Entity Name:

- Please provide the name of the entity that provided the sample to the clinical/diagnostic or reference laboratory listed in Section A.

Blocks B15-B21 – Sample Provider Information:

Instructions

- □ Enter sample provider point of contact name, address, email address, and phone number.

Block B22 – Comments/Notes:

- □ Please provide any information as it relates to the case.

Signature:

- □ For all entities, the individual named in Block A5 (RO, ARO or Laboratory Supervisor) must sign and date the signature line.

Instructions

Answer all items completely and type or print in ink. Questions concerning the completion of this form can be directed to the respective agency below:

Division of Agricultural Select Agents and Toxins
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Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4
Atlanta, GA 30329
FAX: (404) 471-8469
Email: cdcform4@cdc.gov

Part 2 – Report of Identification

Section C – Sample Provider Information

Blocks C1-C3:

- □ Enter the name of individual, email address and telephone number completing the form.

Block C4 – Entity Facility Name:

- □ Please provide the legal name of your entity facility name. Please do not abbreviate the entity name (e.g., International Business Machine Corporation instead of IBM).

Block C5-C7 – RO/Lab Supervisor Information:

- □ Responsible Official or Laboratory Supervisor Name:
  - ➢ For entities registered with APHIS or CDC, please provide the complete name of your entity's Responsible Official (RO), exactly as it appears on the current certificate of registration. If the RO is listed in Block C1, please skip to Block C8.
  - ➢ For non-registered entities, please provide the full legal name of your entity's Facility or Laboratory Supervisor or the individual who supervises the laboratory that handled or manipulated the identified select agent or toxin (e.g., Microbiology Supervisor).
- □ Enter the email address and telephone number of the Responsible Official or Laboratory Supervisor.

Blocks C8-11 – Entity's Address:

- □ Enter the address of the entity listed in Block C4.

Section D – Specimen(s) Containing Select Agent or Toxin Provided to Reference Laboratory

Block D1-D2 – Select Agent or Toxin Identified by Reference Laboratory:

- □ Select only one select agent or toxin identified in specimen.
- □ Enter the date that your facility was notified about the select agent or toxin was that identified by the reference laboratory.

Block D3 – Number of Select Agent/Toxin Samples:

- □ Enter the number of select agent/toxin samples that were produced and tested for the patient or animal. If more samples are anticipated, see Block D12 for more information.

Block D4 – Sample Type:

Instructions

- When selecting clinical/diagnostic specimen or isolate, **indicate where the sample type originated from: human, animal, or plant**. Refer to the description of the terms listed in the Frequently Asked Questions.

Block D5 – Zip Code for Case/Patient/Sample Origin:

- Enter the zip code from which the patient, animal, or plant is located. If the zip code is unknown, please enter the city and state.

Block D6 – Date Sample(s) Shipped to Reference Laboratory:

- Enter the date the samples were transferred to the reference laboratory.

Block D7 – Name of Reference Laboratory:

- Enter the name of the reference laboratory to which the samples were transferred.
- If the samples were transferred to multiple laboratories, list additional laboratories in the 'Comment/Notes'.

Block D8 – Disposition of Select Agent or Toxin (Check All That Apply):

- Refer to the description of the terms listed in the Frequently Asked Questions.

Retained:

- Check the 'Retained' box if all or part of the identified select agent or toxin was retained by your entity.

Destroyed:

- Check the 'Destroyed on site' box only if the entire identified select agent or toxin was destroyed on site. Must be onsite.

Not Applicable:

- Check the 'Not applicable' box if the entire specimen was transferred to the Reference Laboratory.

Block D9 – Exposure Outside Primary Containment:

- If there is any possibility that personnel handled the sample containing a select agent or toxin outside primary containment (e.g., working with culture on open bench), this box should be checked 'Yes' and an APHIS/CDC Form 3 must be submitted.

Block D10 – Source of the Samples:

- If your entity was the source of the samples that were sent to the reference laboratory check 'Yes' and skip to field D21.

Block D11 – Sample Provider Notified:

- Please select 'Yes' if the facility that provided the specimen has been notified of the identification of the select agent or toxin.

Block D12 – International Sample Providers:

- If the sample provider is international, select 'Yes' and provide the country of origin.

Block D13 – Sample Provider Entity Name:

- Please provide the name of the entity that provided the sample to the clinical/diagnostic or reference laboratory listed in Section C.

Block D14-20 – Sample Provider Information:

- Enter sample provider point of contact name, address, email address, and phone number.

Instructions

Block D21 – Comments/Notes:

- □ Please provide any information as it relates to the case.

Signature:

- □ For all entities, the individual named in Block C5 (RO, ARO or Laboratory Supervisor), must sign and date signature line.