DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health
Laboratory

Instructions for Completing Preparedness Forms

Contact the DPHL at 302.802.5000 **prior** to collecting a sample to discuss specimen/sample type, to confirm testing methods available, and to coordinate transportation. DPHL administration will complete the DPHL *Preparedness and Ebola Call Log* to collect the necessary information. Utilize the latest version of the *Specimen Collection Chart* to determine the specimen collection criteria.

All preparedness samples require a Chain of Custody (CoC), except bioterrorism (BT) cultures for rule-out of a BT agent and a clinical Ebola specimen (see below). All clinical specimens require a LIMS Test Requisition. All environmental samples must be properly pre-screened for explosives and radiation; screening must be documented on the *Field Screening Form*. All non-clinical samples (i.e., environmental, food, etc.) require a *Request for Non-Clinical Preparedness Testing Form*. These forms must be completed in full prior to submission for testing.

Request for Non-Clinical Preparedness Testing: General guidelines

- Required for all non-clinical preparedness samples (environmental, food, etc.)
- One form is requested for each sample/batch of samples for testing. Use a separate form for each batch of samples collected.
- This document details the sampling site and address, the requested analyses, incident information, storage conditions, etc. and serves as the test requisition.
- A *Field Screening Form* and *Chain of Custody Form* must accompany this form.

Chain of Custody: General guidelines

- All preparedness samples require a Chain of Custody Form.
- Make all record entries with waterproof blue or black ink. Do not obliterate entries by erasures or markings in records. All corrections to record-keeping errors shall be made by one line marked through the error. The individual making the correction must sign (or initial) and date the correction.
- The collector initiates the *Chain of Custody* (*CoC*). Use a separate *Chain of Custody form* for each sample batch. A batch may consist of a single sample or multiple samples.
- Each person who accepts custody of a legal sample also accepts responsibility for ensuring the security of that sample.
- A sample is considered under custody if it is in your possession, in your view after being in your possession, or placed in a secure area (i.e., sealed container for shipping or an area accessible by authorized personnel only) after being in your possession.
- To simplify record keeping and maintenance of custody, limit the number of people physically handling the sample.
- If a legal sample is to be left unattended, store in a locked compartment.
- When possible, the sample transport container should also be locked or sealed (i.e. evidence tape or other custody seal) in a manner to deter tampering.
- The *CoC* establishes an intact, contiguous record of the physical possession including collected samples, sample aliquots, and sample extracts, or digestates.
- Bioterrorism clinical isolates do not require a chain of custody as their collection and custody cannot be proven. These specimens do require completion of a *DPHL Preparedness Call Log for Rule Out Isolates*. Refer to the appropriate section below. If requested, DPHL may start a *CoC* when the specimen is received in the laboratory performing the testing.

LIMS Test Requisition: General guidelines

- Required for all clinical preparedness samples.
- Details individual patient information.
- Use a separate *LIMS Test Requisition* form for each patient.
- Ensure the correct testing is marked on the form.

Sample Transport: General Guidelines

- All documentation must accompany samples/specimens.
- Utilize a waterproof, sealable bag or zipper bag to maintain all records in a manner that facilitates documentation tracking and allows historical reconstruction of all analytical events and ancillary procedures that produced the resultant sample analytical data.
- Place the completed *Chain of Custody form, Request for Non-Clinical Preparedness Testing* (non-clinical samples only), *LIMS Test Requisition* (clinical specimens only), *Field Screening Form* (non-clinical samples only), and any other supporting documentation, sealed tightly in its own plastic zippered bag.
    - If transporting the specimens to DPHL, attach the bag to the exterior of the sample transport container.
    - If shipping the specimens to another laboratory, place the documents inside the shipping container.
- The submitter is responsible for ensuring sample security if the sample/specimen is in their custody.
- Samples/Specimens may be delivered to the laboratory using any of the following methods:
    - Delivery by the Submitter: **Contact DPHL at 302.802.5000 prior to transport/delivery.**
    - DPHL courier: Call 302.802.5000 to arrange pickup of clinical specimens or water samples. Please note that using the DPHL courier may increase transport time.
    - Professional Carrier: FedEx, DHL, or UPS. Specify rush delivery. Use the appropriate Packing Instruction. Note: some carriers have restrictions on items carried.

Additional Sample Requirements

- For bioterrorism samples, refer to "Laboratory Specimen Collection Procedures Chart" located on our Laboratory Preparedness and Biosafety section (https://www.dhss.delaware.gov/dph/lab/labprep.html).
- For chemical terrorism or exposure samples, refer to "Testing Available for Chemical Exposure Agents", located in the same above webpage.
- Clinical chemical exposure sample collection, packaging, and shipping must follow CDC's "Chemical Exposure Event Specimen Collection" located on CDC's chemical emergency webpage http://emergency.cdc.gov/chemical/lab.asp. This website details the collection scheme, packaging and shipping diagrams, and shipping information.
- If directed to ship clinical samples to CDC:
    - Contact DPHL for further directions and the shipping address.
    - Follow guidelines provided in the CDC document "Shipping Instructions for Specimens Collected from People Who May Have Been Exposed to Chemical Terrorism Agents." (https://emergency.cdc.gov/labissues/specimens_shipping_instructions.asp).
    - Include CDC shipping forms from the CDC website (https://www.cdc.gov/laboratory/specimen-submission/form.html) based on specifications for test/sample.

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DPH Chain of Custody Form

1. **Water System Name/Submitter**: Name of the person and agency submitting the sample.
2. **Comments**: Use this space to indicate any additional information that may be pertinent.
3. **Sample Description**: Use this space to describe the sample (e.g., 50 mL urine cup).
4. **Barcode Number**: Use the barcode number or any other unique identifier (patient ID number or use date 05202012-1, 05202012-2, etc.). Each sample must have its own unique identifier and must correlate with all other accompanying documentation (i.e., request forms).
5. **Sample Date**: Note the date of sample collection.
6. **Sample Time**: Note the time of sample collection. It is strongly recommended that all time be recorded using 24-hour notation (e.g., 2:00 p.m. is 1400 hours).
7. **Clinical /Other:** Use these columns to indicate the number of samples submitted for preparedness testing; if food or environmental, use the Other column.
8. **Blank:** Use these columns to indicate the number of blank collection containers being submitted for testing (required for chemical and water testing).
9. **Total Number of Containers:** Add these columns up vertically for the number of containers including blanks.
10. **Preservative:** Fill in the preservative or leave blank.
11. **Container Type:** Indicate container type used (e.g., red-top tube, sterile cup).
12. **Container Volume:** Fill in the volume of sample if known (e.g., 50 mL).
13. **Number of Containers:** Fill in the number of containers submitted for that sample type for each barcode.
14. **Page of** : Complete the number of pages at the bottom of the form.

Transfer Section

1. Transfer of custody often occurs for transport of a specimen/sample, packaging of a specimen/sample, or transfer to another organization for storage, testing, referral, or destruction. Two fully completed lines should result for each transfer of custody.
    a. The Chain of Custody (CoC) records must account for all times associated with the sample.
    b. If samples are stored in the field prior to delivery to the laboratory, detail the location, storage conditions (i.e., chemical or thermal preservation), and security condition (i.e., locked or sealed cooler) of those samples on the COC form.
    c. As the custody of the sample changes, the former receiver becomes the relinquisher and the new individual receiving the sample becomes the new receiver.
    d. Detail the sample's destruction or disposal on the CoC form.
2. The individual collecting the sample and who initiates custody completes the **Sampled by** box.
    a. **Printed Name**: The collector prints their full name.
    b. **Signature**: The collector signs their full name.
    c. **Date Transferred**: The collector prints the date transferred.
    d. **Time**: The collector prints time in 24-hour format or uses time with a.m./p.m.
    e. **Temp Ctl (°C)**: The collector enters the current temperature of the sample in Celsius; if at room temperature RT is acceptable; if not applicable indicate N/A.
    f. **Sealed (√):** The collector checks if seals are intact (note: biological specimens do not require seals). If the seals are not intact indicating the condition of the seals.
    g. **Special Requests:** List the organization for everyone maintaining custody. Use this space to list a reason for the transfer or other pertinent information.

3. The individual receiving custody completes the **Received by** box.
    a. **Printed Name**: The receiver prints their full name.
    b. **Signature**: The receiver signs their full name.
    c. **Date Transferred**: The receiver prints the date transferred
    d. **Time**: The receiver prints time in a 24-hour format or uses time with a.m./p.m.
    e. **Temp Ctl (°C)**: The receiver enters the current temperature of the sample in Celsius; if at room temperature RT is acceptable; if not applicable indicate N/A
    f. **Sealed (√):** The receiver checks if the seals are intact (note: biological specimens do not require seals). If the seals are not intact indicating the condition of the seals.
    g. **Special Requests:** List the organization for everyone maintaining custody. Use this space to list a reason for the transfer or other pertinent information.

4. **The individual rel**inquishing custody completes the **Relinquished by** box.
    a. **Printed Name**: The relinquisher prints their full name.
    b. **Signature**: The relinquisher signs their full name.
    c. **Date Transferred**: The relinquisher prints the date transferred.
    d. **Time**: The relinquisher prints time in a 24-hour format or uses time with a.m./p.m.
    e. **Temp Ctl (°C)**: The relinquisher enters the current temperature of the sample in Celsius; if at room temperature RT is acceptable; if not applicable indicate N/A
    f. **Sealed (√):** The relinquisher checks if seals are intact (note: biological specimens do not require seals). If the seals are not intact indicating the condition of the seals.
    g. **Special Requests:** List the organization for everyone maintaining custody. Use this space to list a reason for the transfer or other pertinent information.

Request for Non-Clinical Preparedness Testing Form

1. **Submitter Information**
    a. **Submitter Agency:** List the submitter's agency.
    b. **Submitter Name:** Print the submitter's name.
        i. The submitter may be different from the collector.
    c. Organization Address, City, State, Zip (Code): physical address of submitter
    d. Contact Person for Results: person telephoned with preliminary and results
        i. May be different from submitter or collector
    e. **Sample Date and Time:** date and time sample collected
    f. **Sample Location and Conditions:** area of collection and temperature and conditions (may affect stability and testing)
        i. For example, first-floor bathroom, conference room table, etc.
        ii. For example, wet pavement, 5°F, blowing snow, overcast
    g. **Additional Information**: any other pertinent information provided

2. **Incident Information**
    a. **Incident Description:** what occurred, was observed, or is speculated, impact or how sample came about
    b. **Incident Address:** physical address of incident
    c. Signs and Symptoms, Onset: Include this information; if none, mark N/A or none.
    d. **Level of Risk:** High, Moderate, Low, or Exercise
        i. Rank risk assessment for the sample based on field observations and incident assessment.

3. **Sample Information**
    a. **Sample Classification: select one –** Clinical, Environmental, Food, Other (specify)
    b. **Sample ID:** List all unique identifiers (must match the CoC and other documentation) and provide sample description.
        i. Multiple samples can be listed on the same form.
        ii. "See back/attached for detailed list" is acceptable.
    c. **Sample Type:** Select the most appropriate one.
    d. **Number of samples:** total number of samples (exclude blanks)

e. **Number of containers:** total number of outer containers
f. **Container type:** describe the container (i.e. 16 oz. plastic jar)
g. **Testing Requested:** Mark one or more based on desired testing (if unsure, consult lab on arrival)
h. **Includes (list number):** List the number of duplicates, spiked samples, spiked duplicates, and blanks.

NOTE: The Field Screening Form for each sample or sample batch MUST accompany this form.

DPH Field Screening Form

1. **General Information**
   a. Submitter completes form
   b. Required for non-clinical samples (environmental, food, other only)
   c. If items are not completed:
      i. Submitter may choose to perform screening in and/or at their vehicle.
      ii. Submitters may choose to request other agency assistance (DNREC, CST) to perform screening.
      iii. Submitters may ask for assistance completing form.
   d. Lists rejection criteria – if it meets the criteria, the sample is rejected and does not enter DPHL.

2. **Submitter Information**
   a. **Submitter/Tester:** List both if they are not the same individual.
   b. **Date:** Screening date may or may not be the collection or submission date.
   c. **Location:** Place sample collected
   d. **Sample ID:** Submitter-determined number or name; must match CoC and other documentation.
   e. **Sample Description/Identifier:** Description of sample to allow differentiation of this sample from any other

3. **Screening Procedures**
   a. **Result:** ALL testing fields are required except the following:
      i. FTIR/RAMAN – strongly recommended
      ii. HHA (Hand-Held Assay)
      iii. Other
   b. **Result:** enter result provided by equipment or test (include units if applicable)
   c. **Date/Time:** screening performed
   d. **Equipment/Method Used:** description of what was used
   e. **Calibration/Control Passed:** required field; some methods do not have calibration or control
   f. **Comments:** not required, but any other pertinent information is acceptable.

4. **Cleared for Preparedness Testing**
   a. **Submitter printed name/signature:** submitter prints and signs
   b. **DPHL receiver printed name/signature:** DPHL receiver prints and signs name
      i. YES: DPHL receiver accepts sample (circle YES)
      ii. NO: DPHL receiver rejects sample (circle NO and list reason),

NOTE: DPHL receiver can assist in referring sample to other facilities or for further screening.

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LIMS Test Requisition Form (Clinical Specimens and Isolates Only)

1. **MCI #**: If known, include the patient's assigned MCI number.
2. **Submitter/Practitioner Name**: Enter the name of the individual or practice submitting the specimen for analysis.
3. **Collection Date and Time**: Note the date and time of the specimen collection.
4. **Name**: List the patient's full name as last name [space] first name [space] middle initial. Include any additional qualifiers such as Jr., III, etc.
5. **Address**: List the patient's full address.
6. **City**: List the patient's city or town.
7. **State**: List the patient's state.
8. **Zip**: List the patient's zip code.
9. **Birth Date**: List the patient's birth date; include the month, day, and four-digit year.
10. **Race**: List the patient's race; if more than one applies, mark all applicable.
11. **Gender**: Select the patient's gender.
12. **Ethnicity**: Select the patient's ethnicity.
13. **Clinician** (Name and ID #): List the clinician ordering the test. If known, provide the PFN.
14. **Test Requested Block:** in the Special Requests Section:
    a. For **BT** clinical specimens, check "Test for:" and write the organism or agent to be tested and clinical source.
    b. For **BT** rule-out isolates, check "Rule Out" and write the organism or agent to be tested and source of the original specimen (blood culture).
    c. For **CT**, check "Test for:" and write chemical terrorism testing; multiple tests may be ordered on the same specimen. Multiple sources may be submitted for the same patient.
15. **Gonorrhea/Chlamydia DNA Amplification Questions for Youth through Age 18 Block:** Leave this entire block blank; this block is not applicable for preparedness testing.

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Preparedness Clinical Specimen Shipping Manifest

(for Chemical Terrorism)

This form is required for all clinical chemical preparedness samples and can serve as a list of contents for shipping samples to referral laboratories. Prepare one form for each shipping container being utilized.

Forms are located on the Centers for Disease Control and Prevention (CDC) website: https://emergency.cdc.gov/chemical/lab.asp

Blood and urine specimens cannot be shipped in the same container and must be packaged separately.

Header

1. **Page of :** Complete the number of pages at the top of the form.

Shipper Block (top left column)

1. **Date Shipped**: List the date the container is shipped by commercial carrier or by DPHL courier.
2. **Shipped by**: Note the date of sample collection.
3. **Shipped by**: List the name of the certified shipper (if applicable) or the individual packaging the sample.
4. **Contact Telephone**: List a telephone number that can be used to contact the individual packing the sample or shipping the sample (if applicable) in case of damage, missing specimens, or other questions.
5. **Signature**: The individual packing the sample or the certified shipper (if applicable) signs their full name.

Receiving Laboratory Block (top right column)

1. **Date Received**: Leave this field blank. This is completed by the receiving laboratory.
2. **Received by**: Leave this field blank. This is completed by the receiving laboratory.
3. **Signature**: Leave this field blank. This is completed by the receiving laboratory.

Blood Block (blood form only)

1. **Total Number of Specimens in This Container**: List the total number of specimens in the container.
2. **Purple Top Tubes**: List the total number of purple top vacutainer tubes containing specimens in the container.
3. **Green- or Gray-Top Tubes**: List the total number of green top or gray top vacutainer tubes containing specimens in the container.
4. **Total Number of Blank Tubes in This Container**: List the total number of blank tubes in the container.
5. **Blank Purple Top Tubes**: List the total number of blank (non-filled) purple top vacutainer tubes in the container.
6. **Blank Green- or Gray-Top Tubes**: List the total number of blank (non-filled) green top or gray top vacutainer tubes in the container.
7. **Comments**: List any applicable comments for the shipment.
    a. If the samples are shipped with a temperature preservative, such as dry ice, ice packs, or other material, list the temperature preservative and volume.
        i. For example, shipped on 5 lb. dry ice
        ii. For example, shipped on 10 cold packs
8. **Shipping Address**: Unless directed to ship to another laboratory address, utilize DPHL's provided shipping address.

Blood Patient/Victim Identification Block (blood form only)

1. Each line must be completed for each patient.
2. **Patient/Victim ID Label**: Provide a label with two unique identifiers that allows matching to each sample. Facility generated barcodes and patient identification labels are acceptable as are DPHL LIMS barcode labels. Handwritten information is acceptable. Retain a way to match this information to your patients for further reporting and information gathering.
3. **PT1, PT2, PT3, GT1**: Place a √ in each box for samples shipped below the sample description. Place an X in each box for samples not shipped (PT = Purple Top, GT = Green top). Refer to "Chemical Exposure Event Specimen Collection" document at CDC website: https://emergency.cdc.gov/chemical/lab.asp.
4. **Comments**: Indicate the size of the tube collected in the comments field. Include any patient specific comments, such as an estimate of severity of signs and symptoms of exposure (i.e., 8 out of 10), location in relation to incident, known exposure, etc. If patient is deceased or if any antidote or medication is administered, note in the comments section as well.

Urine Block (urine form only)

1. **Total Number of Specimens in This Container**: List the total number of urine specimens in the container.
2. **Total Number of Blank Urine Cups in This Container**: List the total number of blank urines in the container.
3. **Comments**: Provide an overview of the incident, event, or reason for specimens submitted. Detail any comments applicable to the overall collection, i.e., first forty patients with worst exhibitions of signs and symptoms or patients near the event, etc. List any applicable comments for the shipment.
4. **Shipping Address**: Unless directed to ship to another laboratory address, utilize DPHL's provided shipping address.

Urine Patient/Victim Identification Block (urine form only)

1. Each line must be completed for each patient.
2. **Patient/Victim ID Label**: Provide a label with two unique identifiers that allows matching to each sample. Facility generated barcodes and patient identification labels are acceptable as are DPHL LIMS barcode labels. Handwritten information is acceptable. Retain a way to match this information to your patients for further reporting and information gathering.
5. **UC (amount)**: Place a √ in each box for samples shipped; include the volume collected in mL. Place an X in each box for samples not shipped. Refer to "Chemical Exposure Event Specimen Collection" document at CDC website: https://emergency.cdc.gov/chemical/lab.asp.
3. **Comments**: Include any patient specific comments, such as an estimate of severity of signs and symptoms of exposure (i.e., 8 out of 10), location in relation to incident, known exposure, etc. Note on shipping manifest if urine sample is collected by means other than clean catch (e.g., catheterization). If patient is deceased or if any antidote or medication is administered, note in the comments section as well.