Kansas Department of Health and Environment
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Standard Operating Guide:

How to Complete the Multi-patient Clinical Specimen Evidence Chain-of-Custody Receipt Form

Version 1.0

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Kansas Department of Health and Environment
Division of Health and Environmental Laboratories
Laboratory Response Program
Chain-of-Custody Form Preparation for an Event

1.0 Purpose:

1.1 Describe how to fill out the "Multi-patient Clinical Specimen Evidence Chain-of-Custody Receipt" form by field staff at the various agencies that may submit samples due to a criminal, terrorist or natural even. This form will tie in with the Universal Laboratory Specimen Submission Form (ULSSF) that is utilized for patient demographic information to provide the Division of Health and Environmental Laboratories (DHEL) with the ability to track clinical and environment specimens that are collected.

2.0 Applicability:

2.1 All submitting agencies and field staff submitting multiple samples to DHEL due to an event.

2.2 Sample Data Management Staff and any other laboratory staff that receive samples from an event.

3.0 Resources:

3.1 Chain-of-Custody Form
3.2 Universal Laboratory Specimen Submission Form (ULSSF)
3.3 Collection, Packaging and Shipping Guidance Document

4.0 Procedures:

4.1 Complete Section A: Collection and Packaging Information.

4.1.1 In the "Incident Name" field, enter a name for the event if the event has been given a specific name, i.e., "Attack on State Capitol Building." If no name has been given for the event, then enter in the date of the incident and location of the incident. In the absence of an incident name it is important to note the date and location of the incident in case multiple events are underway as in a typical Al Qaida (or Al Qaida imitator) attack.

4.1.2 In the "Specimen(s) Collected By" field print the name and title of person, facility name and address, city, state, zip code and phone number. If more than one person is collecting for an event, each collector will fill out a

separate form. Only one person can be listed for this field.

4.1.3 In the "Person at KDHE Contacted to Receive Specimen(s)" field print the name of the person who was notified at DHEL to receive the specimens.

4.1.3.1 Notification of an incident must be made through the EPI Hotline, (877) 427-7317. Once you have called into this number the EPI On-call will screen the call and notify the laboratory about the incident.

4.1.3.2 The EPI On-call will provide the name of the caller and the call back number to the Laboratory on-call staff.

4.1.3.3 The Laboratory on-call staff will then contact the caller and arrange the details on where the samples should be dropped of at the State Laboratory. The person from the Laboratory who calls the caller back should be the name written into the "Person at KDHE Contacted to Receive Specimen(s)" field.

4.1.4 In the "Send Reports To" field print the name and title of person of the requesting physician or the requesting facility name and identification number. Note: under CLIA and HIPPA results for clinical specimens can only be sent to the submitter of record that appears on the ULSSF or those who have a public health interest. "Public health interest" is determined by Kansas Statute.

4.2 Complete Section B: Type of Specimen(s) Being Submitted.

4.2.1 **For Biological Event(s)**: The clinical specimens that may need to be collected are identified in this section. Specimen type will be determined by the suspected biological agent involved in event.

4.2.1.1 Mark the type of specimen(s) that has been collected and packaged.

4.2.1.2 When packaging clinical specimens unless the shipper is utilizing an "Overpack" only like specimens with the same packaging requirements can be packaged within the same packaging system.

4.2.2 **For Chemical Event(s)**: The clinical specimens required for collection during a chemical emergency or terrorist event are both blood and urine. During an event that involves chemical agents following specimens must be collected: three Purple Top Blood Tubes, one Green or Gray Top Blood Tube, one urine specimen.

4.2.2.1 As the clinical blood specimens are packaged utilize the check boxes in the **"Specimens to be collected"** as a checklist to ensure that the necessary specimens have been collected.

4.2.2.1.1 EDTA tubes and Potassium Oxalate or Sodium Fluoride or Sodium Heparin Tubes must be packaged in separate secondary containers.

4.2.2.1.2 Both types of specimens can be shipped in the same outer packaging as long as they are separated in the secondary containers.

4.2.2.1.3 Reference the "Collection, Packaging and Shipping Guidance Document" developed by DHEL for additional

guidance on packaging and shipping of clinical specimens for the analysis of chemicals of concern.

4.2.2.2 As the clinical urine specimens are packaged utilize the check box in the "**Specimens to be collected**" as a means to ensure that the necessary specimens have been collected.

4.2.2.2.1 Reference the "Collection, Packaging and Shipping Guidance Document" developed by DHEL for additional guidance on packaging and shipping of clinical specimens for the analysis of chemicals of concern.

4.2.2.3 Clinical specimens collected for chemical analysis must be packaged according to specimen type.

4.2.2.4 Blank specimen container: This section has been provided to ensure that the appropriate blank specimen containers (empty containers) have been packaged.

4.2.2.4.1 Blank specimen containers must be provided per Lot Number of blood tubes or urine containers utilized.

4.3 Complete Section C: Specimen(s) Identification.

4.3.1 This section has been developed to incorporate the bar code from the ULSSF or other specimen identifier as assigned by the submitting facility. If the submitting facility provides an identifier other than the bar code from the ULSSF they must identify where it came from.

4.3.2 Completion of the ULSSF: Following is the process that should be used when completing the ULSSF to link with the "**Multi-patient Evidence Chain-of-Custody Receipt**."

4.3.2.1 Clinical specimens for biological analysis: The submitting facility will complete the ULSSF just as they would for day-to-day specimen submission.

4.3.2.2 Clinical specimens for chemical analysis:

4.3.2.2.1 The submitting facility will complete page one (the front page) of the ULSSF, which will contain the demographic and other specimen information.

4.3.2.2.2 There are no clinical tests that can be selected for the analysis of chemical agents, therefore the only section on page two (the back) of the ULSSF that can be completed is the "**Submitter Comments**" section.

4.3.2.2.3 In the "**Submitter Comments**" section the submitter should identify the suspected chemical agent and provide the following specimen information for each patient:

- EDTA Tube #1 (Purple Top Tube)
- EDTA Tube #2 (Purple Top Tube)
- EDTA Tube #3 (Purple Top Tube)
- Either (Select which ever your facility has on hand)

- 1 Potassium Oxalate & Sodium Fluoride (Gray Top Tube)
  OR
- 1 Sodium Heparin Tube (Green Top Tube)

- Urine Specimen

4.3.2.3 Once the ULSSF has been completed place one bar code from the ULSSF onto the chain-of-custody.

4.3.2.3.1 One bar code for each patient should be placed on the chain-of-custody; there is a limitation of 30 patients per chain-of-custody form.

4.4 Completion of Section D: Receipt/Transfer

4.4.1 The first person to sign off in the Chain-of-Custody Receipt/Transfer section should be the "Collector" that is named in Section A.

4.4.2 Complete the date and time field for each transfer that occurs. A transfer is when one person places the specimens in another person care. The person transferring the specimens should be the person posting the date.

4.4.3 The last person at a collection facility to sign off in the "Receipt/Transfer" section should be the person who packaged the specimens, otherwise known as the "HazMat employee."

4.4.3.1 The Chain-of-Custody should be placed in a sealable bag within the outer package on top of the Styrofoam insert.

4.4.4 Complete the reason for the transfer. This field should be completed for each transfer that occurs.

4.4.5 When transferring to a transporter, the type of transporter should be indicated, and if a tracking number is given, it should be recorded. For example, Federal Express, and if a tracking number, enter it.

4.4.6 The transporter **does not** sign off on the Chain-of-Custody.

4.4.7 Once the shipment has reached its destiny, the receiving entity will open the package retrieve the Chain-of-Custody and sign off on the reception of the package. A copy of the Chain-of-Custody should then be made and the original sent back to the originating facility.

4.4.8 The receiving entity should note that type of transporter from whom they received the samples, and it should match that which was entered before the sample were given to the transporter. If a tracking number is present, check to make sure they match that on the form.

4.5 The Chain-of-Custody will be carried through the DHEL as the specimens are processed.

5.0 QA/QC Requirements:

5.1 All Chain-of-Custodies received by DHEL will be checked to ensure that the shipper filled out the form completely.

5.2 All packages submitted with a Chain-of-Custody will be checked by Sample and Data Management to ensure that all the specimens and the specimen submission form(s) identified on the Chain-of-Custody have been included within the package.

6.0 Corrective Actions:

6.1 If the Chain-of-Custody or specimen submission form is not completed correctly it will be the responsibility of the recipient to contact the shipper and clarify any discrepancies found.

7.0 Definitions:

7.1 Chain-of-Custody: A record of the sequences of individuals and organizations who had custody of a sample or a group of samples.

7.2 Universal Laboratory Specimen Submission Form: The Division of Health and Environmental Laboratories clinical specimen submission form.

7.3 ULSSF: Universal Laboratory Specimen Submission Form.

7.4 Specimens: Clinical specimen or clinical human specimens.

7.5 EDTA Tubes: A tube that contains a colorless compound that reacts with metals. Use: anticoagulant, treatment of lead poisoning. $C_{10}H_{16}N_2O_8$
Full form ethylene diamine tetra-acetate

7.6 Blank specimen container: A sterile or clean empty container that has not been used that must be submitted to the Laboratory for quality control purposes.

7.7 Collector: The person who collects the specimens, e.g. Medical Technologist, phlebotomist.

7.8 HazMat Employee: Is an employee that has certified through training to package and ship diagnostic specimens and infectious substances, per 49 CFR sections 100-181.

8.0 References:

8.1 Center for Disease Control and Prevention guidance for "Chemical Terrorism Event Specimen Collection" and chain-of-custody.

8.2 Kansas Bureau of Investigation chain-of-custody.

8.3 States of Iowa, Missouri and Minnesota chain-of-custodies.

9.0 Appendices:

9.1 Multi-patient Clinical Specimen Evidence Chain-of-Custody Receipt
9.2 Universal Laboratory Specimen Submission Form
9.3 DHEL's "Collection, Packaging and Shipping Guidance Document"