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Service Area: ECLS
Program: Chemical Terrorism/Medicinal Marijuana/Biomonitoring
Unit: CT/MM/BM

Title: **SPaSE**

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Objective: Collect, package and ship urine and blood specimens in compliance with required annual LRN-C SPaSE exercise

Reference: **CDC Laboratory Information for Chemical Emergencies at: http://www.bt.cdc.gov/chemical/lab.asp**

I. Collection of Specimen: CDC requires 40 minimum patients for the exercise.

Materials Needed:

- 4-mL non-gel, purple-top EDTA tubes for whole blood – Becton Dickenson BD# 367844 or equivalent –need three (3) tubes for each patient
- 4-mL no-gel, green or purple top tubes for whole blood – Becton Dickenson BD#8362540 or equivalent – needs one (1) tube for each patient
- 100-mL screw-cap plastic urine containers – VWR Catalog # 25384-146 – need one (1) container for each patient.
- Indelible ink marker for labeling – i.e., "Sharpies" or lab markers
- Freezer, -70ºC ±5 ºC
- Refrigerator, 5ºC ±3 ºC
- Shipping Boxes (large)– 2 boxes for urine and 1 box for blood.
- Yellow solution – Tap water mixed with a few drops of yellow food color (food color available at any supermarkets) or actual human urine if available.
- Red solution- Tap water mixed with a few drops of red food color (food color available at any supermarket) or actual human blood < 2 weeks old if available.
- Dry ice pellets – from Dry Ice Corporation, 856-224-4956, P.O. Box 141, Gibbstown, NJ 08027, or other available suppliers. Schedule delivery on the day of shipment. Dry Ice Corporation requires minimum delivery amount of 100 lbs. of dry ice pellets. Make sure amount in PO can cover this plus delivery fee.

A. "Collection" of Whole Blood performed the day before shipment to CDC.

1. Prepare "blood" by mixing 3-5 drops of red food color to about 1 liter of tap water.
2. Fill three 4-mL non-gel, purple-top (EDTA) tubes with the red solution, making sure that these are not overfilled to ensure proper closure.
3. From each patient, a minimum of three 4-mL purple-top (EDTA) tubes filled with "blood" is required.
4. Using indelible ink, mark each purple-top tube of blood ***in the order collected*** (e.g., # 1, # 2, # 3).
5. In addition, fill with red solution, one 4-mL, non-gel, green- or gray-top tube. Only one (1) tube is needed from each patient.
6. Each patient should have three 4-mL blood purple-top EDTA tubes, and one 4-mL green top tube, for a total of four (4) tubes.

7. Note or record the lot number(s) of all tubes used.
8. Label the specimens as directed below in section II.
9. Store specimens in the refrigerator at 5 ºC ±3 ºC until shipment.

B. Collection of Urine performed the day before shipment to CDC

1. Prepare "urine" by mixing 3-5 drops of yellow food color into 1 liter of tap water.
2. Pour approximately 40 mL of yellow-colored solution into a 100-mL urine cup.
3. Use a screw-cap plastic container; do not overfill.
4. Freeze specimen as soon as possible inside a −70 ºC ±5 ºC freezer.

C. Blanks

For each **lot number** of tubes and urine cups used for collection, provide the following to be used as blanks for measuring background contamination:

1. Two (2) empty, unopened purple-top tubes for each lot
2. Two (2) empty, unopened green- or gray-top tubes for each lot
3. Two (2) empty, unopened urine cups for each lot

II. Labeling Specimens

Materials Needed:

- Laser Address Labels – 1 x 2 $^{5}/_{8}$ inches, or equivalent to Avery 5160 ™
- Laser Address Labels - ½ x 1 ¾ inches, or equivalent to Avery 5167

1. **Go to My Computer,** V:\CT\SPASE, open the EXCEL workbook called **CT Sample Log-in "Date" Template**. "Date" will be the most recent SPaSE exercise (i.e 02-27-2017).
2. At the bottom of the workbook, tabs are labeled: Directions, Urine Login, Blood Login, UR Mnfst, Ur Evid, Bld Mnfst, Bld Evid., Ur Labels, Bld Labels, BS Cat. B, Shipping Labels and Contacts.
3. Double click on the tab "Directions". Follow instructions on how to generate labels, manifests, evidence, and other documents needed to comply with CDC exercise requirements.
4. For SPaSE exercises, medical records, specimen IDs, and time of collections are made-up by the shipper, however the date of collection must be on or before the date of the exercise.

III. Packaging Specimens on the morning of shipment: See attached Picture Guide

CT Blood Shipping Pictorial Version 5.08
(**http://emergency.cdc.gov/labissues/pdf/chemspecimenshipping-blood.pdf**)

CT Urine Shipping Pictorial Version 5.08
(**http://emergency.cdc.gov/labissues/pdf/chemspecimenshipping-urine.pdf**)

***Any analyst who participates in the SPaSE exercise must have their Div. 6.2 training certificate completed prior to packaging and shipping the items. This is good for two years.**

https://www.cdc.gov/labtraining/training-courses/packing-shipping-division-6.2-materials.html

*** If all samples shipped for SPaSE are synthetic, the shipping laboratory must be recognized by the United States Department of Transportation as a shipper under the special permit, DOT-SP 14599. Once approved as a shipper, the laboratory must include a copy of the special permit with all shipping containers, among other requirements. The application process can be begun here:**

https://www.phmsa.dot.gov/hazmat/special-permits/special-permits-applications

If the shipper is not recognized under DOT-SP 14599 as a shipper, that laboratory must include at least one actual human sample in each shipping container.

A. Secondary Packaging for Blood Tubes

Materials:
Gridded box, 64 cells, 5 ¾ x 5 ¾ x 4 $^{7}/_{8}$ inches, Part # BC564 – Leigh Labs, P.O Box 1306, Waxhaw, NC 28173. (p) 704-916-1968, (f) 866-404-2996, info@leighlabs.com

• To facilitate processing, package all blood tubes from the same patient together.
• Place absorbent material between the blood tubes and the first layer of secondary packaging. Use enough absorbent material to absorb the entire contents of the blood tubes.
• Separate each tube of blood collected from other tubes or wrap tubes to prevent tube-to-tube contact. Regardless of the method used, the first layer of secondary packaging must be secured with one continuous strip of evidence tape and initialed half on the tape and half on the first layer of secondary packaging by the person making the seal.

Examples of some ways to do this are to—
 Pack blood tubes in a gridded box lined with absorbent material. Seal the top half of the box to the bottom half with one continuous piece of evidence tape (and write your initials half on the tape and half on the box.
 Pack a sealable polystyrene foam container or blood tube shipment sleeve and transport tube with individually wrapped tubes. Seal the polystyrene foam container or

transport tube with one continuous piece of evidence tape and write your initials half on the tape and half on the container.
• Wrap and seal the first layer of secondary packaging (e.g., gridded box) with absorbent material.
• Seal one wrapped gridded box or alternative container inside a clear, leak-proof biohazard polybag equivalent to Saf-T-Pak product STP-701, STP-711 or STP-731.
• Place this bag inside a white Tyvek® outer envelope (or equivalent) and seal the opening with a continuous strip of evidence tape initialed half on the packaging and half on the evidence tape by the individual making the seal.
• According to 49 CFR 173.199(b), if specimens are to be transported by air, either the primary receptacle or the secondary packaging used must be capable of withstanding, without leaking, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi). Verify in advance that the manufacturer of either the blood tube or secondary packaging used in your facility is in compliance with the pressure differential requirement.

B. **Outer Packaging for Blood Tubes**

• Use polystyrene foam-insulated, corrugated fiberboard shipper (may be available from your transfusion service or send-outs department).
• For cushioning, place additional absorbent material in the bottom of the shipper.
• Add a single layer of refrigerator packs on top of absorbent material.
• Place the packaged specimens on top of the refrigerator packs.
• Use additional cushioning material to minimize shifting while the shipper is in transit.
• Place additional refrigerator packs on top of the secondary packaging to maintain a shipping temperature of 1° C-10° C for the duration of transit.
• Place blood shipping manifest in a sealable plastic bag and put on top of packs inside the shipper.
• Keep chain-of-custody documents for your files.
• Place lid on shipper and secure with filamentous shipping tape.
• Place your return address in the upper left-hand corner of the shipper top and put CDC's receiving address in center.
• Affix labels and markings adjacent to the shipper's/consignee's address that appears on the shipper.
• Place the UN 3373 label and the words "Biological Substance, Category B" adjacent to the label on the front of the shipper.

C. **Secondary Packaging for Urine Cups**

Gridded box, 6 cells, 8 x 6 x 3 inches, Part # BC368 – Leigh Labs, P.O Box 1306, Waxhaw, NC 28173. (p) 704-916-1968, (f) 866-404-2996, info@leighlabs.com

• Separate each urine cup from other urine cups, or wrap individual urine cups to prevent

contact between urine cups. Regardless of the method used, the first layer of secondary packaging must be secured with one continuous strip of evidence tape and initialed half on the tape and half on the first layer of secondary packaging by the person making the seal.

Examples of some ways to do this are to—

 Pack urine cups in a gridded box lined with absorbent material. Seal the top half of the box to the bottom half with one continuous piece of evidence tape and write your initials half on the tape and half on the box.

 Seal individually wrapped urine cups inside a clear, leak-proof biohazard polybag equivalent to Saf-T-Pak product STP-701, STP-711 or STP-731. Secure the closure of the bag with one continuous strip of evidence tape initialed half on the tape and half on the bag by the individual making the seal.

• Place urine cups boxed or individually wrapped and secured properly with evidence tape, in the next layer of secondary packaging. An example of acceptable material is the Saf-T-Pak Disposable 2-Part Pressure Vessel system or its equivalent.

• Secondary packaging must have its closure secured with a single strip of evidence tape initialed half on the packaging and half on the evidence tape by the person making the seal.

D. Outer Packaging for Urine Cups

• Use polystyrene foam-insulated, corrugated fiberboard shipper. • For cushioning, place additional absorbent material in the bottom of the shipper.

• Place a layer of dry ice on top of the absorbent material. Do not use flakes or large chunks of dry ice for shipment because large chunks have the potential for shattering urine cups during transport.

• Ensure that specimens will remain frozen or will freeze during transport.

• Place packaged urine cups in the shipper.

• Use additional absorbent or cushioning material between wrapped urine cups to minimize shifting while shipper is in transit.

• Place an additional layer of dry ice on top of samples.

• Place the urine shipping manifest in a sealable plastic bag and put on top of dry ice inside the shipper.

• Keep chain-of-custody documents for your files.

• Place lid on shipper and secure with filamentous shipping tape.

• Place your return address in the upper left-hand corner of the shipper top and put CDC's receiving address in center.

• Place the UN 3373 label and the words "Biological Substance, Category B" adjacent to the label on the front of the shipper.

• If the proper shipping name, (either dry ice or carbon dioxide, solid) and Class 9/UN 1845 is not preprinted on the hazard label, add it in an area adjacent to the label, on the same side of the shipper as the UN 3373 marking.

• Note the weight of dry ice (in kg.) on the preprinted area of the hazard label, or place that information adjacent to the Class 9/UN 1845 hazard label. The amount should not exceed 10 kg.

• Orientation arrows are not required on a shipper containing "Biological substance, category B." If you use arrows, be sure to orient the inner packaging so that closures are aligned with the arrows.

IV. Packaging Evaluation: Go through example of SPaSE Results evaluation form and use as a checklist of "must do items" to ensure successful results.

V. Documentation –Refer to tabs in EXCEL workbook mentioned in Section II.2.

1. Print manifests and evidence forms.
2. Blood and urine specimen are packaged separately so each package must have its own prepared manifest.
3. Place each shipping manifest (with specimen identification numbers) in a plastic zippered or Ziploc bag.
4. Place the sealed manifest on top of the ice packs or dry ice of the foam-insulated shipper before closing the outer box and secure the box lid with filamentous shipping tape.
5. Close the lid of the polystyrene foam-insulated, corrugated fiberboard shipper.
6. Seal opening with just one strip of filamentous tape.
7. Complete the evidence form and indicate the courier's name as **FedEx**.

VI. SHIPPING SPECIMENS

1. Note weight and dimensions of each package (LxHxW in inches). Record the amount of dry ice pellets used for each package containing urine samples.
2. Take the prepared packages to the FedEx shipping station located on the fourth floor in Room L410A.
3. The FedEx computer desk in in L410A along with the shipping scale to weigh the boxes.
4. Complete FedEx airway bill by using the Federal Express Ship Manager. Don't forget to complete "Hazardous Material" information regarding UN number for Dry Ice and indicate its weight in kilograms (kg).
5. Fill in the dimensions of the shipper for "other".
6. Fill-in the shipper's name, address and contact number as per IATA packing instruction 650.

FROM: New Jersey Department of Health
Environmental and Chemical Laboratory Services
ATTN: Shipper's Name
3 Schwarzkopf Drive,
Ewing, NJ 08628

Office Phone: 609-530-2659
Office Fax: 609-530-2661
e-mail address: CTStaff.Name@doh.nj.gov

7. Fill-in the recipient as:

TO: Centers for Disease Control and Prevention
CDC Warehouse
3719 N. Peachtree Rd.
Chamblee, GA 30341
ATTN: Emergency Response Branch
Bldg 110, 4th Fl, Rm 4201
(770) 488-0195

8. Call FedEx to schedule for pick-up before 4 PM on the day of shipment.
9. Indicate the number of boxes being picked-up, and that it is for **Priority Overnight Delivery**

VII. LRN-C Notification and Contacts (Very Important!)

1. Ensure that FedEx had picked-up the shipment before leaving for the day.
2. **Send an e-mail the LRN-C QA (**LRN-C_QA_Program@cdc.gov**)** that packages are en-route to the CDC address in Georgia, via **FedEx priority overnight delivery**. Include tracking numbers and number of packages in the shipment and **Div. 6.2 training certificate**.

Exercise specimens should be packaged for shipment in accordance with the most recent version of "Shipping Instructions for Specimens Collected from People Potentially Exposed to Chemical Toxicants" (**http://emergency.cdc.gov/chemical/lab.asp**).
• For more information about instructions for shipping blood and urine specimens to CDC after a chemical event, refer to:
o CT Blood Shipping Pictorial Version 5.08
(**http://emergency.cdc.gov/labissues/pdf/chemspecimenshipping-blood.pdf**), and
o CT Urine Shipping Pictorial Version 5.08
(**http://emergency.cdc.gov/labissues/pdf/chemspecimenshipping-urine.pdf**)
• Please ship 40 complete sets of specimens for the exercise (a complete set of specimens include 3 x 4-mL purple top, and 1 x 4-mL green top vacutainer tubes containing blood, and 1 x 40-mL urine in a cup).