

#### Florida Bureau of Public Health Laboratories

Tips for Ensuring Specimen Acceptability



## Sign up for official Packaging and Shipping Training Here:

All shippers of substances designated by the Dept. of Transportation as Hazardous Materials, including infectious or potentially infectious materials, are required to be trained per federal regulations (cf. 49 CFR 172.704 and 173.199). Ensuring adequate and appropriate training is each employer's responsibility. Failure to comply with the regulations, including training, may result in unsafe or unsatisfactory specimen shipments, as well as the assessment of significant civil monetary penalties that may be assessed per violation, per day.

BPHL offers grant-funded infectious substances packaging and shipping classes that can assist submitters in meeting their training responsibilities. Information can be found at:

https://www.floridahealth.gov/programs-and-services/public-health-laboratories/educational-opportunities/packaging-and-shipping-training.html



#### **CLIA Requirements**

#### Title 42 Chapter IV Subchapter G Part 493

#### § 493.1242 Standard: Specimen submission, handling, and referral.

- (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable:
  - (1) Patient preparation.
  - Specimen collection.
  - (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.
  - (4) Specimen storage and preservation.
  - (5) Conditions for specimen transportation.
  - (6) Specimen processing.
  - (7) Specimen acceptability and rejection.
  - (8) Specimen referral.
- (b) The laboratory must document the date and time it receives a specimen.
- (c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.
- (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)
   (1) through (a)(7) of this section.



# A laboratory's written policies and procedures for specimen submission, handling, and referral are based upon the following:

- Manufacturer's instructions
- Assay parameters
- Standard Operating Procedures



Specimen acceptability, submission, and handling criteria can be found for each test on the updated test menu at the following link:

www.FloridaPublicHealthLab.com



#### Common Reasons for Specimen Rejections

- No date of collection provided
- Specimen leaked into transport container during shipping
- Specimen in wrong collection kit
- Swab not broken at score line or the wrong swab was used
- Duplicate test order/specimen received
- No requisition form/test order received or incomplete
- Patient identifiers on specimen do not match requisition/test order
- Elevated temperatures
- An expired collection device was used
- Quantity not sufficient or specimen was not filled within the fill line indicated on the collection device



#### Tips for a Successful Cooler Arrival

- Prechill boxes and specimens so ice pack "strength" is not partially used chilling specimen.
  - Specimen should be stored appropriately after collection and prior to shipping
- Use coolers with a better R rating (better quality insulation).
- To better maintain temperature, we recommend putting specimens in 95 kPA bags instead of cans.
- Fill boxes with insulating material such as newspaper (try to avoid free air space).



### Tips for a Successful Cooler Arrival

- Use only rock hard, solid frozen ice packs.
- "Sandwich" specimen between the frozen ice packs
- Use additional ice packs in the summer.
   Florida heat melts them quickly.



## **Example of Cooler Packaging**



# Compare Demographics on Specimen and Requisition to Ensure They Match

Specimen must be labeled with at least 2 unique patient identifiers!

Make sure the requisition contains ALL required information!





## Place Specimen into BioBag with Absorbent Material

Close bag all the way in case of leaks!

Make sure specimen tubes are closed all the way!





### Place Requisition in Outer Pocket of BioBag



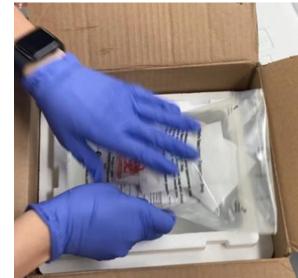


## "Sandwich" Specimen Between the Frozen Ice Packs in the Cooler









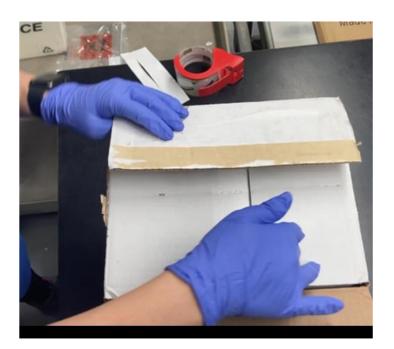






### Close Cooler and Ship According to Regulations







Please Reach Out to Leah Kloss (Leah.Kloss@flhealth.gov) Or Leila Filson (Leila.Filson@flhealth.gov) if You Have Any Further **Packaging and Shipping** Questions