New Jersey Public Health and Environmental Laboratories Technical Bulletin - Supplement

March 2016

Zika Testing: Specimen Collection, Processing, Packaging and Shipping

SAMPLE SPECIFICATIONS FOR ZIKA RT-PCR AND IgM TESTING

- **6 ml of SERUM AND 6 ml of URINE required**
  - **6 ml of serum**
    Note: 4.0 -5.0 ml serum may be accepted if no additional specimen can be drawn, however, the ability of the laboratory to perform tests to rule out cross reactivity with related flavivirus infections will be limited. Less than 3.0 ml serum cannot be tested.
  - **6 ml of urine with no preservative**
- **Other specimens (optional):** Consult with the Communicable Disease Service (CDS) at 609-826-5964, Monday through Friday 8 AM -5 PM to discuss requirements for testing CSF, amniotic fluid and tissue. Arrangement for convalescent serum testing must also be made through the CDS.

A. ZIKA SPECIMEN COLLECTION AND HANDLING – AT THE HOSPITAL

1. Collect sufficient blood in red top, tiger top, or serum separator tubes to yield 6 ml serum. Do NOT collect blood in tubes with anticoagulant. (green, purple, blue tops, etc.).
2. Label the tube(s) with two unique patient identifiers, date and collector's initials, following standard CLIA requirements.
3. Collect urine in sterile, labeled container, without preservative, at least 6 ml.
4. Deliver the blood and urine to the clinical laboratory as soon as possible. **Serum and urine must be frozen at -70 to -80ºC within 6 hours of collection.**

B. ZIKA SPECIMEN PROCESSING - IN THE HOSPITAL LABORATORY

1. Upon receipt, immediately centrifuge the blood tube(s) using standard laboratory procedures for serum separation.
2. Immediately split 6 ml of serum (3 ml plus 3 ml) to two plastic screw cap tubes. These tubes are considered "primary containers" in shipping instructions below and must be screw capped, leak proof and able to withstand -70 to -80º C temperatures.
3. Immediately transfer 6 ml of urine (3 ml plus 3 ml) to two plastic screw cap tubes. These tubes are considered "primary containers" in shipping instructions below and must be screw capped, leak proof and able to withstand -70 to -80º C temperatures. **Label the Urine tubes as "Urine".**

4. Label the tube(s) with two unique patient identifiers, date and collector's initials, following standard CLIA requirements.
5. Immediately freeze the serum and urine (4 tubes) at -70 to -80ºC. Package and ship as described below.
6. ***Note: If a large number of patient specimens are to be included in one shipment, note that there is a one-liter volume limit per box for Biological substances, Category B.***

C. SRD-1 Form – IN THE HOSPITAL LABORATORY

Enter date and time of collection on the pre-approved SRD-1 form provided by the patient.

D. ZIKA Packaging and Shipping – FROZEN Serum and Urine– from THE HOSPITAL LABORATORY TO THE PUBLIC HEALTH LABORATORY

PHEL HOURS OF OPERATION: Monday – Friday 8 AM – 5 PM.

Ship only Monday – Thursday unless emergency testing arrangements are made through CDS. Keep all specimens frozen at -70 to -80^{0}C until ready to ship.

Frozen serum, and urine specimens should be packaged and shipped as a Biological Substance, Category B, UN3373 on dry ice. Dry ice is available through a number of vendors across the state. http://www.dryicedirectory.com/ (*Dry ice is optimal to maintain specimen integrity, however, if dry ice is not attainable, frozen specimens may be shipped overnight to the NJDOH PHEL on FROZEN cold packs*.) Once received in the NJDOH PHEL, specimens will be analyzed in-house OR shipped to the appropriate LRN facility for analysis. The following instructions may be utilized to ensure the shipment is in compliance with USDOT 49 CFR 173.199 (IATA Packaging Instruction 650) for Category B substances and IATA Packaging Instruction 954 for Dry Ice.

1. **Assemble Materials**:
   a. Two completed copies of the SRD-1 form to accompany shipment. (keep third one for your files)
   b. One Styrofoam lined sturdy fiberboard box designed for DRY ICE shipments.
   c. A leak-proof secondary container such as one of the following:
      i. sealable Tyvek bag with biohazard label - designed to withstand air pressure of 95 kPa *OR*
      ii. a rigid, plastic, leak proof screw cap secondary container also designed to withstand 95 kPa air pressure.
   d. DRY ICE. Dry ice is available through a number of vendors across the state. http://www.dryicedirectory.com/ OR sufficient number of cold packs which have been previously FROZEN may substitute.
   e. Absorbent material – enough absorbent material to absorb entire specimen contents should breakage occur in transport.
   f. Bubble wrap
   g. Parafilm or adhesive tape
   h. Filamentous tape
   i. Sealable Ziploc bag for documents
   j. UN 3373 label
   k. Miscellaneous Class 9 label (if using Dry Ice)
   l. To and From labels

2. **Prepare your primary containers – FROZEN SPECIMENS**
   - **a.** Seal with parafilm or other adhesive tape.
   - **b.** Individually wrap each primary container with bubble wrap.

3. **Prepare your secondary container.**
   a. Place sufficient absorbent material inside secondary container along with the bubble wrapped tubes.
   b. Ensure that sufficient bubble wrap is used to cushion the specimens inside the secondary container. If a Tyvek bag is used, remove all air before sealing.
   c. Seal the secondary container.

4. **Enclose two copies of your completed SRD-1 form(s)** in a Ziploc bag and tape to your secondary container. (This serves as your itemized list of contents required by USDOT.)

5. **Complete the package**
   a. Place your secondary container inside the Styrofoam lined dry ice fiberboard box, surrounding with sufficient DRY ICE OR fill with previously FROZEN cold packs. ***Dry ice must always be placed between the secondary and the outer container, NEVER inside the secondary container***.
   b. Place the Styrofoam lid on the container – DO NOT TAPE SHUT.
   c. Close the box and tape once across the seam with filamentous tape. DO NOT tape all edges shut. Dry Ice box is designed for release of CO_2 gas.

6. **Label and mark the outside of the box**
   a. To: and From: labels. **Indicate the responsible person's name and phone number** on the outside of the box. Ship to:

      New Jersey Department of Health
      Public Health and Environmental Laboratories
      3 Schwarzkopf Dr.
      Ewing, NJ 08628
      Attn: Dr. Nelson Delgado
      Emergency phone: 609-209-9004

   b. Label with the USDOT UN 3373 label.
   c. Next to the UN 3373 label, mark the box with the words "Biological Substance, Category B, UN3373"
   d. If Dry Ice is used Label the box with the USDOT Miscellaneous Class 9 label.
   e. If Dry Ice is used, Mark the box with the words:" Dry Ice, UN1845 ____kg" next to the Class 9 label, and indicate the number of kg of Dry Ice enclosed.
   f. If FROZEN cold packs are used in lieu of Dry Ice, skip "d" and "e" above.

7. **MONDAY THROUGH THURSDAY ONLY: Ship the box OVERNIGHT** via FedEx, UPS or other overnight carrier.

8. **Airway Bill**: You will be required to fill out an airway bill to pay for the shipment with commercial carriers. Indicate on the airway bill the amount of dry ice in the box, check off that dry ice is a Dangerous Good and indicate that a signature is required for shipment receipt.
9. **FAX a copy** of the SRD-1 form to the NJDOH Communicable Disease Service (CDS) secure fax at (609) 826-4874 at the time of shipping.

NOTES ON DRY ICE

When Dry Ice is used as a coolant in a shipment, IATA Packaging Instruction 954 must be followed in addition to the specific packaging instructions for the substance being shipped. IATA Packaging Instruction 954 indicates:

1. The outer container must be designed for release of CO_2 gas from dry ice.
2. Dry ice must always be placed between the secondary and the outer container, NEVER inside the secondary container.
3. The Styrofoam lid must NOT be sealed shut. The outer box must be taped with one piece of tape to seal the open flaps together, NOT sealed all the way around.
4. The outside of the box should be labeled as above with the following additions:
    a. Class 9, USDOT Miscellaneous label
    b. Next to the Class 9 label, the following words: Dry Ice, UN1845 and the number of kg of Dry Ice.
5. Indicate on the airway bill the amount of dry ice in the box, check off that dry ice is a Dangerous Good.

Questions?

- For questions regarding indications for testing, or pre-approval for testing call the NJ Communicable Disease Service at (609)-826-5964 Monday through Friday 8:00 AM – 5:00 PM.
- For questions regarding specimen collection, handling, packaging or shipping contact the PHEL Zika Team at Zika.phel@doh.nj.gov
- For general laboratory questions contact PHEL at 609-530-8516 Monday through Friday 8:00 AM – 5:00 PM.

REMINDER: Ship to PHEL ONLY Monday through Thursday