

August, 2017

Zika Testing: Specimen Collection, Packaging and Shipping

SAMPLE SPECIFICATIONS FOR ZIKA Trioplex rt RT-PCR AND MAC ELISA IgM TESTING

- 3 ml of serum (2 ml for infants)
- 3 ml of urine clean catch (adults and infants) with no preservative
- If the patient is a newborn, follow the instructions in the NJDOH Zika Delivery Packet: http://www.nj.gov/health/cd/documents/topics/zika/njdoh_zika_delivery_packet.pdf
- **Other specimens:** Consult with the Communicable Disease Service (CDS) at 609-826-5964 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 blood in red top, tiger top or serum separator tubes. 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 at minimum 3 ml of clean catch urine in sterile container, without preservative.
4. Deliver the blood and urine to the clinical laboratory WITHIN ONE HOUR of collection.

B. ZIKA SPECIMEN PROCESSING - IN THE HOSPITAL LABORATORY

1. Upon receipt, centrifuge the blood tube(s) using standard laboratory procedures for serum separation.
2. Immediately pour 3 ml of serum into a plastic screw cap cryotube. The cryotube is considered the "primary container" in shipping instructions below and must be screw capped and leak proof.
3. Immediately transfer 3 ml of urine into a screw cap plastic cryotube. The cryotube is considered the "primary container" in shipping instructions below and must be screw capped and leak proof. **Label the Urine tubes as "Urine"**.
4. Label the cryotube(s) with two unique patient identifiers, date and collector's initials, following standard CLIA requirements.
5. Refrigerate specimens at 2-8°C if shipment will occur within the same day. Freeze the specimens at -15 to -25°C if shipment is to occur later.
6. **Note: If many 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

- Complete the SRD-1 form per instruction attached to the form. Ensure that the clinician has provided an NJZ approval number.

D. For Specimens Shipped within 24 Hours of Collection

Refrigerate serum and urine at (2-8°C) for a minimum of 1-2 hours prior to shipment.
(Note: the PHEL is open Monday – Friday 8AM -5PM to accept overnight or same day shipments. Do not ship overnight on Fridays, unless by special arrangement.)

Refrigerated serum, and urine specimens should be packaged and shipped as a Biological Substance, Category B, UN3373 on **frozen cold packs** within 24 hours of collection. The following instructions may be utilized to ensure the shipment follows USDOT 49 CFR 173.199 (IATA Packaging Instruction 650) for Category B substances.

1. Assemble Materials

- a. Two completed copies of the SRD-1 form.
- b. One Styrofoam lined sturdy fiberboard box designed for cold shipments.
- c. A leakproof 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. Sufficient number of cold packs **which have been previously frozen.**
- 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. To and From labels



2. Prepare your primary container (s)

- 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 box surrounding with sufficient frozen cold packs.
- 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.



6. Label and mark the outside of the box with

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

- a. Label with the USDOT UN 3373 label.
 - b. Next to the UN 3373 label, mark the box with the words “Biological Substance, Category B, UN3373”
1. **MONDAY THROUGH THURSDAY ONLY: Ship the box OVERNIGHT** via FedEx, UPS or other overnight carrier. NOTE: Same day deliveries by couriers (refrigerated OR frozen), may be shipped on frozen cold packs using these instructions.
 2. **Airway Bill:** You will be required to fill out an airway bill to pay for the shipment. Indicate on the airway bill the term “Biological Substance, Category B, UN 3373”. Indicate that a signature is required for shipment receipt.
 3. **FAX a copy** of the SRD-1 form to the NJDOH secure fax at (609) 826-4874 at the time of shipping. NJDOH will notify the PHEL of the impending sample.

E. For specimens collected Monday – Thursday which CANNOT be shipped within 24 hours of Collection AND all specimens collected Friday – Sunday:

Freeze at -15 to -25°C (NOT -70 to -80°C) and ship to the Public Health and Environmental Laboratories on Dry Ice Monday through Thursday only.

Frozen (-15 to -25°C) serum and urine specimens should be packaged and shipped as a Biological Substance, Category B, - UN3373 on dry ice. Dry ice is available through many vendors across the state. <http://www.dryicedirectory.com/> Once received in the NJDOH PHEL, specimens will be analyzed in-house OR shipped to the appropriate LRN laboratory 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. (keep one for your files)
- b. One Styrofoam lined sturdy fiberboard **box designed for DRY ICE shipments.**
- c. A leakproof 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.
- c. **DRY ICE.** Dry ice is available through many vendors across the state. <http://www.dryicedirectory.com/>
- d. Absorbent material – enough absorbent material to absorb entire specimen contents should breakage occur in transport.
- e. Bubble wrap



- f. Parafilm or adhesive tape
- g. Filamentous tape
- h. Sealable Ziploc bag for documents
- i. UN 3373 label
- j. Miscellaneous Class 9 label
- k. To and from labels



2. **Prepare your primary container (s)**
 - 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. **FILL** the box with DRY ICE
 - b. ***Dry ice must always be placed between the secondary and the outer container, NEVER inside the secondary container.***
 - c. Place the Styrofoam lid on the container – **DO NOT TAPE SHUT.**
 - d. 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 CO₂ gas.***

6. **Label and mark the outside of the box** with
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

- a. Label with the USDOT UN 3373 label.
- b. Next to the UN 3373 label, mark the box with the words “Biological substance, Category B, UN3373”
- c. Label the box with the USDOT Miscellaneous Class 9 label.
- d. 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.



7. **MONDAY THROUGH THURSDAY ONLY: Ship the box OVERNIGHT** via FedEx, UPS or other overnight carrier. NOTE: Same day deliveries by couriers (refrigerated OR frozen), may be shipped on frozen cold packs using these instructions.
8. **Airway Bill:** You will be required to fill out an airway bill to pay for the shipment. 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 LAB-5 form to the NJDOH secure fax at (609) 826-4874 at the time of shipping. NJDOH will notify the PHEL of the impending sample.

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 CO₂ 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. No more than 200kg of Dry Ice are allowed per shipment by air. (FedEx and other air carriers.)
5. 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.
6. 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 local health department in the patient's jurisdiction. Link to Local Health Department directory: <http://www.state.nj.us/health/lh/>
- If the patient is a newborn, follow the instructions in the NJDOH Zika Delivery Packet: http://www.nj.gov/health/cd/documents/topics/zika/njdoh_zika_delivery_packet.pdf
- For laboratory questions contact PHEL at zikaphel@doh.nj.gov or call 609-530-8516 Monday-Friday 8AM-5PM.
- For all other questions regarding Zika testing - contact the NJ Communicable Disease Service at 609-826-5964, Monday-Friday 8AM-5PM.