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May 25, 2017

TO: Birth Facilities and Local Health Departments (LHDs)
FROM: New York State Department of Health (NYSDOH) Bureau of Communicable Disease Control

HEALTH ADVISORY: ZIKA VIRUS TESTING AT BIRTH

Please distribute to the Labor and Delivery, Laboratory and Pathology Service, Pediatrics, Neonatology, Infection Control Department, Emergency Department, Infectious Disease Department, Obstetrics/Gynecology (including Nurse Practitioners and Midwives), Family Medicine, Director of Nursing, and the Medical Director.

SUMMARY

- This advisory provides updated information on Zika virus testing at birth. **NYSDOH requests that it be posted conspicuously in the labor and delivery units of birth facilities and in other areas as described above.**
- Infants born to mothers with laboratory evidence of Zika virus infection during pregnancy or infants with possible Zika-related brain/eye abnormalities and potential maternal Zika exposure should have nucleic acid amplification and serological testing as well as a head ultrasound. Recommendations are also provided for placenta and umbilical cord testing for Zika virus.
- Additional information on the evaluation of infants of mothers with possible Zika infection can be found in the August 26, 2016, Morbidity and Mortality Weekly Report (MMWR) entitled “Update: Interim Guidance for the Evaluation and Management of Infants with Possible Congenital Zika Virus Infection—United States, August 2016” at <https://www.cdc.gov/mmwr/volumes/65/wr/mm6533e2.htm>.
- Zika virus test results will be returned to the provider or facility listed as the submitter. Therefore, birth facilities should establish policies/procedures that ensure the infant’s outpatient pediatric care provider is made aware of the mother’s Zika risk and testing information as well as the results of the infant’s laboratory testing results, head ultrasound, and other Zika-related evaluations.
- For testing at birth originating in facilities within **New York City (NYC)**, approval for testing and additional information can be obtained by calling 866-692-3641 Monday-Friday, 9 am to 5 pm. Additional information on Zika virus can also be found at <http://www1.nyc.gov/site/doh/providers/reporting-and-services.page>.
- For testing at birth originating in facilities in **New York State (NYS) outside of NYC**, approval for testing and additional information can be obtained by calling 888-364-4723 Monday-Friday, 9 am to 5 pm. Additional information on Zika virus can also be found at http://www.health.ny.gov/diseases/zika_virus/providers.htm.

Joint Recommendations for Day of Delivery Testing and Specimen Collection for Zika Virus

New York State Department of Health (NYS DOH) and New York City Department of Health and Mental Hygiene (NYC DOHMH)

I. Testing Guidance

Testing guidance is based on the location of the birth facility, regardless of the patient's residence. For example, a NY State resident delivering at a NY City facility should be tested in accordance with NYC recommendations.

Criteria for maternal testing on day of delivery	Women who have not had Zika virus testing after their most recent potential exposure ¹
Criteria for collecting formalin-fixed placenta and umbilical cord specimens	<p>Collect for women with the following laboratory results:</p> <ul style="list-style-type: none"> ▪ PCR/NAAT² negative, IgM positive, and PRNT positive for Zika and dengue (undifferentiated flavivirus) ▪ PCR/NAAT negative, IgM positive, and a Zika PRNT result that is pending ▪ PCR/NAAT negative, IgM negative, and Zika PRNT positive results ▪ An infant with pre- or postnatal findings of microcephaly, intracranial calcifications or other possible Zika-related brain/eye abnormalities AND mother with potential exposure (regardless of maternal test results) <p><i>Placenta testing is not recommended for women who have tested 1) NAAT positive or 2) IgM positive and PRNT positive for Zika and negative for dengue</i></p>
Criteria for infant testing	<ul style="list-style-type: none"> ▪ Infants born to mothers with laboratory evidence of Zika virus infection during pregnancy ▪ An infant with pre- or postnatal findings of microcephaly, intracranial calcifications or other possible Zika-related brain/eye abnormalities AND mother with potential exposure (regardless of maternal test results)
Specimens for infants meeting criteria	<ul style="list-style-type: none"> ▪ 2.5-3ml of blood in a serum tube (ideally within 2 days of birth) ▪ Minimum of 1ml urine in a sterile cup sealed with parafilm (ideally within 2 days of birth)
Neuroimaging for infants meeting criteria	<ul style="list-style-type: none"> ▪ Head ultrasound prior to hospital discharge for all infants meeting criteria ▪ Consider advanced neuroimaging if clinical abnormalities consistent with congenital Zika syndrome are present

¹ Exposure is defined here as travel to or residence in an area with active mosquito-borne transmission of Zika virus (<https://www.cdc.gov/zika/geo/countries-territories.html>) or unprotected vaginal, anal, or oral sexual exposure with a partner who traveled to or resided in an area with active mosquito-borne transmission of Zika virus during pregnancy or in the eight weeks prior to conception.

² rRT-PCR is a form of NAAT (nucleic acid amplification testing).

II. How should specimens be prepared and handled?

Pre-approval should be obtained prior to submitting specimens. Specimens arriving at the lab without pre-approval will have delays in testing or will not be tested.

Facilities within NYC

- During business hours, call the NYC DOHMH Provider Access Line at 1-866-692-3641 for consultation, pre-approval, forms, and to arrange transportation of specimens to the NYC Public Health Laboratory.

New York State Facilities outside of NYC

- Contact NYS DOH via the NYSDOH Zika Information Line at 1-888-364-4723, Monday to Friday 9am to 5pm, for consultation, pre-approval, and to arrange transportation of specimens to the NYS Wadsworth Laboratory.

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Label all specimens. Failure to properly label a specimen will result in rejection and the specimen will not be tested.

Specimens must be labeled with:

- Patient's first and last name
- Patient's date of birth
- Date and time of collection
- Specimen type (serum, urine, CSF, etc.)
- The container for each placental specimen should also be labeled on the outside with:
 - Mother's name and date of birth (do not include infant's information)
 - Area of placenta sampled (e.g., maternal vs. fetal side, placental disk, etc.)
 - "Formalin-fixed"

Seal Specimen Containers

- Close specimen containers tightly and seal with parafilm.
- Leaking specimens will not be tested.
- Hemolyzed specimens will not be tested.

Specimen handling for facilities with a centrifuge and -70°C freezer	
Maternal serum – only for women who have not had Zika virus testing after their most recent potential exposure	<ul style="list-style-type: none"> ○ Collect blood in serum separator tube(s)* <ul style="list-style-type: none"> ○ Facilities within NYC: <u>12ml</u> of blood in two 6ml serum separator tubes ○ NYS facilities outside of NYC: <u>6ml</u> of blood in a serum separator tube ○ Centrifuge blood within 6 hours; specimens that are not centrifuged immediately should be refrigerated immediately until centrifuged. ○ Transfer serum, using sterile technique, to separate, labeled sterile tube(s) (at least 3 ml serum required) and discard the clot that remains in the blood tube. ○ Store specimen in -70°C freezer and ship on dry ice.
Maternal urine - only if testing serum	<ul style="list-style-type: none"> ○ Collect 3-20 ml of urine in a sterile leak-proof container. ○ Store specimen in -70°C freezer and ship on dry ice.
Placenta, fetal membranes, umbilical cord – Formalin-fixed specimens only.	<ul style="list-style-type: none"> ○ At least 3 full-thickness pieces (0.5-1cm x 3-4cm thick) from middle third of placental disk and at least one piece from placental margin; sample maternal and fetal sides of placenta, along with any pathologic lesion, if present. In addition, please include the following: <ul style="list-style-type: none"> ○ 5 x 12cm strip of fetal membranes. ○ Four segments, each 2.5cm in length, of umbilical cord; please obtain segments that are proximal, middle, and distal to umbilical cord insertion site on the placenta. ○ Indicate placenta weight. ○ Tissues may be refrigerated at +4°C for <24 hours until fixed in formalin. ○ Place the sections in a screw top sterile cup containing formalin. Tightly screw the lid to prevent leakage. ○ Volume of formalin used should be about 10x the mass of tissue. Place in 10% neutral buffered formalin for a minimum of 3 days. Once fully fixed the tissue can be transferred to 70% ethanol for long term storage. ○ Store formalin-fixed tissues at room temperature. Ship at room temperature. ○ Paraffin blocks may be submitted as well.
Infant serum – collected directly from the infant, within 2 days of birth	<ul style="list-style-type: none"> ○ Collect 2.5-3 ml of blood by venipuncture in a serum separator tube.* ○ Centrifuge within 6 hours of collection and transfer serum to a separate tube using sterile technique. ○ Store specimen in -70°C freezer and ship on dry ice.

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Infant urine	<ul style="list-style-type: none"> ○ Collect at least 1 ml of urine in a sterile leak-proof container. ○ Store specimen in -70°C freezer and ship on dry ice.
Infant CSF and Amniotic fluid	These specimen types are <i>not</i> routinely requested for Zika testing. If these specimens are obtained for other studies, aliquot a sample for Zika testing. If available, amniotic fluid may be tested upon consultation with the Department of Health.
Infant CSF	<ul style="list-style-type: none"> ○ Collect in sterile container (tube or cryovial). ○ Store specimen in -70°C freezer and ship on dry ice.
Amniotic Fluid	<ul style="list-style-type: none"> ○ Collect in sterile container (15 or 50 ml conical tube). ○ Store specimen in -70°C freezer and ship on dry ice.
Specimen handling for facilities with centrifuge and refrigerator, but no -70°C freezer or dry ice	
<ul style="list-style-type: none"> ○ Process as indicated above. ○ Refrigerate centrifuged serum and urine at 2-8°C immediately after collection. ○ Ship overnight with cold packs to lab for arrival within 72 hours of collection. ○ Preferably, specimens should arrive between Monday and Friday, between 9am and 4pm. ○ Specimens can arrive after business hours and on weekends and holidays. ○ Label the outer packaging: "Store at -70°C upon arrival." Failure to label the outer packaging correctly may result in specimens not being tested. 	
Specimen handling for facilities <u>in NY City</u> without a centrifuge (specimens sent to NY State <i>must</i> be centrifuged before shipping)	
<ul style="list-style-type: none"> ○ Specimens may only be collected on non-holiday WEEKDAYS. Specimens received at NYC PHL after 2 pm or on weekends/holidays cannot be appropriately processed or tested and these specimens will be REJECTED. Specimens <i>must</i> be collected by 11 am. Hold specimens in a refrigerator (2-8°C) or on cold packs. Ship to the NYC PHL on cold packs. ○ Specimens <i>must</i> arrive at the NYC PHL by 2 pm AND within 6 hours of collection. ○ Label the outer packaging: "STAT specimen – process immediately." Failure to label the outer packaging correctly may result in specimens not being tested. Even with STAT specimen handling, these specimens are at a high risk of hemolysis and providers are encouraged to refer patients to centers that have centrifuge capability. 	

*Serum separator tube cap colors include red top, tiger top, speckle top, and gold top. These tubes contain clot activator, so that serum can be readily obtained. Do NOT use blood tubes that contain anti-coagulants including green, yellow, or purple top tubes.

III. Who should I notify and what forms do I need to send with specimens?

Facilities within NY City

- During business hours, call the NYC DOHMH Provider Access Line at 1-866-692-3641 for consultation, pre-approval, forms, and to arrange transportation of specimens to the NYC Public Health Laboratory.
 - If specimens are approved for testing, DOHMH staff will email or fax the completed NYC Public Health Laboratory test request form for each specimen.
- Each form should be paired with the correct specimen and placed in the outer pocket of the submission bag and the specimen inside the bag.

New York State Facilities outside of NY City

- Contact NYS DOH via the NYS DOH Zika Information Line at 1-888-364-4723, Monday to Friday 9am to 5pm, for consultation, pre-approval, and to arrange shipment.
- Specimens may be collected and stored as outlined above until shipping can be arranged.

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- Wadsworth's Infectious Disease Requisition (IDR) form:
http://www.wadsworth.org/sites/default/files/WebDoc/1065760803/infectious_diseases_requisition_DOH_4463.pdf
 - The IDR form should be completed in full and accompany each specimen being submitted.
 - If present, symptoms should be clearly noted on the IDR.

IV. How should specimens be stored and transported?

- Serum and urine specimens may be stored and shipped:
 1. If specimens are frozen ship on dry ice. (Follow shipping regulations for UN 3373 Biological Substance, Category B and UN 1875, Class 9 for dry ice).
 2. If specimens are refrigerated, shipping must occur within 48 hours of specimen collection. Prepare as above in order to arrive at the lab within 72 hours after collection.
 - Refrigerate immediately and ship on cold packs.
 - Cold packs should be *frozen* before placed in the box, not just refrigerated.
 - Sufficient cold packs should be used to keep the specimens refrigerated during shipping.
- For formalin fixed (wet) or formalin-fixed paraffin-embedded tissues, specimens should be sent at room temperature. Fixed tissues should not be shipped with refrigerated or frozen samples. The NYS/NYC public health laboratory will ship fixed placenta specimens to the CDC for testing.
- CSF and amniotic fluid specimens should be handled in the same manner as serum and urine specimens.
- Indicate the temperature shipment requirements on the outside of the package.

Facilities within NYC

- Label outer packaging as "Store at -70 C upon arrival" if specimens have been centrifuged.
- Label outer packaging as "STAT specimen – process immediately" if specimens have NOT been centrifuged.
- Courier arrangements to the NYC Public Health Laboratory can be made by calling the NYC DOHMH Provider Access Line at 1-866-692-3641 during business hours.

Facilities outside of NYC

- After receiving approval from NYS DOH, specimens must be shipped overnight with cold packs or dry ice to:
The Wadsworth Center, David Axelrod Institute
120 New Scotland Avenue
Albany, NY 12208
- Delivery to Wadsworth Center should occur between Monday and Friday, preferably between 9am and 4pm. However, deliveries are accepted at all hours and any day of the week.

V. How will test results be reported?

Zika test results will be sent to the provider or facility listed as the submitter. Birth facilities should establish procedures for the transmission of laboratory test results, clinical assessment, and maternal Zika exposure/testing to the infant's outpatient pediatric provider to ensure appropriate ongoing care of the infant.

Facilities within NYC

- Facilities may receive some results via secure fax if a secured fax number is provided. Otherwise, results will be mailed.

New York State Facilities outside of NYC

- If the submitter has a NYS Health Commerce System account with CLIMS access, results will be transmitted electronically. Otherwise, results will be mailed.

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VI. Other Resources

- NYSDOH: http://www.health.ny.gov/diseases/zika_virus/providers.htm
- NYC DOHMH: <http://www1.nyc.gov/site/doh/providers/reporting-and-services-main.page>
- Infectious Diseases Requisition (IDR) form required for shipment of specimens to Wadsworth Center.
https://www.wadsworth.org/sites/default/files/WebDoc/1065760803/infectious_diseases_requisition_DOH_4463.pdf
- CDC Clinical Guidance: <https://www.cdc.gov/zika/hc-providers/clinical-guidance.html>
- Update: Interim Guidance for the Evaluation and Management of Infants with Possible Congenital Zika Virus Infection — United States, August 2016.
https://www.cdc.gov/mmwr/volumes/65/wr/mm6533e2.htm?s_cid=mm6533e2_w
- Preventing Transmission of Zika Virus in Labor and Delivery Settings Through Implementation of Standard Precautions—United States, 2016. <https://www.cdc.gov/mmwr/volumes/65/wr/mm6511e3.htm>