NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

January 24, 2018

TO: Healthcare Providers, Healthcare Facilities, Clinical Laboratories, and Local Health Departments (LHDs)

FROM: New York State Department of Health (NYSDOH)
Bureau of Communicable Disease Control

HEALTH ADVISORY: ZIKA VIRUS UPDATE

Please distribute to staff, including Nurse Practitioners and Nurse Midwives, in Obstetrics/Gynecology, Pediatrics, Internal Medicine, Primary Care, Infectious Diseases, Emergency Medicine, Family Medicine, Laboratory Services, Director of Nursing, Medical Director, Travel Medicine, and Infection Control

Summary: (New information is designated by yellow highlight.)

- **Zika virus (ZIKV) infection is a recognized cause of severe congenital abnormalities for the infants of some women infected during pregnancy.**
- **CDC continues to recommend that pregnant women not travel to areas with a risk of ZIKV, and that all travelers take precautions to avoid mosquito bites during travel.**
- **Recommendations for testing pregnant women have evolved given the dramatic decrease in ZIKV infection in the Western hemisphere. The NYSDOH recommends ZIKV testing for symptomatic pregnant women and for those pregnant women with epidemiologic exposures and ultrasound abnormalities that suggest ZIKV infection. Testing of other pregnant women with possible exposure to ZIKV may be considered on a case-by-case basis.**
- **Commercial testing is readily available. In addition, the NYSDOH public health laboratory, Wadsworth Center, will continue to offer ZIKV testing free of charge. After February 28, 2018, the NYSDOH will no longer designate centers for the collection and transport of ZIKV specimens to Wadsworth.**
- **Medical practitioners should remain alert to the possibility of local mosquito-borne transmission of ZIKV in areas of the United States that harbor *Aedes aegypti* or *Aedes albopictus* mosquitoes. *A. albopictus* mosquitoes, though not found to be an efficient transmitter of ZIKV, have been found in the lower Hudson Valley, Long Island and New York City (NYC). Suspected local transmission should be immediately reported to the local health department.**

Introduction and purpose:

In 2016, the NYSDOH developed a response to the ZIKV epidemic in the Western Hemisphere inclusive of testing through the NYSDOH Wadsworth Center, the state's public health laboratory, and a Zika Information Line (888-364-4723) for concerned citizens and medical care professionals.

ZIKV infection is usually an asymptomatic or mild self-limited illness. Symptoms include fever, arthralgias/myalgias, rash and conjunctivitis.

ZIKV is an established cause of severe congenital anomalies. In 2016, approximately 10% of completed pregnancies with laboratory confirmed maternal Zika virus infection in the United States resulted in a fetus or infant with ZIKV-associated birth defects.[i] While many questions and challenges remain, the epidemiology of the ZIKV epidemic in the Western Hemisphere, recommendations from the Centers for Disease Control and Prevention (CDC), and the availability of testing have evolved. This document updates NYSDOH recommendations regarding ZIKV and information on obtaining ZIKV testing for persons residing in NYS outside of New York City (NYC).

Epidemiology:

As of December 31, 2017, 1,464 cases of ZIKV infection have been diagnosed in persons residing in NYS, with 1,119 in NYC and 345 in NYS outside of NYC. Cases peaked in July 2016, with 221 new diagnoses. Cases have continued to decline with an average of 11 cases per month from June through December 2017. Statewide, 545 cases have occurred among pregnant women, with 8 cases among infants meeting the definition of congenital ZIKV syndrome. No cases of local mosquito-borne transmission have been documented in NYS.

Cases peaked in the Western Hemisphere in early to mid-2016, with a comparatively very low level of transmission in 2017 in South and Central America and Mexico, and the Caribbean.[ii] Limited mosquito-borne transmission has been documented in the continental United States in Miami, FL, and Brownsville, TX.

Travel recommendations:

Persons considering travel should consult CDC recommendations for their intended destination, available at https://wwwnc.cdc.gov/travel/page/zika-information. This website is updated as information about ZIKV changes. Pregnant women are advised not to travel to areas with a risk of ZIKV. All travelers should avoid mosquito bites. Information on protective measures is available at https://www.health.ny.gov/diseases/zika_virus/mosquitoes.htm. Based on lack of evidence for sustained local transmission, travel precautions were discontinued for Miami, FL, on June 2, 2017[iii], and for Brownsville, TX, on August 29, 2017[iv], and no areas within the continental United States currently have travel precautions. However, the primary vector for ZIKV, the *Aedes aegypti* mosquito, is found in many areas of the southern United States, and local transmission may occur. Travel precautions continue for Mexico and for the United States territories of Puerto Rico and the US Virgin Islands.

Precautions to avoid sexual transmission:

Persons wishing to avoid sexual transmission should use condoms or not have oral, anal or vaginal sex.[v] This is particularly important for pregnant women, who should abstain from sexual

activity or use barrier precautions for the duration of their pregnancy if their sexual partner(s) travels to an area with a risk of ZIKV infection. Potential ZIKV exposure is also an important consideration for couples who wish to conceive. After travel to an area with a risk of ZIKV (or symptom onset, if symptoms occur), **men should wait 6 months before attempting conception and women should wait at least 8 weeks before attempting conception** with use of barrier precautions to prevent sexual transmission in the interim.[vi]

Indications for testing:

Providers are encouraged to ask about recent travel or residence in an area with recognized ZIKV transmission in assessing patients for ZIKV infection. All pregnant women should be asked about travel/possible ZIKV exposure *before* and *during* the current pregnancy at each prenatal visit. Providers are reminded that this may be especially important for pregnant women arriving in NYS seeking prenatal care after having been displaced by hurricanes, including residents of Puerto Rico or the US Virgin Islands who may be relocating to NYS.

ZIKV testing is currently recommended by the NYSDOH and CDC[vii] for:

- Anyone with possible recent ZIKV exposure who has experienced symptoms consistent with ZIKV
- Symptomatic pregnant women with possible ZIKV exposure
- Asymptomatic pregnant women with ongoing possible ZIKV exposure (ongoing exposure is defined as residence in or frequent travel to an area with risk of ZIKV transmission)
- Pregnant women with possible ZIKV exposure who have a fetus with prenatal ultrasound findings consistent with congenital ZIKV infection
- Infants with clinical findings consistent with congenital ZIKV syndrome and possible maternal ZIKV exposure during pregnancy, regardless of maternal testing results
- Infants without clinical findings consistent with congenital ZIKV syndrome born to mothers with laboratory evidence of definitive or possible ZIKV infection during pregnancy

ZIKV testing may be considered for:

- Asymptomatic pregnant women with possible recent but no ongoing exposure to ZIKV (i.e., travelers)
    - Testing may be considered on a case-by-case basis as part of a shared provider-patient decision-making process
- Infants without clinical findings consistent with congenital ZIKV syndrome born to mothers with possible ZIKV exposure in pregnancy who have not had laboratory assessment for their most recent ZIKV exposure during pregnancy
    - Testing may be considered on a case-by-case basis as part of a shared provider-patient decision-making process

ZIKV testing is not recommended for:

- Non-pregnant asymptomatic individuals
- Preconception screening

Timing of diagnostic tests:

If diagnostic specimens are obtained less than 8 days after symptom onset or less than 3 weeks after the last potential ZIKV exposure and do not show evidence of ZIKV, then convalescent testing is needed to assure infection did not occur. If indicated, convalescent specimens should be obtained approximately 3 weeks after the initial specimen was collected.

Availability and selection of diagnostic tests:

Commercial laboratories: Multiple commercial laboratories now offer testing appropriate for assessing persons who may have had recent ZIKV infection. Test types offered include:

- **Molecular testing (PCR/NAAT)** may be referred to as nucleic acid amplification testing (NAAT) or polymerase chain reaction (PCR) depending on the laboratory and assay used. Molecular testing is available for plasma, serum and/or urine and if positive can provide definitive evidence of ZIKV infection. Molecular testing is most likely to be positive in the early weeks after infection. However, a negative molecular test does not exclude ZIKV infection.
- **ZIKV IgM antibody** becomes detectable in serum one to three weeks after infection. It persists for a variable time, but it is usually detectable for at least 12 weeks after infection. Because false positive IgM values can occur, additional testing is needed with plaque reduction neutralization tests (PRNT) to assess total antibody to ZIKV before clinical decision-making based on a positive IgM. Commercial labs are required to ship IgM positive serum to the NYSDOH Wadsworth Center for PRNT. Occasionally, the medical provider may need to obtain additional serum from the patient for PRNT testing.

NYSDOH Wadsworth Center Laboratories: The Wadsworth Center will continue to provide comprehensive ZIKV testing, inclusive of whole blood, urine and serum PCR, serum IgM, PRNT (if indicated), and an additional test for ZIKV antibodies known as the Microsphere Immunofluorescence Assay (MIA). Health care providers can request ZIKV testing from Wadsworth Center without specifying the precise tests to be conducted. Whole blood PCR for ZIKV has recently been added to the test menu following reports of extended positivity in this sample type. PRNT and MIA testing for ZIKV done through Wadsworth also includes PRNT and MIA assays for Dengue virus antibodies, as serologic cross-reactivity is common and many patients will have been exposed to both viruses. (If recent Dengue is a primary clinical concern, the clinician will need to order additional testing available through commercial laboratories as appropriate, such as Dengue PCR and Dengue IgM.) In selected circumstances and with preapproval, the laboratory can perform testing on other body fluids such as cerebrospinal fluid and amniotic fluid. Requests for testing body fluids other than whole blood, serum, and urine should be directed to the Virology Laboratory at 518-474-4177.

After February 28, 2018, the NYSDOH will no longer designate centers for collection and transport of specimens to Wadsworth Center. However, Wadsworth will continue to accept specimens submitted from laboratories or provider offices. Preauthorization will not be required. Instructions for shipping specimens, entitled "Zika Virus: Recommendations for Diagnostic Testing, Specimen Collection, and Submission," are included in this Health Advisory, and any subsequent updates will be posted at https://www.health.ny.gov/diseases/zika_virus/providers.htm. Testing through the Wadsworth Center is free of charge. However, charges and/or copays for phlebotomy and specimen handling services may occur dependent on the patient's source of payment for medical services.

Prior to February 28, 2018, medical providers should continue to contact the Zika Information Line at 888-364-4723 for Wadsworth testing authorization.

Test interpretation:

Documents designed to assist with the interpretation of laboratory results reported from Wadsworth Center are available at: https://www.health.ny.gov/diseases/zika_virus/providers.htm.

Additional information on interpretation of laboratory results, including results from commercial laboratories, is available at: https://www.cdc.gov/zika/hc-providers/pregnant-women/testing-and-diagnosis.html.

Providers are reminded to be aware of testing challenges and limitations. Both PCR/NAAT and IgM testing are time-limited in their ability to detect evidence of ZIKV. Generally, PCR/NAAT is only positive for days to weeks following infection while IgM testing is only positive for weeks to a few months following infection. In addition, serological cross-reactivity with related Flaviviruses (e.g., dengue and yellow fever viruses) is common. PRNT can be performed to measure virus-specific neutralizing antibodies, but cross-reactivity with PRNT is also common following other Flavivirus exposure or vaccination.

Result interpretation can be particularly challenging when dealing with pregnant women with ongoing or prolonged potential exposure to ZIKV. ZIKV IgM antibodies may persist in the body for months after infection, making it difficult to determine if the woman was infected before or after she became pregnant or during the periconception period. Definitive exclusion of ZIKV infection may not be possible, especially in the absence of appropriately timed specimens evaluated by serology inclusive of total antibody assays (ie, MIA and/or PRNT). Providers are reminded to discuss complexity of testing and test results with patients are part of pre-test counseling. Additional resources related to patient counseling are available at https://www.cdc.gov/zika/hc-providers/pregnant-women/patient-counseling.html.

Health care providers can access ZIKV subject matter experts to assist with test interpretation and other Zika-related questions through the NYSDOH Zika Information Line at 888-364-4723 on workdays Monday through Friday from 9 am to 5 pm through February 28, 2018. As of March 1, 2018, routine questions may be directed to the LHD; contact information for LHDs is available at https://www.health.ny.gov/contact/contact_information/. Assistance with test interpretation can be obtained by calling the NYSDOH Bureau of Communicable Disease Control at 518-473-4439.

Reporting suspected ZIKV cases:

Hospitals and providers must report all cases of ZIKV virus (and all other arboviral diseases) to the LHD where the patient resides.

- When a provider obtains LHD authorization for ZIKV testing at the public health laboratory, the suspected ZIKV case is considered reported, though additional information may be requested from the provider. If the provider orders ZIKV testing commercially and the test shows evidence of Zika virus, the provider must report the case to the LHD.
- If **local, mosquito-borne transmission of ZIKV is suspected** because a patient with any laboratory evidence of possible ZIKV infection does not report travel to a country with active mosquito-borne ZIKV transmission or a sexual partner who has traveled to these areas, LHD notification should be immediate. Contact information for LHDs is available at https://www.health.ny.gov/contact/contact_information/. Providers who cannot reach the LHD can access 24/7/365 public health consultation from NYSDOH at 518-473-4439 during business hours and 866-881-2809 evenings, weekends, and holidays.

Care of pregnant women with laboratory evidence of ZIKV infection:

The CDC has recently updated guidance related to the prenatal management of pregnant women with laboratory evidence of possible ZIKV infection.[viii] This guidance is available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6629e1.htm?s_cid=mm6629e1_w.

Serial fetal ultrasounds should be considered to assess fetal neuroanatomy and overall growth. The optimal timing and frequency of ultrasounds is unknown, and available information suggests that the time from infection to detection of microcephaly on ultrasound can be highly variable. Amniocentesis is of uncertain utility in the diagnosis of congenital ZIKV infection.

Care of infants born to mothers exposed to ZIKV:

CDC guidance for infants with possible congenital ZIKV infection has been recently updated.[ix] This guidance is available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6641a1.htm?s_cid=mm6641a1_w.

Updated guidance on testing at the day of delivery, entitled "Zika Virus: Recommendations for Day of Delivery Testing and Specimen Collection," can be found in this health advisory. Any subsequent updates will be posted at https://www.health.ny.gov/diseases/zika_virus/providers.htm.

All infants born to mothers with possible ZIKV infection during pregnancy should receive evaluation that includes a newborn hearing screen at birth, preferably using auditory brainstem response (ABR) methodology, and ongoing well-child visits inclusive of comprehensive physical examination, age-appropriate vision screening, and developmental monitoring and screening using validated tools. Additional information on the care of infants with possible ZIKV exposure or congenital ZIKV infection can be found at https://www.cdc.gov/zika/hc-providers/infants-children.html. Infants with congenital ZIKV syndrome may benefit from Early Intervention Program referral. Additional information is available at https://www.health.ny.gov/community/infants_children/early_intervention/.

Additional resources:

NYSDOH ZIKV information: https://www.health.ny.gov/diseases/zika_virus/providers.htm
CDC: https://www.cdc.gov/zika/hc-providers/index.html
NYC Department of Health and Mental Hygiene:
http://www1.nyc.gov/site/doh/providers/reporting-and-services.page

NYSDOH Zika Information Line (through February 28, 2018)**:** 888-364-4723
NYSDOH Bureau of Communicable Disease Control (after February 28, 2018)**:**
518-473-4439 or bcdc@health.ny.gov

[i]MMWR. Vital Signs: Update on Zika Virus–Associated Birth Defects and Evaluation of All U.S. Infants with Congenital Zika Virus Exposure — U.S. Zika Pregnancy Registry, 2016. April 7, 2017 / 66(13);366-373. Available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6613e1.htm?s_cid=mm6613e1_w. Accessed November 28, 2017.

[ii] Pan American Health Organization, Regional Zika Epidemiological Update (Americas) August 26, 2017. Available at http://www.paho.org/hq/index.php?option=com_content&view=article&id=11599%3Aregional-zika-epidemiological-update-americas&catid=8424%3Acontents&Itemid=41691&lang=en. Accessed October 30, 2017.

[iii] CDC. Advice for people living in or traveling to South Florida. Available at https://www.cdc.gov/zika/intheus/florida-update.html. Accessed November 28, 2017.

[iv]CDC. Advice for people living in or traveling to Brownsville, Texas. Available at https://www.cdc.gov/zika/intheus/texas-update.html. Accessed November 28, 2017.

[v] https://www.cdc.gov/zika/prevention/sexual-transmission-prevention.html.

[vi] CDC. Women & Their Partners Trying to Become Pregnant. https://www.cdc.gov/zika/pregnancy/women-and-their-partners.html. Accessed October 30, 2017.

[vii] CDC. Testing Guidance. https://www.cdc.gov/zika/hc-providers/testing-guidance.html. Accessed December 12, 2017.

[viii]MMWR. Update: Interim Guidance for Health Care Providers Caring for Pregnant Women with Possible Zika Virus Exposure — United States (Including U.S. Territories), July 2017. July 28, 2017 / 66(29);781-793. Available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6641a1.htm?s_cid=mm6641a1_w. Accessed November 29, 2017.

[ix] MMWR. Update: Interim Guidance for the Diagnosis, Evaluation, and Management of Infants with Possible Congenital Zika Virus Infection — United States, October 2017. October 20, 2017 / 66(41);1089–1099. Available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6629e1.htm?s_cid=mm6629e1_w. Accessed December 12, 2017.

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

Questions and Answers on Zika Virus (ZIKV) for Health Care Providers

General Topics

What are the symptoms of ZIKV infection?

Only about one in five infected people develop any symptoms. If symptoms occur, they usually start 2-7 days after exposure. The most common symptoms are fever, maculopapular rash, joint pain, and conjunctivitis. Other symptoms may include headache, muscle pain, pain behind the eyes, and vomiting.

Symptoms typically last several days to a week. Infection with ZIKV is usually mild, and hospitalization is uncommon. There have been rare reports of death in patients with pre-existing diseases or other health conditions.

Cases of Guillain-Barré Syndrome (also known as GBS) have been reported in patients following ZIKV infection. Although the association between GBS and ZIKV appears strong, the precise relationship is not known, and GBS remains a rare condition.

How is the ZIKV transmitted?

ZIKV is spread to people primarily through the bite of an infected mosquito. Also, a person with ZIKV can pass it to his or her sex partner(s) through vaginal, anal, or oral sex and the sharing of sex toys. A pregnant woman can pass ZIKV to her fetus during pregnancy or around the time of birth.

What repellant should I recommend for prevention of mosquito bites?

To prevent ZIKV and other diseases spread by mosquitoes, use Environmental Protection Agency (EPA)-registered insect repellents on exposed skin. The insect repellent should include one of the following ingredients: DEET, picaridin, IR3535, oil of lemon eucalyptus, para-menthane-diol, or 2-undecanone. Higher percentages of active ingredient provide longer protection. Always follow the label instructions when using insect repellent. Information on additional protective measures is available at https://www.health.ny.gov/diseases/zika_virus/mosquitoes.htm.

Is there treatment for ZIKV infection? Is there a vaccine for ZIKV?

No vaccines or medications are available to prevent or treat ZIKV infections. Acetaminophen may provide symptomatic relief for fever and joint/muscle pain. Because dengue infection may not be clinically distinguishable from ZIKV infection at presentation, aspirin and other non-

steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen should be avoided so as not to exacerbate potential hemorrhagic complications of dengue.

Are there areas of ZIKV risk in the continental United States?

No areas within the continental United States currently have ZIKV travel precautions. Local mosquito-borne transmission of ZIKV has been documented in discrete areas of Florida and Texas. Based on lack of evidence for sustained local transmission, the Centers for Disease Control and Prevention (CDC) discontinued travel precautions for Miami, FL, on June 2, 2017, and for Brownsville, TX, on August 29, 2017. Additional information about areas of ZIKV risk can be found at https://www.cdc.gov/zika/intheus/florida-update.html (Florida), https://www.cdc.gov/zika/intheus/texas-update.html (Texas), and https://wwwnc.cdc.gov/travel/page/world-map-areas-with-zika (worldwide).

The primary vector for ZIKV, the *Aedes aegypti* mosquito, is found in many areas of the southern United States, and local transmission may occur. Another species of mosquito, *Aedes albopictus*, may also be capable of transmitting ZIKV. This mosquito has a broader range in the United States and has been found in New York State (NYS) in the lower Hudson Valley, Long Island, and New York City (NYC). Persons residing in, or traveling to, areas where these mosquito vectors are present should protect themselves from mosquito bites.

Which patients should I test for ZIKV?

ZIKV testing is **recommended** by NYS Department of Health (DOH) and CDC for:

- Any individual with recent potential exposure that presents with symptoms consistent with ZIKV
- Symptomatic pregnant women with possible ZIKV exposure
- Asymptomatic pregnant women with ongoing exposure to ZIKV (ongoing exposure is defined as residence in or frequent travel to an area with risk of ZIKV transmission)
- Pregnant women with possible ZIKV exposure who have a fetus with prenatal ultrasound findings consistent with congenital ZIKV infection
- Infants with clinical findings consistent with congenital ZIKV syndrome and possible maternal ZIKV exposure during pregnancy, regardless of maternal testing results
- Infants without clinical findings consistent with congenital ZIKV syndrome born to mothers with laboratory evidence of definitive or possible ZIKV infection during pregnancy

ZIKV testing **may be considered** for:

- Asymptomatic pregnant women with recent possible (but no ongoing exposure) to ZIKV
    - Testing may be considered on a case-by-case basis as part of a shared provider-patient decision-making process
- Infants without clinical findings consistent with congenital ZIKV syndrome born to mothers with possible ZIKV exposure in pregnancy who have not had laboratory assessment for their most recent ZIKV exposure during pregnancy
    - Testing may be considered on a case-by-case basis as part of a shared provider-patient decision-making process

ZIKV testing is **not recommended** for:

- Asymptomatic non-pregnant individuals
- Preconception screening

How can I arrange ZIKV testing for my patients?

Several commercial laboratories provide PCR testing on urine and serum (or plasma) as well as IgM antibody testing. Practitioners ordering ZIKV testing through commercial laboratories will need to order the tests most appropriate for the patient's circumstance.

Wadsworth Center, the NYSDOH public health laboratory, provides comprehensive ZIKV testing including PCR testing on serum, whole blood, and urine as well as IgM antibody testing. Health care providers can request ZIKV testing without specifying the precise tests to be conducted. Before February 28, 2018, providers should contact the Zika Information Line at 888-364-4723 for testing authorization.

After February 28, 2018, the NYSDOH will no longer designate centers for collection and transport of specimens to Wadsworth. However, Wadsworth will continue to accept specimens submitted from laboratories or provider offices.

Instructions for specimen preparation and submission can be found at https://www.health.ny.gov/diseases/zika_virus/providers.htm.

What tests do I need to order if I suspect that my patient may have been exposed to ZIKV?

Symptomatic patients with recent possible exposure (within 3 months) should be evaluated with serum ZIKV IgM antibody testing and PCR/NAAT of urine and serum (or plasma and/or whole blood, depending on the assays offered by the testing laboratory). PCR is a form of NAAT, or nucleic acid amplification testing. Because false positive IgM values can occur, additional testing is needed with plaque reduction neutralization tests (PRNT) to assess total antibody to ZIKV before clinical decision-making based on a positive IgM. Commercial labs are required to ship IgM positive serum to the NYSDOH Wadsworth Center for PRNT. Occasionally, the medical provider may need to obtain additional serum from the patient for PRNT testing.

Patients with ZIKV infection more than 3 months before testing may test PCR/NAAT and IgM negative. If defining the past ZIKV exposure status is important clinically, testing for total antibody via microsphere immunofluorescence assay (MIA) and plaque reduction neutralization tests (PRNT) is available through the NYSDOH Wadsworth Center.

How should ZIKV test results be interpreted?

Documents designed to assist with the interpretation of laboratory results reported from Wadsworth Center are available at:
https://www.health.ny.gov/diseases/zika_virus/providers.htm.

Additional information on interpretation of laboratory results, including results from commercial laboratories, is available at:
https://www.cdc.gov/zika/hc-providers/pregnant-women/testing-and-diagnosis.html.

ZIKV test interpretation has challenges and limitations. Both PCR/NAAT and IgM testing are time-limited in their ability to detect evidence of ZIKV. Generally, PCR/NAAT is only positive for days to weeks following infection while IgM testing is only positive for weeks to a few months following infection. In addition, serological cross-reactivity with related Flaviviruses (e.g., dengue and yellow fever viruses) is common. PRNT can be performed to measure virus-specific

neutralizing antibodies, but cross-reactivity with PRNT is also common following other Flavivirus exposure or vaccination.

Health care providers can access ZIKV subject matter experts to assist with test interpretation and other Zika-related questions through the NYSDOH Zika Information Line at 888-364-4723 on workdays Monday through Friday from 9 am to 5 pm through February 28, 2018. As of March 1, 2018, routine questions may be directed to the LHD; contact information for LHDs is available at https://www.health.ny.gov/contact/contact_information/. Assistance with test interpretation can be obtained by calling the NYSDOH Bureau of Communicable Disease Control at 518-473-4439.

Conception and Pregnancy

Why is ZIKV a concern for women who are pregnant, or trying to become pregnant?

ZIKV is an established cause of congenital ZIKV syndrome, which may include microcephaly, intracranial calcifications, cerebral atrophy, abnormalities of the cerebrum, corpus callosum, and cerebellum, porenchphaly, hydrancephaly, fetal brain disruption sequence, neural tube defects, spina bifida, eye abnormalities, chorioretinal anomalies, deafness and congenital contractures.

Other abnormalities have been reported in conjunction with maternal ZIKV infection, such as pregnancy loss, intrauterine growth retardation, and post-birth development of microcephaly.

My patient is asking to be tested as part of pre-conception counseling. How should I proceed?

Testing blood, urine, or genital secretions to assess ZIKV as part of preconception assessment is **not** recommended.

Also, patterns of Zika shedding in semen or vaginal fluids are not well-understood. Zika shedding in these secretions may be intermittent. Studies are underway to better understand this biological response and inform interpretation of test results from semen and vaginal fluids.

Additional information that may be helpful in preconception counseling can be found at https://www.cdc.gov/zika/hc-providers/clinical-guidance/sexualtransmission.html.

How long after travel to an area with risk of ZIKV transmission should a couple abstain/practice safe sex before attempting to conceive?

Non-pregnant couples with a partner who traveled to an area with risk of ZIKV should consider using condoms or abstaining from sex. The recommended duration of the waiting period before attempting conception depends on the sex of the potentially exposed person:

- Females who have traveled should wait at least 8 weeks after the travel (in absence of symptoms) or at least 8 weeks after illness onset (if symptoms develop)
- Males who have traveled should wait at least 6 months after travel (in absence of symptoms) or at least 6 months after illness onset (if symptoms develop). Further information can be found at https://www.cdc.gov/zika/hc-providers/clinical-guidance/sexualtransmission.html.

My pregnant patient is planning a trip. How can I assess the risk of ZIKV at her intended destination, and what guidance should I provide if ZIKV infection is a risk?

Persons considering travel should consult CDC recommendations for their intended destination, available at https://wwwnc.cdc.gov/travel/page/zika-information. This site is updated as information about ZIKV changes. Pregnant women are advised not to travel to areas with a risk of ZIKV infection.

If the patient decides to travel, she should be advised to avoid mosquito bites. Information on protective measures is available at https://www.health.ny.gov/diseases/zika_virus/mosquitoes.htm.

An already pregnant couple wants to know about the safety of sex after the non-pregnant partner visits an area with risk of ZIKV transmission. What should I advise them?

If the sexual partner of a pregnant woman travels to an area with risk of ZIKV, the couple should use condoms from start to finish every time they have oral, anal or vaginal sex or not have sex for the entire pregnancy, even if the traveler does not have symptoms of ZIKV or feel sick.

CDC and NYSDOH recommend that until more is known, sexual partners of pregnant women who have traveled to or lived in an area where ZIKV is active during the pregnancy should not have sex or should always and correctly use condoms every time they have sex (vaginal, anal or oral) during pregnancy. Information on using condoms correctly is available from CDC at How to Use a Condom Consistently and Correctly (cdc.gov).

Should pregnant women who may have been exposed to ZIKV through travel or sexual contact be tested?

Symptomatic pregnant women who have traveled to or resided in a ZIKV-affected area during pregnancy or the eight weeks prior to pregnancy should be tested. Testing can be considered for asymptomatic pregnant women with recent possible exposure to ZIKV but no ongoing exposure on a case-by-case basis as part of a shared provider-patient decision-making process.

Similarly, symptomatic pregnant women should be tested if during pregnancy or in the eight weeks prior to conception, they had unprotected vaginal, anal or oral sex with a partner who traveled to an area with active mosquito-borne transmission of ZIKV. Testing can be considered for asymptomatic pregnant women with possible sexual exposure to ZIKV on a case-by-case basis as part of a shared provider-patient decision-making process. Testing should be considered regardless of whether the sex partner had symptoms.

My pregnant patient received testing through NYSDOH's Wadsworth Center. How do I interpret the test results?

The following documents provide guidance on test interpretation. They are available at https://www.health.ny.gov/diseases/zika_virus/providers.htm.

- "A Healthcare Provider's Guide to Zika Virus Laboratory Results from the NYSDOH Wadsworth Center - May 25, 2017"

- "Interpretation of Zika Virus Serology Performed at the New York State Department of Health Wadsworth Center - May 31, 2017"

Result interpretation can be particularly challenging when dealing with pregnant women with ongoing or prolonged potential exposure to ZIKV. ZIKV IgM antibodies may persist in the body for months after infection, making it difficult to determine if the woman was infected before or after she became pregnant or during the periconception period. Definitive exclusion of ZIKV infection may not be possible, especially in the absence of appropriately timed specimens evaluated by serology inclusive of total antibody assays (ie, MIA and/or PRNT). Providers are reminded to discuss complexity of testing and test results with patients are part of pre-test counseling.

Additional resources related to patient counseling are available at https://www.cdc.gov/zika/hc-providers/pregnant-women/patient-counseling.html. Medical providers can also contact the NYSDOH Zika Information Line at 888-364-4723 Monday through Friday 9 am to 5 pm on workdays for assistance through February 28, 2018. After that date, inquiries may be directed to NYSDOH ZIKV subject matter experts at 518-473-4439.

I have a pregnant patient with laboratory evidence of ZIKV infection. What is the likelihood that her infant will be affected?

In 2016 in the United States, approximately 10% of infants born to mothers with laboratory confirmed maternal ZIKV infection during pregnancy had ZIKV associated birth defects. (See https://www.cdc.gov/mmwr/volumes/66/wr/mm6613e1.htm#T1_down.) Some infants described as normal at birth born to mothers with ZIKV infection during pregnancy in Brazil have developed microcephaly and other neurological findings in the months after birth. The incidence of these later complications is unknown.

I have a pregnant patient with laboratory evidence of ZIKV infection. Are there additional precautions that need to be in place during labor and delivery?

Standard Precautions are recommended to prevent exposure of healthcare personnel to ZIKV. ZIKV has been demonstrated in multiple body fluids and tissues, including blood, urine, breast milk, semen, and vaginal fluids. Additional information on infection control and potential Zika exposures in healthcare settings can be found at https://www.cdc.gov/zika/hc-providers/infection-control.html.

Infants

Is it safe for ZIKV-infected mothers to breastfeed their infants?

Current recommendations from both the CDC and the World Health Organization (WHO) are that women should be encouraged and supported to breastfeed their infants, regardless of maternal or infant ZIKV testing results. Although ZIKV RNA has been identified in breast milk, there are no reports of ZIKV infection associated with breastfeeding.

Which infants should be tested at birth?

ZIKV testing is recommended for:

- Infants with clinical findings consistent with congenital ZIKV syndrome regardless of maternal testing results
- Infants without clinical findings consistent with congenital ZIKV syndrome born to mothers with laboratory evidence of possible ZIKV infection during pregnancy

What tests should I order on the day of delivery for an infant who I suspect may have been exposed to ZIKV? Is placental testing advised?

The following tests should be ordered if infant testing is indicated:

- Serum (or plasma), whole blood, and urine PCR/NAAT
- IgM antibody

Placenta testing with PCR/NAAT can be considered for women with laboratory evidence of ZIKV who do not have a definitive diagnosis of ZIKV infection during pregnancy. Placental testing should also be considered in the setting of infant abnormalities consistent with congenital ZIKV syndrome if the mother had potential exposure to ZIKV during pregnancy but did not receive testing. Evidence of ZIKV nucleic acid in the placenta confirms a diagnosis of ZIKV infection during pregnancy for the mother, but it does not confirm congenital ZIKV infection.

Further information about testing at birth is available at https://www.health.ny.gov/diseases/zika_virus/providers.htm. Telephone inquiries may be directed to the Zika Information Line at 888-364-4723 through February 28, 2018, and to 518-473-4439 thereafter.

An infant was born with laboratory evidence of or clinical findings consistent with congenital ZIKV infection. How should I proceed?

Infants with evidence of congenital ZIKV infection and/or laboratory evidence of infant ZIKV infection should have:

- A standard newborn evaluation
- Comprehensive ophthalmologic exam by age 1 month
- Head ultrasound by age 1 month
- Automated ABR by age 1 month

Infants with clinical findings may need referral to pediatric subspecialists, developmental specialists, and/or early intervention services.
See https://www.cdc.gov/mmwr/volumes/66/wr/mm6641a1.htm for further information about the diagnosis, evaluation and management of infants with possible congenital ZIKV infection.
Information on referral to Early Intervention Services in NYS can be found at https://www.health.ny.gov/community/infants_children/early_intervention/.

Where can health care providers go for detailed guidance on recognizing, managing, and reporting ZIKV infections?

NYSDOH: https://www.health.ny.gov/diseases/zika_virus/providers.htm
CDC: https://www.cdc.gov/zika/hc-providers/index.html

NYC Department of Health and Mental Hygiene (for New York City residents):
http://www1.nyc.gov/site/doh/providers/reporting-and-services.page

NYSDOH Zika Information Line (through February 28, 2018)**:** 888-364-4723
NYSDOH Bureau of Communicable Disease Control (after February 28, 2018)**:**
518-473-4439 or bcdc@health.ny.gov

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

Zika Virus: Recommendations for Diagnostic Testing, Specimen Collection, and Submission

New York State Department of Health Wadsworth Center Laboratories

This document provides information on specimen collection and submission for Zika virus specimens sent to the New York State Department of Health (NYSDOH) Wadsworth Center.

For testing on the day of delivery, please see "**Zika Virus: Recommendations for Day of Delivery Testing and Specimen Collection"** at https://www.health.ny.gov/diseases/zika_virus/providers.htm.

I. What specimens should be obtained for testing?

The following specimens are needed for routine diagnostic testing:

Patient	Blood (in serum separator tube*)	Whole Blood (in EDTA anti-coagulant tube**)	Urine
Adults	6 ml	0.4-1.0 mL	3-5 ml
Children	3-6 ml	0.4-1.0 mL	3-5 ml
Infants	1.5 – 2.0 ml	0.4-1.0 mL	1-5 ml

**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.*
***Plastic whole blood tubes with **Lavender** tops which contain EDTA anti-coagulant. Do NOT use green or yellow top blood tubes.*

Whole blood has been added as an acceptable specimen type because it had been shown to provide an extended window for PCR detection of Zika virus RNA for as long as 4 months from last known exposure. Serum is the priority specimen, and whole blood and urine should only be submitted if serum is also being submitted.

Cerebrospinal fluid (CSF), amniotic fluid, and other body tissues are not routinely used for diagnosis but may be tested under selected circumstances with pre-approval. To discuss submission, please call 518-474-4177 and ask for the Virology Laboratory.

II. How should specimens be prepared and handled?

Label all specimens. Failure to properly label a specimen will result in delayed testing and possible specimen rejection.
Specimens must be labeled with:

- Patient's first and last name
- Patient's date of birth
- Date and time of collection
- Specimen type (serum, whole blood, urine, CSF, etc.)

Seal Specimen Containers

- Close specimen containers tightly and seal with parafilm.

- Leaking specimens will not be tested.
- Hemolyzed serum specimens will not be tested.

Specimen handling for facilities with a -70^{0}C freezer	
Serum	○ Collect blood in serum separator tube(s)* ○ 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) and discard the clot that remains in the blood tube. ○ Store specimen in -70^{0}C freezer and ship on **dry ice**.
Whole Blood	○ Collect blood in PLASTIC lavender top tube** ○ Store specimen in -70^{0}C freezer and ship on **dry ice**.
Urine	○ Collect urine in a sterile leak-proof container. ○ Store specimen in -70^{0}C freezer and ship on **dry ice**.
Specimen handling for any facilities with a refrigerator, (especially those with no -70^{0}C freezer or dry ice)	
○ Process as indicated above. ○ Refrigerate centrifuged serum, whole blood 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. However, 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.	

**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. **PLASTC Lavender top tubes should be used for whole blood. Do NOT use green or yellow top blood tubes.*

CSF and Amniotic fluid	These specimen types are *not* routinely requested for Zika testing. If these specimens are obtained for other studies, Zika testing may be performed upon consultation with the NYSDOH (call 518-474-4177 and ask for the Virology Laboratory).
CSF	○ Collect in sterile container (tube or cryovial). ○ Store specimen in -70^{0}C freezer and ship on dry ice.
Amniotic fluid	○ Collect in sterile container (15 or 50 ml conical tube). ○ Store specimen in -70^{0}C freezer and ship on dry ice.

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

- Through February 28, 2018, contact NYSDOH via the NYSDOH Zika Information Line at 1-888-364-4723, Monday to Friday 9am to 5pm, for consultation, pre-approval, and to arrange shipment.
- As of March 1, 2018, preapproval for routine diagnostic testing will not be needed. To discuss submission of nonroutine specimen types such as CSF, please call 518-474-4177 and ask for the Virology Laboratory.
- Specimens may be collected and stored as outlined above until shipping can be arranged.
- 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, whole blood, and urine specimens may be stored and shipped:
  - 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.)
  - If specimens are refrigerated, shipping must occur within 48 hours of specimen collection. Prepare as above so that specimens 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.
- CSF and amniotic fluid specimens should be handled in the same manner as serum, whole blood, and urine specimens.
- Indicate the temperature shipment requirements on the outside of the package.
- 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. If the submitter has a NYSDOH Health Commerce System account with Clinical Laboratory Information Management System (CLIMS) access, results will be transmitted electronically. Otherwise, results will be mailed.

VI. Other Resources

- NYSDOH: https://www.health.ny.gov/diseases/zika_virus/providers.htm
- "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

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

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

New York State Department of Health Wadsworth Center Laboratories

I. Testing guidance

Testing guidance is based on the location of the birth facility, regardless of the patient's residence. The following guidance is for deliveries at a New York State (NYS) facility outside of New York City (NYC), and specimens should be sent to the NYS public health laboratory, Wadsworth Center, for testing. A NYS resident delivering at a NYC facility should be tested in accordance with NYC recommendations, which can be found at http://www1.nyc.gov/site/doh/providers/reporting-and-services.page.

Criteria for maternal testing on day of delivery	○ Women with symptoms of Zika virus infection who have not had Zika virus testing after their most recent potential exposure[1] ○ Women with potential exposure to Zika virus infection during pregnancy not known to have Zika virus infection who give birth to an infant with microcephaly, intracranial calcifications or other possible Zika-related brain/eye abnormalities
Criteria for infant testing	○ Infants born to mothers with laboratory evidence of Zika virus infection during pregnancy (PCR/NAAT positive *and/or* IgM positive plus PRNT positive) ○ 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)
Criteria for collecting formalin-fixed placenta and umbilical cord specimens	**Testing can be considered for** *1) symptomatic pregnant women or 2) mothers of infants with possible Zika virus-associated birth defects and potential exposure during pregnancy or periconception period* **if the woman is untested or has the following laboratory results**: ○ PCR/NAAT[2] negative, IgM positive, and PRNT positive for Zika and dengue (undifferentiated flavivirus) ○ PCR/NAAT negative, IgM positive, and a pending Zika PRNT result ○ PCR/NAAT negative, IgM negative, and Zika PRNT positive Testing is **NOT** recommended for any women with a laboratory confirmed diagnosis, which includes those who have been PCR/NAAT positive *or* IgM positive and PRNT positive for Zika and PRNT negative for dengue.
Specimens for infants meeting criteria ***(ideally collected within 2 days of birth)***	○ 1.5-2.0 ml blood in a serum tube ○ 0.4-1.0 mL whole blood in lavender top (EDTA-anti-coagulated) tube ○ Minimum 1 ml urine in a sterile container sealed with parafilm

[1] Exposure is defined here as travel to or residence in an area with a Zika travel notice (https://wwwnc.cdc.gov/travel/page/zika-travel-information) or unprotected vaginal, anal, or oral sexual exposure with a partner who traveled to or resided in an area with a Zika travel notice 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?

Label all specimens. Failure to properly label a specimen will result in testing delays and may result in specimen rejection.

Specimens must be labeled with:

- Patient's first and last name
- Patient's date of birth
- Date and time of collection
- Specimen type (whole blood, 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 for testing	Volume and container	Specimen handling for facilities with a -70°C freezer
Maternal specimens • **only for women who meet criteria for testing in Section I** • **whole blood and urine should be submitted only if also testing serum**	**serum: collect 6 ml 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**.
	whole blood: collect **1 ml blood** in a **PLASTIC** lavender top tube**	○ Store specimen in -70°C freezer and ship on **dry ice**.
	urine: collect **3-5 ml urine** in a sterile leak-proof container	○ Store specimen in -70°C freezer and ship on **dry ice**.
Infant specimens • **only for infants who meet criteria for testing in Section I** • **collect directly from the infant ideally within 2 days of birth**	**serum:** collect **1.5–2.0 ml 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**.
	whole blood: collect **0.4-1.0 ml blood** in a PLASTIC lavender top tube**	○ Store specimen in -70°C freezer and ship on **dry ice**.
	urine: collect **1 - 5 ml** 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**
• **Wadsworth Center submits specimens to the Centers for Disease Control and Prevention (CDC) for testing**
	Place the sections in a screw top sterile cup containing formalin. Tightly screw the lid to prevent leakage.	○ At least 2 full-thickness pieces (0.5-1 cm x 3-4 cm thick) from middle third of placental disk and at least 1 piece from placental disk margin; sample maternal and fetal sides of placenta, along with any pathologic lesion, if present. In addition, please include the following:
		  ○ fetal membranes: 5 x 12 cm strip from the area of rupture and including a small piece of the edge of the disk
		  ○ umbilical cord: at least 2 representative segments, each 2.5 cm in length; label as proximal, middle or distal to the 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 in 10% neutral buffered formalin for a minimum of 3 days. Formalin volume should be about 10x the mass of tissue. After fixation transfer to 70% ethanol for long term storage/shipping (if not paraffin-embedded).
		○ Store formalin-fixed tissues at room temperature. Ship at room temperature.
		○ Paraffin blocks may be submitted as well.

Infant CSF and amniotic fluid • **specimen are *not* routinely requested for Zika testing** • **if obtained for other studies, aliquot a sample for Zika testing**	**CSF:** collect in sterile container (tube or cryovial)	○ Store specimen in -70°C freezer and ship on **dry ice**.
	amniotic fluid: collect in sterile container (15 or 50 ml conical tube).	○ Store specimen in -70°C freezer and ship on **dry ice**.

*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.

**Whole blood must be collected in lavender top tubes that contain EDTA anti-coagulant.

Specimen handling for facilities with a refrigerator, but no -70°C freezer or dry ice
○ Process as indicated above. ○ Refrigerate whole blood, urine and centrifuged serum 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. However, 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.

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

- Through February 28, 2018, contact NYS Department of Health (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 shipment.
- As of March 1, 2018, preapproval for routine diagnostic testing will not be needed. To discuss submission of nonroutine specimen types such as CSF, please call 518-474-4177 and ask for the Virology Laboratory.
- Specimens may be collected and stored as outlined above until shipping can be arranged.
- 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, whole blood 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.
- CSF and amniotic fluid specimens should be handled in the same manner as serum, whole blood and urine specimens.
- Indicate the temperature shipment requirements on the outside of the package.
- 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 Wadsworth Center will ship fixed specimens to the CDC for testing.
- Specimens must be shipped overnight with cold packs or dry ice (except formalin fixed tissues, which are shipped at room temperature) 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. If the submitter has a NYS Health Commerce System account with Clinical Laboratory Information Management System (CLIMS) access, results will be transmitted electronically. Otherwise, results will be mailed.

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.

VI. Other Resources

- NYSDOH: https://www.health.ny.gov/diseases/zika_virus/providers.htm
- NYC DOHMH: http://www1.nyc.gov/site/doh/providers/reporting-and-services-main.page
- CDC Clinical Guidance: https://www.cdc.gov/zika/hc-providers/index.html
- MMWR, "Update: Interim Guidance for the Diagnosis, Evaluation and Management of Infants with Possible Congenital Zika Virus Infection — United States, October 2017" 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