New Jersey Department of Health (NJDOH) monitors Zika-related guidance issued by the Centers for Disease Control and Prevention (CDC) and is responsible for determining how CDC recommendations can best be implemented in New Jersey. Zika testing is now widely available at most commercial laboratories. If extenuating circumstances exist, the criteria for Zika testing at the NJDOH Public Health and Environmental Laboratory (PHEL) and testing recommendations for pregnant women can be found on the NJDOH Zika web page in the Laboratory Testing and Information section: https://nj.gov/health/cd/topics/zika.shtml

Criteria for Obtaining Zika Virus Testing at NJ PHEL - Updated 4/10/2019
CDC Zika Testing and Management Recommendations for Pregnant Women - Updated 4/10/2019

All pregnant women presenting for delivery should be screened for a history of Zika virus exposure (travel and sexual) during the current pregnancy and 8 weeks before conception.

If screening reveals that the mother had a history of Zika virus exposure, the documents in this packet are intended to streamline the process for evaluating and testing infants with possible congenital Zika virus infection. Use the NJDOH Zika Delivery Checklist for Birthing Hospitals to guide step-by-step actions.

1. NJDOH Zika Delivery Checklist for Birthing Hospitals
2. CDC Screening Tool: Screening Pregnant Women for Zika Testing
3. CDC Algorithm: Evaluation for Infants with Possible Congenital Zika Virus Infection
4. CDC Algorithm: Implementing CDC Guidance for Clinical Management and Evaluation of Infants Born to Mothers with Possible Zika Virus Exposure During Pregnancy: and Testing of Placental, Fetal, or Infant Autopsy Tissues
5. Zika Delivery Testing Forms (Maternal and Infant)
6. NJDOH Zika Delivery Specimen Collection Guidance table
7. CDC Zika Neonate Assessment Form
8. CDC Zika Clinical Summary for (Outpatient) Pediatric Healthcare Provider

The Zika Delivery Packet can be found on the NJDOH Zika web page in the Resources and References sidebar under Pregnant Women and Infants: https://nj.gov/health/cd/topics/zika.shtml

The latest comprehensive CDC Zika recommendations for infants can be found at: https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6641a1.pdf

The NJDOH Zika Team can be reached at: CDS.ZikaTeam@doh.nj.gov or 609-826-5964.
NJDOH Zika Delivery Checklist for Birthing Hospitals

Updated April 10, 2019

☐ Screen all pregnant women presenting for delivery for any possible Zika virus exposure that occurred during the current pregnancy (including 8 weeks prior). Refer to CDC’s “Screening Pregnant Women for Zika Testing” contained in this packet.

If the woman had Zika exposure, continue with the steps listed below.

☐ Test symptomatic pregnant women who were possibly exposed to Zika (who lived in or traveled to or had unprotected sex with a partner who lived in or traveled to an area with risk of Zika). Last exposure must have been within the prior 12 weeks.

☐ Review the CDC Algorithm: “Evaluation for Infants with Possible Congenital Zika Virus Infection” and perform the relevant infant evaluations and specimen collection.

☐ Save placental/cord tissue for Zika testing if:

1. Normal infants:
   a. The mother was symptomatic & tested positive for Zika through serologic methods or;
   b. Maternal Zika results are pending at time of delivery
2. Infants with Congenital Zika Syndrome:
   a. The mother tested positive for Zika through serologic methods or;
   b. The mother was not tested, or tested negative >12 weeks after Zika exposure

☐ To guide specimen collection, processing and shipping, consult the “NJDOH Zika Delivery Specimen Collection Guidance” table.

☐ For approval of testing, complete and return the following forms to the NJDOH Zika Team by sending an encrypted e-mail to CDS.ZikaTeam@doh.nj.gov or faxing to 609-826-4874 [Phone: 609-826-5964]

1. NJDOH Zika Virus Patient Information Worksheet (Maternal)
2. NJDOH Zika Delivery Testing Form (Infant).”

NJDOH Zika Team will provide your laboratory with required authorization forms to ship specimens.

☐ For infants either (1) with clinical findings consistent with Congenital Zika Syndrome or; (2) who are born to a mother with laboratory evidence of possible Zika virus infection during pregnancy, complete:

1. The “CDC Zika Neonate Assessment Form” and return to NJDOH as directed at the top of the form, and;
2. The “CDC Zika Clinical Summary for Pediatric Healthcare Provider” and forward to the infant’s outpatient pediatrician.
SCREENING PREGNANT WOMEN FOR ZIKA TESTING

To Be Administered by a Nurse or Other Healthcare Provider

Pregnant women should be asked about any possible Zika virus exposure, before and during their pregnancy, at each prenatal visit. Use this tool to evaluate pregnant women for exposure to Zika virus and symptoms of Zika virus disease to determine whether testing is indicated. Visit CDC’s map to determine areas with risk of Zika.

Questions to ask your patient to determine if she needs Zika testing:

✓ Have you traveled during pregnancy?
  - Where did you travel?
  - How long did you stay?
✓ Have you lived in any area where mosquitoes are spreading Zika during your pregnancy?
✓ Has your partner lived in or traveled to any area where mosquitoes are spreading Zika during your pregnancy?
  - When and where did your partner travel?
  - Did your partner have any signs or symptoms of Zika (including fever, rash, headache, joint pain, red eyes, or muscle pain) when he or she were on the trip, or after returning?
  - Did you have sex without a condom with your partner after they returned from the trip?
✓ Have you had any symptoms of Zika during your pregnancy?
  - Use the chart on page 2 of this document to discuss Zika symptoms. The most common symptoms of Zika are fever, rash, headache, joint pain, red eyes, and muscle pain.

Use the responses to the questions above to determine if Zika testing is indicated.

Testing is recommended for

- Symptomatic pregnant women possibly exposed to Zika (who lived in or traveled to or had unprotected sex with a partner who lived in or traveled to an area with risk of Zika), and
- Asymptomatic pregnant women who have ongoing exposure (who live in or frequently travel) to areas with risk of Zika.

Testing is not routinely recommended for asymptomatic pregnant women with recent possible Zika exposure but without ongoing possible exposure. However, testing may be considered as a shared decision between patients and providers, according to patient preferences and clinical judgement, or if a state or local area recommends it.
Zika Symptoms

The most common symptoms for Zika are fever, rash, headache, joint pain, red eyes, and muscle pain.
EVALUATION FOR INFANTS WITH POSSIBLE CONGENITAL ZIKA VIRUS INFECTION

Ask about possible maternal Zika virus exposure*

Possible Zika virus exposure

If no maternal Zika virus exposure is identified, routine pediatric care is recommended.

Does infant have findings consistent with congenital Zika syndrome (CZS)?

YES

Does initial evaluation normal?

NO

Is there laboratory evidence of maternal Zika virus infection during pregnancy?

Laboratory evidence of possible maternal Zika virus infection during pregnancy†

INITIAL EVALUATION

• Standard evaluation (Refer to Box 1).
• Zika virus NAT (serum and urine) and IgM (serum) testing within a few days after birth, if possible.**
• Consider Zika virus NAT and IgM testing on cerebrospinal fluid (CSF).
• Head ultrasound by 1 month of age.
• Comprehensive ophthalmologic exam by 1 month of age.
• Automated auditory brainstem response (ABR) by 1 month of age.**
• Evaluate for other causes of congenital anomalies.

Refer to developmental specialist and early intervention. Provide family support services. Consider additional consultations with specialists based on clinical findings of infant (Refer to Box 2).

NO

Testing and clinical evaluation for congenital Zika virus beyond a standard evaluation is not routinely recommended.

If findings suggestive of CZS are identified at any time, refer to appropriate specialists and evaluate for congenital Zika virus infection.

Laboratory evidence of congenital Zika virus infection (Refer to Table 1)

INITIAL EVALUATION

• Standard evaluation (Refer to Box 1).
• Zika virus NAT (serum and urine) and IgM (serum) testing within a few days after birth, if possible.**
• Head ultrasound by 1 month of age.
• Comprehensive ophthalmologic exam by 1 month of age.
• Automated ABR by 1 month of age.**

Is there laboratory evidence of congenital Zika virus infection? (Refer to Table 1)

Laboratory evidence of congenital Zika virus infection

No laboratory evidence of congenital Zika virus infection

• Congenital Zika virus infection is unlikely.
• Infant should continue to receive routine care, and health care providers should remain alert for any new findings of possible congenital Zika virus infection.

* Possible Zika virus exposure includes travel to, or residence in an area with mosquito-borne Zika virus transmission or sex without the use of condoms with a partner who has traveled to or resides in an area with mosquito-borne Zika virus transmission.
† Laboratory evidence of possible Zika virus infection during pregnancy is defined as 1) Zika virus infection detected by a Zika virus RNA NAT on any maternal, placental, or fetal specimen (referred to as NAT-confirmed), or 2) diagnosis of Zika virus infection, timing of infection cannot be determined or unspecified flavivirus infection, timing of infection cannot be determined by serologic tests on a maternal specimen (i.e., positive/equivocal Zika virus IgM and Zika virus PRNT titer ≥10, regardless of dengue virus PRNT value; or negative Zika virus IgM, and positive or equivocal dengue virus IgM, and Zika virus PRNT titer ≥10, regardless of dengue virus PRNT titer). The use of PRNT for confirmation of Zika virus infection, including in pregnant women, is not routinely recommended in Puerto Rico (https://www.cdc.gov/zika/laboratories/lab-guidance.html).
§ This group includes women who were never tested during pregnancy as well as those whose test result was negative because of issues related to timing or sensitivity and specificity of the test. Because the latter issues are not easily discerned, all mothers with possible exposure to Zika virus during pregnancy who do not have laboratory evidence of possible Zika virus infection, including those who tested negative with currently available technology, should be considered in this group.
** Automated ABR by 1 month of age if newborn hearing screen passed but performed with otoacoustic emission (OAE) methodology

If CSF is obtained for other purposes, Zika virus NAT and IgM antibody testing should be performed on CSF.
TABLE 1

Interpretation of results of laboratory testing of infant's blood, urine, and/or cerebrospinal fluid for evidence of congenital Zika virus infection

<table>
<thead>
<tr>
<th>Infant test results*</th>
<th>IgM</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Any result</td>
<td>Confirmed congenital Zika virus infection†</td>
</tr>
<tr>
<td>Negative</td>
<td>Nonnegative§</td>
<td>Probable congenital Zika virus infection¶,**</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>Congenital virus infection unlikely††</td>
</tr>
</tbody>
</table>

Abbreviations: NAT = nucleic acid test; IgM = immunoglobulin M
*Infant serum, urine, or cerebrospinal fluid.
†Distinguishing between congenital and postnatal infection is difficult in infants who live in areas where there is ongoing transmission of Zika virus and who are not tested soon after birth. If the timing of infection cannot be determined, infants should be evaluated as if they had congenital Zika virus infection.
§Nonnegative serology terminology varies by assay and might include “positive,” “equivocal,” “presumptive positive,” or “possible positive.” For explanation of a specific interpretation, refer to the instructions for use for the specific assay performed.
¶Laboratory results should be interpreted in the context of timing of infection during pregnancy, maternal serology results, clinical findings consistent with congenital Zika syndrome, and any confirmatory testing with plaque reduction neutralization testing.
**A negative Zika virus plaque reduction neutralization test suggests that the infant's Zika virus IgM test is a false positive.
††Congenital Zika virus infection is unlikely if specimens are collected within the first few days after birth and the clinical evaluation is normal; however, health care providers should remain alert for any new findings of congenital Zika virus infection.

BOX 1. Standard evaluation recommended at birth and during each well visit for all infants with possible congenital Zika virus exposure during pregnancy

- Comprehensive physical exam, including growth parameters
- Developmental monitoring and screening using validated screening tools recommended by the American Academy of Pediatrics [link]
- Vision screening as recommended by the American! Academy of Pediatrics Policy Statement “Visual System Assessment in Infants, Children, and Young Adults by Pediatricians” [link]
- Newborn hearing screen at birth, preferably with automated auditory brainstem response

BOX 2. Consultations for infants with clinical findings consistent with congenital Zika syndrome

- Consider consultation with the following specialists:
  - Infectious disease specialist for evaluation for other congenital infections (e.g., toxoplasmosis, syphilis, rubella, cytomegalovirus, or herpes simplex virus) and assistance with Zika virus diagnosis, testing, and counseling
  - Neurologist by age 1 month for comprehensive neurologic examination and consideration for other evaluations such as advanced neuroimaging and EEG
  - Ophthalmologist for comprehensive eye exam by age 1 month
  - Clinical geneticist for confirmation of the clinical phenotype and evaluation for other causes of microcephaly or congenital anomalies
  - Early intervention and developmental specialists
  - Family and supportive services
- Additional possible consultations, based on clinical findings of the infant:
  - Endocrinologist for evaluation of hypothalamic or pituitary dysfunction and consideration for thyroid testing
  - Lactation specialist, nutritionist, gastroenterologist or speech or occupational therapist for evaluation for dysphagia and management of feeding issues
  - Orthopedist, physiatrist, or physical therapist for the management of hypertonia, clubfoot or arthrogrypotic-like conditions
  - Pulmonologist or otolaryngologist for concerns about aspiration
IMPLEMENTING CDC GUIDANCE FOR CLINICAL MANAGEMENT AND EVALUATION OF INFANTS BORN TO MOTHERS WITH POSSIBLE ZIKA VIRUS EXPOSURE DURING PREGNANCY; AND TESTING OF PLACENTAL, FETAL, OR INFANT AUTOPSY TISSUES (1, 2)

Notes: This tool summarizes general CDC guidance for the following scenarios. Please consult CDC or your state or local health department for case-specific questions. Health departments should adapt CDC guidance depending on local capacity and circumstances.

INFANT OR FETUS WITH CLINICAL FINDINGS CONSISTENT WITH CZS (3)

<table>
<thead>
<tr>
<th>Maternal Zika virus laboratory results and interpretations (4)</th>
<th>WITH maternal laboratory evidence of possible Zika virus infection during pregnancy (4)</th>
<th>No maternal laboratory evidence of possible Zika virus infection during pregnancy (4, 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Zika virus infection</td>
<td>Zika or flavivirus infection, timing cannot be determined</td>
<td>&gt;12 weeks after exposure/symptoms (7) and either maternal testing negative, or mother not tested (8)</td>
</tr>
<tr>
<td>Maternal testing ≤12 weeks after exposure/ symptoms (7) negative (9)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

LIVE BIRTHS

Clinical evaluation and management

At birth, standard evaluation. (10) Infant Zika virus laboratory testing: NAT on serum and urine, consider CSF, IgM on serum, consider CSF. (11, 12) By one month: head ultrasound, comprehensive ophthalmologic exam, automated ABR. Refer to developmental specialist, early intervention, and family support services; consider other consultations (e.g., genetics, ID, neurology). (13)

Testing of placental tissues

Not indicated. (14) Should be considered to aid in maternal diagnosis. (15) Not indicated.

Testing of fetal and placental tissues

May be considered to aid in fetal diagnosis. May be considered to aid in fetal and maternal diagnosis. Not indicated.

Testing of infant autopsy and placental tissues

Should be considered to aid in infant diagnosis. Not indicated.

PREGNANCY LOSS OR INFANT DEATH FOLLOWING LIVE BIRTH

For infants with clinical findings consistent with CZS with maternal testing pending; consider collecting, fixing, and storing placental tissues until results are available. Do not wait for maternal test results, but instead proceed with infant clinical management and testing.

For infants without findings consistent with CZS with maternal testing pending and placental specimen was collected within 12 weeks of all exposure, consider collecting, fixing, and storing placental tissues, and collecting and storing infant serum and urine. Once available, maternal test results should be considered in accordance with this framework.

Symptoms of Zika virus disease include acute onset of fever, maculopapular rash, arthralgia, or conjunctivitis.

All or part of possible maternal Zika virus exposure, or symptom onset, occurred >12 weeks before maternal serum specimen was collected.

Includes pregnant women with negative Zika virus NAT and negative Zika virus IgM ≤12 weeks after symptom onset or exposure.

Standard evaluation at birth includes a comprehensive physical exam, including growth parameters; newborn hearing screen at birth; preferably with automated ABR; developmental monitoring and screening using validated screening tools recommended by the American Academy of Pediatrics. (https://www.aap.org/en-us/academic-and-policy/health-health/well-baby/developmental-screening/Pages/Developmental-Screening-Tools-in-Infants-and-Toddlers.aspx) and other validated tools recommended by the American Academy of Pediatrics Policy Statement: Visual System Assessment in Infants, Children, and Young Adults by Pediatricians (http://pediatrics.aappublications.org/content/137/1/e20153596)

CDC interim infant testing guidance recommends that Zika virus testing should be performed on CSF if it is/was collected for other reasons. Since there are reports of congenital Zika virus infection in infants born to mothers with the only sample tested positive, healthcare providers should consider obtaining CSF for Zika virus RNA and IgM antibody testing in infants with clinical findings of possible congenital Zika syndrome but whose initial laboratory tests are negative on serum and urine.

Because levels of Zika virus RNA and IgM antibodies decline over time, laboratory testing of infants should be performed as early as possible, preferably within the first five days after birth, although testing within the first few weeks to months after birth might still be useful.

Consultations with specialists may include ID specialist for evaluation for other congenital infections (e.g., toxoplasmosis, syphilis, rubella, cytomegalovirus, or herpes simplex virus) and assistance with Zika virus diagnosis, testing, and counseling; neurologist by age 1 month for comprehensive neurologic examination and consideration for other evaluations such as advanced neuroimaging and EEG; ophthalmologist for comprehensive eye exam by age 1 month; clinical geneticist for confirmation of the clinical phenotype and evaluation for other causes of microcephaly or congenital anomalies; early intervention and developmental specialists; family and supportive services. Additional possible consultations, based on clinical findings of the infant include endocrinologist for evaluation of hypothalamic or pituitary dysfunction and consideration for thyroid testing, lactation specialist, nutritionist, gastroenterologist, or speech or occupational therapist for evaluation for dysphagia and management of feeding issues; orthopedist, physiatrist, or physical therapist for the management of hypotonia, clubfoot or arthrogryposis-like conditions; pulmonologist or otolaryngologist for concerns about aspiration.

Placental testing does not routinely provide additional diagnostic information in the setting of a maternal or infant diagnosis of acute or confirmed congenital Zika virus infection, respectively.

Placental testing is not indicated for the subset of women with maternal laboratory test interpretation “Zika virus infection, timing cannot be determined” whose only possible exposure to Zika occurred during this pregnancy, as the positive Zika virus NAT and PRNT results likely represent acute Zika virus infection during pregnancy when compared with women whose positive serologic results may reflect an infection prior to pregnancy.

Contact CDC’s Infectious Diseases Pathology Branch at pathology@cdc.gov for case-specific questions.

(1) Zika virus testing on formalin-fixed, paraffin embedded tissue specimens is conducted at CDC’s Infectious Diseases Pathology Branch (IDPB) and includes Zika virus RT-PCR on placental and fetal/infant tissues. Zika virus IHC may be performed on placental specimens into the second trimester, fetal tissues from any gestational age, and infant autopsy tissues.

(2) Placental tissues include placental disc, umbilical cord, and fetal membranes. Zika virus RNA can be focal within placental tissues, and testing of three sections of placenta, one section of umbilical cord, and one section of fetal membrane is recommended. (https://www.cdc.gov/zika/laboratories/test-specimens-tissues.html). For pregnancy losses and infant deaths, submission of fetal or infant autopsy tissues, if available, in addition to submission of placental tissues, is preferred, but if not available will not preclude placental testing.

(3) Clinical findings consistent with CZS include severe microcephaly, decreased brain tissue with hypomyelination, mesial temporal lobe volume reduction, subcortical calcifications, cerebral atrophy, and gliosis, or more severe changes. Congenital Zika syndrome is more severe than CZS.


(5) Maternal or infant diagnosis of acute or confirmed congenital Zika virus infection, respectively.

(6) CDC interim infant testing guidance recommends that Zika virus testing should be performed on CSF if it is/was collected for other reasons. Since there are reports of congenital Zika virus infection in infants born to mothers with the only sample tested positive, healthcare providers should consider obtaining CSF for Zika virus RNA and IgM antibody testing in infants with clinical findings of possible congenital Zika syndrome but whose initial laboratory tests are negative on serum and urine.

(7) Zika virus IgM remains positive for up to 6 months after infection; testing specimens within the first few weeks to months after birth might still be useful.

(8) Does not include insufficient information for interpretation; no laboratory evidence of Zika virus infection.

(9) Does not include insufficient information for interpretation; no laboratory evidence of Zika virus infection.

(10) Includes pr egnant women with negative Zika virus NAT and negative Zika virus IgM ≤12 weeks after symptom onset or exposure.

(11) CDC interim infant testing guidance recommends that Zika virus testing should be performed on CSF if it is/was collected for other reasons. Since there are reports of congenital Zika virus infection in infants born to mothers with the only sample tested positive, healthcare providers should consider obtaining CSF for Zika virus RNA and IgM antibody testing in infants with clinical findings of possible congenital Zika syndrome but whose initial laboratory tests are negative on serum and urine.

(12) Because levels of Zika virus RNA and IgM antibodies decline over time, laboratory testing of infants should be performed as early as possible, preferably within the first five days after birth, although testing within the first few weeks to months after birth might still be useful.

(13) Consultations with specialists may include ID specialist for evaluation for other congenital infections (e.g., toxoplasmosis, syphilis, rubella, cytomegalovirus, or herpes simplex virus) and assistance with Zika virus diagnosis, testing, and counseling; neurologist by age 1 month for comprehensive neurologic examination and consideration for other evaluations such as advanced neuroimaging and EEG; ophthalmologist for comprehensive eye exam by age 1 month; clinical geneticist for confirmation of the clinical phenotype and evaluation for other causes of microcephaly or congenital anomalies; early intervention and developmental specialists; family and supportive services. Additional possible consultations, based on clinical findings of the infant include endocrinologist for evaluation of hypothalamic or pituitary dysfunction and consideration for thyroid testing, lactation specialist, nutritionist, gastroenterologist, or speech or occupational therapist for evaluation for dysphagia and management of feeding issues; orthopedist, physiatrist, or physical therapist for the management of hypotonia, clubfoot or arthrogryposis-like conditions; pulmonologist or otolaryngologist for concerns about aspiration.

(14) Placental testing does not routinely provide additional diagnostic information in the setting of a maternal or infant diagnosis of acute or confirmed congenital Zika virus infection, respectively.

(15) Placental testing is not indicated for the subset of women with maternal laboratory test interpretation “Zika virus infection, timing cannot be determined” whose only possible exposure to Zika occurred during this pregnancy, as the positive Zika virus NAT and PRNT results likely represent acute Zika virus infection during pregnancy when compared with women whose positive serologic results may reflect an infection prior to pregnancy.

(16) Contact CDC’s Infectious Diseases Pathology Branch at pathology@cdc.gov for case-specific questions.

(17) Persons with ongoing possible Zika virus exposure include those who reside or in frequently travel (e.g., daily or weekly) to an area with risk of Zika virus transmission.
IMPLEMENTING CDC GUIDANCE FOR CLINICAL MANAGEMENT AND EVALUATION OF INFANTS BORN TO MOTHERS WITH POSSIBLE ZIKA VIRUS EXPOSURE DURING PREGNANCY; AND TESTING OF PLACENTAL, FETAL, OR INFANT AUTOGENOUS TISSUES (1, 2)

CDC’s Response to Zika

PREGNANCY; AND TESTING OF PLACENTAL, FETAL, OR INFANT AUTOGENOUS TISSUES (1, 2)

CDC’s Response to Zika

Notes: This tool summarizes general CDC guidance for the following scenarios. Please consult CDC or your state or local health department for case-specific questions. Health departments should adapt CDC guidance depending on local capacity and circumstances.

INFANT OR FETUS WITHOUT CLINICAL FINDINGS CONSISTENT WITH CZS (3)

Maternal Zika virus laboratory results and interpretations (4)

WITH maternal laboratory evidence of possible Zika virus infection during pregnancy (4)

Acute Zika virus infection

Zika or flavivirus infection, timing cannot be determined

LIVE BIRTH

Clinical evaluation and management

At birth: standard evaluation, (10) Infant Zika virus laboratory testing; NAT on serum and urine; IgM on serum. (12) By one month; head ultrasound, comprehensive ophthalmologic exam, automated ABR. If laboratory evidence of congenital Zika virus infection in infant, follow recommendations for infants with clinical findings consistent with CZS even in the absence of clinically apparent abnormalities.

Testing of placental tissues

Not indicated. (14)

May be considered on a case-by-case basis (16) to aid in maternal diagnosis for women who either had symptoms of Zika virus disease during pregnancy, or had ongoing possible Zika virus exposure (17) for the full duration of pregnancy. (15)

PREGNANCY LOSS OR INFANT DEATH FOLLOWING LIVE BIRTH

Testing of fetal and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.

Testing of infant autopsy and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.

INFANT OR FETUS WITH CLINICAL FINDINGS CONSISTENT WITH CZS (3)

Maternal laboratory evidence of possible Zika virus infection during pregnancy (4)

Acute Zika virus infection

Zika or flavivirus infection, timing cannot be determined

LIVE BIRTH

Clinical evaluation and management

At birth: standard evaluation, (10) Infant Zika virus laboratory testing; NAT on serum and urine; IgM on serum. (12) By one month; head ultrasound, comprehensive ophthalmologic exam, automated ABR. If laboratory evidence of congenital Zika virus infection in infant, follow recommendations for infants with clinical findings consistent with CZS even in the absence of clinically apparent abnormalities.

Testing of placental tissues

Maternal testing at any time negative, or mother not tested

INFANT OR FETUS WITHOUT CLINICAL FINDINGS CONSISTENT WITH CZS (3)

Maternal Zika virus laboratory results and interpretations (4)

WITH maternal laboratory evidence of possible Zika virus infection during pregnancy (4)

Acute Zika virus infection

Zika or flavivirus infection, timing cannot be determined

LIVE BIRTH

Clinical evaluation and management

At birth: standard evaluation, (10) Infant Zika virus laboratory testing; NAT on serum and urine; IgM on serum. (12) By one month; head ultrasound, comprehensive ophthalmologic exam, automated ABR. If laboratory evidence of congenital Zika virus infection in infant, follow recommendations for infants with clinical findings consistent with CZS even in the absence of clinically apparent abnormalities.

Testing of placental tissues

Not indicated. (14)

May be considered on a case-by-case basis (16) to aid in maternal diagnosis for women who either had symptoms of Zika virus disease during pregnancy, or had ongoing possible Zika virus exposure (17) for the full duration of pregnancy. (15)

PREGNANCY LOSS OR INFANT DEATH FOLLOWING LIVE BIRTH

Testing of fetal and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.

Testing of infant autopsy and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.

INFANT OR FETUS WITH CLINICAL FINDINGS CONSISTENT WITH CZS (3)

Maternal Zika virus laboratory results and interpretations (4)

WITH maternal laboratory evidence of possible Zika virus infection during pregnancy (4)

Acute Zika virus infection

Zika or flavivirus infection, timing cannot be determined

LIVE BIRTH

Clinical evaluation and management

At birth: standard evaluation, (10) Infant Zika virus laboratory testing; NAT on serum and urine; IgM on serum. (12) By one month; head ultrasound, comprehensive ophthalmologic exam, automated ABR. If laboratory evidence of congenital Zika virus infection in infant, follow recommendations for infants with clinical findings consistent with CZS even in the absence of clinically apparent abnormalities.

Testing of placental tissues

Not indicated. (14)

May be considered on a case-by-case basis (16) to aid in maternal diagnosis for women who either had symptoms of Zika virus disease during pregnancy, or had ongoing possible Zika virus exposure (17) for the full duration of pregnancy. (15)

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INFANT OR FETUS WITH CLINICAL FINDINGS CONSISTENT WITH CZS (3)

Maternal Zika virus laboratory results and interpretations (4)

WITH maternal laboratory evidence of possible Zika virus infection during pregnancy (4)

Acute Zika virus infection

Zika or flavivirus infection, timing cannot be determined

LIVE BIRTH

Clinical evaluation and management

At birth: standard evaluation, (10) Infant Zika virus laboratory testing; NAT on serum and urine; IgM on serum. (12) By one month; head ultrasound, comprehensive ophthalmologic exam, automated ABR. If laboratory evidence of congenital Zika virus infection in infant, follow recommendations for infants with clinical findings consistent with CZS even in the absence of clinically apparent abnormalities.

Testing of placental tissues

Not indicated. (14)

May be considered on a case-by-case basis (16) to aid in maternal diagnosis for women who either had symptoms of Zika virus disease during pregnancy, or had ongoing possible Zika virus exposure (17) for the full duration of pregnancy. (15)

PREGNANCY LOSS OR INFANT DEATH FOLLOWING LIVE BIRTH

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Testing of infant autopsy and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.

INFANT OR FETUS WITH CLINICAL FINDINGS CONSISTENT WITH CZS (3)

Maternal Zika virus laboratory results and interpretations (4)

WITH maternal laboratory evidence of possible Zika virus infection during pregnancy (4)

Acute Zika virus infection

Zika or flavivirus infection, timing cannot be determined

LIVE BIRTH

Clinical evaluation and management

At birth: standard evaluation, (10) Infant Zika virus laboratory testing; NAT on serum and urine; IgM on serum. (12) By one month; head ultrasound, comprehensive ophthalmologic exam, automated ABR. If laboratory evidence of congenital Zika virus infection in infant, follow recommendations for infants with clinical findings consistent with CZS even in the absence of clinically apparent abnormalities.

Testing of placental tissues

Not indicated. (14)

May be considered on a case-by-case basis (16) to aid in maternal diagnosis for women who either had symptoms of Zika virus disease during pregnancy, or had ongoing possible Zika virus exposure (17) for the full duration of pregnancy. (15)

PREGNANCY LOSS OR INFANT DEATH FOLLOWING LIVE BIRTH

Testing of fetal and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.

Testing of infant autopsy and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.

INFANT OR FETUS WITH CLINICAL FINDINGS CONSISTENT WITH CZS (3)

Maternal Zika virus laboratory results and interpretations (4)

WITH maternal laboratory evidence of possible Zika virus infection during pregnancy (4)

Acute Zika virus infection

Zika or flavivirus infection, timing cannot be determined

LIVE BIRTH

Clinical evaluation and management

At birth: standard evaluation, (10) Infant Zika virus laboratory testing; NAT on serum and urine; IgM on serum. (12) By one month; head ultrasound, comprehensive ophthalmologic exam, automated ABR. If laboratory evidence of congenital Zika virus infection in infant, follow recommendations for infants with clinical findings consistent with CZS even in the absence of clinically apparent abnormalities.

Testing of placental tissues

Not indicated. (14)

May be considered on a case-by-case basis (16) to aid in maternal diagnosis for women who either had symptoms of Zika virus disease during pregnancy, or had ongoing possible Zika virus exposure (17) for the full duration of pregnancy. (15)

PREGNANCY LOSS OR INFANT DEATH FOLLOWING LIVE BIRTH

Testing of fetal and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.

Testing of infant autopsy and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.

INFANT OR FETUS WITH CLINICAL FINDINGS CONSISTENT WITH CZS (3)

Maternal Zika virus laboratory results and interpretations (4)

WITH maternal laboratory evidence of possible Zika virus infection during pregnancy (4)

Acute Zika virus infection

Zika or flavivirus infection, timing cannot be determined

LIVE BIRTH

Clinical evaluation and management

At birth: standard evaluation, (10) Infant Zika virus laboratory testing; NAT on serum and urine; IgM on serum. (12) By one month; head ultrasound, comprehensive ophthalmologic exam, automated ABR. If laboratory evidence of congenital Zika virus infection in infant, follow recommendations for infants with clinical findings consistent with CZS even in the absence of clinically apparent abnormalities.

Testing of placental tissues

Not indicated. (14)

May be considered on a case-by-case basis (16) to aid in maternal diagnosis for women who either had symptoms of Zika virus disease during pregnancy, or had ongoing possible Zika virus exposure (17) for the full duration of pregnancy. (15)

PREGNANCY LOSS OR INFANT DEATH FOLLOWING LIVE BIRTH

Testing of fetal and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.

Testing of infant autopsy and placental tissues

May be considered on a case-by-case basis (16) to aid in maternal and/or fetal/infant diagnosis for pregnancies where there were maternal symptoms of Zika virus disease during pregnancy, or where there was ongoing possible maternal Zika virus exposure.
To request Zika Virus testing at the NJ Public Health and Environmental Laboratory (PHEL) for pregnant women who present for delivery and meet current Zika testing criteria, complete this form and send to the NJDOH Zika Team by encrypted e-mail to: CDS.ZikaTeam@doh.nj.gov or fax to 609-826-4874.


---

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name (Last name, First name)</td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td>/ /</td>
</tr>
<tr>
<td>Patient Sex</td>
<td>□ Male □ Female</td>
</tr>
<tr>
<td>Patient Address</td>
<td>City</td>
</tr>
<tr>
<td>CDRSS #</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>White</td>
</tr>
<tr>
<td>Maternal Zika Exposure History (select all that apply)</td>
<td></td>
</tr>
<tr>
<td>Date of delivery</td>
<td>/ /</td>
</tr>
<tr>
<td>Are there infant abnormalities suggestive of Zika at delivery?</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>Maternal Symptom</td>
<td>□ Currently symptomatic □ Recovered / Formerly symptomatic □ Asymptomatic*</td>
</tr>
<tr>
<td>*Asymptomatic persons do not meet NJDOH testing criteria unless fetal/infant abnormalities are detected, there is ongoing travel exposure, in cases of fetal loss/infant death, or other extenuating circumstance</td>
<td></td>
</tr>
<tr>
<td>Travel to area with Zika</td>
<td></td>
</tr>
<tr>
<td>Ongoing travel (at least weekly) to area with Zika</td>
<td></td>
</tr>
<tr>
<td>Unprotected sexual contact with Zika exposed partner</td>
<td></td>
</tr>
<tr>
<td>Travel location(s):</td>
<td></td>
</tr>
<tr>
<td>Travel dates:</td>
<td>/ /</td>
</tr>
<tr>
<td>Date(s) of first and last unprotected sexual contact with Zika exposed partner:</td>
<td></td>
</tr>
<tr>
<td>Sexual partner’s travel location(s), if applicable:</td>
<td></td>
</tr>
<tr>
<td>Sexual partner’s travel dates:</td>
<td>/ /</td>
</tr>
<tr>
<td>□ Congenital/Perinatal □ Laboratory/Healthcare □ Other Exposure (specify)</td>
<td></td>
</tr>
<tr>
<td>□ Blood Transfusion □ Organ Recipient</td>
<td></td>
</tr>
<tr>
<td>Exposure dates:</td>
<td>/ /</td>
</tr>
<tr>
<td>List all signs and symptoms with onset/resolution dates:</td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td></td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td></td>
</tr>
<tr>
<td>Arthralgia (joint pain)</td>
<td></td>
</tr>
<tr>
<td>Neurological symptoms (specify)</td>
<td></td>
</tr>
<tr>
<td>Other Symptoms (e.g., Headache, Myalgia, Eye pain, etc.):</td>
<td></td>
</tr>
<tr>
<td>Immunization history and year of immunization if known:</td>
<td></td>
</tr>
<tr>
<td>□ Yellow Fever Vaccine □ Japanese Encephalitis Vaccine □ Tickborne Encephalitis Vaccine</td>
<td></td>
</tr>
<tr>
<td>Previous history (year) of flavivirus/arboviral disease</td>
<td></td>
</tr>
<tr>
<td>□ West Nile Virus □ Chikungunya Virus □ Previous Zika diagnosis (mm/yyyy)</td>
<td></td>
</tr>
<tr>
<td>□ Dengue Virus □ Powassan Virus □ Other flavivirus/arboviral disease</td>
<td></td>
</tr>
<tr>
<td>Submitter Information (Physician who is ordering Zika test)</td>
<td></td>
</tr>
<tr>
<td>Name of Health Care Provider</td>
<td></td>
</tr>
<tr>
<td>Institution Name</td>
<td>Address</td>
</tr>
<tr>
<td>Phone ( ) -</td>
<td>Fax (to receive test results) ( ) -</td>
</tr>
<tr>
<td>Point of Contact if not Provider</td>
<td>Lab Name (where the patient will go to have their blood drawn)</td>
</tr>
</tbody>
</table>
**NJDOH ZIKA DELIVERY TESTING FORM (INFANT)**

1. Complete this form and send to NJDOH by encrypted e-mail to: [CDS.ZikaTeam@doh.nj.gov](mailto:CDS.ZikaTeam@doh.nj.gov) or fax to 609-826-4874.

2. Collect specimens as indicated in the CDC algorithms and according to the NJDOH specimen collection guidance provided in the Zika Delivery Packet.

3. NJDOH will provide the birthing hospital laboratory with the required authorization form for shipping to NJDOH.

### Infant Information

<table>
<thead>
<tr>
<th>Infant Name - as it appears on hospital records (Last name, First name)</th>
<th>Date of Birth</th>
<th>Patient Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em><strong>/</strong></em>/___</td>
<td>□ Male □ Female</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infant Home Address</th>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
<th>Home Telephone Number</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>Hispanic Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ White □ American Indian/Alaskan Native □ Other/Unknown</td>
<td>□ Yes □ Other/Unknown □ No</td>
</tr>
</tbody>
</table>

| □ Black □ Asian/Pacific Islander |

### Maternal Information

<table>
<thead>
<tr>
<th>Mother’s Name (Last name, First name)</th>
<th>Date of Birth</th>
</tr>
</thead>
</table>

### Birth Information

<table>
<thead>
<tr>
<th>Gestational age: weeks days</th>
<th>Delivery type:</th>
<th>Delivery complications:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ Vaginal □ C-section</td>
<td>□ Yes □ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Birth head circumference cm</th>
<th>Microcephaly</th>
<th>Other abnormalities</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ No □ Yes</td>
<td>□ No □ Yes (If yes, describe)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Birth weight grams</th>
<th>Birth length cm</th>
</tr>
</thead>
</table>

### Healthcare Provider Ordering the Zika Test

<table>
<thead>
<tr>
<th>Name of Health Care Provider</th>
<th>Patient Medical Record # / ID #</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Institution Name</th>
<th>Address</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Phone</th>
<th>Fax (to receive test results)</th>
<th>E-mail Address:</th>
</tr>
</thead>
</table>

### Birthing Hospital Contact Information

<table>
<thead>
<tr>
<th>Primary Zika Contact for Birthing Hospital:</th>
<th>Phone:</th>
<th>Fax:</th>
<th>E-mail:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Infection Preventionist:</th>
<th>Phone:</th>
<th>Fax:</th>
<th>E-mail:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Nursery Where Infant is an Inpatient:</th>
<th>Phone:</th>
<th>Fax:</th>
<th>E-mail:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Laboratory Contact for Zika Specimen Sendout:</th>
<th>Phone:</th>
<th>Fax:</th>
<th>E-mail:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Laboratory Contact for Pathology (placental tissue):</th>
<th>Phone:</th>
<th>Fax:</th>
<th>E-mail:</th>
</tr>
</thead>
</table>
# Zika Delivery Specimen Collection Guidance

**LABEL ALL SPECIMENS** with: Infant’s full name, date of birth, date and time of collection, and type of specimen (FOR TISSUE, USE MOTHER’S NAME)

**FREEZE ALL SPECIMENS** (except fixed-tissue) AT -70°C AND SHIP OVERNIGHT TO NJ PHEL ON DRY ICE AS A CATEGORY B INFECTIOUS SUBSTANCE – 49 CFR 173.199 (CATEGORY B) AND 49 CFR 173.217 (DRY ICE)

## Serum from Infants and Mothers

<table>
<thead>
<tr>
<th>Minimum Volume</th>
<th>Container</th>
<th>Storage</th>
<th>Additional Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collect enough blood to yield:</td>
<td>Collect in serum separator tube (tiger top, speckle top, or gold top).</td>
<td>Freeze at -70° to -80°C and ship on dry ice.</td>
<td>For information on packaging and shipping refer to the Zika Technical Bulletins at: <a href="http://nj.gov/health/phel/index.shtml">http://nj.gov/health/phel/index.shtml</a></td>
</tr>
<tr>
<td>Infant: 1.5-2.0 ml of serum</td>
<td>Promptly send to laboratory.</td>
<td>EXCEPTION: store at 4°C only if specimens will be received at PHEL within 24 hours of collection.</td>
<td></td>
</tr>
<tr>
<td>Mother: 3.0 ml of serum</td>
<td>In lab: aspirate 1.5-2.0 ml of serum into a leak-proof, screw-capped tube.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNACCEPTABLE: Blood in anticoagulant or plain red top tubes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Additional Instructions
- Collect in serum separator tube (tiger top, speckle top, or gold top).
- Promptly send to laboratory.
- In lab: aspirate 1.5-2.0 ml of serum into a leak-proof, screw-capped tube.
- UNACCEPTABLE: Blood in anticoagulant or plain red top tubes
- Freeze at -70° to -80°C and ship on dry ice.
- EXCEPTION: store at 4°C only if specimens will be received at PHEL within 24 hours of collection.

## Urine from Infants and Mothers

<table>
<thead>
<tr>
<th>Minimum Volume</th>
<th>Container</th>
<th>Storage</th>
<th>Additional Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collect urine on same day as serum:</td>
<td>Collect in clean container.</td>
<td>Freeze at -70° to -80°C and ship on dry ice.</td>
<td>For information on packaging and shipping refer to the Zika Technical Bulletins at: <a href="http://nj.gov/health/phel/index.shtml">http://nj.gov/health/phel/index.shtml</a></td>
</tr>
<tr>
<td>3.0 ml of urine</td>
<td>Promptly send to laboratory.</td>
<td>EXCEPTION: store at 4°C only if specimens will be received at PHEL within 24 hours of collection.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>In lab: transfer to clean, leak-proof screwcap tube.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNACCEPTABLE: Urine in tube with preservative or submitted in urine cup</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Additional Instructions
- Collect in clean container.
- Promptly send to laboratory.
- In lab: transfer to clean, leak-proof screwcap tube.
- UNACCEPTABLE: Urine in tube with preservative or submitted in urine cup
- Freeze at -70° to -80°C and ship on dry ice.
- EXCEPTION: store at 4°C only if specimens will be received at PHEL within 24 hours of collection.

## Placenta, Cord, Membranes and/or Other Tissues

**Fix specimens in 10% neutral buffered formalin and/or formalin fixed paraffin-embedded tissue blocks (FFPE)**

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Container/Preservatives</th>
<th>Storage</th>
<th>Additional Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placenta and fetal membranes:</td>
<td>Tissues should be placed into one or more containers containing adequate formalin.</td>
<td>Fixed tissues should be stored and shipped at room temperature. (Please use cold packs in the shipment).</td>
<td>Tissue testing must be pre-approved by NJDOH during business hours. Please process tissue according to these instructions if awaiting approval.</td>
</tr>
<tr>
<td>At least 3 full thickness pieces (0.5–1 cm x 3–4 cm) from the middle third of placental disk and at least 1 piece from the placental disk margin.</td>
<td>Volume of formalin used should be about 10x mass of tissue.</td>
<td>Tissue can be fixed in formalin for 3 days, and then transferred to 70% ethanol for shipping purposes or for long term storage at ambient temperature.</td>
<td>Include information about placenta weight and sample both maternal and fetal side of the placenta.</td>
</tr>
<tr>
<td>5 x 12 cm strip of fetal membranes.</td>
<td>Label all specimens to identify location of sample.</td>
<td></td>
<td><strong>SHIP TO NJ PHEL AS AN “EXEMPT HUMAN SPECIMEN” IF FIXATIVE VOLUME IS LESS THAN 30ml.</strong></td>
</tr>
<tr>
<td>Include sections of the placental disk, fetal membranes, and pathologic lesions when possible.</td>
<td></td>
<td></td>
<td>IF OVER 30 ml OF FIXATIVE IS USED, CONTACT <a href="mailto:zika.phel@doh.nj.gov">zika.phel@doh.nj.gov</a> for shipping instructions.</td>
</tr>
<tr>
<td>Umbilical cord:</td>
<td>4 or more 2.5 cm segments of cord tissues.</td>
<td>Fixed tissue sample should not be shipped with frozen samples.</td>
<td></td>
</tr>
<tr>
<td>Umbilical cord segments should be obtained proximal, middle, and distal to umbilical cord insertion site on the placenta.</td>
<td></td>
<td>Use cold packs to prevent overheating of these specimens during shipment throughout the summer months.</td>
<td></td>
</tr>
</tbody>
</table>
U.S. Zika Pregnancy Registry and Birth Defects Surveillance — Integrated Neonate Assessment Form

These data are considered confidential and will be stored in a secure database at the Centers for Disease Control and Prevention

Please return completed form to NJ Department of Health Zika Team by encrypted e-mail at: CDS.ZikaTeam@doh.nj.gov or by faxing to 609 826-4874  [Phone: 609-826-5964]

Infant Name: __________________, __________________       Delivery Hospital: ________________________

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Live birth</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stillbirth ≥20 weeks</td>
<td></td>
</tr>
<tr>
<td>NAD.5. Gestational age at delivery: [ ] LMP Date: _______________</td>
<td>NAD.6. Based on: [ ] 1st trimester ultrasound</td>
<td>NAD.7. Maternal age at delivery _____ years</td>
<td></td>
</tr>
<tr>
<td>_____ weeks _____ days</td>
<td>[ ] 2nd trimester ultrasound</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>[ ] 3rd trimester ultrasound</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>[ ] Other ______________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.8. State/Territory reporting: Select State</td>
<td>NAD.9. County reporting: ______________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.10. Delivery type: [ ] Vaginal [ ] Cesarean section</td>
<td>NAD.11. Delivery complication: [ ] No [ ] Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.12. If yes, please describe:</td>
<td>NAD.13. Arterial cord blood pH (if performed): __________</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NAD.14. Venous cord blood pH (if performed): __________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.15. Placental exam (based on path report): [ ] No [ ] Yes</td>
<td>NAD.16. If yes, [ ] Normal [ ] Abruption [ ] Inflammation [ ] Other abnormality (please describe)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.17. Apgar score: 1 min ______/ 5 min ______</td>
<td>NAD.18. Infant temp (if abnormal): ______ °F or ______ °C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.19. Birth head circumference: [ ] cm ______ [ ] in</td>
<td>NAD.20. Molding present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.27. Repeat head circumference: [ ] cm ______ [ ] in</td>
<td>NAD.28. Date performed: _________ or Age ______ day(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.29. Physician report: [ ] Normal [ ] Abnormal</td>
<td>NAD.30. HC percentile: ________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.31. Admitted to Neonatal Intensive Care Unit: [ ] No [ ] Yes If yes, reason: ____________________</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.32. Neonatal death: [ ] No [ ] Yes</td>
<td>NAD.33. Date: ________ or Age at death ______ days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.34. Cause of death: ____________________</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.35. Microcephaly (head circumference &lt;3%ile): [ ] No [ ] Yes</td>
<td>NAD.36. Seizures: [ ] No [ ] Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAD.37. Neurologic exam: (check all that apply)</td>
<td>NAD.38. (please describe below)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[ ] Not performed [ ] Unknown [ ] Normal [ ] Hypertonia/Spasticity [ ] Hyperreflexia [ ] Irritability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[ ] Tremors [ ] Other neurologic abnormalities</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Physical Examination (record earliest measurements taken)
<table>
<thead>
<tr>
<th>NAD.40.</th>
<th>NAD.41.</th>
<th>NAD.43.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Splenomegaly by physical exam:</strong> &lt;br&gt;☐ No ☐ Yes ☐ Unknown</td>
<td><strong>Hepatomegaly by physical exam:</strong> &lt;br&gt;☐ No ☐ Yes ☐ Unknown</td>
<td><strong>Skin rash by physical exam:</strong> &lt;br&gt;☐ No ☐ Yes ☐ Unknown</td>
</tr>
<tr>
<td><strong>(please describe)</strong></td>
<td><strong>(please describe)</strong></td>
<td><strong>(please describe)</strong></td>
</tr>
</tbody>
</table>

**NAD.45. Other abnormalities identified:** please check all that apply

- ☐ Fetal Brain Disruption Sequence (collapsed skull, overlapping sutures, prominent occipital bone, scalp rugae)
- ☐ Encephalocele ☐ Arachnoid ♠ Anencephaly/Acralgia ♠ Spina bifida ☐ Holoprosencephaly/arhinencephaly
- ☐ Microphthalmia/Anophthalmia ☐ Arthrogryposis (congenital joint contractures)
- ☐ Congenital Talipes Equinovarus (clubfoot) ☐ Congenital hip dislocation/developmental dysplasia of the hip
- ☐ Other abnormalities

**NAD.46. (please describe below)**

### Neonate Imaging and Diagnostics

**NAD.47. Hearing screening:** (Date: __________) or Age ______ day(s)

*☐ Pass ☐ Fail ☐ Inconclusive/Needs retest ☐ Not performed*

**NAD.49. Please describe**

**NAD.50. Audiological evaluation:** ☐ Not performed ☐ Auditory brainstem response (ABR) test performed <br>☐ Otoacoustic emissions (OAE) test performed ☐ Acoustic stapedius reflex (ASR) test performed <br>☐ Unknown

**NAD.51. If performed: Date: __________ NAD.52. ☐ Normal ☐ Abnormal**

**NAD.53. Please describe**

**NAD.54. Retinal exam (with dilation):** ☐ Not Performed ☐ Performed ☐ Unknown

*☐ Normal*<br>☐ Microphthalmia/Anophthalmia ☐ Coloboma ☐ Cataract ☐ Intraocular calcifications<br>☐ Chorioretinal atrophy, scarring, macular pallor, gross pigmentary mottling, or retinal hemorrhage, excluding retinopathy of prematurity ☐ Other retinal abnormalities<br>☐ Optic nerve atrophy, pallor ☐ Other optic nerve abnormalities

**NAD.57. (please describe below)**

**NAD.58. Imaging study:** ☐ Cranial ultrasound ☐ MRI ☐ CT ☐ Not Performed

*☐ Normal*<br>☐ Microcephaly ☐ Intracranial calcification ☐ Cerebral / cortical atrophy
**U.S. Zika Pregnancy Registry and Birth Defects Surveillance — Integrated Neonate Assessment Form**

These data are considered confidential and will be stored in a secure database at the Centers for Disease Control and Prevention

<table>
<thead>
<tr>
<th>Infant’s State/Territory ID</th>
<th>Mother’s State/Territory ID</th>
</tr>
</thead>
</table>

**NAD.61. (please describe below)**

**NAD.62. Imaging study:**
- [ ] Cranial ultrasound
- [ ] MRI
- [ ] CT
- [ ] Not Performed

**NAD.63. (Date: _____________) or Age ______ day(s)**

**NAD.64. Findings: check all that apply**
- [ ] Normal
- [ ] Microcephaly
- [ ] Intracranial calcification
- [ ] Cerebral / cortical atrophy
- [ ] Abnormal cortical gyral patterns (lissencephaly, pachygyria, agyria, microgyria, polymicrogyria, schizencephaly)
- [ ] Corpus callosum abnormalities
- [ ] Cerebellar abnormalities
- [ ] Porencephaly
- [ ] Hydranencephaly
- [ ] Moderate or severe ventriculomegaly/hydrocephaly
- [ ] Fetal Brain Disruption Sequence (collapsed skull, overlapping sutures, prominent occipital bone, scalp rugae)
- [ ] Other major brain abnormalities
- [ ] Encephalocele
- [ ] Holoprosencephaly / Arhinencephaly
- [ ] Other abnormalities

**NAD.65. (please describe below)**

**NAD.66. Imaging study:**
- [ ] Cranial ultrasound
- [ ] MRI
- [ ] CT
- [ ] Not Performed

**NAD.67. (Date: _____________) or Age ______ day(s)**

**NAD.68. Findings: check all that apply**
- [ ] Normal
- [ ] Microcephaly
- [ ] Intracranial calcification
- [ ] Cerebral / cortical atrophy
- [ ] Abnormal cortical gyral patterns (lissencephaly, pachygyria, agyria, microgyria, polymicrogyria, schizencephaly)
- [ ] Corpus callosum abnormalities
- [ ] Cerebellar abnormalities
- [ ] Porencephaly
- [ ] Hydranencephaly
- [ ] Moderate or severe ventriculomegaly/hydrocephaly
- [ ] Fetal Brain Disruption Sequence (collapsed skull, overlapping sutures, prominent occipital bone, scalp rugae)
- [ ] Other major brain abnormalities
- [ ] Encephalocele
- [ ] Holoprosencephaly / Arhinencephaly
Infant’s State/Territory ID __________________________ Mother’s State/Territory ID __________________________

U.S. Zika Pregnancy Registry and Birth Defects Surveillance — Integrated Neonate Assessment Form

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- □ Other abnormalities
  NAD.69. *(please describe below)*

<table>
<thead>
<tr>
<th>NAD.70. Was a lumbar puncture performed:</th>
<th>□ Yes □ No □ Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>or Age ______ day(s)</td>
<td></td>
</tr>
</tbody>
</table>

**Postnatal Infection Testing (includes urine culture for CMV)**

<table>
<thead>
<tr>
<th>NAD.72. Toxoplasmosis infection:</th>
<th>□ No □ Yes □ Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAD.73. Cytomegalovirus infection:</td>
<td>□ No □ Yes □ Unknown</td>
</tr>
<tr>
<td>NAD.74. Herpes Simplex infection:</td>
<td>□ No □ Yes □ Unknown</td>
</tr>
<tr>
<td>NAD.75. Rubella infection:</td>
<td>□ No □ Yes □ Unknown</td>
</tr>
<tr>
<td>NAD.76. Lymphocytic choriomeningitis virus infection:</td>
<td>□ No □ Yes □ Unknown</td>
</tr>
<tr>
<td>NAD.77. Syphilis infection:</td>
<td>□ No □ Yes □ Unknown</td>
</tr>
</tbody>
</table>

NAD.78. If yes for any postnatal infection testing, please describe results:

**Postnatal (Infant) Cytogenetic Testing**

<table>
<thead>
<tr>
<th>NAD.79. Cytogenetic Test</th>
<th>□ Karyotype □ FISH □ CGH microarray □ Other, specify</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAD.80. Date:</td>
<td>________</td>
</tr>
<tr>
<td>NAD.81. Infant Age:</td>
<td>______ months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NAD.82. Specimen</th>
<th>□ Cord blood □ Peripheral blood □ Tissue □ Other, specify</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAD.83. Test Result</td>
<td>□ Normal □ Abnormal □ Unknown</td>
</tr>
</tbody>
</table>

NAD.84. Description of cytogenetic test findings (verbatim):
U.S. Zika Pregnancy Registry and Birth Defects Surveillance — Integrated Neonate Assessment Form

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NAD.85. Other tests/results/diagnosis (include dates):

<table>
<thead>
<tr>
<th>Diagnostic Code</th>
<th>Certainty</th>
<th>Verbatim Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Definite</td>
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<td></td>
<td>Possible/Probable</td>
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<td>Possible/Probable</td>
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</tbody>
</table>

Health Department Information

NAD.86. Name of person completing form: ____________________________

NAD.87. Phone: ________________

NAD.88. Email: ____________________ NAD.89. Date of form completion __________

FOR INTERNAL CDC USE ONLY

Mother ID: ____________________ State/territory ID: ____________________

Public reporting burden of this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS E-11, Atlanta, Georgia 30333; ATTN: PRA (0920-1101)

PLEASE PROVIDE NAME / CONTACT INFORMATION FOR THE OUTPATIENT PEDIATRICIAN:

Name: ____________________ Address: ____________________ Phone: ____________
**Clinical Summary for Pediatric Healthcare Provider**

**Instructions for providers:**
- Complete this form for infants EITHER 1) with clinical findings consistent with congenital Zika syndrome OR 2) who are born to a mother with laboratory evidence of possible Zika virus infection during the pregnancy.
- Send this form to the outpatient pediatric healthcare provider who will receive the infant for follow-up care.

<table>
<thead>
<tr>
<th>Infant's Name:</th>
<th>Date of Birth:</th>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Mother's Name:</th>
<th>Date of Birth:</th>
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</tbody>
</table>

**MATERNAL ZIKA VIRUS EXPOSURE** *(Please check any reported exposures.)*

Mother has a history of Zika virus exposure during pregnancy through:

- [ ] travel to area with risk of Zika
- [ ] sexual exposure
- [ ] residence in an area at risk of Zika
- [ ] other exposure

Travel Dates and Location(s):

________________________
________________________
________________________
________________________

Comments:

________________________
________________________
________________________
________________________

**MATERNAL ZIKA VIRUS TESTING** *(Please record labs performed and results.)*

Mother was

[ ] tested

[ ] not tested

<table>
<thead>
<tr>
<th>Date of Collection</th>
<th>Test Type* (e.g., Zika virus NAT, IgM, PRNT)</th>
<th>Result†</th>
</tr>
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<tbody>
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**PRENATAL ZIKA-RELATED IMAGING** *(Please record the overall assessment and describe any abnormalities.)*

Prenatal Imaging Findings:

[ ] normal

[ ] abnormal

Description of Abnormalities:

________________________
________________________
________________________
________________________

**INFANT ZIKA VIRUS TESTING** *(Please record labs performed and results.)*

Infant was

[ ] tested

[ ] not tested

<table>
<thead>
<tr>
<th>Date of Collection</th>
<th>Test Type* (e.g., Zika virus NAT, IgM, PRNT)</th>
<th>Result†</th>
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</tbody>
</table>
### INFANT EVALUATION RESULTS

(Please record evaluation results, describe any abnormalities.)

- Birth Growth Parameters: Weight: _____ lb/kg  
  Length: _____ in/cm  
  HC: _____ in/cm

- Comprehensive Examination:  
  - normal  
  - abnormal  
  Description of Abnormalities:__________________________________________________________

- Postnatal Head Imaging:  
  - normal  
  - abnormal  
  Description of Abnormalities:__________________________________________________________

- Audiology Evaluation:  
  - normal  
  - abnormal  
  Description of Abnormalities:__________________________________________________________

- Ophthalmology Examination:  
  - normal  
  - abnormal  
  Description of Abnormalities:__________________________________________________________

- Other Evaluations:  
  Description of Abnormalities:__________________________________________________________

### CDC INFANT EVALUATION AND FOLLOW-UP CATEGORY

(Check one and refer to guidance for next steps):

- Infant with clinical findings consistent with congenital Zika syndrome regardless of maternal testing results
- Infant without clinical findings consistent with congenital Zika syndrome who was born to a mother with laboratory evidence of possible Zika virus infection during the pregnancy
- Infant without clinical findings consistent with congenital Zika syndrome who was born to a mother without laboratory evidence of possible Zika virus infection

### COMPLETED BY:

Printed Name: ___________________________  
Signature: ___________________________  
Date: ___________________________

### OUTPATIENT PEDIATRIC HEALTHCARE PROVIDER

Name: ___________________________  
Address: ___________________________  
Phone: ___________________________  
Fax: ___________________________  
Email Address: ___________________________

*Nucleic Acid Testing (NAT), Plaque Reduction Neutralization Test (PRNT)*  
†Guidance on lab test interpretation can be found at the following website: [https://www.cdc.gov/zika/hc-providers/testresults.html](https://www.cdc.gov/zika/hc-providers/testresults.html). For questions or assistance please contact your local health department.  
‡Further testing and evaluation of the infant might be needed according to published recommendations. Guidance can be found at the following site: [https://www.cdc.gov/pregnancy/zika/testing-follow-up/evaluation-testing.html](https://www.cdc.gov/pregnancy/zika/testing-follow-up/evaluation-testing.html)