Updated April 4, 2018

NJDOH Zika Delivery Packet

New Jersey Department of Health (NJDOH) monitors all 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. Criteria for Zika testing at the NJDOH Public Health and Environmental Laboratory (PHEL) can be found at:

http://www.nj.gov/health/cd/documents/topics/zika/zika_testing_criteria.pdf

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. CDC's Zika screening tool for pregnant women can be found at the following website: https://www.cdc.gov/zika/pdfs/zikapreg_screeningtool.pdf

For mothers exposed to Zika virus, the documents in this packet are intended to streamline the process for evaluating and testing mothers and their infants at time of delivery and prior to discharge**.** The packet can be found at:

http://www.nj.gov/health/cd/documents/njdoh_zika_delivery_packet_4.4.18.pdf

1. Zika Delivery Checklist for Birthing Hospitals
2. Maternal and Infant Zika Testing Recommendations at Delivery
3. Zika Delivery Testing Forms (maternal and infant)
4. Zika Delivery Specimen Collection Guidance
5. CDC Algorithm: Evaluation for Infants with Possible Congenital Zika Virus Infection (10/19/2017)
6. CDC Roadmap for Babies of Mothers Infected with Zika During Pregnancy Who Appear Healthy (11/3/2017)
7. CDC Roadmap for Babies with Congenital Zika Infection (11/3/2017)

Please note that completion of the CDC's Neonatal Assessment Form is no longer required. Clinicians can refer to documents 5, 6 and 7 above to guide infant evaluation and assessment activities at time of birth through 12 months of age. 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 Communicable Disease Services Zika Team can be reached at: 609-826-5964.

NJDOH Zika Delivery Checklist for Birthing Hospitals

☐ **Review the NJDOH "Maternal and Infant Zika Testing Recommendations at Delivery" on page 3 to determine assessments to perform and if testing is indicated.**

☐ **Perform the following assessments on all infants.**
- Comprehensive physical exam including head circumference
- Standard newborn hearing screening

Depending on the level of possible Zika exposure, consider the following infant testing.
- Infant head ultrasound
- Opthalmologic assessment

☐ **If Zika testing of serum, urine or placental/cord tissue is indicated:**

- **Collect placental/umbilical cord tissue only if mother was symptomatic for Zika or infant has Zika-compatible abnormalities. Send to your pathology lab promptly.**
  - Pathology lab should prepare FIXED specimens ONLY, labeled with mother's name.
  - Prepare several full thickness pieces, including sections of the placental disk, umbilical cord, membranes and any pathologic lesions (see page 6 of packet).
  - Place into one or more containers with adequate formalin; store at room temperature. http://www.state.nj.us/health/phel/documents/zika_supp_tech_bulletin_march2017.pdf

- **Complete and return the maternal "NJDOH Zika Virus Patient Information Worksheet"(p. 4) and the "NJDOH Zika Delivery Testing Form - Infant" (p.5).**
  - Fax to NJDOH Communicable Disease Service at FAX: 609-826-4874 [Phone: 609-826-5964]. NJDOH will provide your laboratory with the authorization forms required to ship the specimens.

- **Collect maternal serum and urine for Zika testing.**
  - Obtain sufficient blood to obtain a total of 3 ml of serum. Collect in a serum separator tube (tiger top, speckle top or gold top) and promptly send to your laboratory (see page 6 of packet).
  - Obtain at least 3 ml of urine in a clean container; promptly send to laboratory.
  - Process, store and ship as directed in the following NJDOH Zika technical bulletins: http://www.state.nj.us/health/phel/documents/zika_tech_bulletin_update_071416.pdf http://www.nj.gov/health/phel/documents/zika_supp_tech_bulletin_march2017.pdf

- **Collect infant serum and urine for Zika testing.**
  - Obtain sufficient blood to obtain a total of 1.5 – 2 ml of serum. Collect in a serum separator tube (tiger top, speckle top or gold top) and promptly send to your laboratory (see page 6 of packet).
  - Obtain at least 3 ml of urine in a clean container (catheterization not necessary); promptly send to laboratory.
  - Process, store and ship in same manner as for maternal specimens.

Maternal and Infant Zika Testing Recommendations at Delivery

To request testing at NJDOH, complete the Zika Delivery Testing Forms on pages 4 and 5 of this packet and fax to 609-826-4874.
Note: Placental/fetal tissue testing is only available through NJDOH.

Apparently normal infants born to mothers who were not tested for Zika but have risk factors	**OR**	**Apparently normal infants whose mother tested negative but:** - **Mother's specimen collected for Zika testing > 12 weeks after exposure** - **Mother had ongoing (daily or weekly) travel exposure**

- ☐ Save and fix placental/cord tissue only if mother had symptoms of Zika during pregnancy (fever, rash, conjunctivitis, arthralgia).
- ☐ Perform the following:
  - Comprehensive physical exam including head circumference
  - Standard newborn hearing screen
- ☐ Depending on level of possible Zika exposure, consider if additional evaluation is warranted, to include:
  - Infant head ultrasound
  - Opthalmologic assessment
- ☐ Based on these assessments, clinicians may consider:
  - Infant testing for Zika: serum (PCR and IgM) and urine (PCR).
- ☐ Collect/order maternal Zika testing: serum (PCR and IGM) and urine (PCR) if mother was symptomatic (fever, rash, conjunctivitis, arthralgia) AND is within 12 weeks of last Zika exposure. [Not required if mother was already tested]

Infants with abnormalities suggestive of congenital Zika virus syndrome **AND** **maternal risk factors for Zika (travel, sexual, etc) regardless of maternal test results**	**OR**	**Infants (normal or with abnormalities) born to mothers who have laboratory evidence of Zika during pregnancy** (includes Zika IgM+ / PRNT pending)

- ☐ Save and fix placental/cord tissue.
- ☐ Collect/order infant Zika testing: serum (PCR and IgM) & urine (PCR) within 2 days of birth
- ☐ Perform the following:
  - Comprehensive physical exam including head circumference
  - Neurologic assessment
  - Infant head ultrasound
  - Standard newborn hearing screen
  - Opthalmologic assessment
- ☐ Collect/order maternal Zika testing: serum (PCR & IgM) & urine (PCR) if mother was symptomatic (fever, rash, conjunctivitis, arthralgia) AND is within 12 weeks of last Zika exposure. [Not required if mother was already tested]

Source: https://www.cdc.gov/mmwr/volumes/66/wr/mm6629e1.htm?s_cid=mm6629e1_w;
https://www.cdc.gov/zika/hc-providers/infants-children/evaluation-testing.html

NJDOH ZIKA VIRUS PATIENT INFORMATION WORKSHEET (MATERNAL)

CDRSS #: _____

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 **fax to the NJDOH Zika Team at 609-826-4874**.

NJDOH guidance on current criteria for testing at: www.state.nj.us/health/cd/topics/zika.shtml.
CDC's Zika Travel Information page – identifies areas experiencing Zika transmission: www.cdc.gov/zika/geo

Patient Name (Last name, First name)	Date of Birth	Patient Sex
	___/___/_____	☐ Male ☐ Female

Patient Address	City	State	Zip Code	Telephone Number
				( ) -

Race				Ethnicity	
White	Black	American Indian or Alaskan Native		Hispanic	
Asian	Pacific Islander/Native Hawaiian	Other_____		Non-Hispanic	

Maternal Zika Exposure History (select all that apply)

Date of delivery _____/_____/_____

Are there infant abnormalities suggestive of Zika at delivery? ☐ Yes ☐ No

Maternal Symptom ☐ Currently symptomatic ☐ Recovered /Formerly symptomatic ☐ Asymptomatic*

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

☐ Travel to area with Zika ☐ Ongoing travel (at least weekly) to area with Zika	Travel location(s):	Travel dates: From: To: ___/___/_____/___/___ From: To: ___/___/_____/___/___
☐ Unprotected sexual contact with Zika exposed partner	Date(s) of first and last unprotected sexual contact with Zika exposed partner:	First Last: ___/___/_____/___/___
	Sexual partner's travel location(s), *if applicable*:	Sexual partner's travel dates: From: To: ___/___/_____/_____/____

☐ Congenital/Perinatal ☐ Laboratory/Healthcare ☐ Other Exposure (*specify*) _____

☐ Blood Transfusion ☐ Organ Recipient

Exposure dates: From: To:
___/___/_____/ ___ ___

List all signs and symptoms with onset/resolution dates:

	Onset Date *(mm/dd/yy)*	Resolution Date *(mm/dd/yy)*
☐ Fever	_____/_____/_____	_____/_____/_____
☐ Rash	_____/_____/_____	_____/_____/_____
☐ Conjunctivitis	_____/_____/_____	_____/_____/_____
☐ Arthralgia (joint pain)	_____/_____/_____	_____/_____/_____
☐ Neurological symptoms (*specify*)	_____/_____/_____	_____/_____/_____

Other Symptoms (e.g., Headache, Myalgia, Eye pain, etc.):

Comments (*if applicable*)

Immunization history and year of immunization if known:

☐ Yellow Fever Vaccine_____ ☐ Japanese Encephalitis Vaccine_____ ☐ Tickborne Encephalitis Vaccine _____

Previous history (year) of flavivirus/arboviral disease

☐ West Nile Virus_____ ☐ Chikungunya Virus_____ ☐ Previous Zika diagnosis (*mm/yy*) _____

☐ Dengue Virus _____ ☐ Powassan Virus _____ ☐ Other flavivirus/arboviral disease _____

Submitter Information (Physician who is ordering Zika test)

Name of Health Care Provider		Patient ID Number

Institution Name	Address

Phone	Fax (to receive test results)	E-mail Address:
( ) -	( ) -	

Point of Contact if not Provider	**Lab Name (where the patient will go to have their blood drawn)**

NJDOH ZIKA DELIVERY TESTING FORM (INFANT)

1. Complete this form and fax it to the NJ Department of Health (DOH): 609- 826-4874.

2. Collect specimens as indicated in the attached "Maternal and Infant Zika Testing Recommendations at Delivery."

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

Infant Information

Infant Name - as it appears on hospital records (Last name, First name)	Date of Birth ___/___/_____	Patient ☐ Male ☐ Female
Infant Home Address / City / State / Zip Code		Home Telephone Number
Race ☐ White ☐ American Indian/Alaskan Native ☐ Other/Unknown ☐ Black ☐ Asian/Pacific Islander	Hispanic Origin ☐ Yes ☐ Other/Unknown ☐ No	

Maternal Information

Mother's Name (Last name, First name)	Date of Birth

Birth Information

Gestational age: ____weeks_____days	Delivery type: ☐ Vaginal ☐ C-section	Delivery complications: ☐ Yes ☐ No
Birth head circumference _____cm Birth weight _____grams Birth length _____cm	Microcephaly ☐ No ☐ Yes Other abnormalities ☐ No ☐ Yes (If yes, describe) _____	

Healthcare Provider Ordering the Zika Test

Name of Health Care Provider		Patient Medical Record # / ID #
Institution Name	Address	
Phone	Fax (to receive test results)	E-mail Address:

Birthing Hospital Contact Information

Primary Zika Contact for Birthing Hospital:	Phone:	Fax:	E-mail:
Infection Preventionist:	Phone:	Fax:	E-mail:
Nursery Where Infant is an Inpatient:	Phone:	Fax:	E-mail:
Laboratory Contact for Zika Specimen Sendout:	Phone:	Fax:	E-mail:
Laboratory Contact for Pathology (placental tissue):	Phone:	Fax:	E-mail:

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 -70ºC 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

Minimum Volume	Container	Storage	Additional Instructions
Collect enough blood to yield: Infant: 1.5-2.0 ml of serum Mother: 3.0 ml of serum	• 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 -80º C and ship on dry ice. • EXCEPTION: store at 4º C only if specimens will be received at PHEL within 24 hours of collection.	For information on packaging and shipping refer to the Zika Technical Bulletins at: http://nj.gov/health/phel/index.shtml

Urine from Infants and Mothers

Minimum Volume	Container	Storage	Additional Instructions
Collect urine on same day as serum: • 3.0 ml of urine	• 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 -70º to -80º C and ship on dry ice. • EXCEPTION: store at 4º C only if specimens will be received at PHEL within 24 hours of collection.	For information on packaging and shipping refer to the Zika Technical Bulletins at: http://nj.gov/health/phel/index.shtml.

Placenta, Cord, Membranes and/or Other Tissues

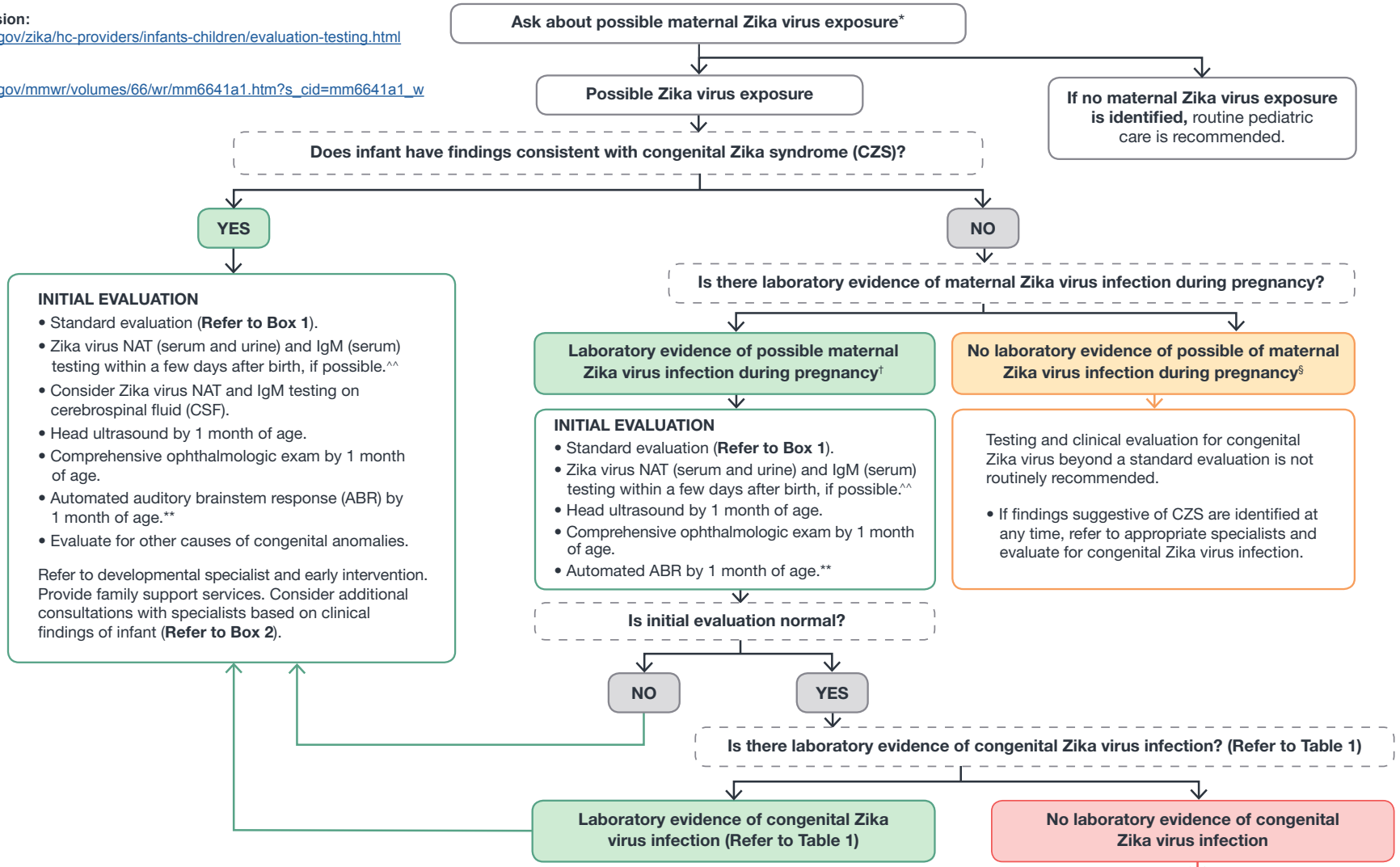
Fix specimens in 10% neutral buffered formalin and/or formalin fixed paraffin-embedded tissue blocks (FFPE)

Requirements	Container/Preservatives	Storage	Additional Instructions
Placenta and fetal membranes: • 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. • 5 x 12 cm strip of fetal membranes. • Include sections of the placental disk, fetal membranes, and pathologic lesions when possible. **Umbilical cord:** • 4 or more 2.5 cm segments of cord tissues. • Umbilical cord segments should be obtained proximal, middle, and distal to umbilical cord insertion site on the placenta.	• Tissues should be placed into one or more containers containing adequate formalin. • Volume of formalin used should be about 10x mass of tissue. • Label all specimens to identify location of sample.	• Fixed tissues should be stored and shipped at room temperature. (Please use cold packs in the shipment). • 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.	• Tissue testing must be pre-approved by CDS during business hours. Please process tissue according to these instructions if awaiting approval. • Include information about placenta weight and sample both maternal and fetal side of the placenta. • SHIP TO NJ PHEL AS AN "EXEMPT HUMAN SPECIMEN" IF FIXATIVE VOLUME IS LESS THAN 30ml. • IF OVER 30 ml OF FIXATIVE IS USED, CONTACT zika.phel@doh.nj.gov for shipping instructions. • Fixed tissue sample should not be shipped with frozen samples. • Use cold packs to prevent overheating of these specimens during shipment throughout the summer months.

EVALUATION FOR INFANTS WITH POSSIBLE CONGENITAL ZIKA VIRUS INFECTION

Accessible Version:
https://www.cdc.gov/zika/hc-providers/infants-children/evaluation-testing.html

MMWR:
https://www.cdc.gov/mmwr/volumes/66/wr/mm6641a1.htm?s_cid=mm6641a1_w



* 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.

CS284288 October 19, 2017

TABLE 1

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

Infant test results*		
NAT	**IgM**	**Interpretation**
Positive	Any result	Confirmed congenital Zika virus infection†
Negative	Nonnegative§	Probable congenital Zika virus infection¶,**
Negative	Negative	Congenital virus infection unlikely ¶,††

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 (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Screening/Pages/Screening-Tools.aspx)
- Vision screening as recommended by the American Academy of Pediatrics Policy Statement "Visual System Assessment in Infants, Children, and Young Adults by Pediatricians" (www.pediatrics.org/cgi/doi/10.1542/peds.2015-3596)
- Newborn hearing screen at birth, preferably with automated auditory brainstem response

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

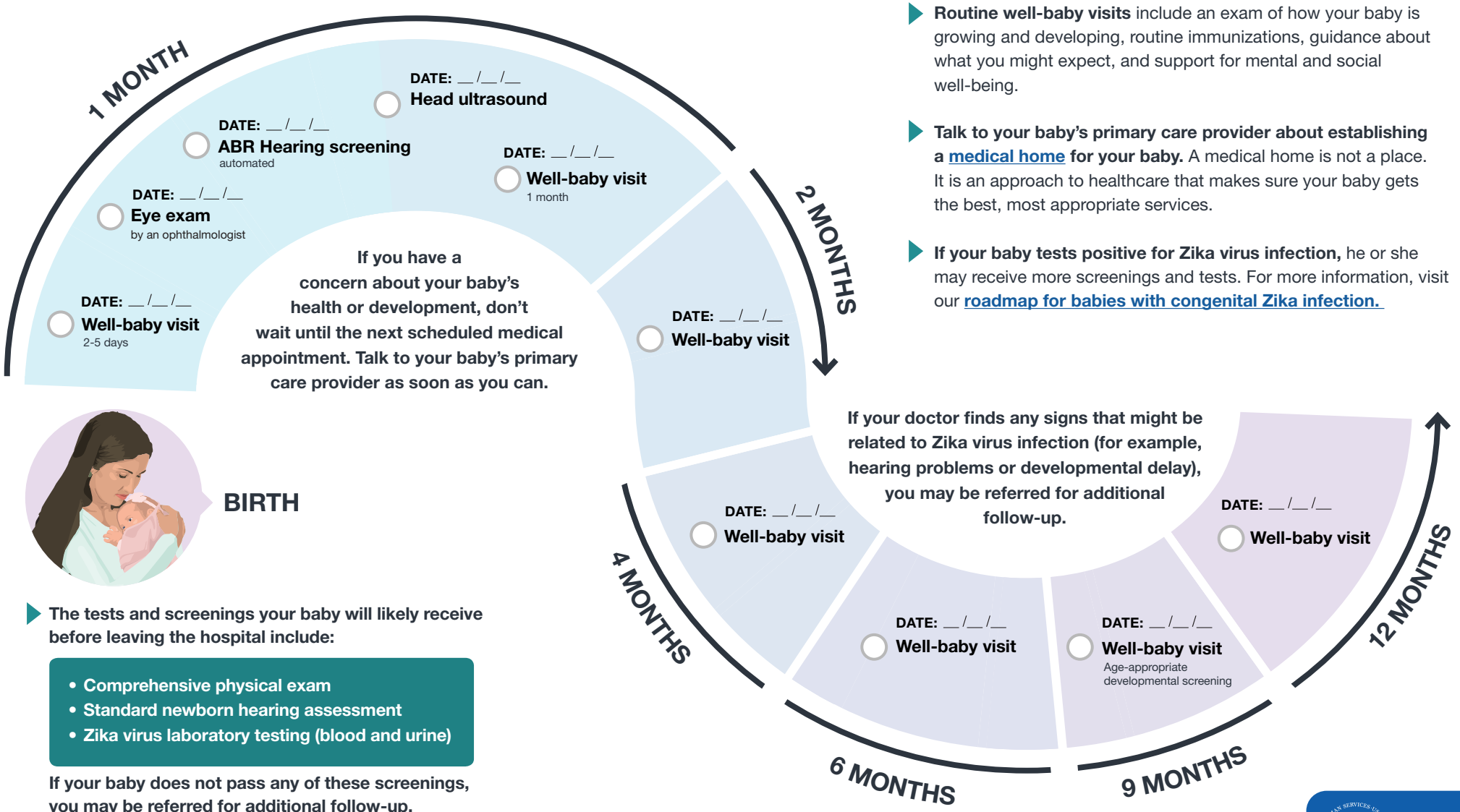
- **Consider consultation with the following specialists:**
  - Infectious disease specialist for evaluation for other congenital infections (e.g., toxoplasmosis, syphilis, rubella, cytomegalovirus, or herpes simplex virus) and assistance with Zika virus diagnosis, testing, and counseling
  - Neurologist 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

ROADMAP FOR BABIES OF MOTHERS INFECTED WITH ZIKA DURING PREGNANCY WHO APPEAR HEALTHY

This document should be used as a guide to discuss the screening and testing your baby may receive with his or her primary care provider. Each baby is different, and it is possible that your baby may need more tests or fewer tests.

Follow the roadmap to ☑ check off each **recommended** doctor's visit for the first year of follow up.

- **Routine well-baby visits** include an exam of how your baby is growing and developing, routine immunizations, guidance about what you might expect, and support for mental and social well-being.
- **Talk to your baby's primary care provider about establishing a medical home for your baby.** A medical home is not a place. It is an approach to healthcare that makes sure your baby gets the best, most appropriate services.
- **If your baby tests positive for Zika virus infection,** he or she may receive more screenings and tests. For more information, visit our **roadmap for babies with congenital Zika infection.**



BIRTH

- **The tests and screenings your baby will likely receive before leaving the hospital include:**
  - **Comprehensive physical exam**
  - **Standard newborn hearing assessment**
  - **Zika virus laboratory testing (blood and urine)**

If your baby does not pass any of these screenings, you may be referred for additional follow-up.

275226-C November 3, 2017

Accessible Version: https://www.cdc.gov/zika/parents/index.html

APPOINTMENT LOG

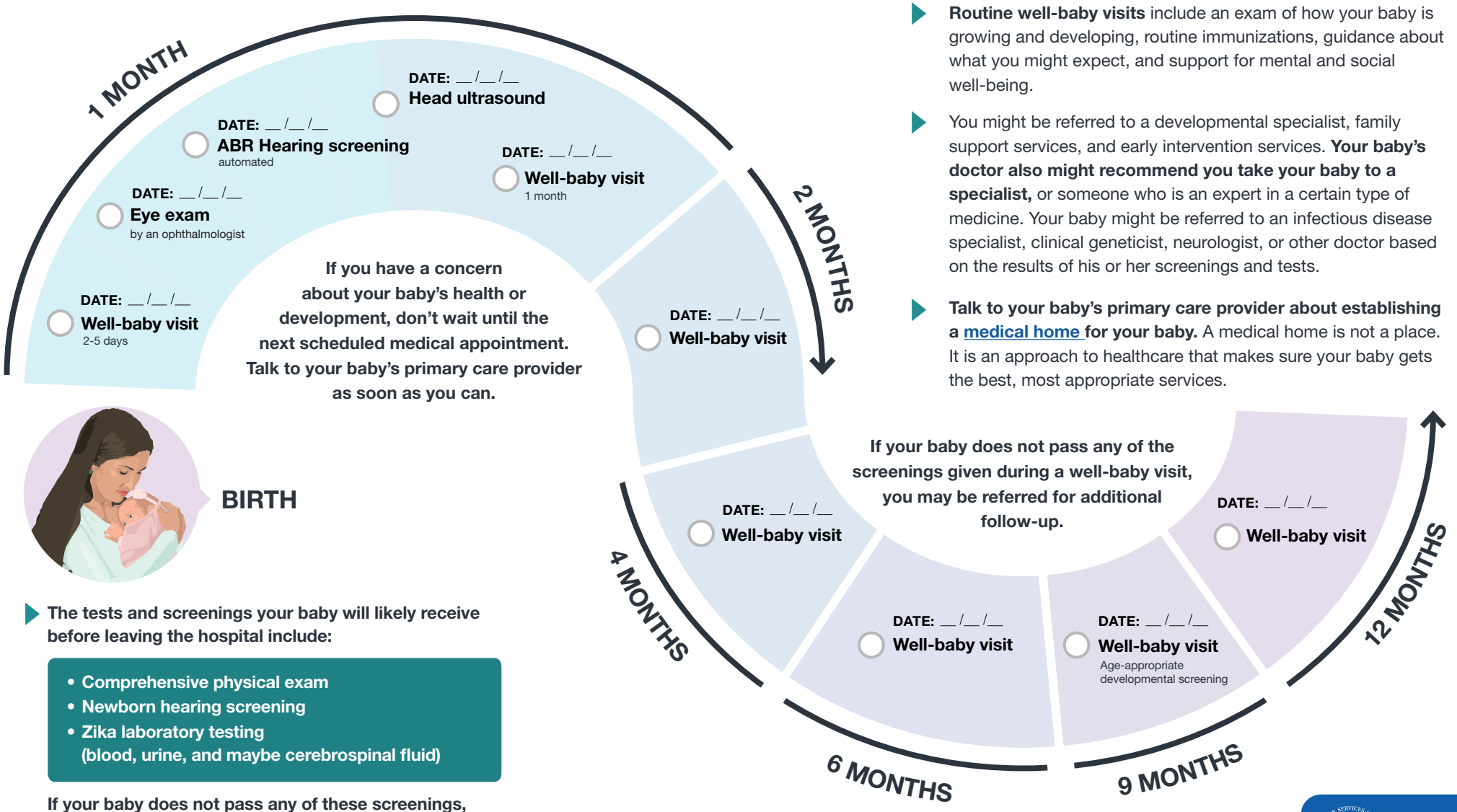
Use this table to keep track of your baby's medical appointments.

DATE	PROVIDER OR CLINIC	NOTES (Reason for visit, tests performed, care provided, etc.)	NEXT APPOINTMENT DATE	CLINIC PHONE NUMBER

ROADMAP FOR BABIES WITH CONGENITAL ZIKA INFECTION

This document should be used as a guide to discuss the screening and testing your baby may receive with his or her primary care provider. Each baby is different, and it is possible that your baby may need more tests or fewer tests. This roadmap outlines care for 1) babies who are born with birth defects or other clinical findings related to Zika virus infection during pregnancy 2) babies who test positive for Zika virus infection but may look healthy at birth.

Follow the roadmap to ✓ check off each recommended doctor's visit for the first year of follow up.



BIRTH

- **Routine well-baby visits** include an exam of how your baby is growing and developing, routine immunizations, guidance about what you might expect, and support for mental and social well-being.
- You might be referred to a developmental specialist, family support services, and early intervention services. **Your baby's doctor also might recommend you take your baby to a specialist,** or someone who is an expert in a certain type of medicine. Your baby might be referred to an infectious disease specialist, clinical geneticist, neurologist, or other doctor based on the results of his or her screenings and tests.
- **Talk to your baby's primary care provider about establishing a medical home for your baby.** A medical home is not a place. It is an approach to healthcare that makes sure your baby gets the best, most appropriate services.

- **The tests and screenings your baby will likely receive before leaving the hospital include:**

  - **Comprehensive physical exam**
  - **Newborn hearing screening**
  - **Zika laboratory testing (blood, urine, and maybe cerebrospinal fluid)**

If your baby does not pass any of these screenings, you may be referred for additional follow-up.

275226-A November 3, 2017

Accessible Version: https://www.cdc.gov/zika/parents/care-for-babies-with-congenital-zika.html

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