

ZIKA VIRUS: COLLECTION AND SUBMISSION OF SPECIMENS FOR ZIKA VIRUS TESTING AT TIME OF BIRTH



General Information

Laboratory testing for congenital Zika virus infection is recommended for infants born to mothers with laboratory evidence of Zika virus infection during pregnancy, and for infants who have abnormal clinical findings suggestive of congenital Zika virus syndrome and a maternal epidemiologic link suggesting possible transmission, regardless of maternal Zika virus test results.

For infants born to mothers with risk factors for maternal Zika virus infection (travel to or residence in [an area of Zika virus](#) transmission or sex with a partner with travel to or residence in such an area) for whom maternal testing was not performed before delivery, assessment of the infant, including comprehensive physical exam and careful measurement of head circumference, neurologic assessment as well as newborn hearing screen should be performed. In addition, based on the level of possible maternal Zika virus exposure (e.g., duration and type of exposure, use of prevention measures, intensity of Zika virus transmission at the location of travel), the provider should consider whether

further evaluation of the newborn for possible congenital Zika virus infection is warranted, in which case a head ultrasound and ophthalmologic assessment should be considered. Based on results of the evaluation, testing of the infant for Zika virus infection could be considered.

Testing of placental tissue specimens by Zika virus reverse-transcription polymerase chain reaction (RT-PCR) is conducted at CDC's Infectious Diseases Pathology Branch (IDPB). Zika virus RT-PCR on placental tissues from women with possible Zika virus exposure can be considered for diagnostic purposes for symptomatic pregnant women and women with infants with possible Zika virus-associated birth defects without a definitive diagnosis of laboratory-confirmed Zika virus infection during pregnancy. For asymptomatic pregnant women who have recent possible Zika virus exposure but without ongoing possible exposure, similar to the updated recommendations for testing of non-tissue clinical specimens (e.g., serum and urine), testing of placental tissues is not routinely recommended.

IMPORTANT: Pre-approval is *required* prior to submission of any tissue specimens. For pre-approval please contact pathology@cdc.gov.

Healthcare Providers:

- Please make sure that your state, territorial, tribal, or local health department has been notified and has received pre-approval from CDC for submission and shipment of tissue specimens before they are collected and sent.
 - » Institutions with surgical pathology available: Please consult surgical pathology regarding appropriate collection and processing of tissue specimens for Zika virus testing.
 - » Institutions without surgical pathology available: Please see table below for general guide on collection of tissue specimens for Zika virus testing.
- **Specimens should ONLY be sent to CDC directly from health departments.** CDC's Zika Pregnancy Hotline (770-488-7100; or email zikapregnancy@cdc.gov) is available 24/7 to healthcare providers and health departments for consultation regarding management of pregnant women and infants with possible Zika virus. This hotline can also assist with questions regarding specimen submission.

Health Departments:

- When submitting specimens, please submit [CDC Form 50.34](#) with all specimens.
 - » Select Test Order Code CDC-10365 "Pathologic Evaluation of Tissues for Possible Infectious Etiologies."
 - » Select "Zika Virus" as the suspect agent from the drop down menu.
 - » The remaining items must be completed electronically and then printed.

- **Pre-approval is required** prior to submission of all tissue specimens (i.e., placenta, umbilical cord). Please contact pathology@cdc.gov to obtain pre-approval. Additional clinical and epidemiologic information may be requested, see <https://www.cdc.gov/zika/laboratories/test-specimens-tissues.html> for minimum required information for pre-approval. If you have additional questions for the Infectious Diseases Pathology Branch, please call 404-639-3133.
- If you have additional questions for the Arboviral Diseases Branch, please call 970-221-6400.

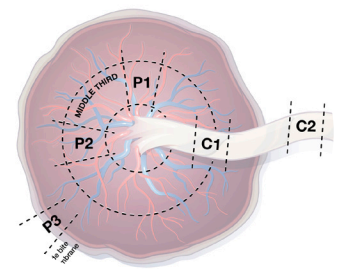


Figure: Collecting placental specimen

Reporting of Results:

- Test results will be reported to the state health department and the submitting healthcare provider. Results will not be directly released to patients.
- Turnaround time will depend on testing volume and established reporting systems.



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Specimen Type	General Instructions	Notes	Storage	Shipping
Infant serum	<p>At least 1.0 ml</p> <p>Transfer serum to a plastic tube measuring approximately 50 mm tall and 15 mm in diameter (e.g., 1.8 mL cryotube or 2.0 mL microtube) with screw cap and secure with thermoplastic, self-sealing lab film.</p>	<p>For antibody and rRT-PCR testing, specimens should be kept cold (2–6 °C) or frozen (-70 °C).</p> <p>For virus isolation testing, specimens should be frozen as soon as possible (-70 °C).</p>	<p>For cold specimens, the sample should be placed in an insulated container with adequate ice packs to ensure specimen (“cold chain”) integrity.</p> <p>For frozen specimens, ship the sample on enough dry ice to ensure specimens remain frozen until received.</p>	<p>Arboviral Diseases Branch Diagnostic Laboratory Centers for Disease Control and Prevention 3156 Rampart Road Fort Collins, Colorado 80521</p> <p>More information about collecting, handling, and shipping is available here.</p>
Placenta and fetal membranes	<p>At least 2 full thickness sections (0.5–1 cm x 3–4 cm in depth) from middle third of placental disk and at least 1 from the placental disk margin</p> <p>One 5 x 12 cm strip of fetal membranes taken from the area of rupture and including a small bite of the edge of the disk.</p> <p>Please include sections of the placental disk, fetal membranes, and pathologic lesions when possible.</p> <p><i>(Please reference the figure on page one.)</i></p>	<p>Please sample both maternal and fetal side of the placenta.</p> <p>Label all specimens to identify location of sample.</p>	<p>Fix specimens in formalin</p> <p>Volume of formalin used should be about 10x the volume of tissue. Place in 10% neutral buffered formalin for 3 days (72 hours). After fixation, if not paraffin-embedded, tissues should be transferred to 70% ethanol for long term storage and shipping.</p> <p>Storage and shipping at room temperature.</p>	<p>Infectious Diseases Pathology Branch Centers for Disease Control and Prevention 1600 Clifton Rd. NE, MS G-32 Atlanta GA 30329-4027</p> <p>Get more instructions regarding collecting and shipping tissue specimens.</p>
Umbilical cord	<p>At least two representative 2.5 cm segments of cord</p>	<p>Label specimen to identify location of sample (e.g., if proximal, middle, and distal to umbilical cord insertion site on the placenta).</p>	<p>Fix specimens in formalin</p> <p>Volume of formalin used should be about 10x the volume of tissue. Place in 10% neutral buffered formalin for 3 days (72 hours). After fixation, if not paraffin-embedded, tissues should be transferred to 70% ethanol for long term storage and shipping</p> <p>Storage and shipping at room temperature.</p>	<p>Infectious Diseases Pathology Branch Centers for Disease Control and Prevention 1600 Clifton Rd. NE, MS G-32 Atlanta GA 30329-4027</p> <p>Get more instructions regarding collecting and shipping tissue specimens.</p>
Infant urine	<p>Provide 0.5–1.0 mL of the specimen in a sterile screw capped vial secured with a small piece of thermoplastic, self-sealing lab film. Please ensure a tight seal as leaking specimens cannot be accepted.</p>	<p>Sterile specimen is not required</p>	<p>For rRT-PCR testing, specimens should be kept cold (2–8 °C) or frozen (≤ 20 °C) for storage and shipping.</p> <p>For frozen specimens, ship the sample on enough dry ice to ensure specimens remain frozen until received.</p>	<p>Arboviral Diseases Branch Diagnostic Laboratory Centers for Disease Control and Prevention 3156 Rampart Road Fort Collins, Colorado 80521</p> <p>Get more information about collecting, handling, and shipping.</p>