



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Center for Emerging and Zoonotic Infectious Diseases
National Center for Chronic Disease Prevention and Health Promotion
National Center for Birth Defects and Developmental Disabilities

January 24, 2021

Dear Colleagues,

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with cases identified in Brazil. In some of the Zika-affected areas, there has been an increase in cases of infants born with microcephaly. Zika virus infections have been confirmed in several infants with microcephaly and in fetal losses of women infected during pregnancy. Despite these observations, very little is known regarding the risks of Zika virus infection during pregnancy.

CDC, in collaboration with State Health Departments, has created a voluntary registry to collect information on women having Zika virus infection during pregnancy, and their babies. We aim to collect clinical information for the mother during pregnancy, results from testing conducted on diagnostic samples at birth, and clinical information for the child through the first year of the child's life. This will help us understand much more about Zika virus infection in pregnancy. Briefly, we have asked health department collaborators to notify, using ArboNET, a national surveillance system, women infected with Zika virus during pregnancy. Upon receiving case reports, we will be working, in collaboration with State Health Departments, to contact attending physician(s) to voluntarily enroll women into the registry.

For the pregnant woman, participation involves agreeing to let their healthcare provider send specimens from delivery and health information to staff at State Health Departments and/or CDC. We will honor patient confidentiality throughout this process. It is the responsibility of the healthcare provider to obtain consent from the patient to participate in the pregnancy registry.

For the healthcare provider, participation involves the following: providing brief clinical information for mothers and/or their infants, and arranging collection of diagnostic specimens in line with CDC's guidelines for the evaluation and testing of infants with possible congenital Zika virus infection (current recommendations available at <http://www.cdc.gov/mmwr/volumes/65/wr/mm6503e3.htm>). Our staff or State Health Department Staff will contact providers approximately one month prior to the woman's estimated delivery date to further coordinate the collection of information and specimens at the time of delivery. The costs of Zika testing of diagnostic specimens will be covered at no charge to the patient.

The following are the diagnostic specimens that will be planned to be collected at time of delivery and planned tests:

Infant serum from umbilical cord or infant	(1 ml or more)	for serology and PCR
Umbilical cord tissue	(section)	for histopathological examination, testing, and PCR
Placental tissue	(section)	for histopathological examination, testing, and PCR
Maternal serum (if not collected previously)		for serology

Following delivery, CDC or State Health Department staff will contact the infant's primary health care provider to obtain follow-up clinical information from routine health exams at approximately two-, six- and 12-months of age.

We will relay results to State Health Departments so results can be provided to participating women, and to the submitting physician if samples are sent directly to CDC.

Thank you for your willingness to participate, and please feel free to call us at 888-xxx-xxxx if you have any questions or concerns. For online information on this registry, please visit: <http://www.cdc.gov/zika/hc-providers/pregnancy-registry>.

Sincerely,
Dr. Susan Hills