

OnSite INSIGHTS

Volume 1, Issue 1, 2016

Zika Virus: Public Health Emergency

On February 1, 2016, the World Health Organization (WHO) declared a Public Health Emergency of International Concern after the rapid increase of microcephaly cases in newborn babies, which is strongly believed to be linked to women with an infectious history of the Zika virus (ZIKV) during pregnancy (<http://www.cdc.gov/zika/index.html>)

- ZIKV recently emerged as an epidemic in Latin America, particularly in Brazil and the Caribbean.
- Many Latin American countries are recommending that women avoid pregnancy until ZIKV is contained.
- It is primarily transmitted by the same mosquitoes as Dengue and Chikungunya (CHIK) viruses, Aedes species (*A. aegypti* and *A. albopictus*).
- Recently, it was found to be transmitted sexually by men, and by blood transfusion.
- Zika fever shares many similar clinical symptoms with Dengue and CHIK fever.

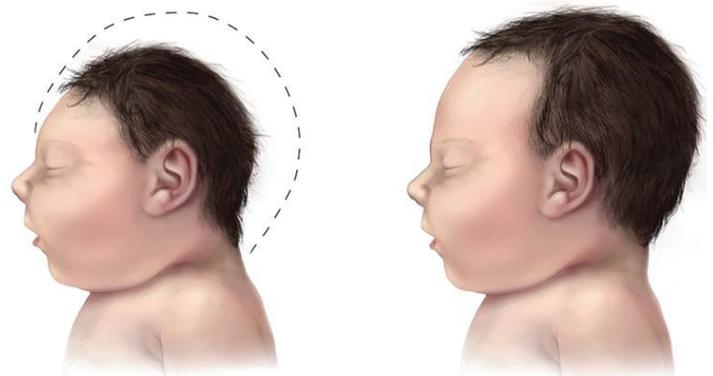


Image from <https://en.wikipedia.org/wiki/Microcephaly>

CTK's Response

A Call to Action!

An early and accurate diagnosis of ZIKV infection is urgently needed. Thus, CTK has initiated development of ZIKV immunodiagnostics. We believe our experience and reputation as a respected global manufacturer of Dengue and CHIK diagnostics positions CTK to help fill this critical demand.



CTK's Approach

Target Discovery & Recombinant Antigen Development

- CTK developed 3 recombinant structure ZIKV antigens, one of which is highly active and was chosen for our test development.
- Using the selected recombinant ZIKV antigen, we tested 4 specimens from highly suspected ZIKV patients with no previous history of Dengue or CHIK infection, using indirect IgM ELISA method:

Specimen A: tested negative for ZIKV by our IgM ELISA prototype and PCR, but strong positive on the CTK *OnSite* Dengue IgG/IgM Rapid Test, suggesting a Dengue rather than a ZIKV infection.

Specimen B: tested positive for ZIKV by PCR, and borderline positive with our ZIKV IgM ELISA prototype, indicating a very early stage of infection, the IgM antibodies started to rise.

Specimens C and D: tested positive for ZIKV with our IgM ELISA prototype, but negative by PCR, suggesting that the specimens may have passed the viraemic stage, and IgM had subsequently cleared the virus from the blood, causing the viral RNA levels to be too low for detection by PCR.

“ This is very exciting! Our preliminary data shows that diagnostic testing for the detection of Zika virus IgM shows great promise. Our results indicate that complimenting PCR /antigen testing with IgG/IgM antibody testing yields a greater understanding of the full spectrum of Zika virus infection in each individual. ”

Dr. Catherine Chen, CEO, CTK

Specimen		Normal, N=8	A	B	C	D
Fever Day		N/A	3	3	3	3
ZIKV IgM ELISA Prototype	OD Value	0.505 (average)	0.451	0.636	0.950	1.503
	Interpretation	Neg.	Neg.	Borderline	Pos.	Strong Pos.
External PCR		N/A	Neg.	Pos.	Neg.	Neg.
<i>OnSite</i> Dengue IgG/IgM RDT		N/A	Strong Pos.	Neg.	Neg.	Neg.

This data shows that detectable levels of ZIKV IgM are visible early after the onset of symptoms, as our specimens were collected at fever day 3. Noteworthy, is that the ZIKV IgM detection window exceeds the PCR detection window. IgM detection, therefore, is an equally important method of detection, which will expand the detection window and act as a complimentary and necessary approach to ZIKV diagnostics.

What's Next

The CTK R&D team is already working to move this project forward. We are also developing antibodies for the purposes of antigen test development, and are, therefore, working concurrently to develop both ZIKV IgG/IgM and antigen diagnostic kits.

We anticipate that the first ZIKV IgM ELISA kit will be on the market in June 2016, before the start of the expected ZIKV season.

For additional information please contact info@ctkbiotech.com or visit <http://ctkbiotech.com>.

MEET US

- Hospitalar, Brazil, May 2016
- AACC, USA, July 2016

Address: 10110 Mesa Rim Road
San Diego, CA 92121

E-mail: info@ctkbiotech.com

Web: www.ctkbiotech.com

Phone: 858-457-8698

Fax: 858-535-1739