

Press Release - Palo Alto

NIRMIDAS BIOTECH AND STANFORD UNIVERSITY DEVELOP A MULTIPLEXED SEROLOGICAL TEST FOR THE DIAGNOSIS OF ZIKA AND DENGUE

Nirmidas Biotech and Hongjie Dai, PhD, in the Department of Chemistry and Benjamin Pinsky, MD, PhD, in the Departments of Pathology and Medicine at Stanford University have developed a multiplexed serological test for rapidly distinguishing Zika virus (ZIKV) infection from dengue virus (DENV) infection, in both acute and convalescent patients.

This breakthrough was published in Nature Medicine on March 6, 2017.

ZIKV and DENV are mosquito-borne flaviviruses that now co-circulate throughout much of the tropical and subtropical world. The clinical presentation of patients with acute ZIKV infection typically includes a combination of fever, headache, retro-orbital pain, conjunctivitis, a maculopapular rash, myalgias, and arthralgias. However, patients with Zika fever are often suspected of having dengue. This considerable overlap in clinical presentations coupled with the potential of ZIKV to cause severe fetal and non-fetal manifestations, including congenital neurologic malformations and fetal demise, as well as Guillain-Barré syndrome, underscores the critical importance of accurate ZIKV diagnostics, and the requirement that tests distinguish ZIKV from DENV infection.

The Centers for Disease Control and Prevention (CDC) has issued testing algorithms for the diagnosis of infection in patients with suspected Zika fever that rely heavily on serological testing, particularly for pregnant women. Major challenges for ZIKV serological testing include the cross-reactivity between anti-ZIKV IgM antibodies and DENV antigens, as well as the cross-reactivity between anti-DENV IgM antibodies and ZIKV antigens. As such, virus-specific IgM detection, a critical component of the diagnostic arsenal for acute infection with mosquito-borne flaviviruses has been of limited utility during the current outbreak in the Americas, requiring time consuming and laborious plaque reduction neutralization testing (PRNT) for confirmation of the identity of the infecting virus.

To address these issues regarding current serological tests, the Nirmidas-Stanford collaboration developed a multiplexed assay on a nanotechnology based plasmonic gold (pGOLD) platform, that is capable of simultaneously detecting IgG, IgM, and IgA antibodies and IgG avidity against both Zika virus and Dengue virus antigens. Importantly, unlike the substantial cross-reactivity observed for IgM antibodies, both ZIKV IgG and IgA antibodies were specific and showed limited cross-reactivity with DENV antigens, allowing clear differentiation of these two infections. Further, ZIKV IgG avidity, a measure of how strongly antibodies bind to the viral



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antigen, reveals whether the infection occurred recently (low avidity) or in the past (high avidity).

In addition to these critical multiplexing capabilities, the tremendous fluorescence signal amplification of the pGOLD nanotechnology platform allows all of these tests to be performed with just 1 microliter of serum and results can be obtained within 2 hours.

“This study demonstrates that the combination of IgG and IgG Avidity testing can facilitate distinguishing Zika virus infection from dengue virus infection in dengue experienced patients”, says Dr. Pinsky. “Importantly, these findings suggest that this test may provide a significant advance in the diagnosis of Zika in pregnancy, as it has the potential to both diagnose and determine the timing of infection, analogous to routine use of IgG and IgG Avidity testing during the work-up of other potentially devastating congenital infections, Cytomegalovirus (CMV) and Toxoplasma gondii.”

Nirmidas is making the pGOLD Zika/Dengue IgG/IgA, IgG/IgM and IgG avidity test available for research use immediately, to facilitate both basic and translational studies to better understand Zika virus infection. Further, “We are currently seeking FDA’s Emergency Use Approval (EUA) in order to move our test into the clinic”, says Dr. Meijie Tang, CEO of Nirmidas Biotech Inc. “It is also important to note that our test is highly affordable, and the cost per antibody per sample is just several dollars”.

Nirmidas Biotech Inc. is a Palo Alto based startup company and a graduate of the Stanford StartX accelerator. Nirmidas’s nanoscale pGOLD platform was developed by Professor Hongjie Dai’s laboratory and licensed from Stanford. ‘I am extremely pleased that basic nanoscience research from the lab has the potential of helping solving real-world problems, an urgent problem in the Zika infection case’, says Dr. Dai.

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About Nirmidas Biotech, Inc.

Nirmidas Biotech, Inc., provides solutions for bio-analytical and diagnostic researchers using plasmonic gold (pGOLD) technology that vastly enhances near-infrared fluorescence signal, optimized over nearly a decade of research. Nirmidas’ pGOLD products include plasmonic gold slides for fluorescence enhanced biological imaging and assays, and multiplexed ELISA like



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assays for detecting a panel of prenatal infectious diseases, type 1 diabetes and Zika/Dengue infections. Nirmidas Biotech has also pioneered commercial fluorescent agents emitting in the NIR-II 1000-1700 nm range, for deep tissue biological imaging in vivo and with tissues. For more information, please visit: <http://www.nirmidas.com>.

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