A RAPID BLOOD TEST FOR POINT-OF-CARE ZIKA VIRAL INFECTION DETECTION AND DIAGNOSIS

GRANT # 7ZK04

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Research Collaborators
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UCLA (Dr. Karin Nielsen)

Industry Partners
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(CDC)

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Drs. Parks, McKinstry, and Strutt (UCF)
Limits of current diagnostic tests for Zika

**RT-PCR technique**
- Detect viral RNA
- Large equipment
- Expensive reagent
- Hours to complete
- False-negative

**Serology testing**
- Detect anti-ZIKV IgM antibody
- ELISA technique
- Expensive reagent
- Hours to complete
- False-positive

**PRNT (plaque reduction neutralization test)**
- Detect virus neutralizing antibody
- Labor intensive
- Days to complete
D2Dx™ (From Diameter to Diagnostics) – A Single-Step Immunoassay Technology

Patents granted
PCT/US09/030087
US9,005,994,B2
Additional pending

Virus protein

Gold nanoparticle (AuNP) technology developed at University of Central Florida

Detecting virus antibody by measuring nanoparticle size!

AuNP

D₀ ~100 nm

D₁ ~150-200 nm

D₂ >> 150-200 nm

Positive

Test score = D₂ / D₁

IgM antibody in blood

No IgM antibody in blood

Negative
Blood Collection and D2Dx™ Testing Process

Nanoparticle test: ~ 20 min

Total collection and processing time: ~ 10 min

Step 1. Add sample solution to the gold nanoparticle probe solution that is pre-added to the disposable sample cell.

Step 2. Incubate the assay solution at room temperature or under other conditions for appropriate amount of time.

Step 3. Place the sample cell to the carousel of NDS1200, and measure the average particle size of the solution.

D2Dx-R assay reader
Compact and portable (~10 lb)
Manufactured by Nano Discovery Inc., Orlando, FL
www.nanodiscoveryinc.com

https://www.youtube.com/watch?v=bwosvv4V0Lo&feature=youtu.be
Test scores of ZIKV vs normal control, DENV and CHIKV group

Higher test scores from Zika-infected Patients

N =

- Normal group: 20
- ZIKV group: 51
- DENV group: 10
- CHIKV group: 10
Sensitivity comparison between D2Dx™ test vs other serology tests

- EUROIMMUN anti-ZIKV IgM
- InBio anti-ZIKV IgM (FDA EUA approved)
- All samples were analyzed by EUROIMMUN, InBios and D2Dx™ test
- All samples were confirmed ZIKV infection positive by two different RT-PCR tests

D2Dx™ has much higher sensitivity compared to the current serology testing
## Performance comparison of D2Dx™ with other serology testing

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EUROIMMUN</th>
<th>InBios</th>
<th>D2Dx™</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
<td>Low (after day 7)</td>
<td>Medium (from day 5-7)</td>
<td>High (from day 2, 50%)</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td>unknown</td>
<td>Significant false positive (~50% according to CDC reports)</td>
<td>Lower cross reactivity with DENV, CHIKV infection, lower false positive rate (~20%)</td>
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<tr>
<td><strong>Speed</strong></td>
<td>5-7 hours (not including blood collection, blood clotting takes at least additional 30 min)</td>
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<td>30 min total including blood collection (use plasma, no need to wait for blood clotting)</td>
</tr>
<tr>
<td>Suitable for point-of-care or mobile-care diagnosis</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Overall cost</td>
<td>Medium</td>
<td>Medium</td>
<td>Low</td>
</tr>
</tbody>
</table>

- **Faster**
- **Cheaper**
- **More sensitive**
Current serology test cannot tell easily whether a Zika-infected woman is fully recovered from the infection or not.

### A Rapid Blood Test to Determine the Active Status and Duration of Acute Viral Infection

Tianyu Zheng a, Caroline Finn b, Christopher J. Parrett b, Kunal Dhume b, Ji Hae Hwang b, David Sidhom b, Tara M. Strutt b, Yuen Yee Li Sip b, Karl K. McKinstry b, Qun Huo a*

*ACS Infectious Diseases, 2017, published online*
Seeking Collaboration and Partnership Opportunities

• **Clinical samples** from ZIKV, CHIKV, DENV, as well as other flavivirus-infected patient samples for further validation studies

• Clinics and investigators to validate our test *independently*

• We are particularly interested in **community screening** of potential ZIKV infection

• We wish to participate in **animal model studies** that addresses the various aspects of ZIKV pathogenesis and immune response of ZIKV infection

• We wish to participate in **ZIKV vaccine development**: our test may be able to determine the success of vaccine in both animal models and human
Industry Partners and Commercialization

Startup company, spinoff from University of Central Florida
President: Dr. Qun Treen Huo
Woman-owned small business
Exclusive license right to D2Dx™ technology and diagnostic tests
Developed and manufactured D2Dx™ assay reader
Products manufactured locally in Florida
Launched product to market in December 2016
Capability to manufacture 100s of assay readers and large quantities of diagnostic test reagents anytime

Established in 2003
CEO: Davian Santana
Veteran-owned, Hispanic-owned small business entity
Contracted with over 200 skilled nursing facilities (SNFs) throughout Florida and services over 4,000 providers throughout the State of Florida
State-of-the-art, 35,000 square foot facility in Clermont, as well as laboratories in Lake City, Florida and Danville, Virginia
Laboratory services include chemistry, coagulation, immunochemistry, hematology, microbiology, molecular testing, serology, urinalysis, and molecular testing

www.nanodiscoveryinc.com
Orlando, FL

www.vista-clinical.com
Clermont, FL
Thank you!