

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

GRANT # 7ZK04



Graduate student
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Principal Investigator

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Leading Institute

University of Central Florida

Research

UCF College of Medicine (Dr. Griff

Collaborators

Parks, Dr. Karl McKinstry, Dr. Tara Strutt)

CDC (Dr. Aaron Brault)

UCLA (Dr. Karin Nielsen)

Industry Partners

Nano Discovery Inc. (Orlando, FL)

Vista Clinical (Clermont, FL)



Dr. Aaron Brault
(CDC)



Dr. Karin Nielsen
(UCLA)

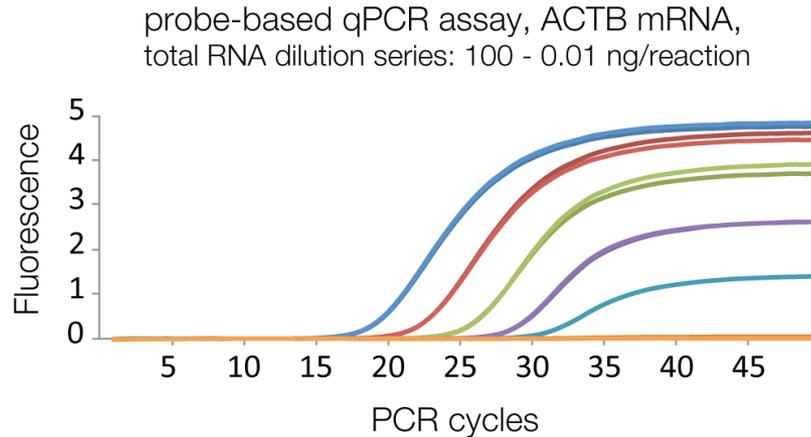


Drs. Parks, McKinstry,
and Strutt (UCF)

Limits of current diagnostic tests for Zika

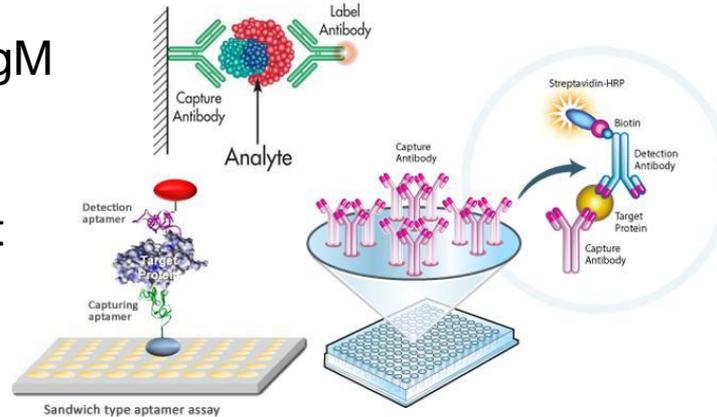
RT-PCR technique

- Detect viral RNA
- Large equipment
- Expensive reagent
- Hours to complete
- False-negative



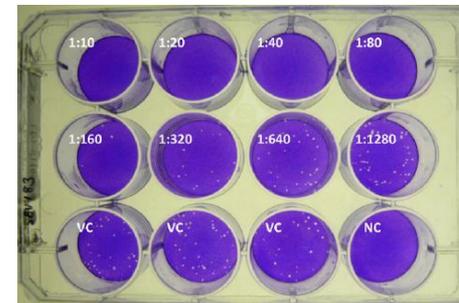
Serology testing

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



PRNT (plaque reduction neutralization test)

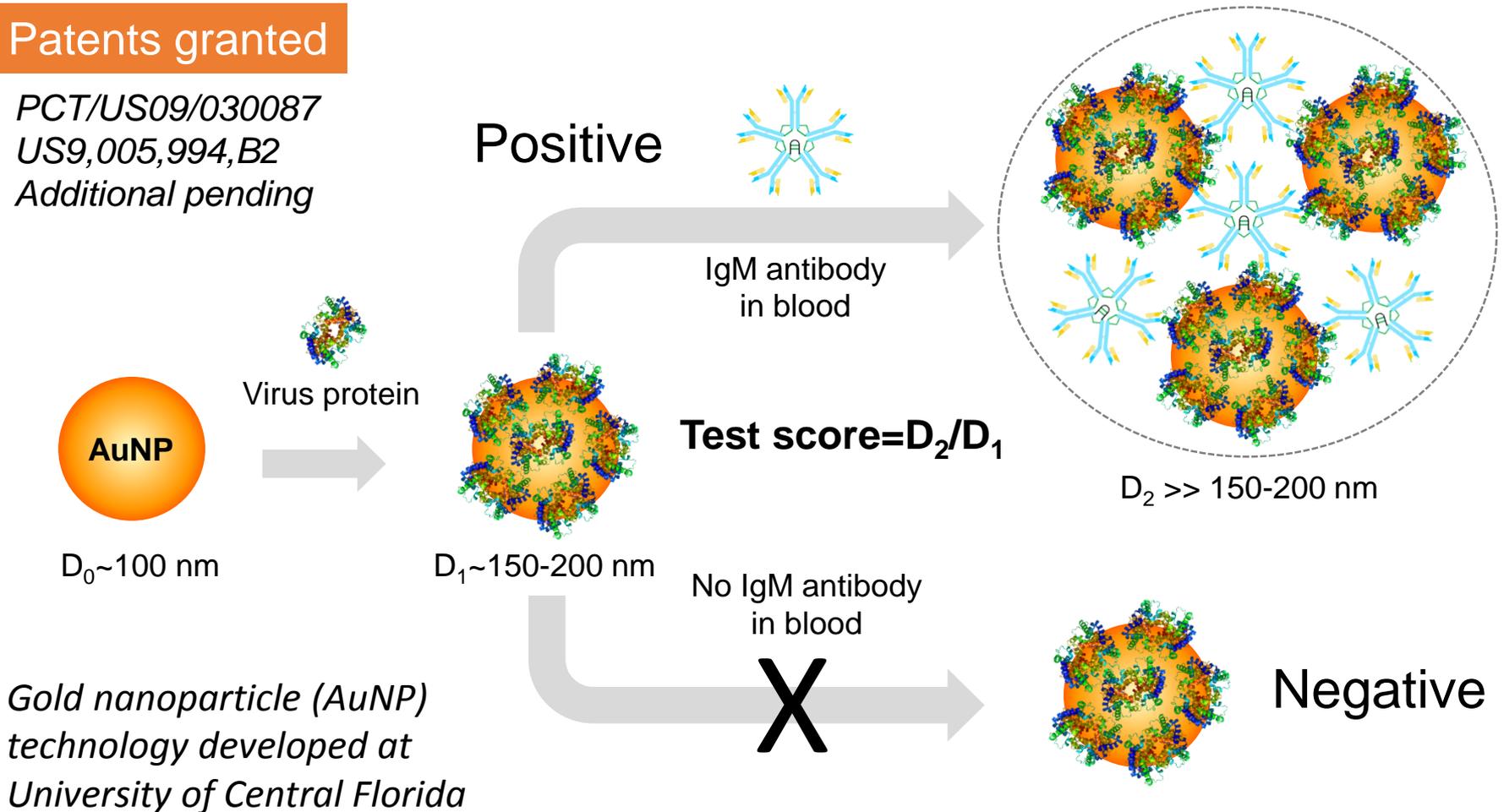
- Detect virus neutralizing antibody
- Labor intensive
- Days to complete



D2Dx™ (*From Diameter to Diagnostics*) – A Single-Step Immunoassay Technology

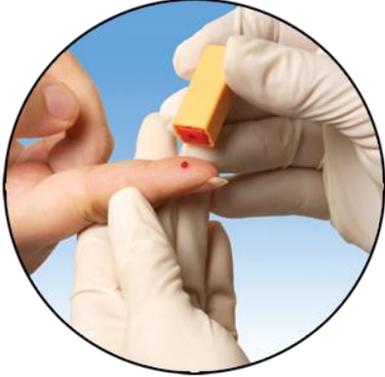
Patents granted

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



Detecting virus antibody by measuring nanoparticle size!

Blood Collection and D2Dx™ Testing Process



Total collection and processing time: ~ 10 min



Testing



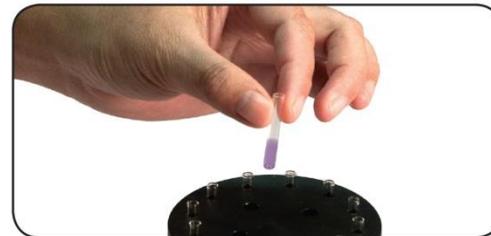
<https://www.youtube.com/watch?v=bwosvv4V0Lo&feature=youtu.be>

Nanoparticle test: ~ 20 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

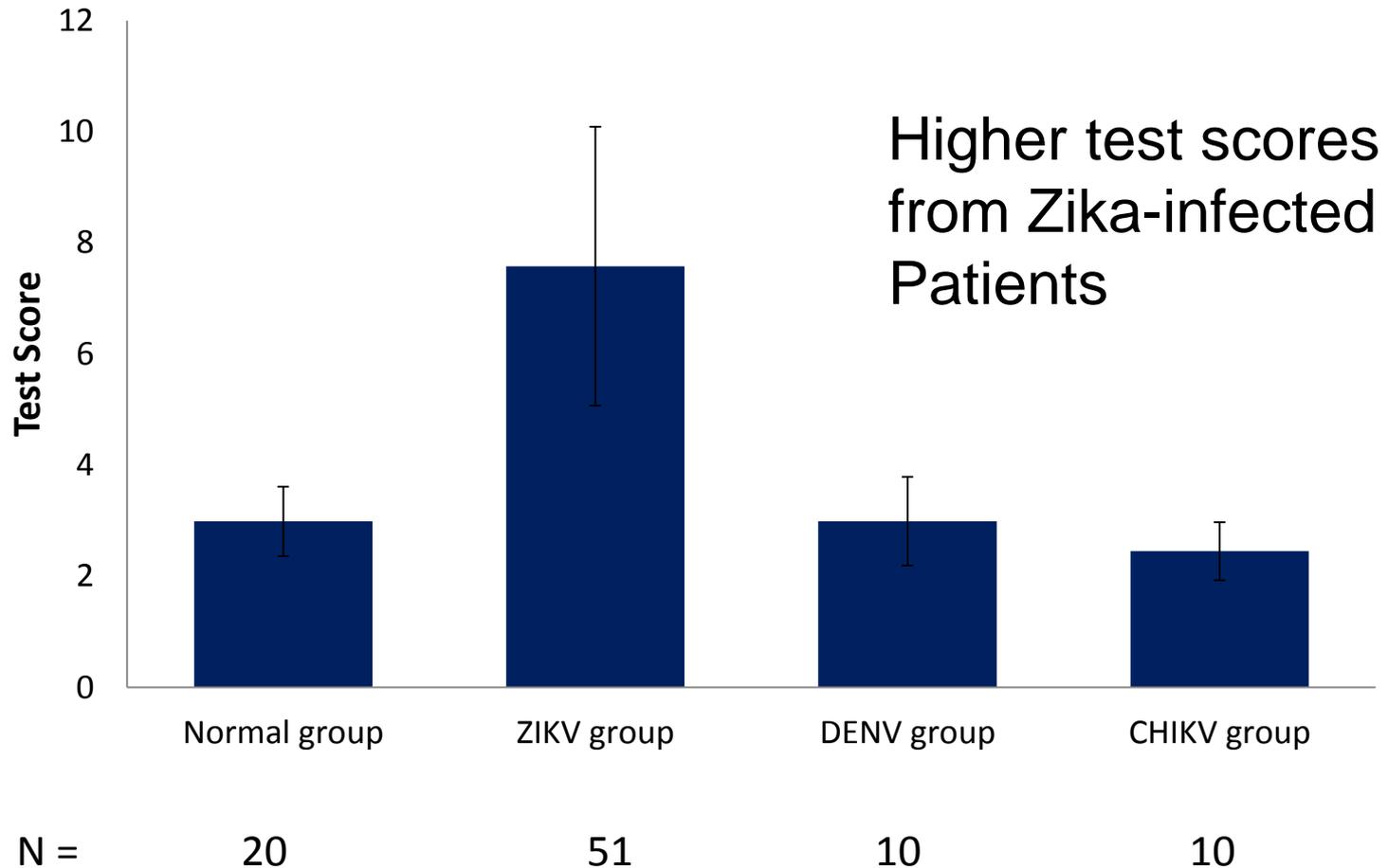
Compact and portable (~10 lb)

Manufactured by Nano

Discovery Inc., Orlando, FL

www.nanodiscoveryinc.com

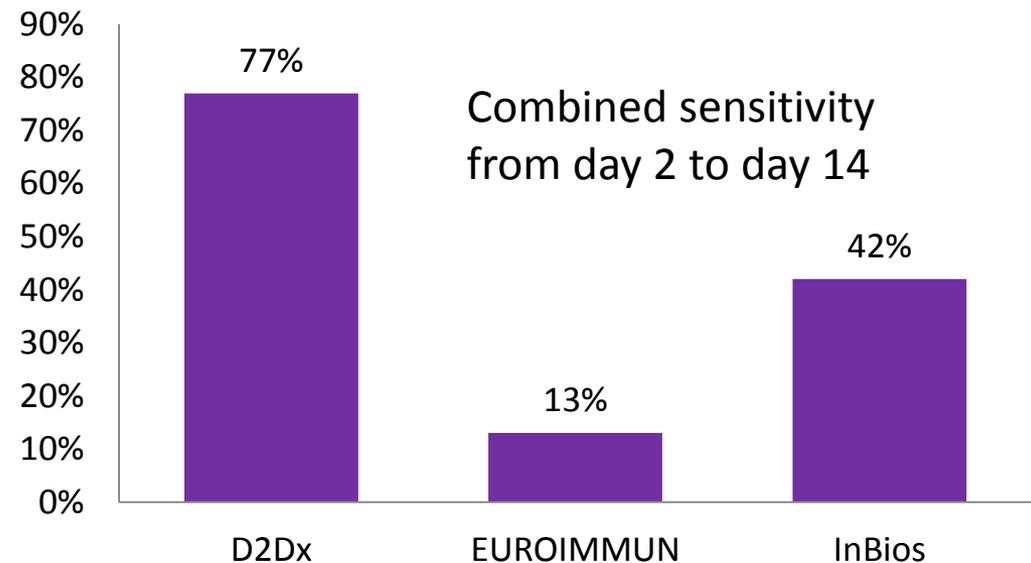
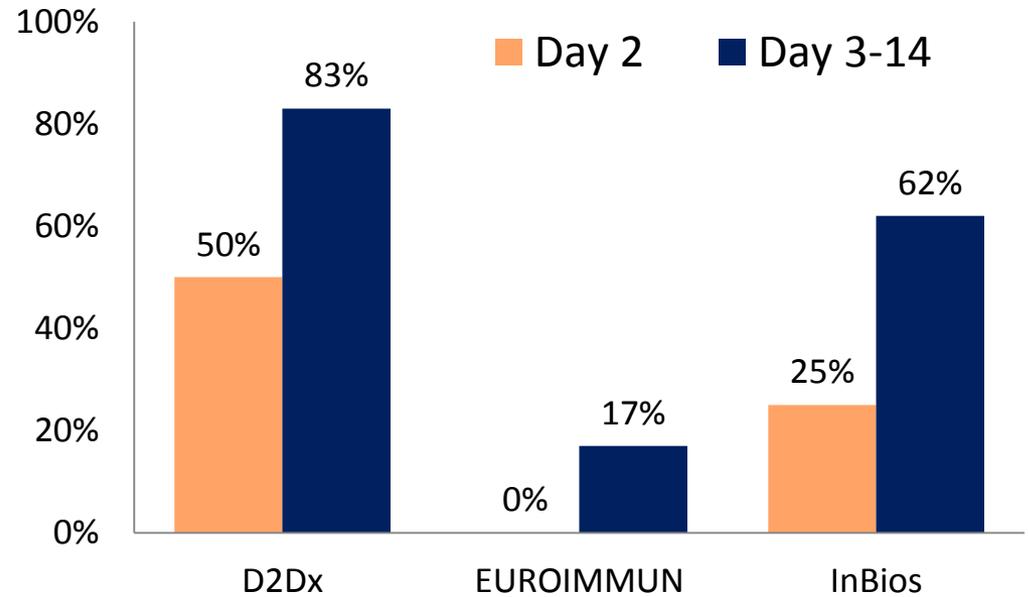
Test scores of ZIKV vs normal control, DENV and CHIKV group



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

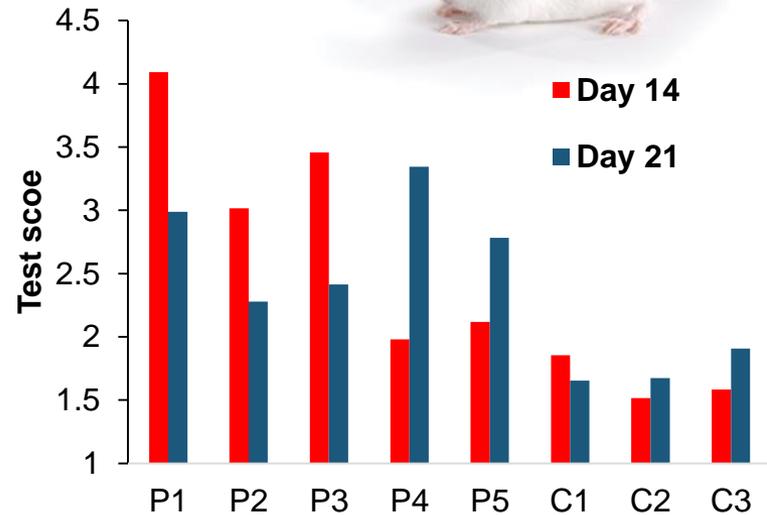
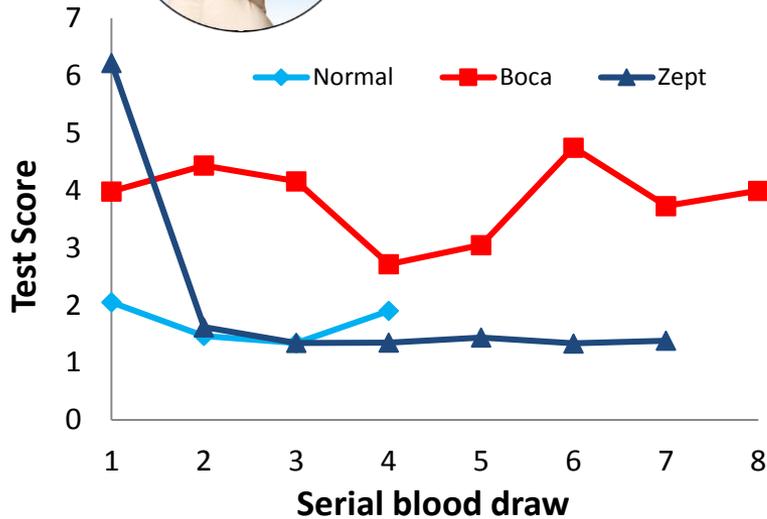
Parameter	EUROIMMUN	InBios	D2Dx™
Sensitivity	Low (after day 7)	Medium (from day 5-7)	High (from day 2, 50%)
Specificity	unknown	Significant false positive (~50% according to CDC reports)	Lower cross reactivity with DENV, CHIKV infection, lower false positive rate (~20%)
Speed	5-7 hours (not including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

Faster

Cheaper

More sensitive

Second test: determine the active status of ZIKV infection



ZIKA VIRUS

Microcephaly
Symptoms include below-average head size

Often caused by failure of brain to grow at normal rate

Head circumference measuring less than 31-32cm

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



www.nanodiscoveryinc.com

Orlando, FL

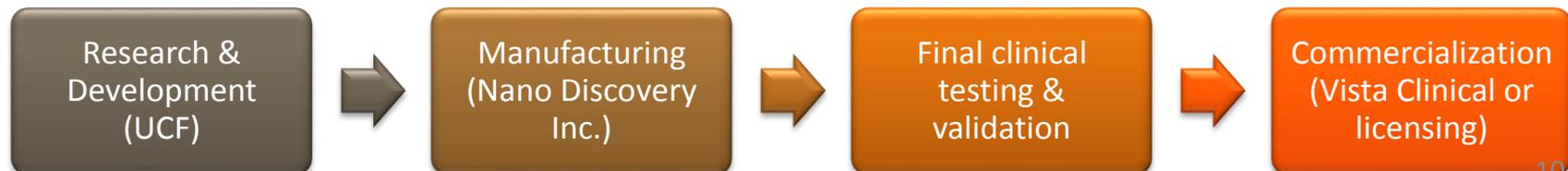
- Startup company, spinoff from University of Central Florida
- President: Dr. Qun Treen Huo
- Woman-owned small business
- Exclusive license right to D2Dx™ technology and diagnostic tests
- Developed and manufactured D2Dx™ assay reader
- Products manufactured locally in Florida
- Launched product to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



www.vista-clinical.com

Clermont, FL

- 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



Thank you!

