

Point of Care Covid-19 Viral Antigen Test Solution NanoDx System: A Real Time POC Platform Solution with FDA Breakthrough Designation

BioDirection

# POINT-OF-CARE

Ton Syste

BENEFITS

· Portable

· Easy-to-Use

· Safe

· Objective

· Fast

· Affordable

PLATFORM DEVICE

• Multiple biomarkers
• Patented algorithm
• Multiple diseases

#### DIGITAL ASSAY TEST

- Finger stick of whole blood
- Nanosensor technology
- Measures targeted biomarkers
- Results in seconds
- No need for reagents
- Rapid application development

#### HANDHELD ANALYZER AND CARTRIDCE • Graphical user interface • Real-time sample analysis • Single-use disposable

#### IOT CLOUD CONNECTIVITY

Software/firmware upgrades
Hospital systems integration
Utilization tracking
Data aggregation
Learning algorithms
QC compliance
Service assistance

#### LOCATION FLEXIBILITY

Hospital
Ambulance
First responder
Urgent care
Doctor's office
Elder care
Patient use

NanoDx C-19 adds simplicity and safety with choice of saliva or finger stick testing

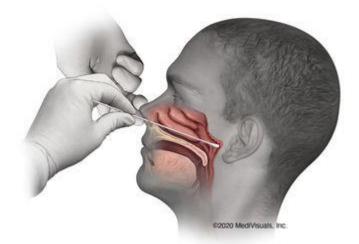


## **Challenges with Throat Swab**

- Deep throat or nose with firm access required
- Standard in PCR tests for Covid-19
- Potential for false negative due to inadequate sampling<sup>1</sup>
  - Undermines confidence in tests
- More PPE required

# **Benefits of Finger Stick or Saliva Sample**

- Easy to administer
- Less room for operator error (layperson)
- Some pain associated<sup>2</sup>
- Less PPE required



1. Harlan Krumholz, MD, Yale University

2. American Diabetes Association





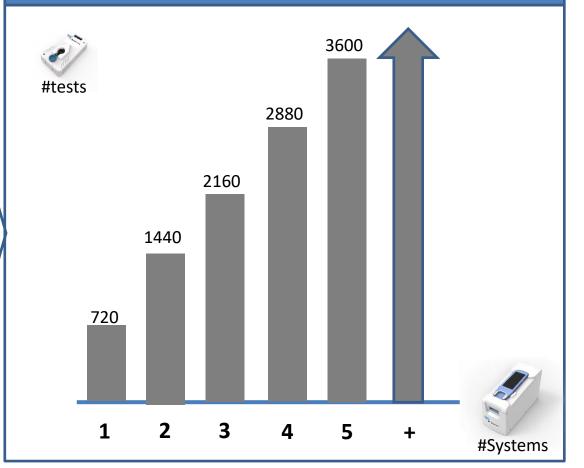




# **Overview of Technology**

- Utilizes nano-wire technology to simplify test to measure electrical current vs. reagent complexity of an ELISA and incubation associated with PCR
- Test done anywhere sample draw occurs
- Removes wait time of transport to lab and return of result. Patient receives result at time of draw
- Utilizes either whole blood finger stick or saliva
- Test result in 2 minutes, total TAT under 5 minutes
- Delivers "Positive" or "Negative" result verified via EUA guidance for Antigen test\*
- COVID-19 application requires no changes to platform design (analyzer nor cassette)
- NanoDx platform technology FDA designated as a breakthrough technology and being fast tracked for approval of the Traumatic Brain Injury use

# 720 tests and notifications per system/day



\*final performance accuracy to be verified upon completion of EUA test protocol, this is not an FDA cleared test

NanoDx COVID-19 addresses the key testing need: Speed and High Sensitivity



# NanoDx Technology Advantages

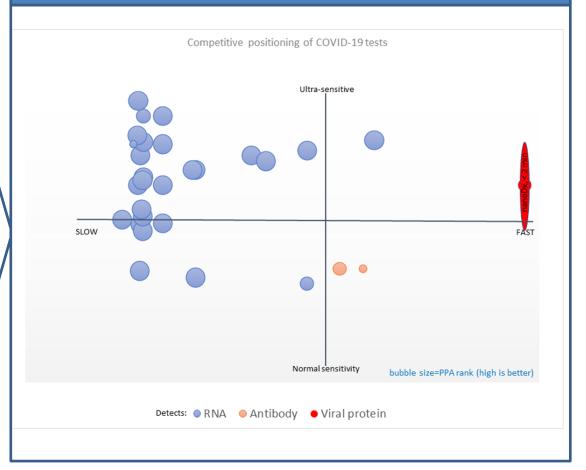
## Key Points on Current Tests Available

- 1. Predominance of current high sensitivity tests are based on PCR and are performed in lab setting
  - 2-hour transit time with 2-hour test time
- 2. Current high-speed POC tests on the market are low sensitivity

## NanoDx addresses the need for speed and accuracy

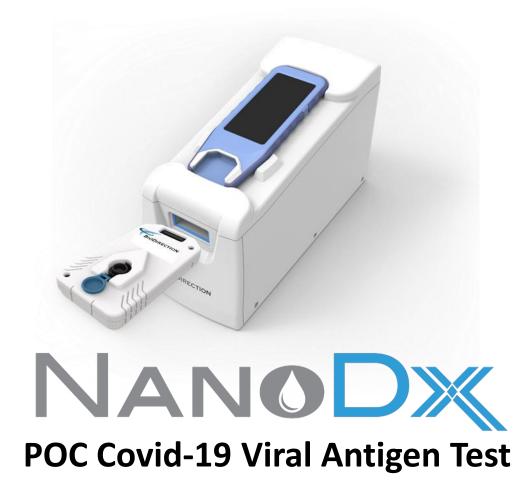
- NanoDx POC sample to result in under 5 minutes, test time in under 2 minutes.
- All at the POC and with high sensitivity without sample preparation nor amplification - simple POC

# Performance vs. Competition



\*final performance accuracy to be verified upon completion of EUA test protocol, this is not an FDA cleared test





- Built on FDA breakthrough designated technology
- Easy to Use any where it is needed
- Blood or Saliva sample reduces discomfort, transmission and improves accuracy
- Each system delivers up to 720 completed and patient notified results a day in under 5 minutes per test

# **True** Point of Care allows the world to get back to business





Work Screen

School Screen

**Sports Screen** 

- Infections will continue, we have just slowed the growth
- Pre-screening may be a reality for large groups to gather
- Back to Work / School Screening
- TSA screening for viruses
- Stadium screening
- Company event screening
- 4 hour or 10-minute tests are not effective



The Near Future: NanoDx leverages IoT to assist towards a return to normalcy; gain access to work, school, events with proof





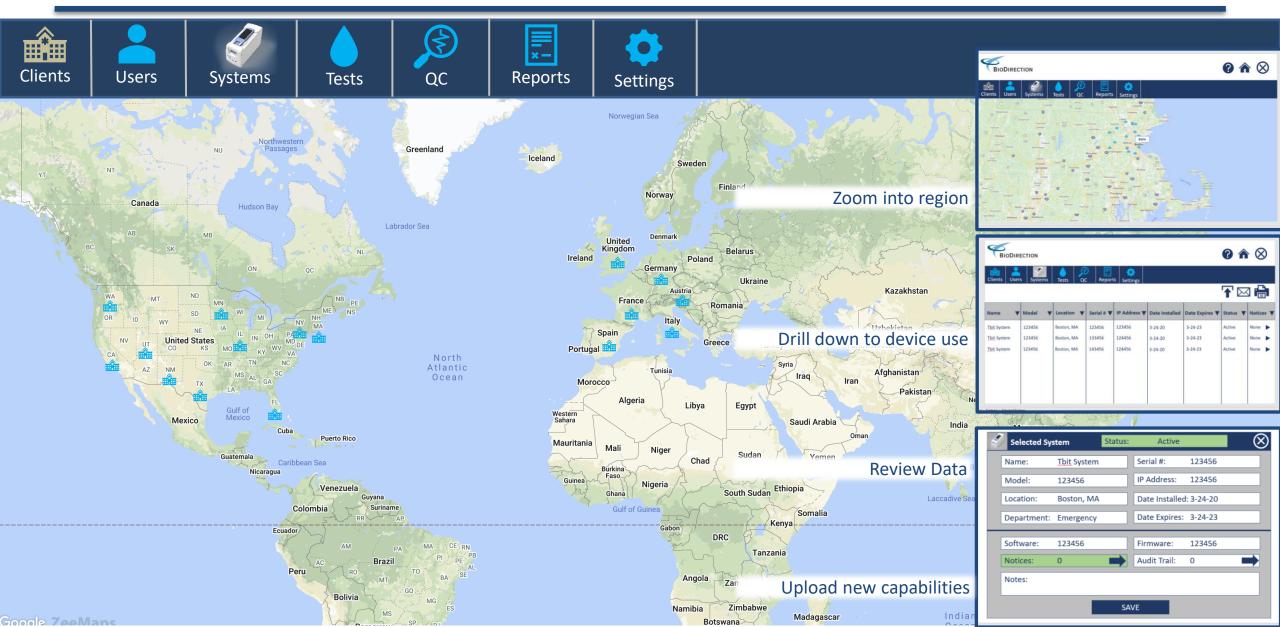


- Scan ID / Image for Authentication
- Ties into IoT
- Ties into Web Portal for CDC
- Easy to track Employee Status

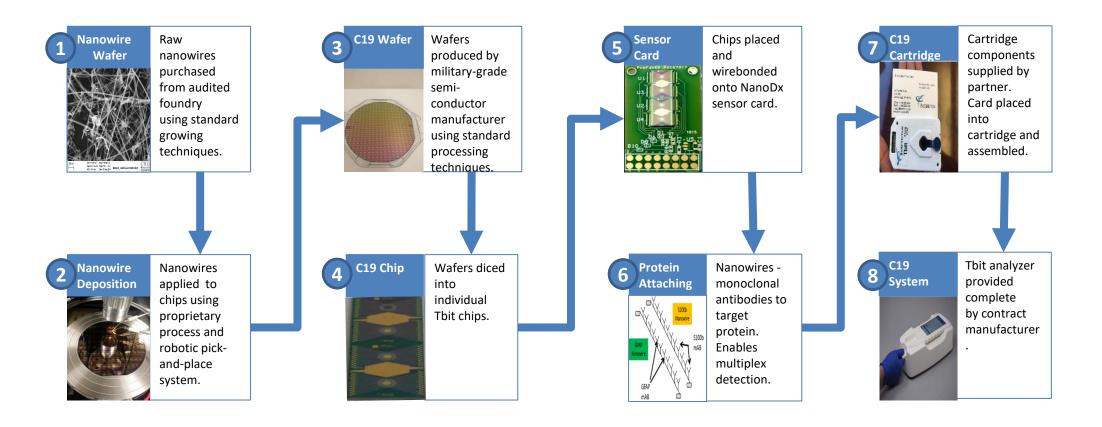
Steve (left) tested positive and has proof on his phone and is exempt from work Stephanie (right) tested negative and can gain access to the conference

# IoT & Web Portal System future option tracks data





Scale up of validated 8-step cartridge manufacturing process does not require a change to our current technology nor materials for scale up. Scale up is solely reliant on installation of additional manufacturing equipment

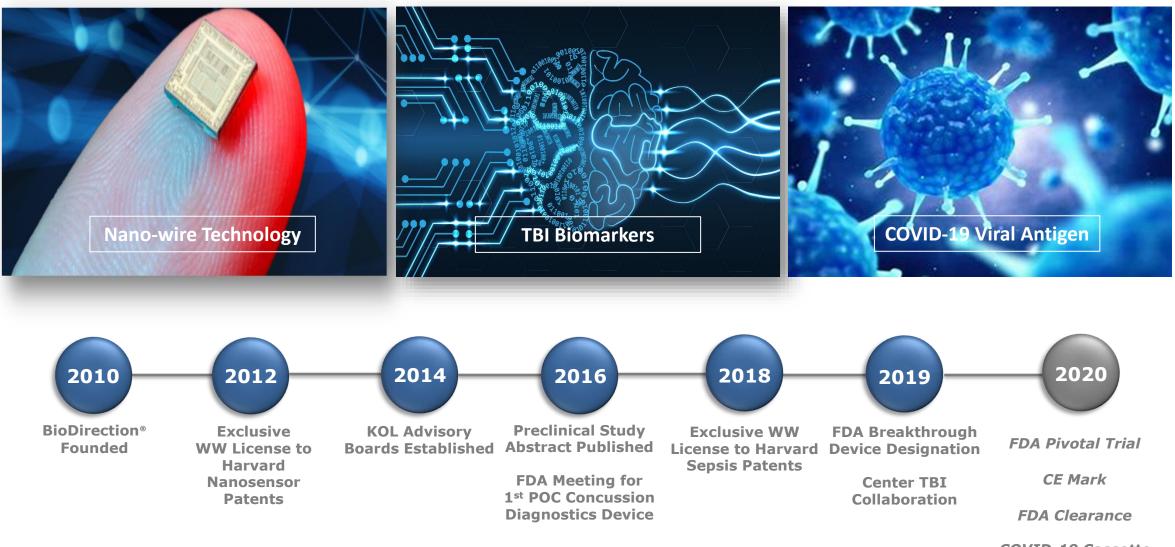




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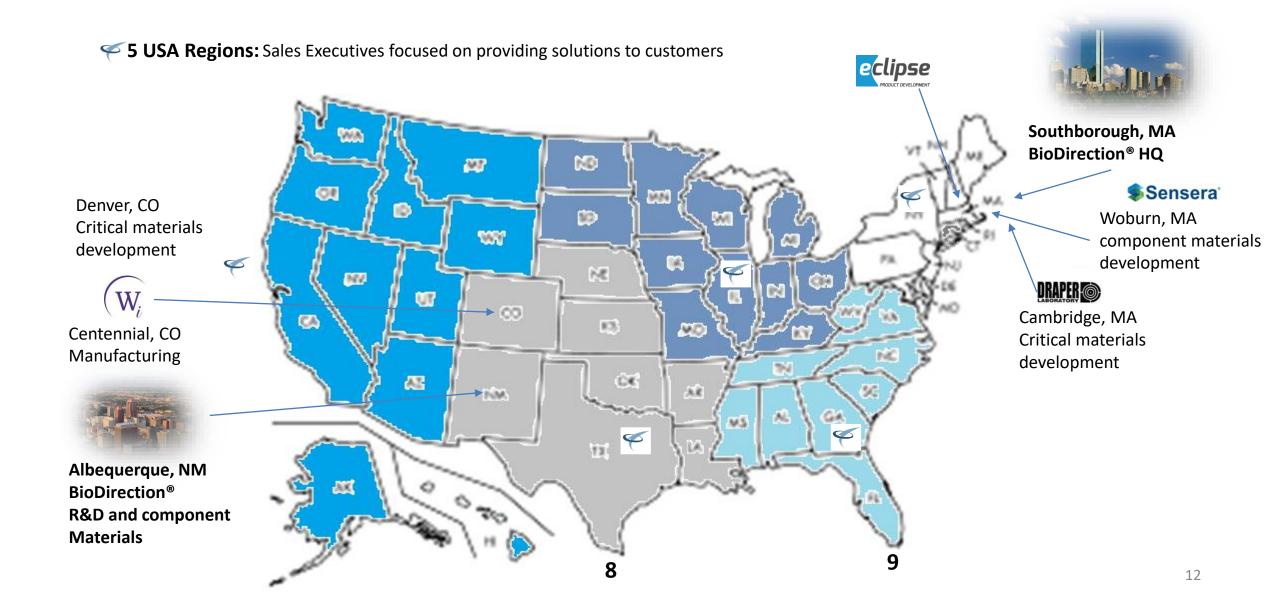
# **NanoDx: A Company History of Innovation**





COVID-19 Cassette Development





# **An Experienced Leadership Team**



## Sharad Joshi President & CEO

Global entrepreneurial medical devices CEO with 34 years of experience and a strong track record of driving rapid global growth and laying the strategic foundations for sustained success.

#### James Wylie Executive Chairman

Proven business leader with 35 years of executive management experience in emerging and global businesses in both public and private sector companies.

#### Sergey Dryga Chief Scientific Officer

Experienced product development leader with expertise in nanotechnology, molecular biology, protein engineering, system integration, and electrical and software engineering.

#### Tony Tremaglio Vice President of Marketing

Entrepreneurial medical device marketing leader with a successful 27-year track record across all stages of global market and product development in emerging to Fortune 500 companies.

## Mike Sampson Vice President North America

Accomplished global commercial leader with a successful 26-year track record in strategic sales, business development and marketing management within the medical device and diagnostics point-of-care IVD industry.

#### Marco Witteveen Vice President Europe

Accomplished commercial leader with a successful 27year track record in strategic sales & marketing management within the medical device & diagnostics point-of-care IVD industry worldwide.