



# The Future Of Near Patient Testing Using Passive Wireless BAW Sensors

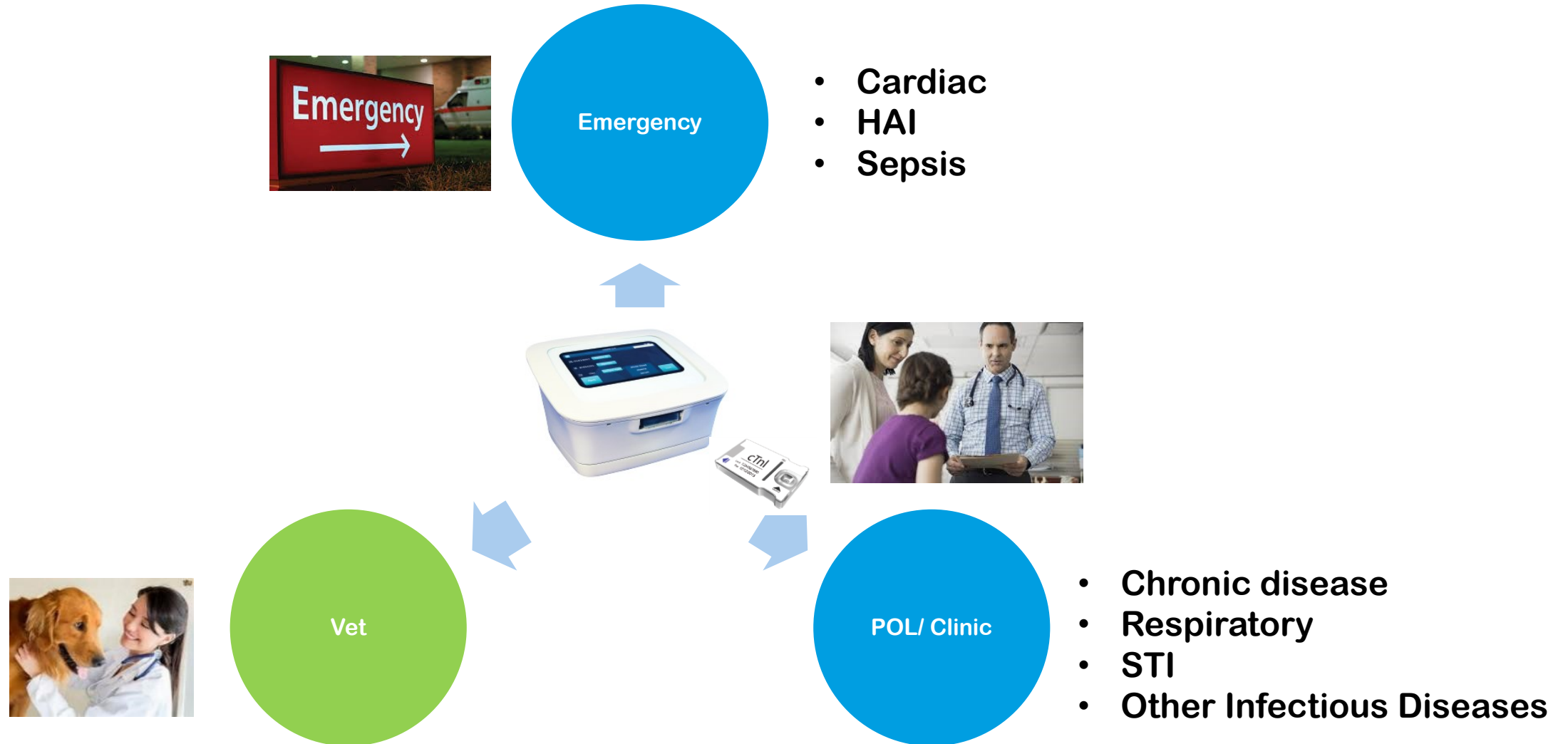
Ubiquitous Deployment of Point of Need (PON) Platforms

# Qorvo Biotechnologies Overview

*Leveraging Qorvo technology into new markets*

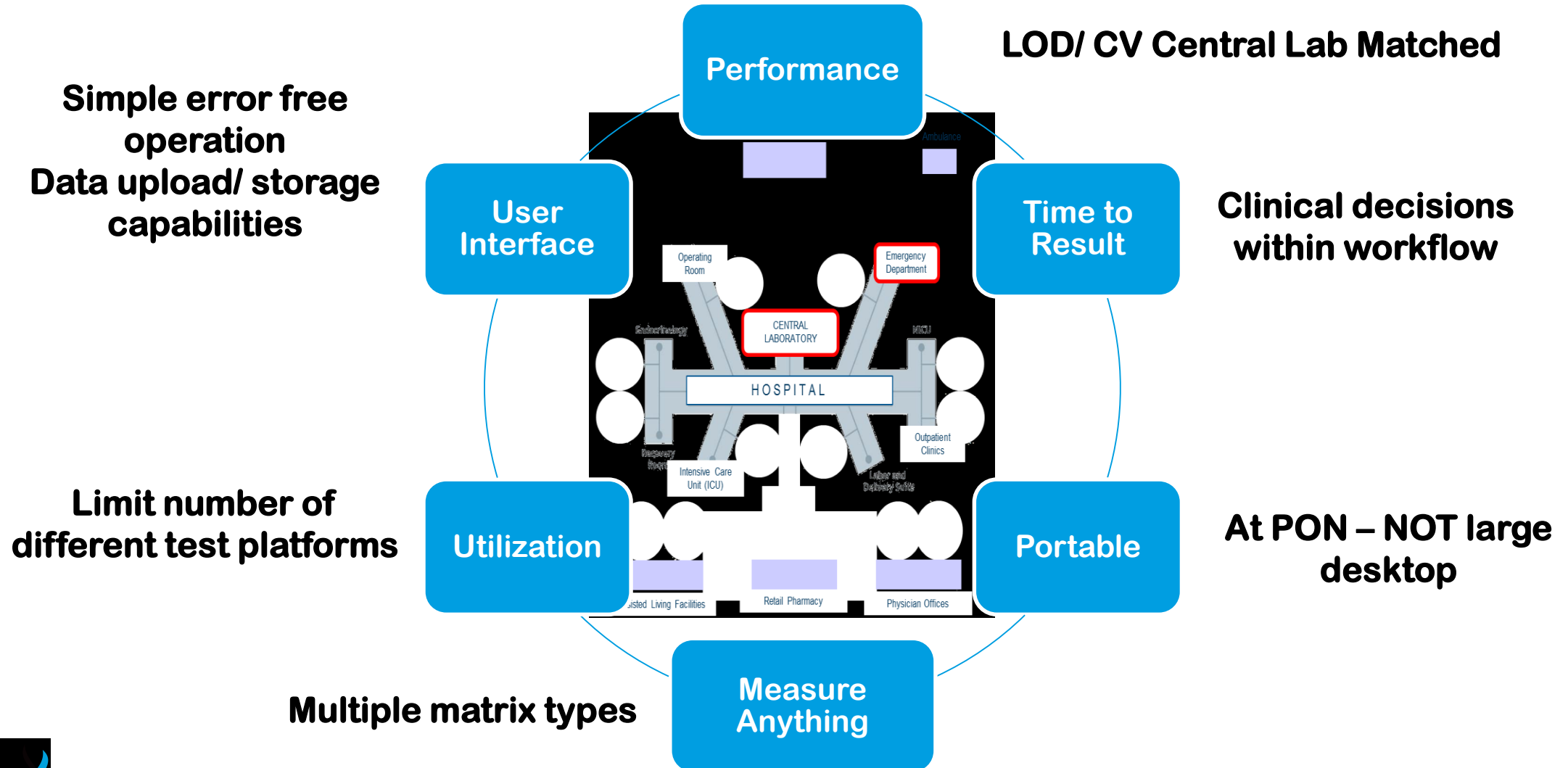
- Strategic investment by \$9B market cap company (NSDQ: QRVO)
- Developed differentiated sensor based on industry-standard electronics and fluorescence-free biochemistry
- Over 30 technical specialists in diagnostic instrumentation, assay development, device fabrication, and biosensor science
- Near verification and validation with industry-leading ISO13485 cartridge and instrument supply chain partners
- Engaged in central lab predicate testing programs
- Owner of solid patent portfolio for overall solution

# Single Platform Addressing All POC growth opportunities



# Near Patient Testing Problem

True Central Lab Matching Needed Across the Clinically Relevant Spectrum



# Qorvo Biotechnologies Platform

*Accurate Enough for the Lab - Simple Enough for Anyone*

- Rapid Time to Result (<15 min) with Enhanced LOD and CV
- Universal Cartridge/ System Platform
  - Immunoassays (<10 pg/ml), Molecular Diagnostics
  - Liquid Sample Flexibility- whole blood, serum, plasma, saliva, urine, stool
  - Multiplex Arrays
- First commercial contract with non-human partner

1 Add Sample



2 Insert Cartridge

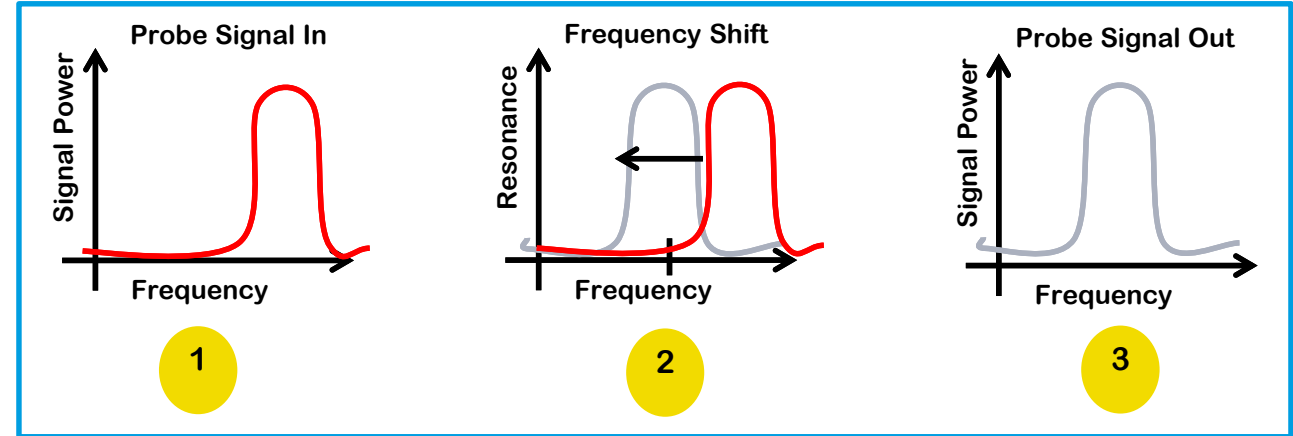
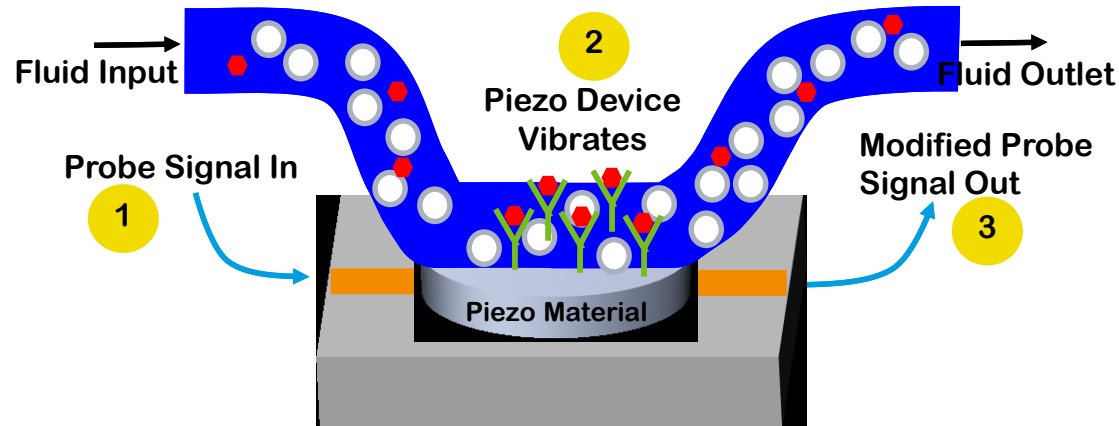


3 Report Result



# Qorvo Liquid Biosensor

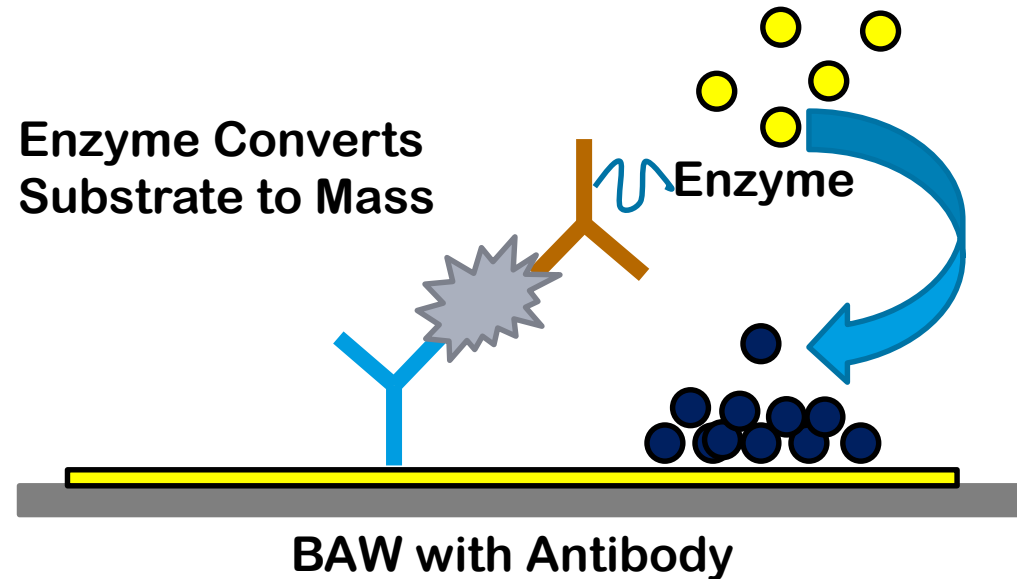
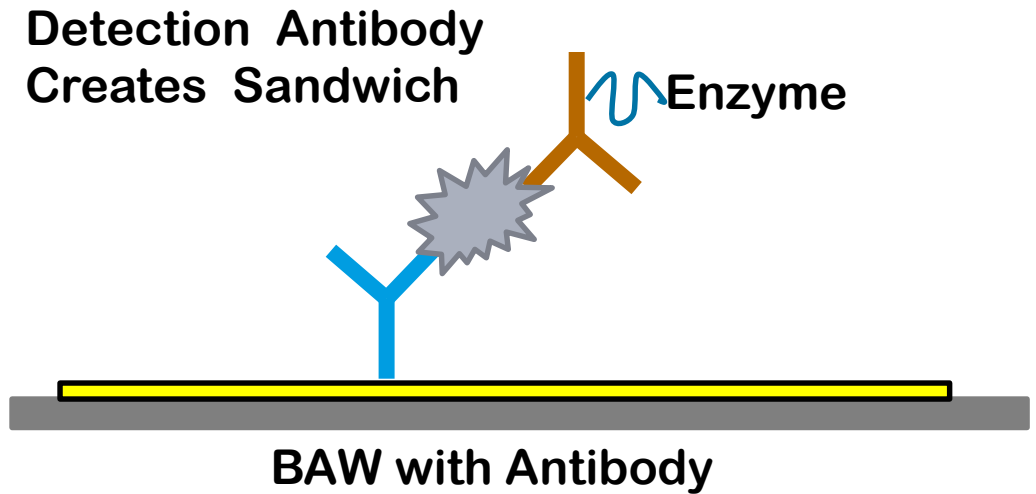
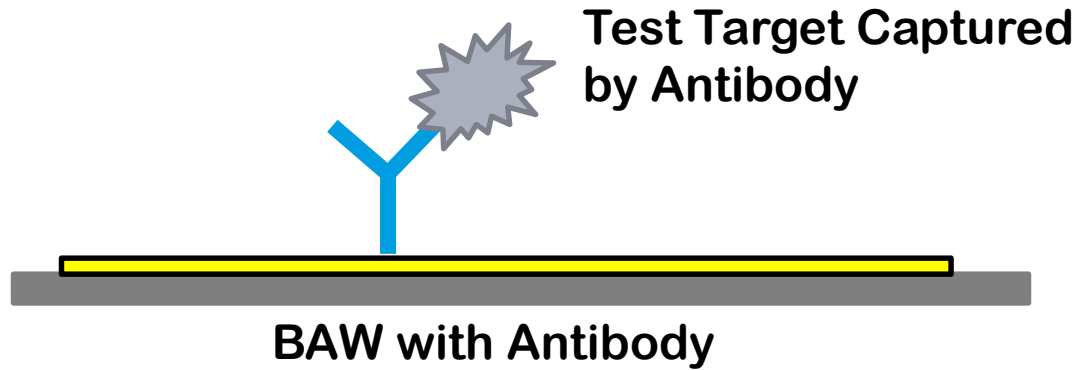
Fluorescence-free detection core produced in high volume



- Test-Reference Platform
- Sensitivity (LOD) increases with frequency
- Enzyme reaction used to increase sensitivity further
- Surface only reactions drive industry leading CV's
- Fundamental technology enables millions of cell phones worldwide

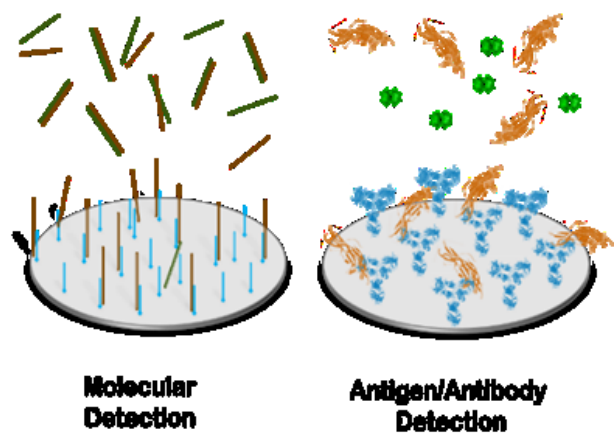
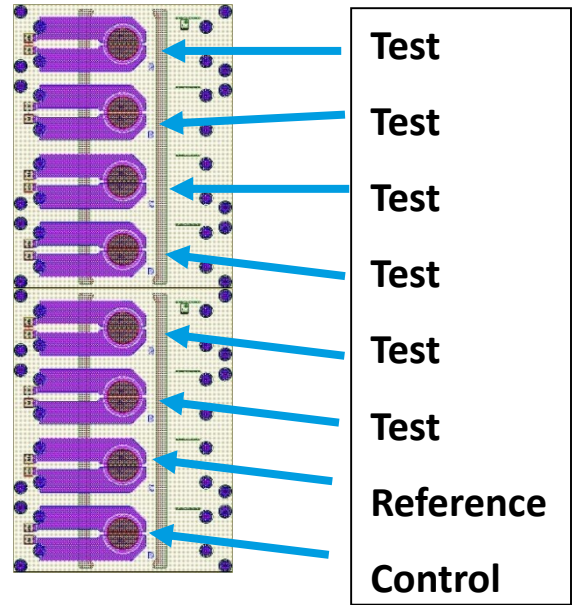
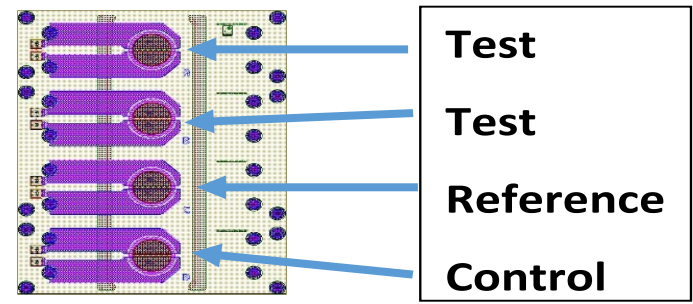
# Enzyme Immunoassay

## Sandwich Assay- industry standard



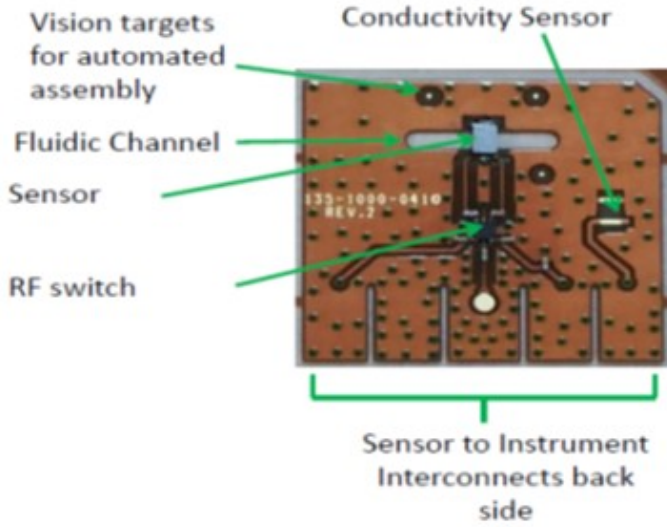
# Sensor Module Components

4 Resonators As First Product, 8 To Follow



Started w/ proteins,  
transitioning to Molecular

*BAW biosensors coated with either an oligo or antibodies for nucleic acid or protein detection*



*BAW die and RF circuit board assembly*



# Assays: Representative Feasibility Data

## Data spans landscape of matrix types

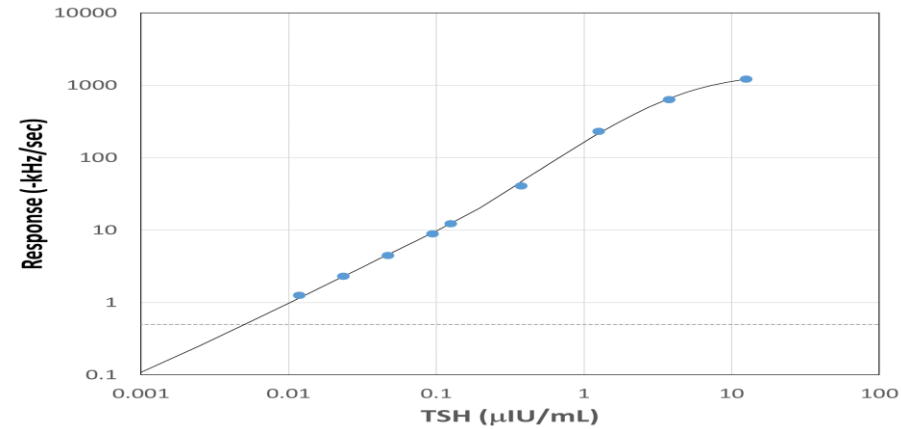
- Sandwich Assays
  - Cardiac Troponin I- *in development*
  - NT-proBNP- *in development*
  - Hepatitis C (HCV)- *in development*
  - Procalcitonin- *in development*
  - Thyroid Stimulating Hormone (TSH- 0.005 mIU/L)
  - Parathyroid Hormone (PTH- 5 pg/ml)
  - Nerve Growth Factor (NGF- 6 pg/ml)
  - Influenza A+B
  - *C.difficile*
- Competitive Assays
- Nucleic Acids- *E.coli, MRSA, NG- in R&D*

# Protein- Platform (Human-TSH Serum)

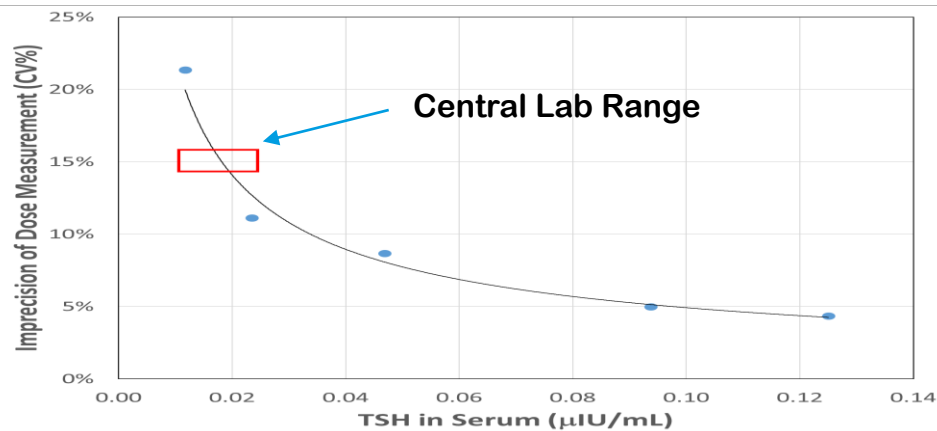
## *True Central Lab Performance at PON for LOD, LOQ, and Predicate Correlation*

- LOD 0.005 uIU/ml; 0.4 pg/ml
- LOQ 0.018 uIU/ml; 1.5 pg/ml
  - Central lab range 0.010-0.020 uIU/ml
- Roche Cobas e601 predicate comparison
  - Slope 1.18
  - 94% correlation

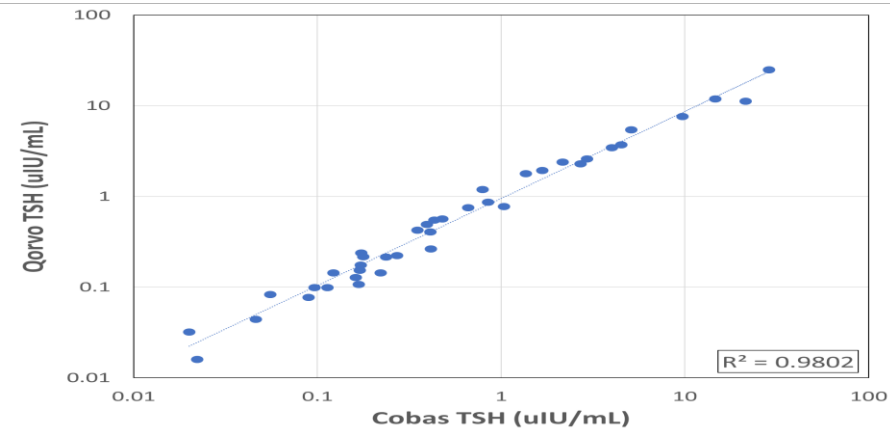
### Analytical Sensitivity (Limit of Detection)



### Functional Sensitivity (Limit of Quantification)



### Predicate Correlation

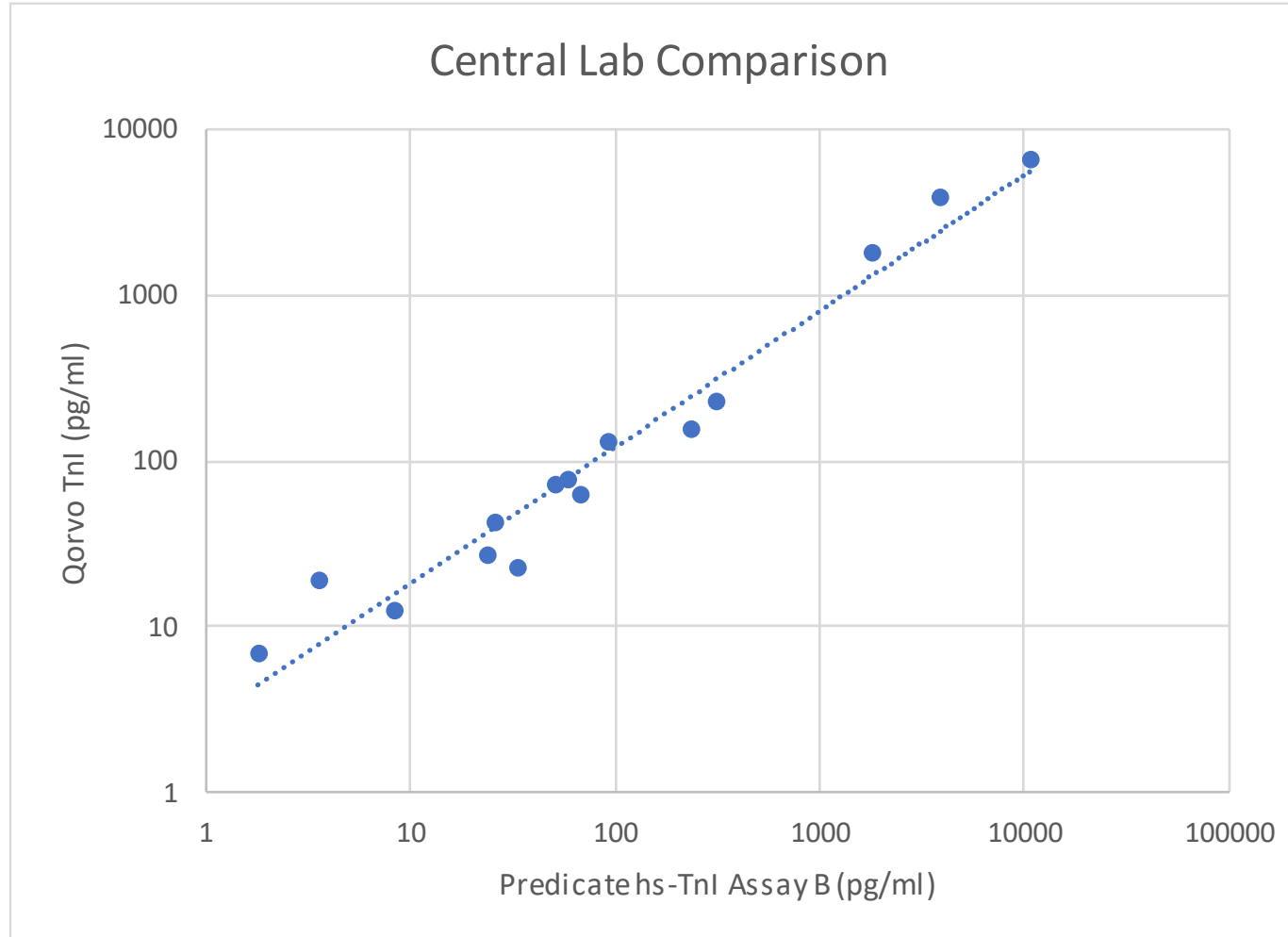


Purified human TSH spiked in TSH/T4/T3 depleted  
Normal Human Serum

Excellent correlation to Roche Cobas e601 central lab  
predicate analyzer

# cTnI LiHep Correlation Study- Plasma

Good Correlation To Predicate Central Lab Across Dynamic Range

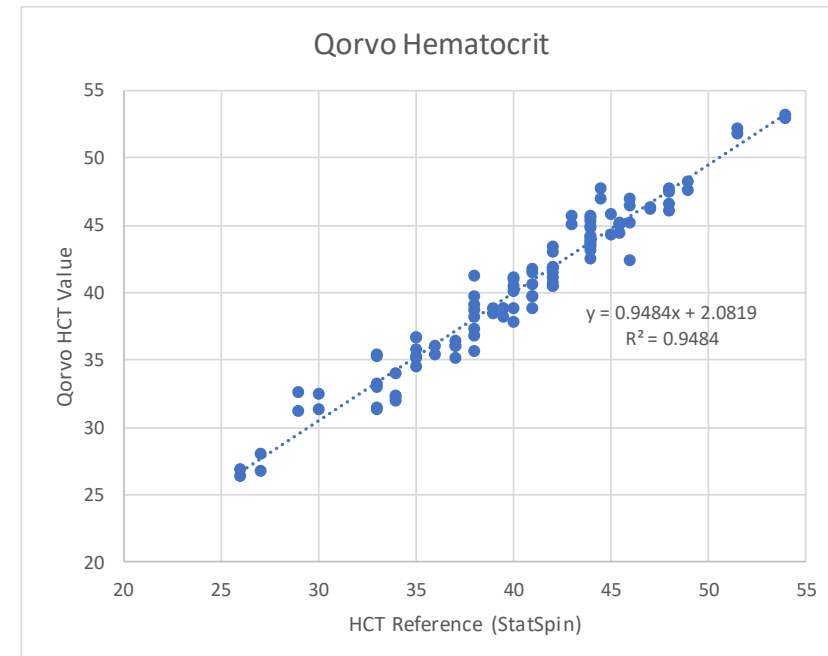
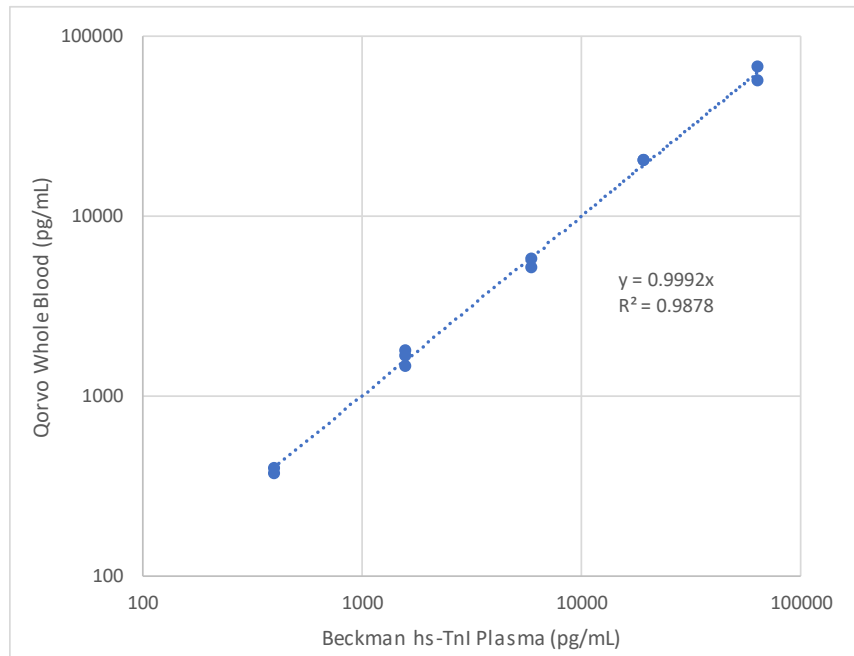


Strong dose matching to samples below 99<sup>th</sup> percentile cutoff

# cTnI Whole Blood Correlation Study

## Qorvo Has Achieved Successful Integration Of On-Chip HCT Measurement/ Correction

- HCT measurement and correction is critical to cTnI POC device success
- Qorvo's electrical detection has enabled us to develop an on-chip measurement of HCT that can correct for it in whole blood samples
- Excellent correlation to predicate central lab tools as well as industry gold standard measurement techniques

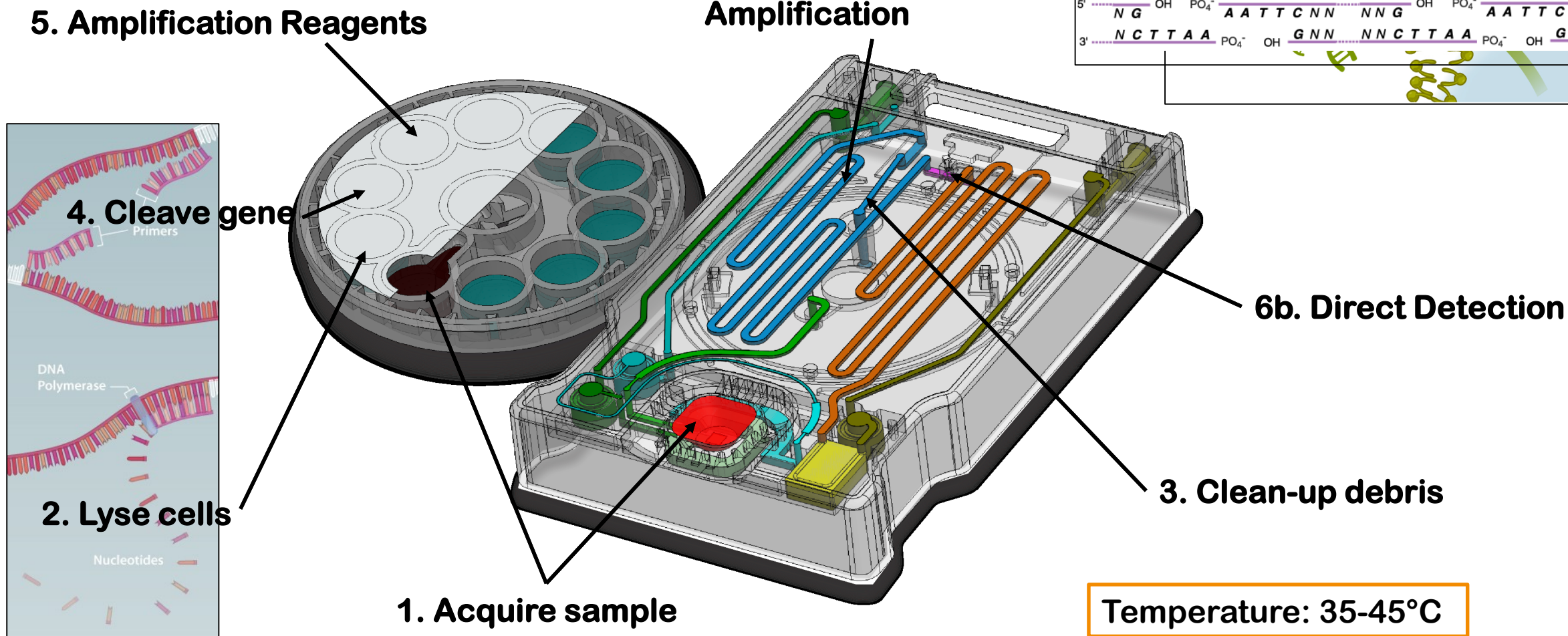


# Platform Growth Opportunities



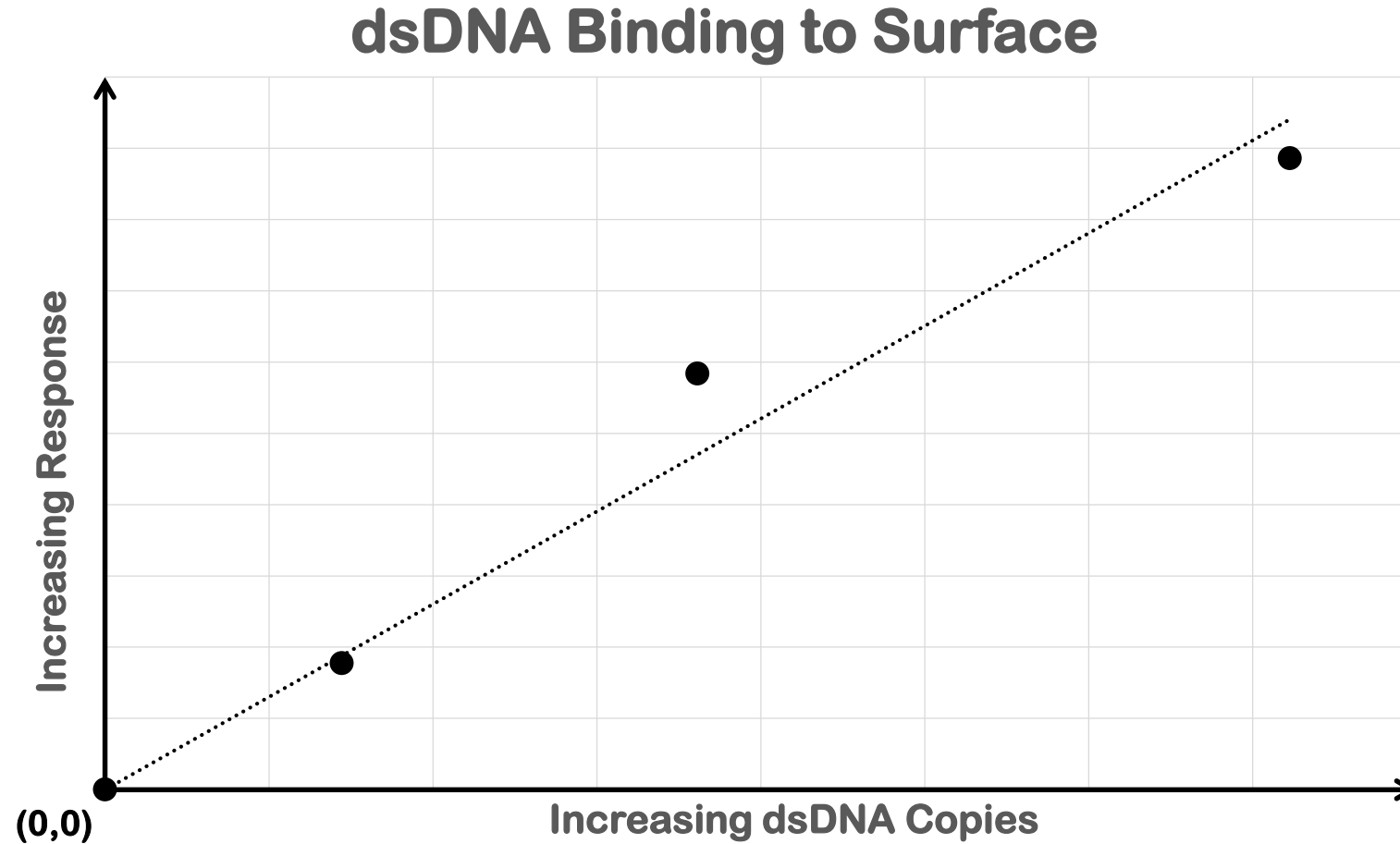
# Process

## Cartridge design pathway for molecular assay



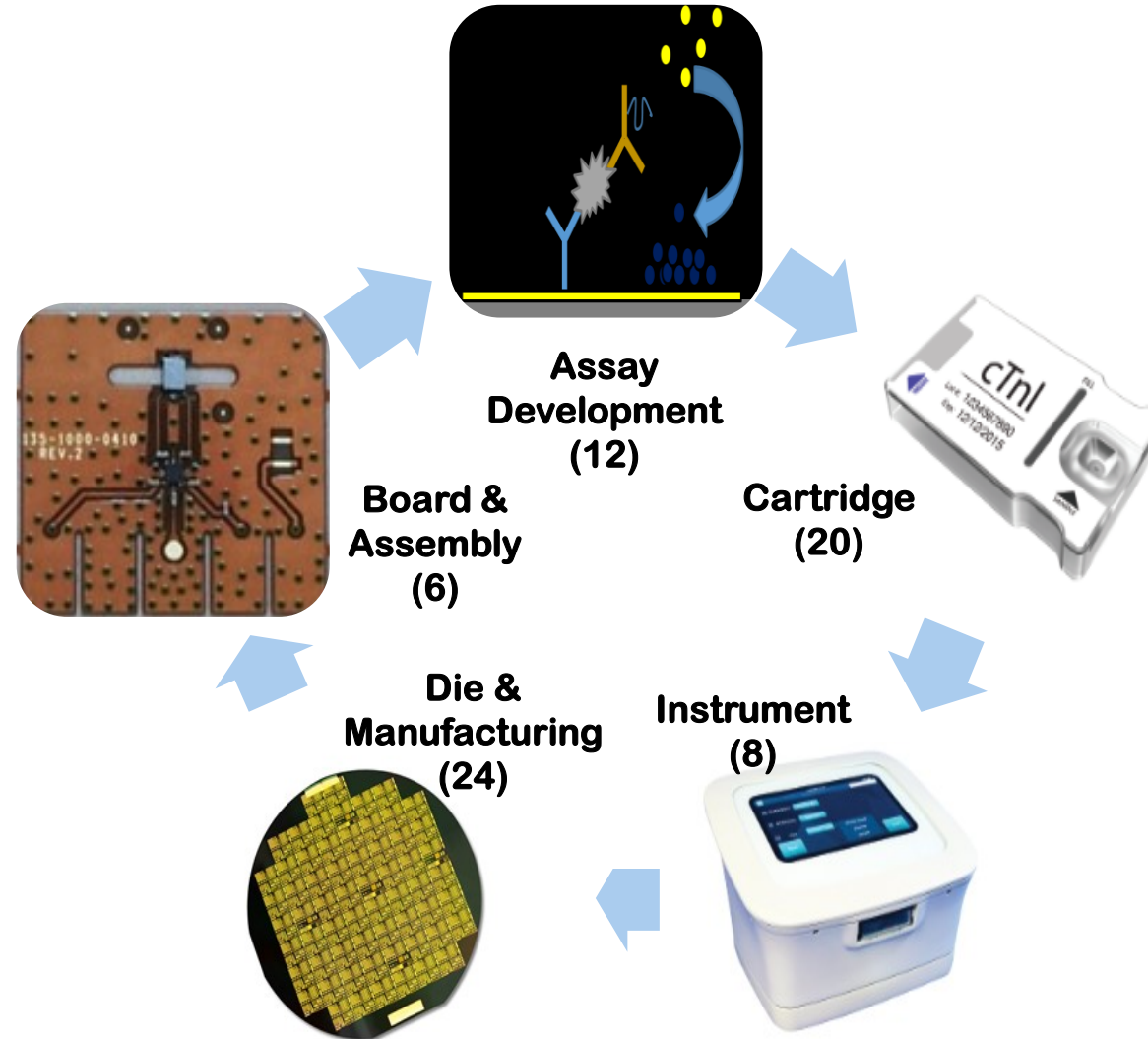
# Direct Detection of dsDNA

Detection of isothermal amplified dsDNA with Qorvo PON system



# IP Mapping- 70 Issued and Disclosed Patents

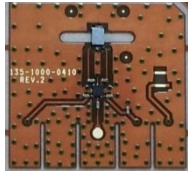
Defensible Differentiation In All Key Areas





# Supply Chain- Capable of Immediate Scaling

High-Volume Industry Standard Processes For Product and Revenue Ramp



Die Manufacture/  
Board Assembly



Cartridge Assembly-  
Includes Qorvo Board

ISO 13485  
3<sup>rd</sup> Party Partners



Instrument Assembly



Production Design Transition Active Throughout Supply Chain

# FIND HepC Award

## Qorvo Biotechnologies Provides Platform For Next Gen High Sensitivity Immunoassays

- Problem
  - 90M active infections worldwide → ~ 70-80% in Low-Middle Income Countries (LMICs)
- FIND- must enable access to diagnosis at POC
  - Serology tests too variable
  - Molecular tests too expensive and only viable at central labs
- Goal- Need a high sensitivity immunoassay platform capable of performance levels not seen before in this space
- Qorvo Biotechnologies awarded feasibility phase after significant FIND diligence
- Validates performance differentiation
- Opened LMIC market channel



# Summary

- **Paradigm shift in fluorescence-free testing is upon us**
  - True central lab performance at near patient setting
- **Easy to use - user adds sample, all other steps performed by the instrument**
- **Workflow compatibility with ED and Dr. Office screening**
- **Completed tech validation and product definition (>45k cartridges tested)**
- **Near verification and validation with industry-leading ISO13485 cartridge and instrument supply chain partners**
- **First commercial contract signed with non-human partner**
- **Unique opportunity for OEM partners to collaborate and drive adoption**

