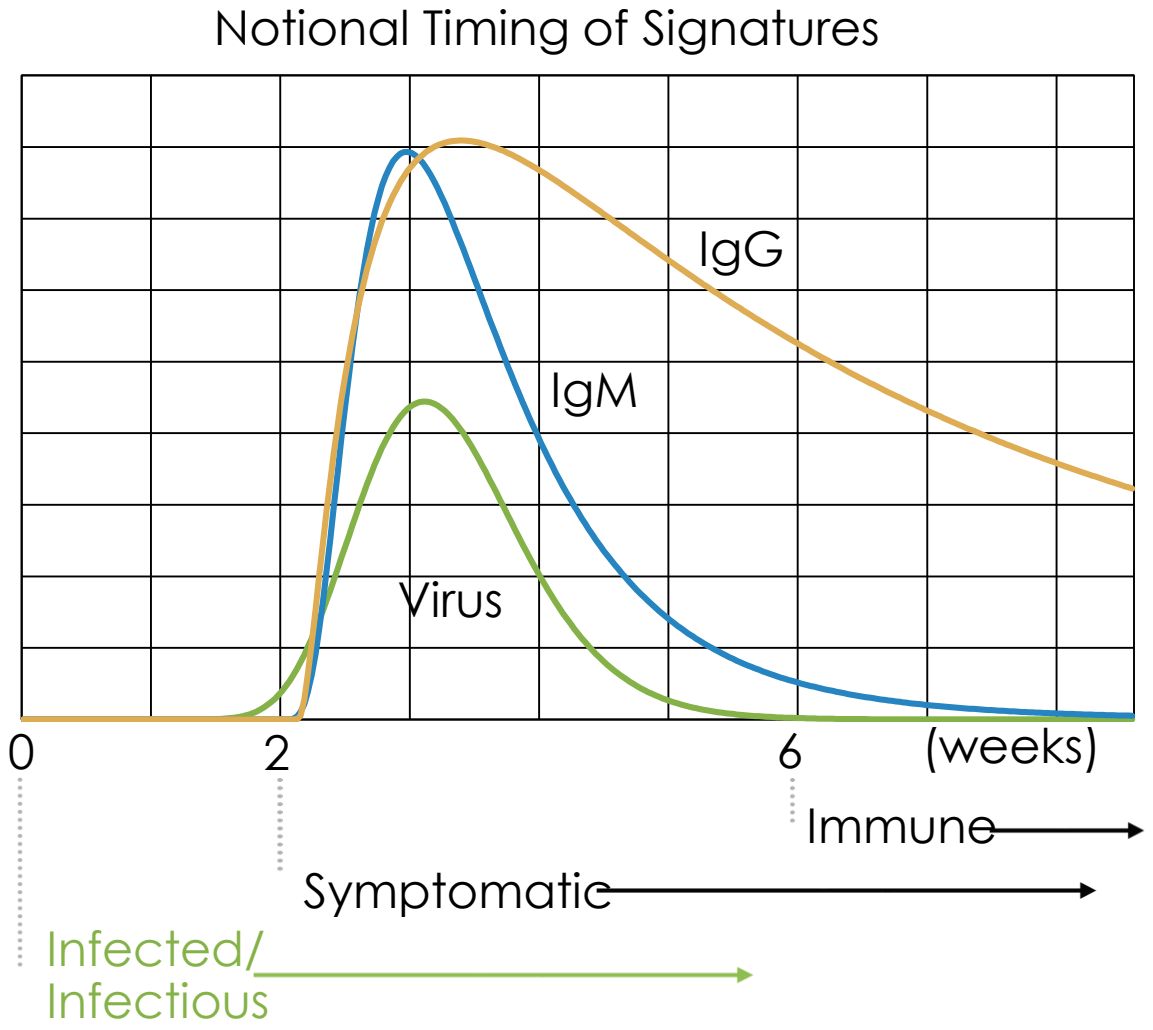
NVBL COVID-19 Testing R&D

J. Patrick Fitch
Project Lead

October 28, 2020

Our R&D Supports Increased Test Capacity and Functionality

- Goals:
  - Diagnose SARS-CoV-2 virus infection
    - Antigen detection (molecular tests)
  - Determine recent or past infection (may correlate with immunity)
    - Antibody detection (serological tests)
- Approach: R&D to
  - Increase availability of established tests for virus detection
  - Develop and demonstrate new protocols and instruments
  - Support collaborating stakeholders (FDA, CDC) with additional options



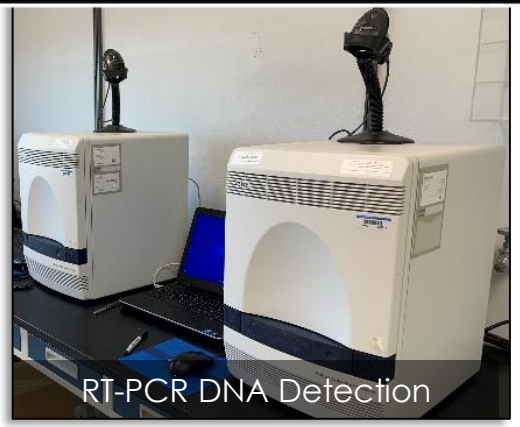
Our R&D Helps Establish Alternative Reagents, Protocols, and Instrumentation for Nucleic Acid Tests

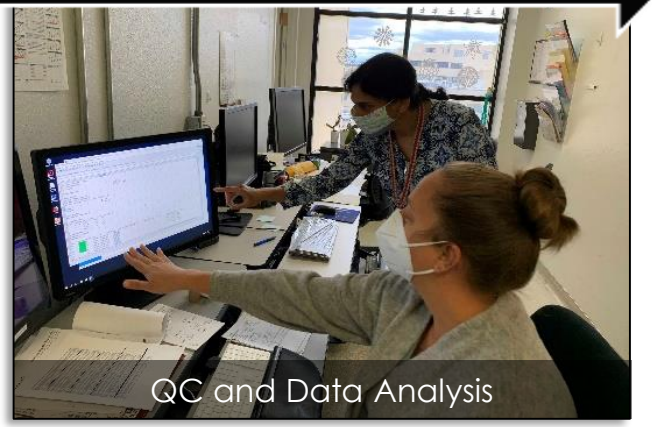
Canonical nucleic acid testing protocol


Collection and Transport


Sample Accession


Virus Extraction


RT-PCR DNA Detection

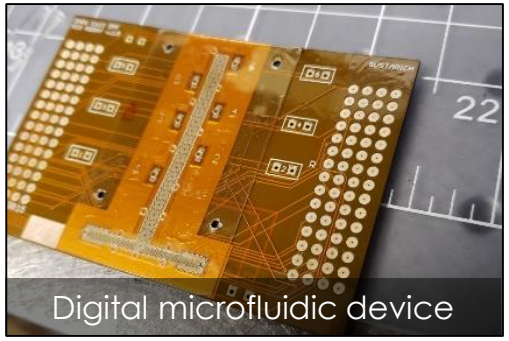

QC and Data Analysis

Alternatives

- Nasopharyngeal swabs
- Sputum
- Breath
- Viral transport media (4)
- Inactivation efficiency

- Pooling studies
- Automation
- Extraction (3)

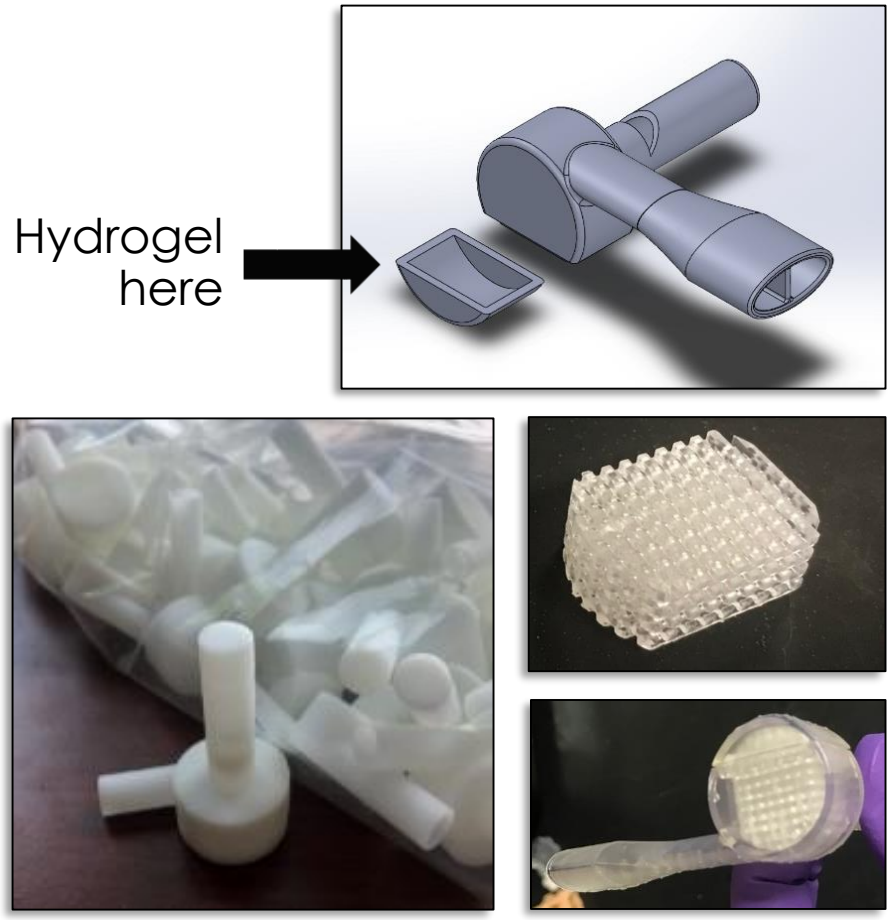
- Test validation
- Target erosion
- New RNA targets
- FDA Test Panel
- Isothermal amplification
- Digital Microfluidic Device for droplet PCR assays


Digital microfluidic device

Targeting Samples from Exhaled Breath

Controlled exhalation onto a hydrogel bed will allow capture of cells, bacteria, fungi and live virus

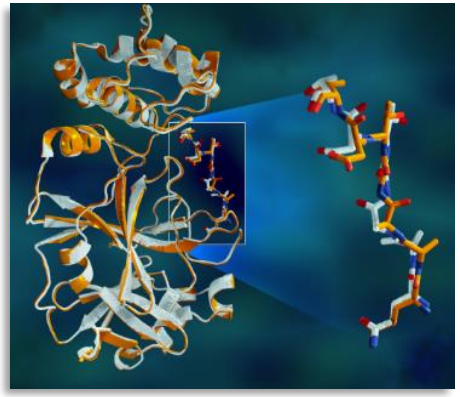
- Keeping it simple for the end user
  - Insert (hydrogel) is housed in a 'whistle'
  - Whistle geometry can be optimized
  - A phone or web app can be used to
    - Provide cues to users
    - Monitor patient variation
  - Hydrogel is analyzed
- Additively manufactured whistles are being tested at UTHSC



NVBL COVID-19 Testing R&D Accomplishments

Identifying new diagnostic targets (>30 PDP submittals)

- Room temperature SARS-CoV-2 Main protease (M^{pro})
- Close coupling of Testing Team, user facilities, and academia



M^{pro} structural differences between room temperature (orange) and cryogenically frozen (white) structure

Data to support national guideline decisions

- Identification and characterization of potential contamination
- Evaluation of sample pooling approaches (lab and field)
- Assessment of multiple viral transport media and protocols
- Evaluation of inactivation and extraction for safety and efficacy
- Assessment of established test panels for other applications

CLIA-registered labs for reference assay support of R&D and mission accomplishment

- FDA-authorized EUA200481 for assay

Protocol evaluation input to national guideline decisions


#NATLABSINTHEFIGHT