RADx Tech Overview and Market Analysis

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POCTRN

CIMIT®
Consortia for Improving Medicine
with Innovation & Technology

NIH National Institute of Biomedical Imaging and Bioengineering

We need more covid-19 tests. We propose a 'shark tank' to get us there.

By **Lamar Alexander** and **Roy Blunt**

Lamar Alexander (R-Tenn.) is chairman of the Senate Health, Education, Labor and Pensions Committee. Roy Blunt (R-Mo.) is chairman of the Senate's health appropriations subcommittee.

There is no safe path forward to combat the novel coronavirus without adequate testing. To contain covid-19 and persuade Americans to leave their homes and return to work and school, the United States will need tens of millions of diagnostic tests. Deborah Birx, the coordinator of the coronavirus task force, says there are now 1 million tests available weekly; by mid-June, there will be 2 million to 2½ million available.

That is impressive — but not nearly enough. We should squeeze every test possible out of current technologies, but we need tens of millions more to really get a handle on how far and wide this disease has spread. This demand will only grow as the country goes back to work and some 100,000 public schools and more than 5,000 colleges reopen, we hope, in August.

Rapid Acceleration of Diagnostics (RADx)

Francis Collins Larry Tabak Rachael Fleurance Rick Bright Tara Schwetz Jill Heemskerk

RADx Tech – $500M

Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Advanced Technology Platforms (RADx-ATP) – $230M

Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput – create ultra-high throughput machines and facilities

RADx Underserved Populations (RADx-UP) – $500M

Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations

RADx Radical (RADx-Rad) – $200M

Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

$1.5B to NIH; $500 Million to NIBIB

The **NEW ENGLAND JOURNAL of MEDICINE** ™

SPECIAL REPORT

Rapid Scaling Up of Covid-19 Diagnostic Testing in the United States — The NIH RADx Initiative

Bruce J. Tromberg, Ph.D., Tara A. Schwetz, Ph.D., Eliseo J. Pérez-Stable, M.D., Richard J. Hodes, M.D., Richard P. Woychik, Ph.D., Rick A. Bright, Ph.D., Rachael L. Fleurence, Ph.D., and Francis S. Collins, M.D., Ph.D.

The first reports of an unusual cluster of pneumonia cases in the city of Wuhan, China, emerged in December 2019, heralding a global pandemic. As of July 13, 2020, more than 3.3 of RADx and their goals, and we end with a review of the challenges ahead.

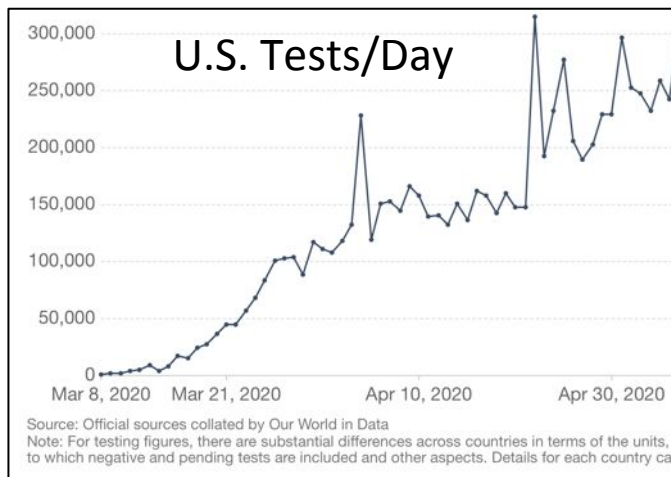On April 24, 2020, Congress appropriated $1.5 billion, from the $25 billion provided in the

OASH

RADx Tech & ATP Goals

1) Expand COVID-19 Testing Technologies: *Number, Type and Access*
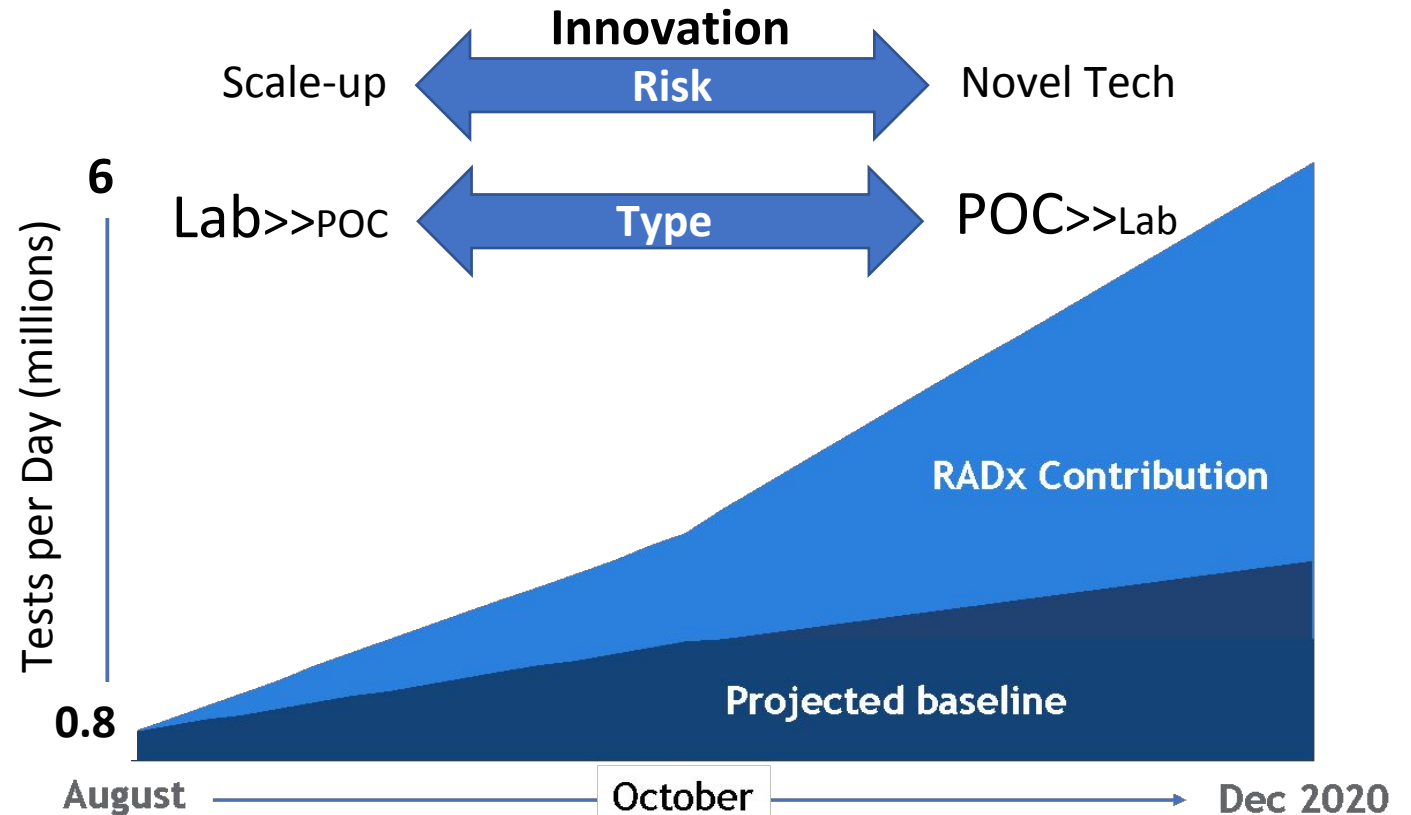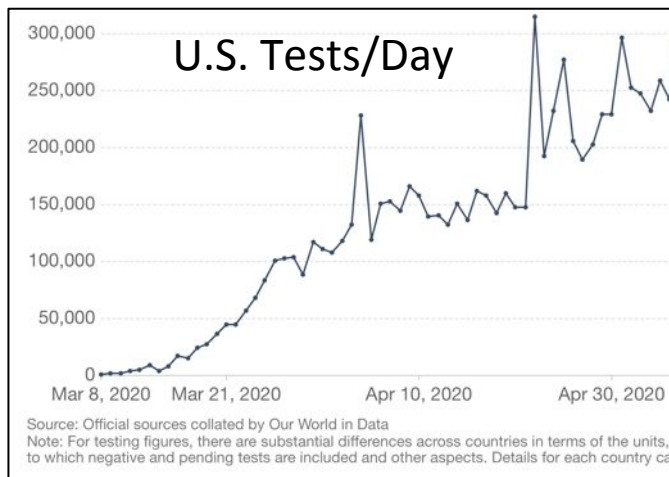**2) Optimize Performance:** *Technologic and Operational; Match Essential "Use Cases"*

Test Settings

- Home-based
- Point of Care (POC)
- Laboratory (CLIA, research)

U.S. Tests/Day

Source: Official sources collated by Our World in Data
Note: For testing figures, there are substantial differences across countries in terms of the units, to which negative and pending tests are included and other aspects. Details for each country ca

RADx Launch: *~250k/day*

Innovation
Scale-up ← **Risk** → Novel Tech
Lab>>POC ← **Type** → POC>>Lab

Tests per Day (millions)

6

0.8

RADx Contribution

Projected baseline

August ——— October ——→ Dec 2020

RADx Tech & ATP Goals

1) Expand COVID-19 Testing Technologies: *Number, Type and Access*

2) Optimize Performance: *Technologic and Operational; Match Essential "Use Cases"*

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Innovation

1) Separation/concentration
2) Fluidics
3) Chemistries, e.g. CRISPR
4) Labels, Reporters
5) Readout Tech
6) Miniaturization
7) Automation

Rapid Acceleration of Diagnostics (RADx)

NIH POCTRN

Fast-Track Program for COVID-19 Test Development and Distribution

Innovative Technologies to Increase U.S. Capacity for COVID-19 Testing

NIH and POCTRN have suspended the RADx Fast-Track Program for COVID-19 Test Development and Distribution submission portal and are currently not accepting new applications. Those who have previously submitted complete applications that meet the eligibility criteria will be reviewed. If additional resources to support the RADx program become available, NIH and POCTRN may re-evaluate this decision and could consider accepting applications once again. In the meantime, those interested in the RADx program are encouraged to pursue other funding opportunities offered by NIH listed here.

Overview:

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is urgently soliciting proposals and **can provide up to $500M** across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities. *Rapid Acceleration of Diagnostics (RADx)*, is a fast-track technology development program that leverages the National Institutes of Health (NIH) Point-of-Care Technology Research Network (POCTRN). RADx will support novel solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches. RADx is structured to deliver innovative testing strategies to the public as soon as late summer 2020 and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American.

NIBIB is providing substantial support to accelerate the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect SARS-CoV-2, the virus that causes COVID-19. NIBIB will support the full range of product development including commercialization and product distribution.

To address the COVID-19 pandemic as quickly as possible, NIBIB is mobilizing and expanding the focus of POCTRN to encompass both point-of-care and more traditional laboratory-based approaches. NIBIB will consider innovations at all stages of readiness to circumvent current limitations to SARS-CoV-2 testing capacity, including:

POCTRN

Point Of Care Technologies Research Network

ACME-POCT

Focus: Microsystems-engineered technologies including microchip-enabled devices.

Affiliation: Emory and Georgia Tech

CAPCaT

Focus: Technologies that enhance the diagnosis, monitoring, management, and/or treatment of heart, lung, blood or sleep disorders.

Affiliation: UMASS Lowell UMASS Medical

To **develop technologies** with clinical applications **using a network model** that **enhances complementary strengths** and **builds multidisciplinary partnerships**.

C-THAN

Focus: Technologies designed to meet the clinical needs of people who live with HIV/AIDS in low- and middle-income countries.

Affiliation: Northwestern

JHU

Focus: Point-of-Care tests for sexually transmitted diseases in diverse care delivery contexts.

Affiliation: Johns Hopkins

POCTRN Coordinating Center at CIMIT
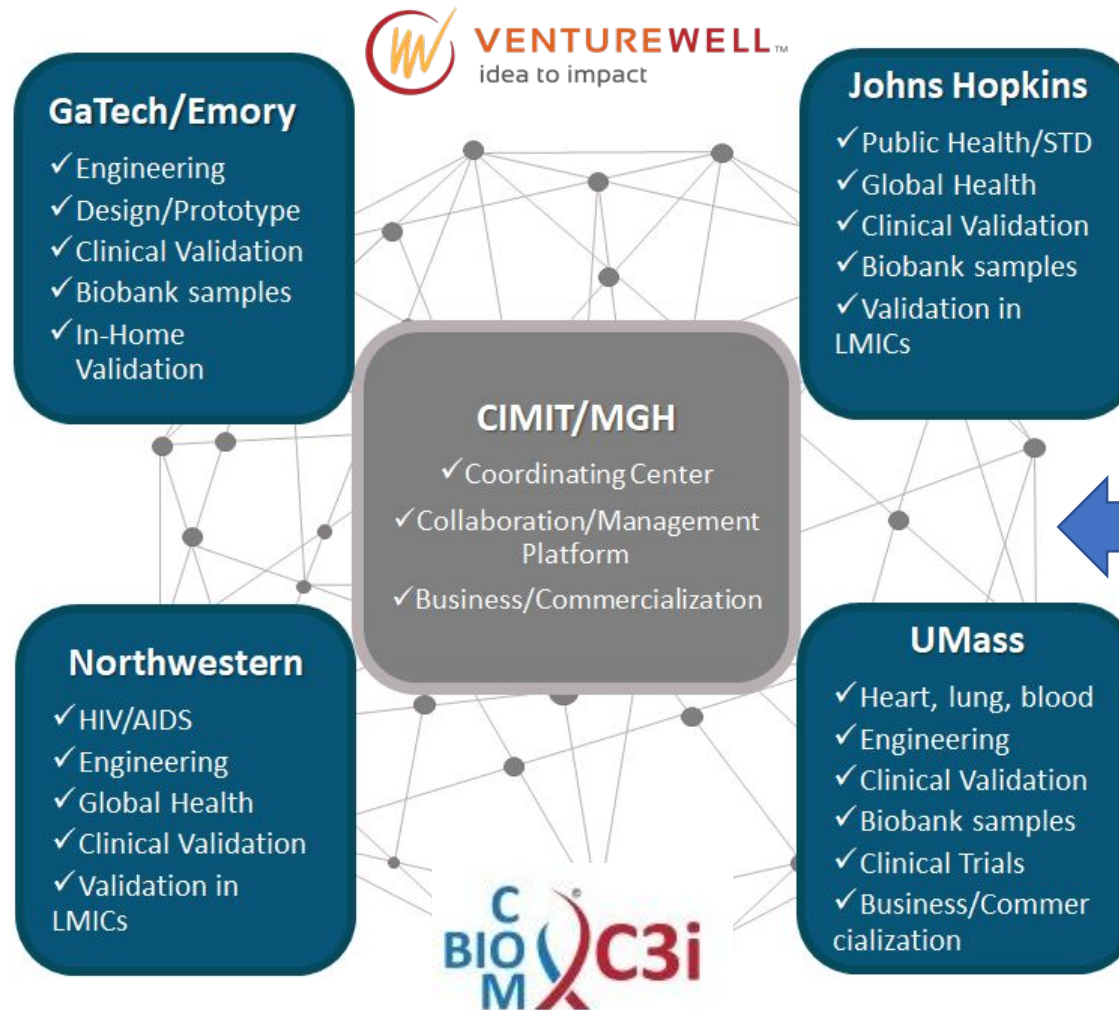
CIMIT, VentureWell, BioComX, Emory-Georgia Tech, John Hopkins, UMass, Northwestern

Steven Schachter, MD
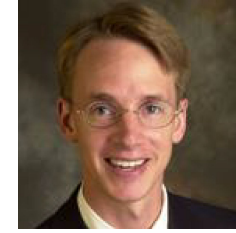CIMIT Co-PI

John Parrish, MD
CIMIT Co-PI

Paul Tessier, PhD
CIMIT

Nancy Gagliano, MD
CIMIT

Wilbur Lam, MD
ACME Co-PI

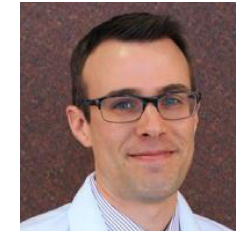Greg Martin, MD
ACME Co-PI

Oliver Brand, PhD
ACME Co-PI

Mike Dempsey
CIMIT

Penny Ford-Carleton, RN
CIMIT

David McManus, MD
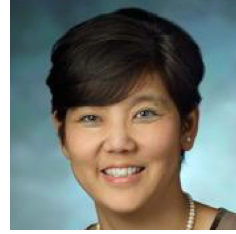CAPCaT Co-PI

Bryan Buchholz, PhD
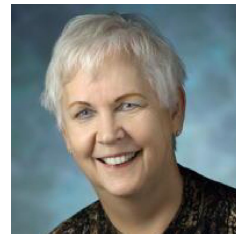CAPCaT Co-PI

Diane Spiliotis
CIMIT
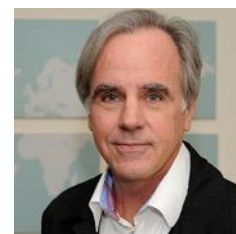
Mark Marino, MPH
VentureWell

Elias Caro, MBA
BioComX

Yuka Manabe, MD
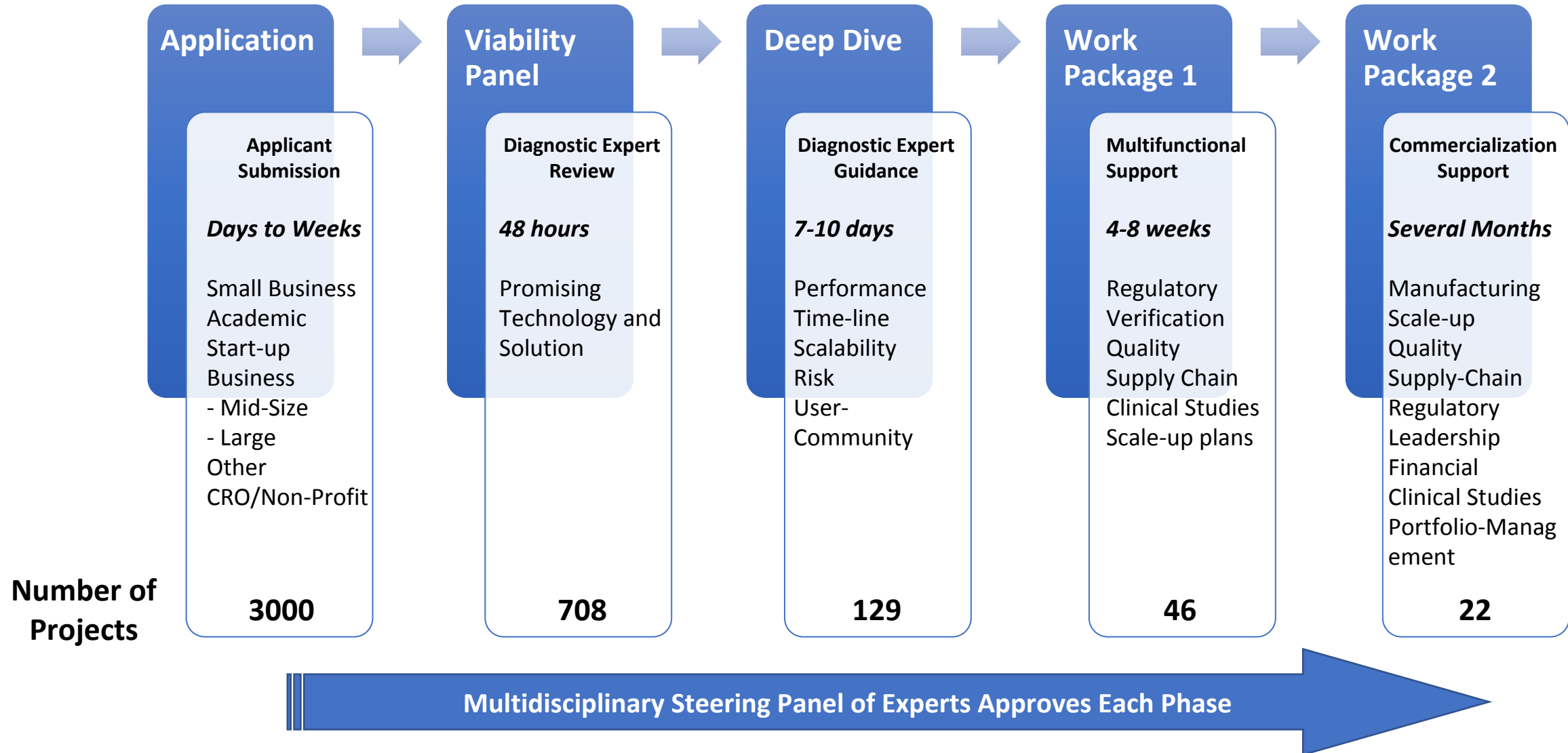Hopkins Co-PI

Charlotte Gaydos, DrPH
Hopkins Co-PI

Robert Murphy, MD
C-THAN Co-PI

Sally McFall, PhD
C-THAN Co-PI

Testing Platforms Scale Up with Strong RADx Support

Application → **Viability Panel** → **Deep Dive** → **Work Package 1** → **Work Package 2**

Application	Viability Panel	Deep Dive	Work Package 1	Work Package 2
Applicant Submission	**Diagnostic Expert Review**	**Diagnostic Expert Guidance**	**Multifunctional Support**	**Commercialization Support**
Days to Weeks	*48 hours*	*7-10 days*	*4-8 weeks*	*Several Months*
Small Business Academic Start-up Business - Mid-Size - Large Other CRO/Non-Profit	Promising Technology and Solution	Performance Time-line Scalability Risk User-Community	Regulatory Verification Quality Supply Chain Clinical Studies Scale-up plans	Manufacturing Scale-up Quality Supply-Chain Regulatory Leadership Financial Clinical Studies Portfolio-Management

Number of Projects

| 3000 | 708 | 129 | 46 | 22 |

Multidisciplinary Steering Panel of Experts Approves Each Phase
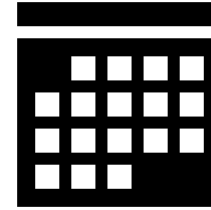
Return to School and Work
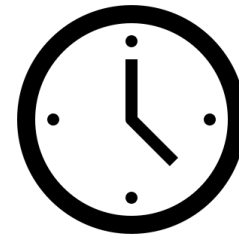
Choosing A COVID Test Should Be Simple

Central Lab
vs
Point Of Care

Symptomatic
vs
Asymptomatic

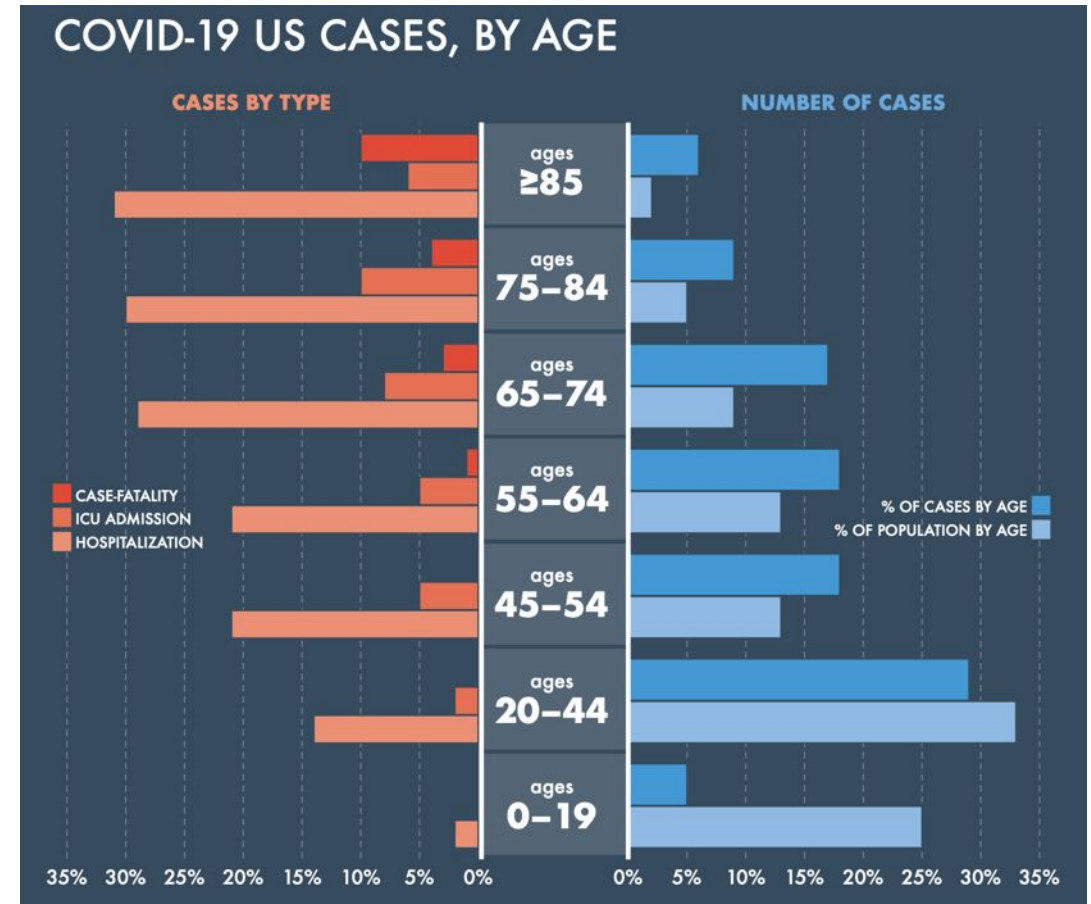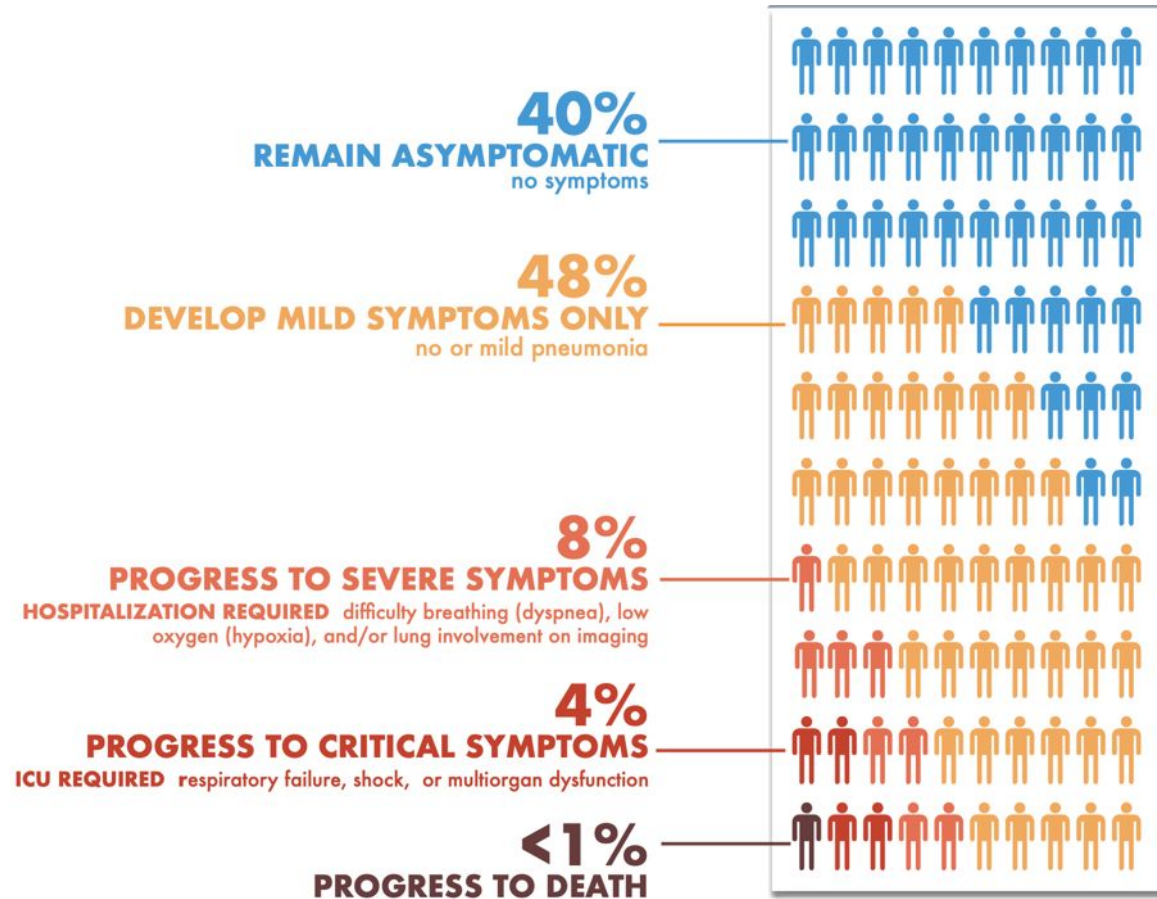Weekly
vs
Daily

Testing Complexities Impacting Adoption

Education and Guidance

Test Availability and Quality

Cost and Decision-Making Autonomy

Risk Reduction Measures
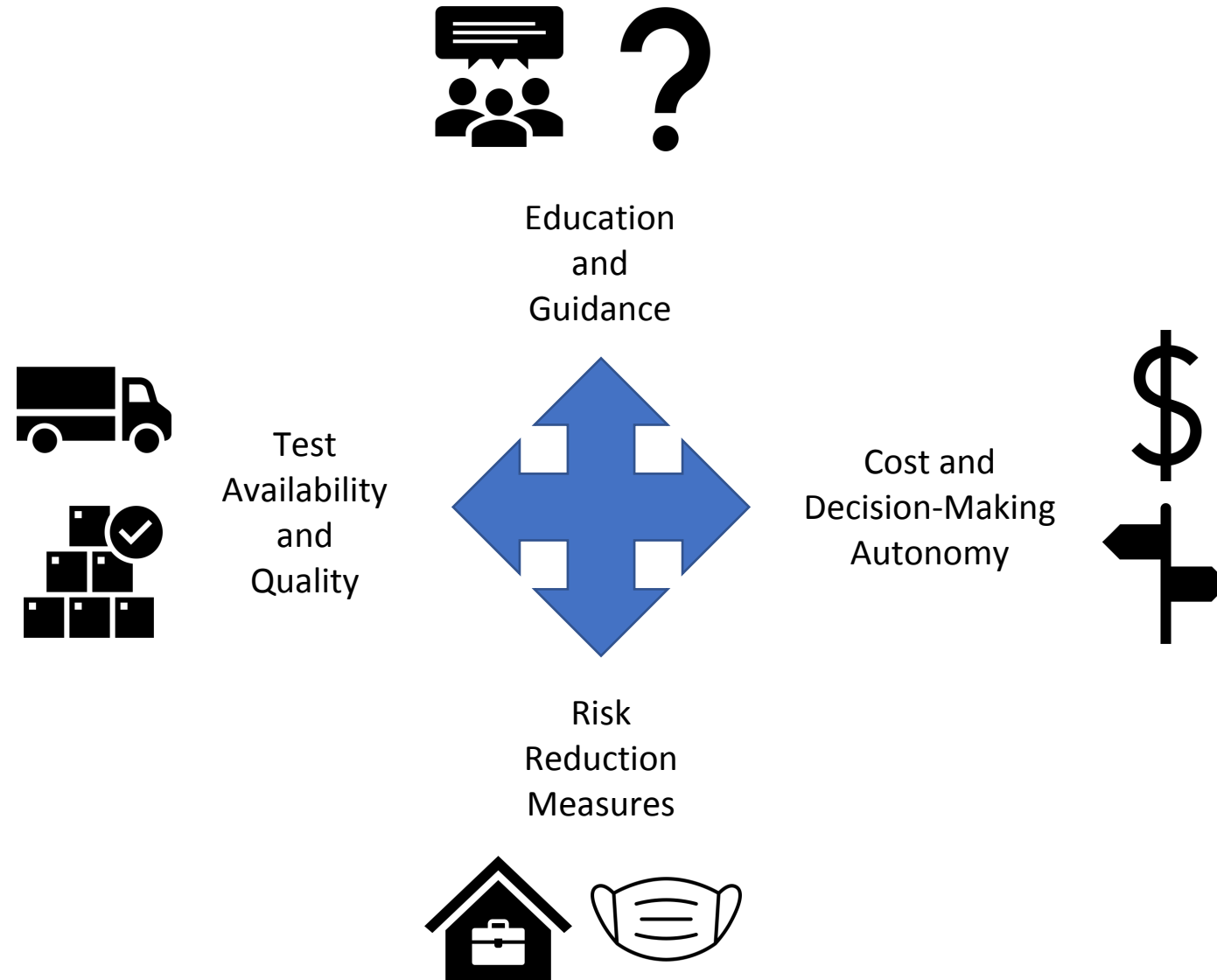
Two Realities Make Testing An Essential Component

40%
REMAIN ASYMPTOMATIC
no symptoms

48%
DEVELOP MILD SYMPTOMS ONLY
no or mild pneumonia

8%
PROGRESS TO SEVERE SYMPTOMS
HOSPITALIZATION REQUIRED difficulty breathing (dyspnea), low oxygen (hypoxia), and/or lung involvement on imaging

4%
PROGRESS TO CRITICAL SYMPTOMS
ICU REQUIRED respiratory failure, shock, or multiorgan dysfunction

<1%
PROGRESS TO DEATH

COVID-19 US CASES, BY AGE

CASES BY TYPE

NUMBER OF CASES

ages ≥85
ages 75–84
ages 65–74
ages 55–64
ages 45–54
ages 20–44
ages 0–19

CASE-FATALITY
ICU ADMISSION
HOSPITALIZATION

% OF CASES BY AGE
% OF POPULATION BY AGE

35% 30% 25% 20% 15% 10% 5% 0%   0% 5% 10% 15% 20% 25% 30% 35%

COVID Testing Adoption in Non-Traditional Settings

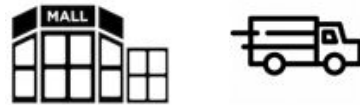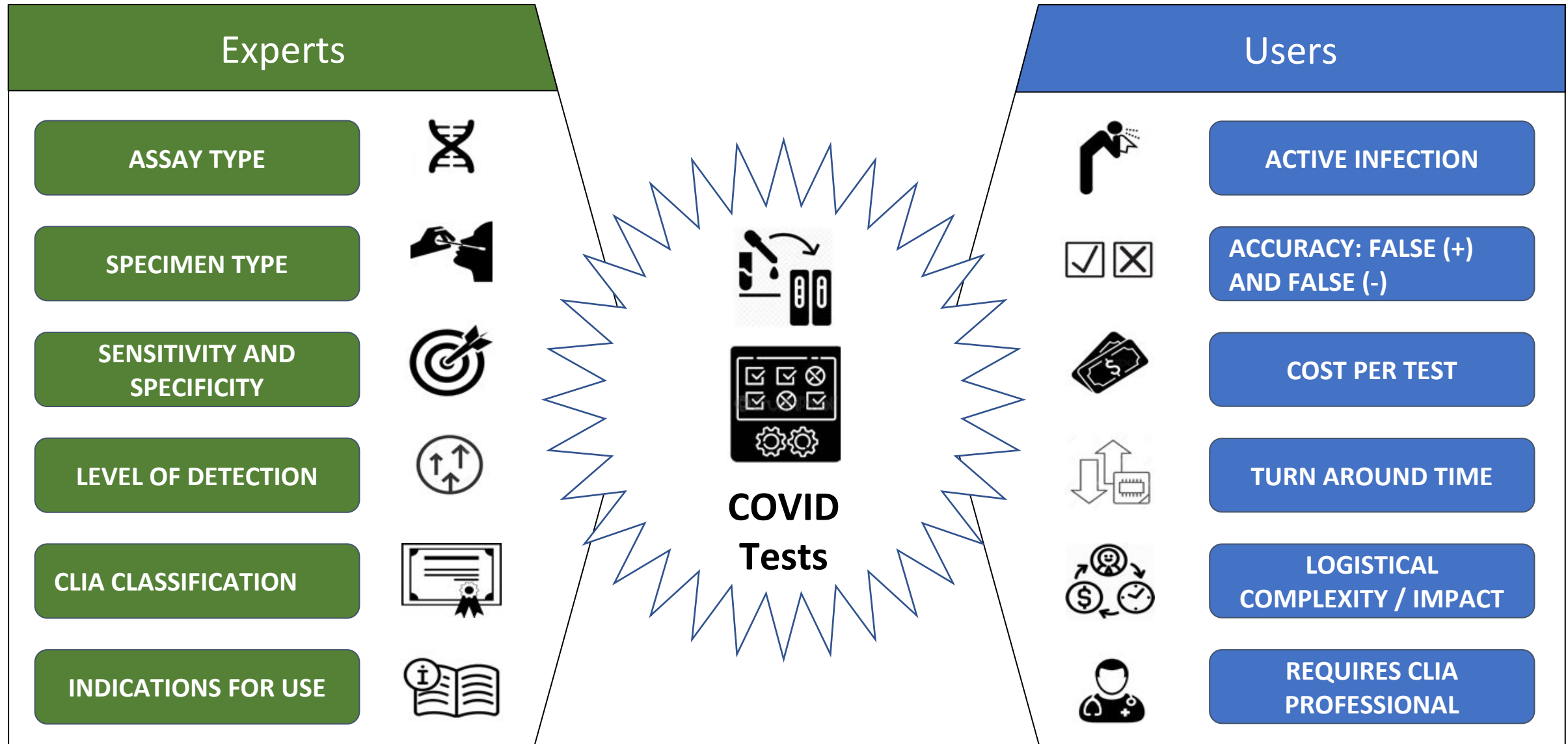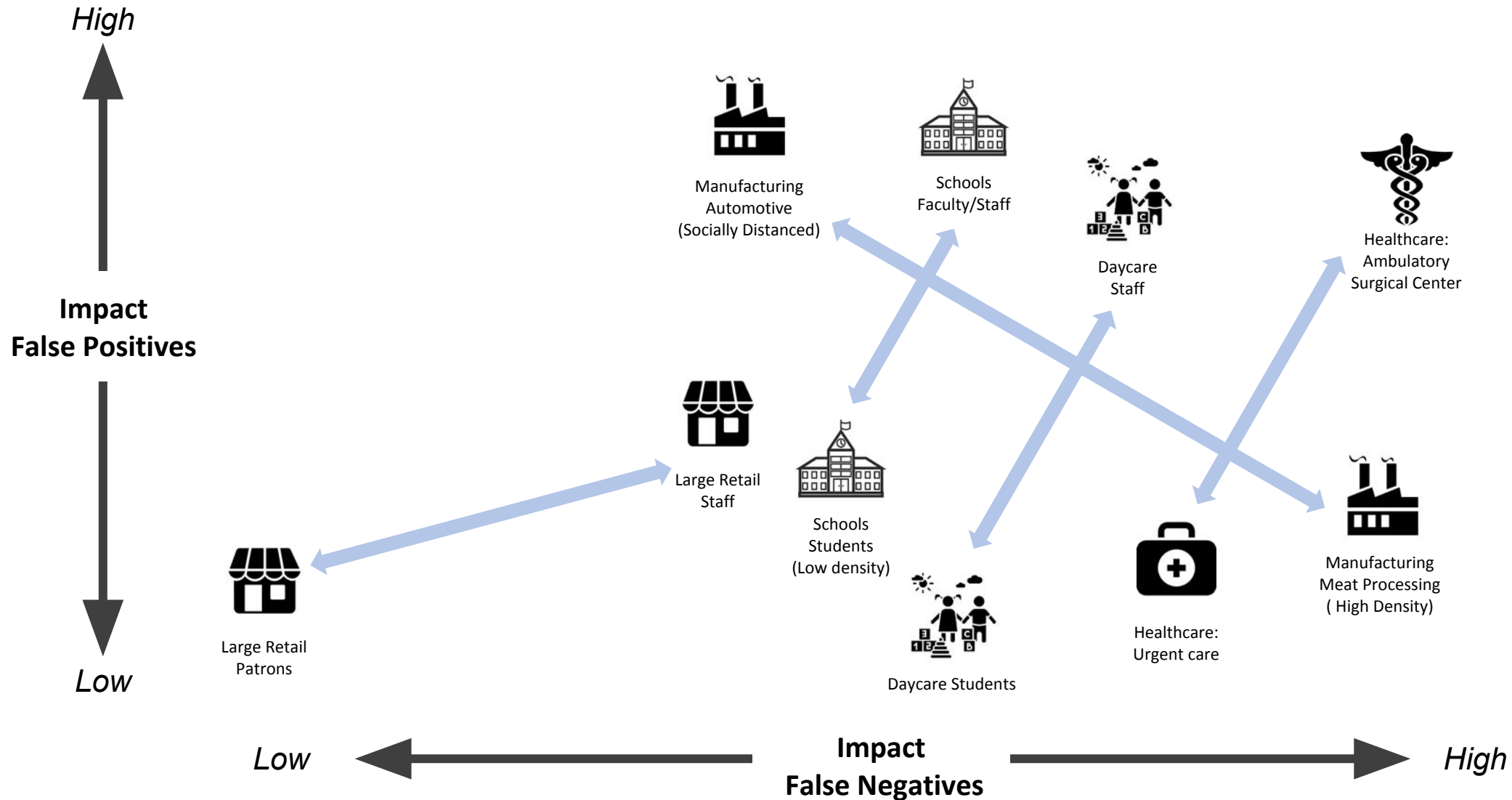|		
Home/Personal		Personal use, Family events
Large Scale Semi-Contained		Manufacturing plants, large schools, and potentially large event gatherings
Small Scale Semi-Contained		Daycare, Elementary Schools, closed to public businesses
Large Scale Public		Large retail, transportation, large community buildings
Medium/Small Scale Public		Retail, restaurants, rural community buildings
Healthcare Settings		Urgent Care, Retail health, MD offices, testing sites, residential communities
Reference Labs		Tests sent out for validation, high throughput centralized settings

Users and Experts View COVID Tests Differently

Experts
- ASSAY TYPE
- SPECIMEN TYPE
- SENSITIVITY AND SPECIFICITY
- LEVEL OF DETECTION
- CLIA CLASSIFICATION
- INDICATIONS FOR USE

COVID Tests

Users
- ACTIVE INFECTION
- ACCURACY: FALSE (+) AND FALSE (-)
- COST PER TEST
- TURN AROUND TIME
- LOGISTICAL COMPLEXITY / IMPACT
- REQUIRES CLIA PROFESSIONAL

Erroneous Test Results Impact Communities Differently

Testing Strategy Need to Align With Impact of Outbreaks
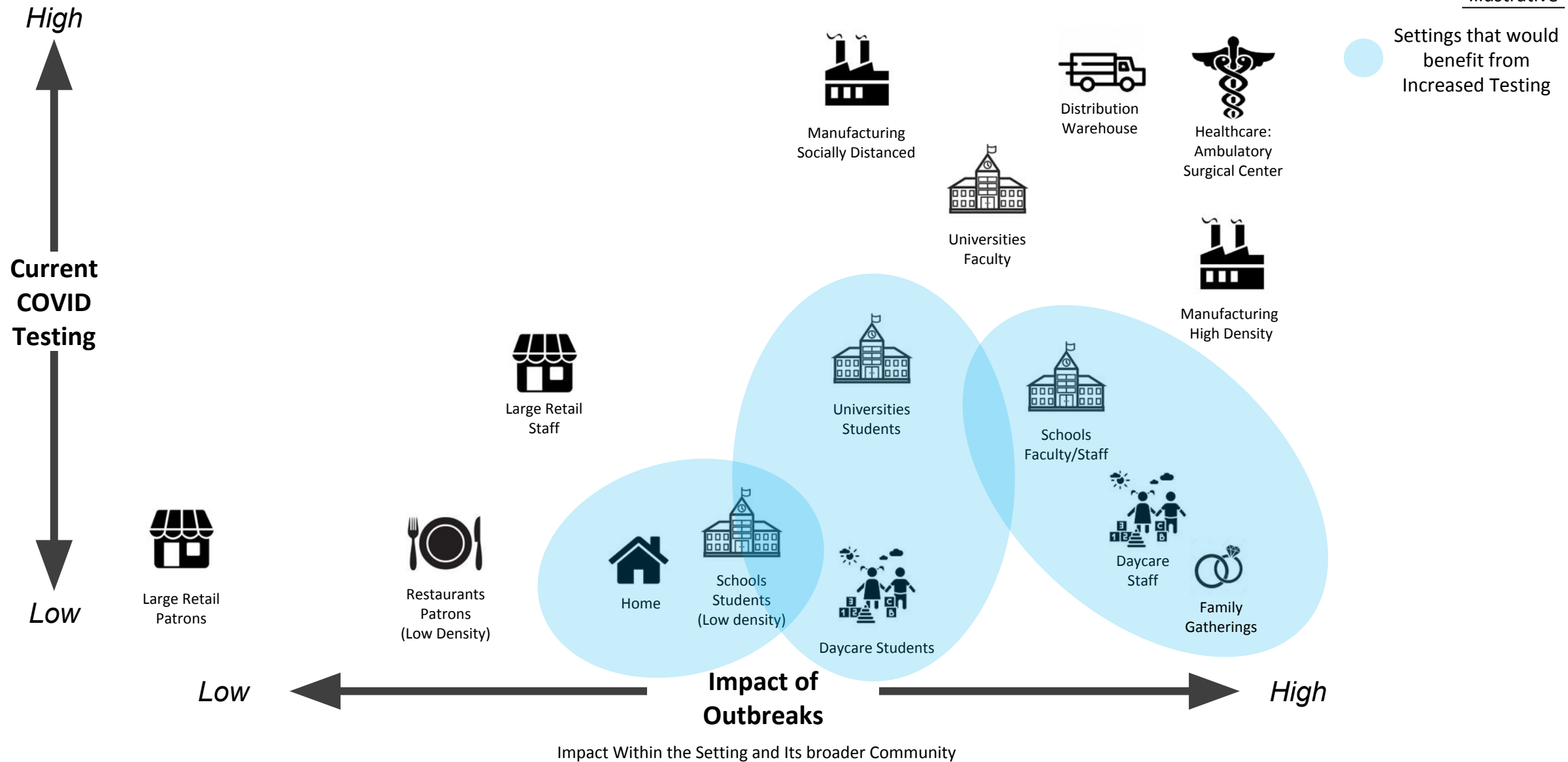
Testing is Only Part of a Broader Equation

Population Prevalence

Testing Frequency

Test Performance

Implement Testing Right

Implement Risk Mitigation

Promote Right Behaviors

Mitigate Downside
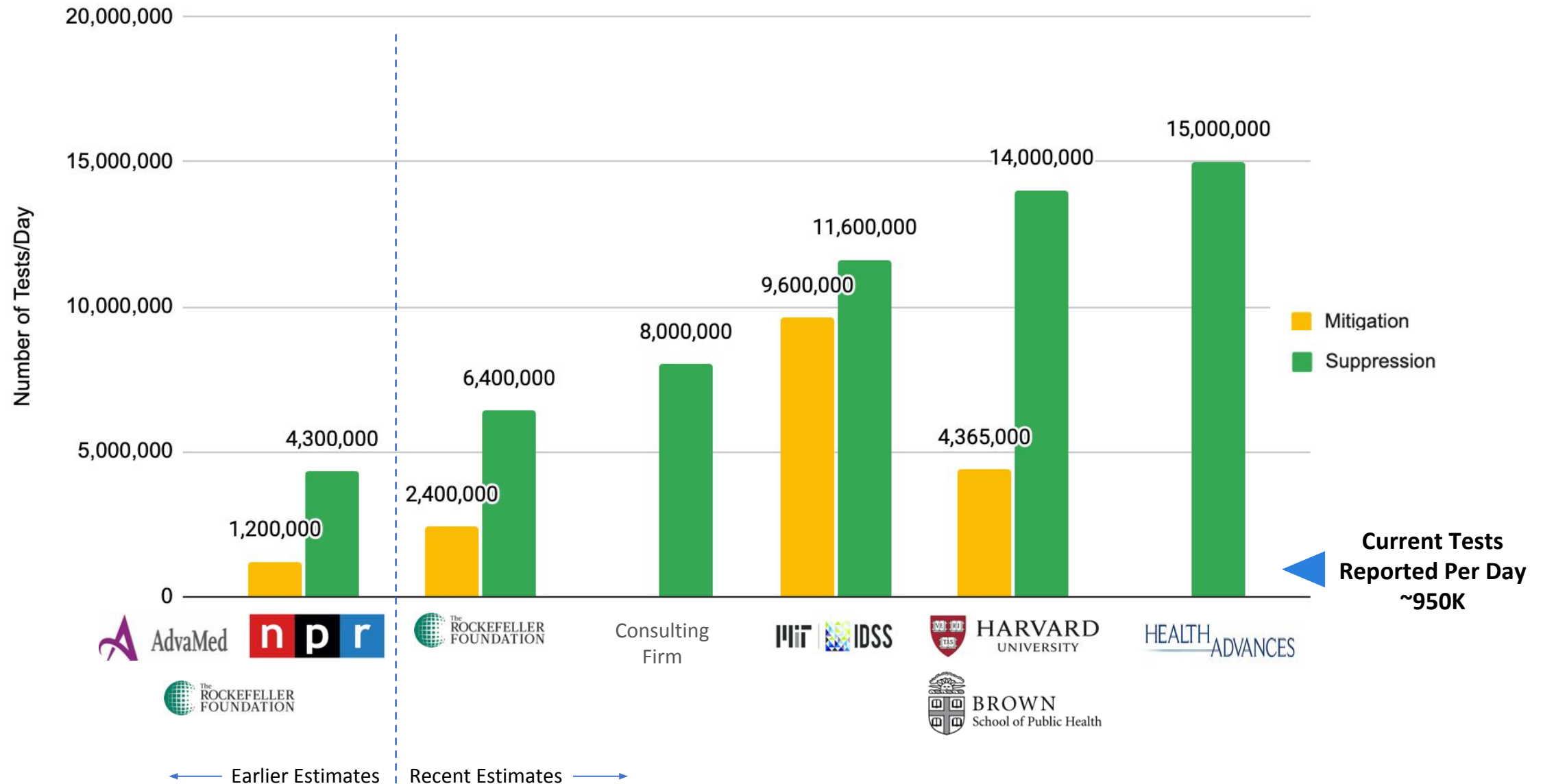
Ease of Access

Paid Sick Leave
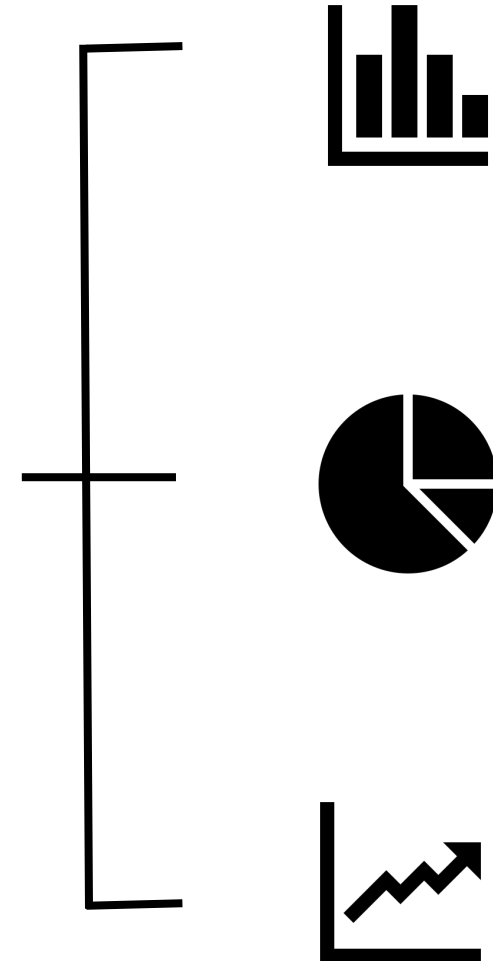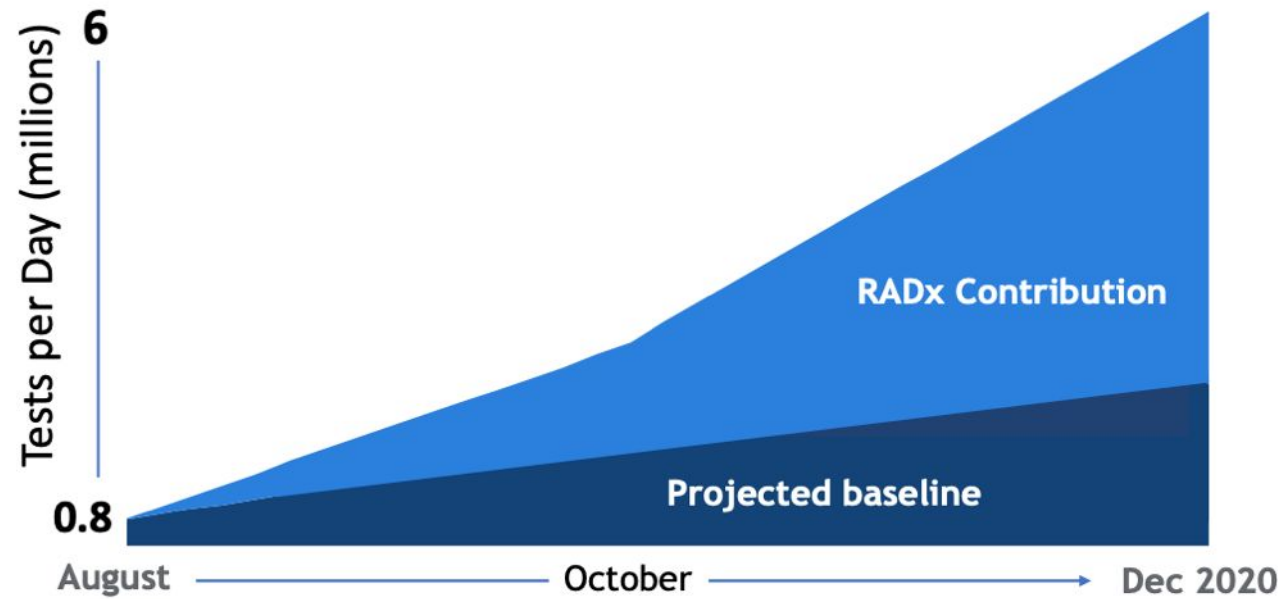
Ability to Distance
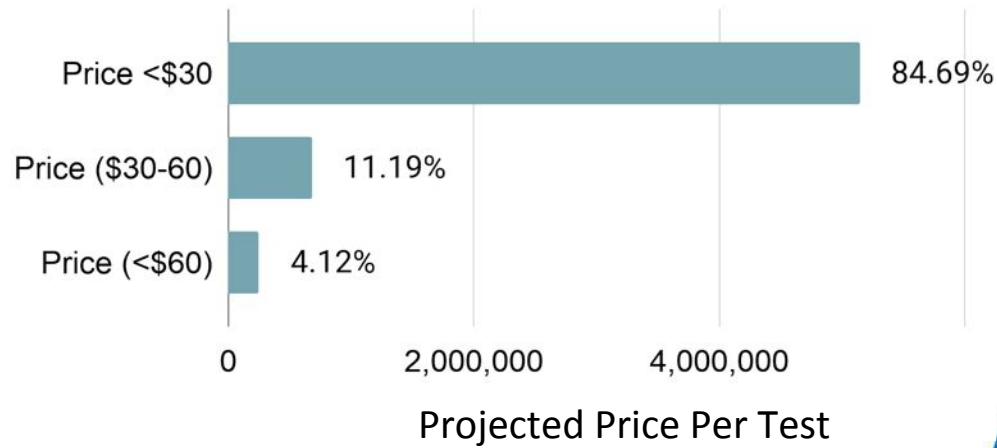
Mask Usage

Workforce Stratification

Projected Testing Need Still Outpaces Capacity

Number of Tests/Day

- 20,000,000
- 15,000,000 — 15,000,000
- 14,000,000
- 11,600,000
- 9,600,000
- 8,000,000
- 6,400,000
- 5,000,000
- 4,300,000
- 4,365,000
- 2,400,000
- 1,200,000
- 0

Mitigation
Suppression

AdvaMed npr The Rockefeller Foundation Consulting Firm MIT IDSS HARVARD UNIVERSITY HEALTH ADVANCES

The Rockefeller Foundation

BROWN School of Public Health

Current Tests Reported Per Day ~950K

← Earlier Estimates | Recent Estimates →

RADx-Tech Projected Portfolio Breakdown

RADx-Tech Projected Portfolio Breakdown

Price <$30 — 84.69%
Price ($30-60) — 11.19%
Price (<$60) — 4.12%

Projected Price Per Test

90%

Point of Care

Professional Sample Collection — 25%

Self/Observed Sample Collection — 75%

<15 mins — 22.20%
<1 hr — 34.49%
<24 hrs — 43.31%
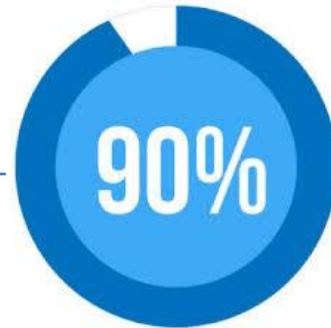
Turn Around Time

Antigen — 20%

Molecular — 80%

QUESTIONS

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Steven C. Schachter, MD
RADx Chief, CIMIT

Manuel Kingsley
RADx Team Lead

Rapid Acceleration of Diagnostics: RADx

OCTOBER 20, 2PM Eastern

RADx Portfolio of Technologies

Presented by Dr. Dan Marshak, RADx Executive

OCTOBER 27, 2:30PM Eastern

Closing the Testing Gap: A Panel Discussion on the Emerging Innovative Technologies and Their Impact on Current Testing Challenges

Moderated by Dr. Bruce Tromberg, Director of NIBIB

Thanks to the Planning Committee:

Richard Creager, Albine Martin, Julie Wilkinson, Dan Marshak, Tania Fernandez, and Michael Masterman Smith

October 13, 2020