

**THE NIH RAPID ACCELERATION OF
DIAGNOSTICS (RAD_x) INITIATIVE**
*HOW YOU CAN TAP INTO A SHARE OF THIS \$500M FOR
COVID-19 DIAGNOSTICS DEVELOPMENT*

MAY 14, 2020



Children'sSM
Healthcare of Atlanta



EMORY
UNIVERSITY



OVERVIEW

- Learn about the ACME POCT, POCTRN, and their roles in RADx
- Define motivation, rationale, and goals for RADx
- Q&A

Use the Q&A feature for all questions

TODAY'S PANEL



Wilbur Lam, MD, PhD
ACME POCT, Principal Investigator
W. Paul Bowers Research Chair &
Associate Professor;
Department of Pediatrics &
Wallace H. Coulter Department of
Biomedical Engineering,
Chief Innovation Officer; Pediatric
Technology Center at Children's
Healthcare of Atlanta and Georgia
Institute of Technology



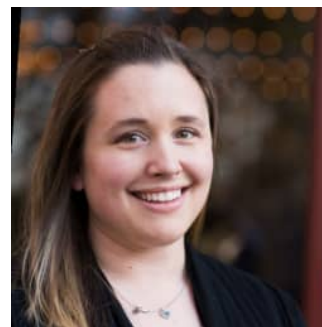
Greg Martin, MD, MSc
ACME POCT, Principal Investigator
President-Elect, Society of Critical
Care Medicine; Professor of
Medicine; Emory University School
of Medicine, Executive Associate
Division Director; Division of
Pulmonary, Allergy, Critical Care,
and Sleep Medicine



Oliver Brand, PhD
ACME POCT, Principal
Investigator
Director; Institute for Electronics
and Nanotechnology at the
Georgia Institute of Technology,
Professor, School of Electrical and
Computer Engineering



Stacy Heilman, PhD
ACME POCT, Technology Training and Dissemination Core
Assistant Professor, Emory University
Pediatric Research Operations Director
Emory University & Children's Healthcare of Atlanta



Erika Tyburski, BS
ACME POCT, Director of Operations;
Sanguina, Inc., CEO

THE NIH'S POINT-OF-CARE TECHNOLOGIES RESEARCH NETWORK (POCTRN)

- Assessment of clinical and user needs to inform device design
- Evaluation of POC devices for performance and potential for clinical impact
- Completion of clinical testing to facilitate translation and commercialization
- Training and education of relevant stakeholders in the development and utilization of POC technologies
- Development of partnerships with industry and other stakeholders to facilitate commercialization

POCTRN Coordinating Center: Consortia for Improving Medicine with Innovation & Technology (CIMIT) at Harvard

The Center for Advancing Point of Care in Heart, Lung, Blood and Sleep Diseases (CAPCAT) at U Mass

The Center for Innovation in Point of Care Technologies for HIV/AIDS at Northwestern

Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases at Johns Hopkins

Atlanta Center for Microsystems Engineered Point-of-Care Technologies (ACME POCT) at Emory/Georgia Tech/Children's

THE ACME POCT'S MISSION

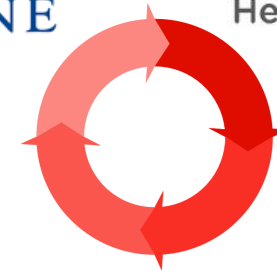
- The **ACME POCT** is focused on the development and translation of microsystems-engineered technologies including microchip-enabled devices such as microelectromechanical systems (MEMs)-based sensors, microfluidics, and smartphone-based systems
- The **mission of the ACME POCT** is to assist and enable inventors from all over the country who have developed or are developing microsystems-based POC technologies to define their clinical needs, conduct clinical validation, and refine their technology with the objective of accelerating the path to translation and clinical adoption
- Funded by National Institute of Biomedical Imaging and Bioengineering (NIBIB)



EMORY
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MEDICINE



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Healthcare of Atlanta



Georgia Institute
of Technology[®]

MICROSYSTEMS-BASED TECHNICAL RESOURCES SHARED ACROSS POCTRN



Georgia Tech – Institute for Electronics and Nanotechnology

Micro/Nanofabrication and Characterization Core Facilities

≈ 200 installed fabrication/characterization tools

≈ 30 technical staff members + 150 faculty experts

≈ 1,000 core facility users per year
(85% internal, 15% external from academia & industry)

Member of NSF-funded National Nanotechnology Coordinated Infrastructure

The Georgia CTSA is focused on accelerating the translation of laboratory discoveries into healthcare innovations for patients by supporting **Emory University, Morehouse School of Medicine (MSM)**, the **Georgia Institute of Technology (Georgia Tech)**, and the **University of Georgia** researchers and their partners.

Resources include:

Discovery

- ❖ **Statewide Network of Adult and Pediatric Clinical Research Sites**
- ❖ **Pilot Grants & Research Technologies**

Education and Training

- ❖ **Master of Science in Clinical Research**
- ❖ **KL2**
- ❖ **TL1**
- ❖ **Certificate Program Translational Research**

Expertise, Problem Solving, and Ancillary Support:

- ❖ **Biostatistics**
- ❖ **Epidemiology**
- ❖ **Research Study Design**
- ❖ **Biomedical Informatics**
- ❖ **Participant Recruitment & Special Populations**
- ❖ **Clinical Study Start-Up and Closeout**
- ❖ **Ethics**
- ❖ **Technology Transfer**
- ❖ **Community Engagement**
- ❖ **Regulatory Knowledge**
- ❖ **Innovation Catalyst**

ACME POCT CENTER CORES AND LEADERSHIP

Administrative (Core 1)

Wilbur Lam, Oliver Brand, Greg Martin, Erika Tyburski

oversee the overall operations of our Center

Technology Development (Core 2)

Oliver Brand, Wilbur Lam, David Gottfried

evaluate and support technological microsystems-based development/refinement of the selected projects leveraging IEN facilities, faculty, and staff

Clinical Translational Validation (Core 3)

Greg Martin, Wilbur Lam

comprise clinicians and biostatisticians affiliated with the Georgia CTSA and will guide clinical validation, usability, and feasibility testing of microsystems-based POC diagnostics for those clinical subspecialties

Technology Training and Dissemination Core (Core 4)

David Ku, Stacy Heilman, Eric Nehl, Sathya Gourisankar

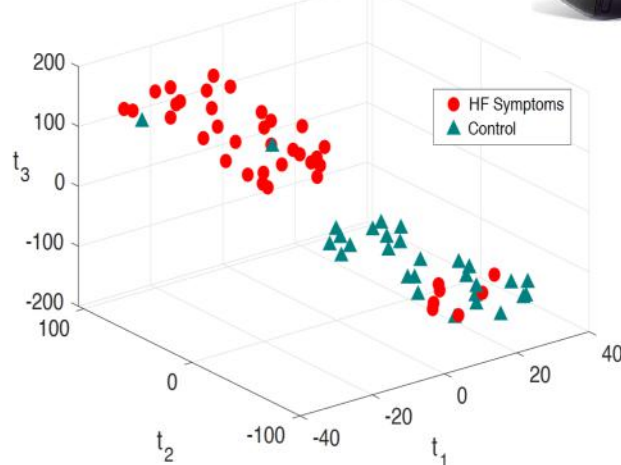
will conduct assessments of clinical/user needs and will develop cross-disciplinary training activities for all stakeholders (clinicians, microsystems engineers, POC technology developers, patients, general public) and broadly disseminate lessons and best practices learned

ACME POCT SEED GRANT PROGRAM – YEAR 1 & YEAR 2 PROJECTS

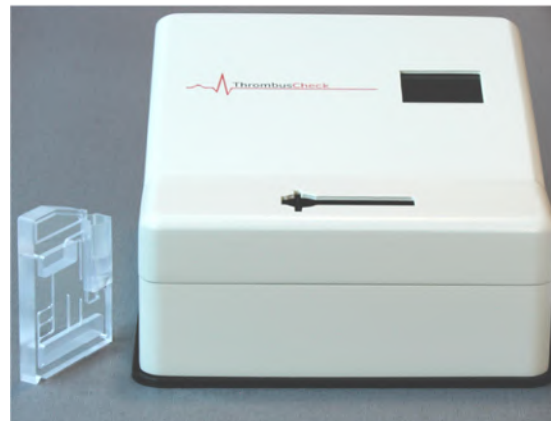
Auscultech Dx, LLC
Mobile phone stethoscope



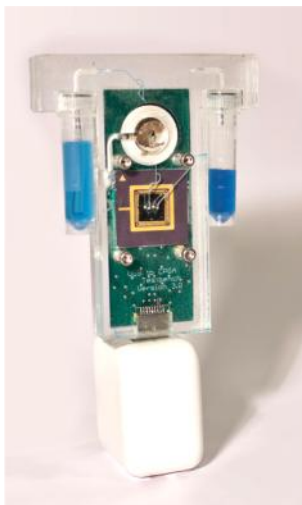
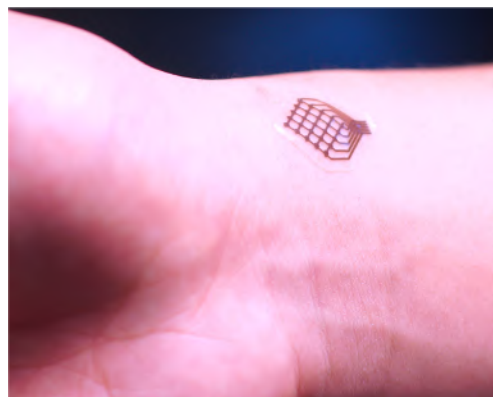
RePreDx detection of heart failure
RePreDx detection of normal



ThrombusCheck
A diagnostic device to personalize medication for heart patients



Seismowatch
cardiovascular screening & management



Microfluidic Cartridge

Prep Module

Cytometry Module

UC Irvine

XHale Patch & XStolic Patch
Band Aid-like Sensors for Continuous
Vital Signs

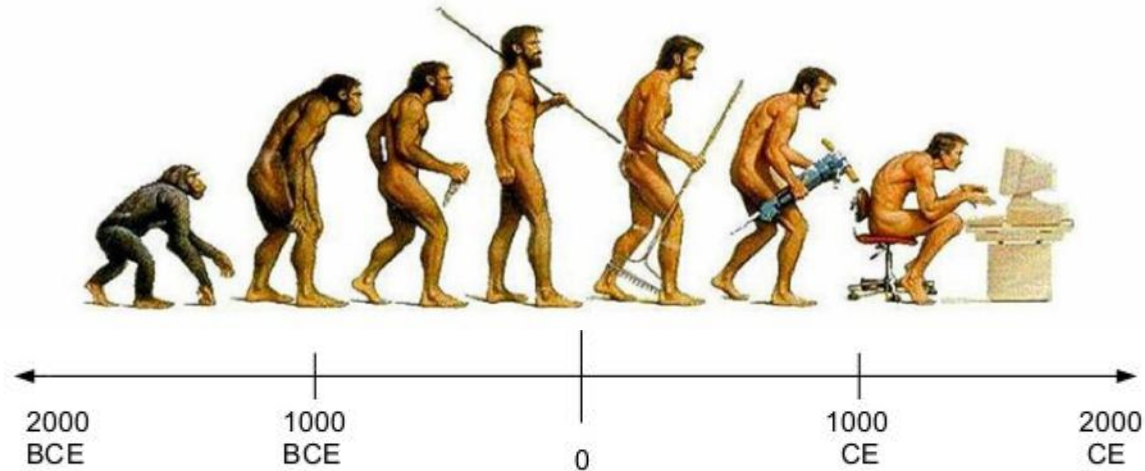
ResonanceDx
Creatinine Sensor
for Kidney Function

**Aptitude Medical
Systems**

TrueFib Fibrinogen Sensor
for Coagulopathy Detection

Cytovale
Microfluidic Sepsis Detection

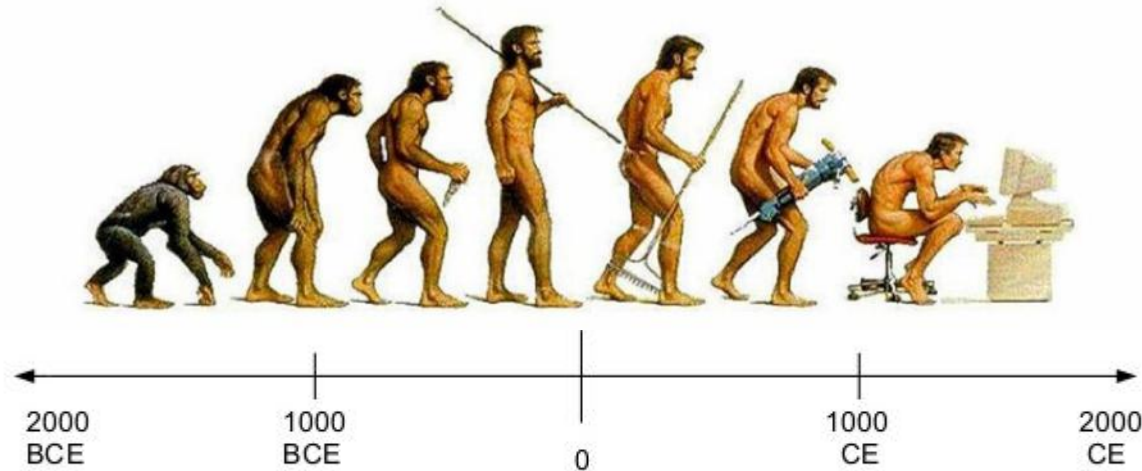
AND THEN THINGS CHANGED...



BEFORE COMMON ERA (BCE)

COMMON ERA (CE)

AND THEN THINGS CHANGED...



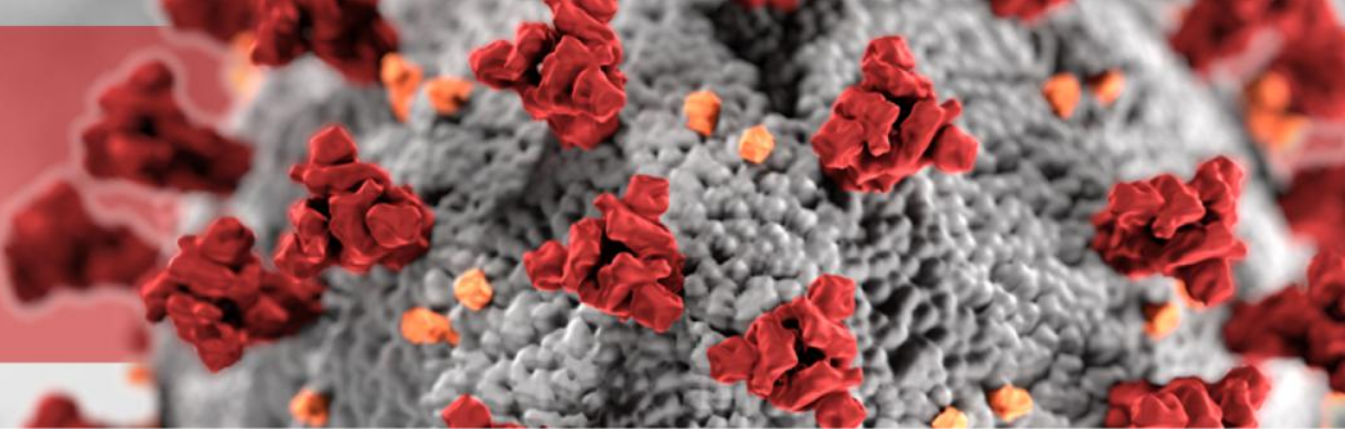
~~BEFORE COMMON ERA (BCE)~~

~~COVID-19~~

~~COMMON ERA (CE)~~

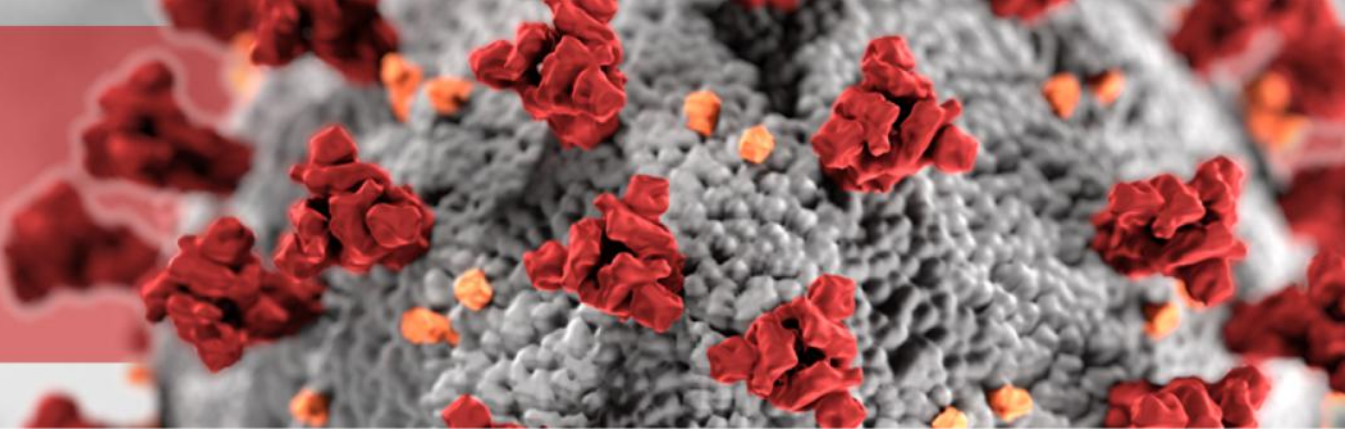
~~COVID-19~~

Rapid Acceleration of Diagnostics (RADx)



- An accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2, the virus that causes COVID-19, testing readily available to every American.
- Supports development and commercialization of innovative technologies to significantly **increase the U.S. testing capacity for SARS-CoV-2** up to 100-fold above what is achievable with standard approaches.
- Structured to **deliver innovative testing strategies to the public as soon as late summer 2020** to provide the information needed to make decisions about returning to normal activities and to help reduce the risk of future outbreaks.
- RADx supports innovative approaches that introduce **new test platforms as well as strategies for solving problems that limit current tests.**
- The NIBIB is urgently soliciting proposals, **on a rolling submission process**, and **can provide up to \$500M** across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests.

Rapid Acceleration of Diagnostics (RADx)



- RADx is specifically for **diagnostics that test for the presence of the SARS-CoV-2 virus, not serology/immunity**
- Development of new tests with improved technical performance and convenience, such as **point-of-care, home-based, and community-based devices**, as well as innovations that **make current lab tests faster, more efficient, and more widely accessible** will be supported
- Tests developed through RADx will be validated, be proven clinically effective, and obtain Emergency Use Authorization (EUA) and/or clearance through the FDA
- Innovations at all stages of readiness will be considered, including:
 - **Early stage:** transformative innovations based on novel testing strategies that have potential for major scale up
 - **Advanced stage:** modification and optimization of existing SARS-CoV-2 testing approaches, including clinical laboratory tests, that can dramatically increase testing capacity
- Review criteria will include: **Technical** (performance, usability), **Clinical, Commercial, and Regulatory** aspects

NIH Rapid Acceleration of Diagnostics (RADx) Initiative for COVID-19

NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES

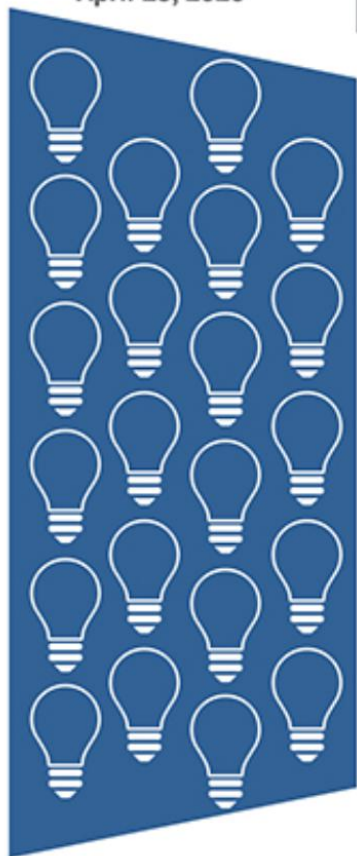
PHASE 0:
"Shark Tank"-Like Rapid Selection Process

PHASE 1:
Validation and Risk Review

PHASE 2:
Clinical Tests, Regulatory Approval, and Scaling Up

**END OF SUMMER/
FALL 2020**

Rolling Submissions and Selections Begin
April 29, 2020



~1 week
Investigators receive \$25k



~1 month
Investigators receive \$1M

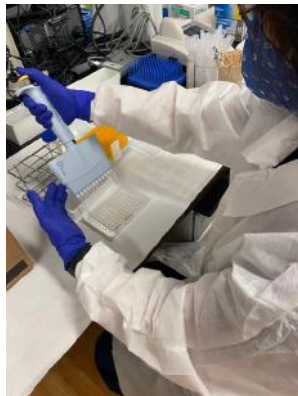


Multiple months
No budget limit for investigators

FAST TRACK FOR ADVANCED DIAGNOSTIC TECHNOLOGIES



ACME POCT WILL SERVE AS RADx'S TEST VALIDATION CORE



Emory/Children's Laboratory for Innovative Assay Development (ELIAD)

- John Roback, MD, PhD (Emory) and Sunita Park, MD (Children's)
- CLIA-certified clinical "testing" laboratory dedicated to assessing and validating novel diagnostic tests, including those for COVID-19
- >1300 COVID-19 patient biospecimens (nasopharyngeal, sputum, other oral, blood/plasma/serum, etc.) curated with clinical information
- Conduct different tiers of test validation (contrived SARS-CoV-2 "spiked in" samples, banked patient samples, fresh patient samples, community testing), can be used for EUA submission

HomeLab (Georgia Tech)

- Brad Fain, PhD and Sarah Farmer, PhD
- Network of >600 Atlanta-area households available to evaluate medical technologies in their homes & communities
- Conduct usability assessments (including human factors analysis & heuristics evaluation) of COVID-19 tests
- Performed in intended use locations (home, school, clinical labs, public areas, etc.)



THANK YOU!

- <https://www.pocotr.org/-/acme-poct>
- <https://directorsblog.nih.gov/2020/04/29/rising-to-the-covid-19-challenge-rapid-acceleration-of-diagnostics-radx/>
- <https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics>
- application website: <https://www.pocotr.org/radx>
- Contact: erika.acmepoct@gmail.com

any questions?

NIH Rapid Acceleration of Diagnostics (RADx) Initiative for COVID-19

NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES

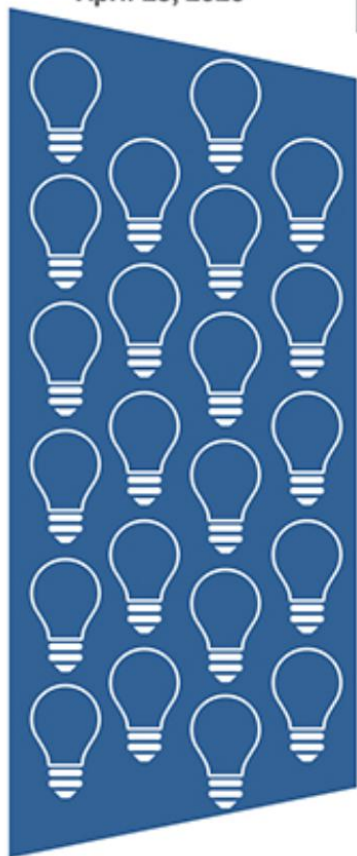
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