

The meeting will begin shortly

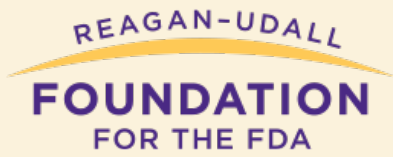
# Over-the-Counter Diagnostics: Advancing Home as a Health Care Hub

Hybrid Public Meeting

Wednesday, March 25, 2026 | 1-4:30pm ET

*Apple, Checkable, Consumer Healthcare Products Association, Hims & Hers, and National Association of Chain Drug Stores provided funding for this meeting.*





# Welcome

**Susan C. Winckler, RPh, Esq**

Chief Executive Officer

Reagan-Udall Foundation for the FDA



# Housekeeping



Due to the meeting size, your microphone and video will remain off during the meeting



Please share your questions using the Zoom Q&A function




This public meeting is being recorded.



The slides, transcript, and video will be available at [www.ReaganUdall.org](http://www.ReaganUdall.org)

# Agenda

- 
- 1pm**      **Welcome**
  - 1:05pm**      **Snapshot of OTC Diagnostics**
  - 1:20pm**      **Current Environment for OTC Diagnostics**
  - 2:30pm**      **Integrating OTC Diagnostics into Care Delivery**
  - 3:25pm**      **User Perspective**
  - 3:30pm**      **Next Generation OTC Diagnostics**

*All times listed in Eastern Time*

# Snapshot of OTC Diagnostics

**PRESENTER:** Elizabeth Richardson, MSc, Canal Row Advisors

# A Snapshot of the OTC Diagnostics Landscape

Liz Richardson, Canal Row Advisors

# Health care is increasingly shifting into the home

*OTC diagnostic technologies are integral to this shift*



**58%**

American adults reported using telehealth at some point in 2024 (Rock Health 2024)



**72%**

of Americans have taken an at-home test of some kind (Rock Health 2023)



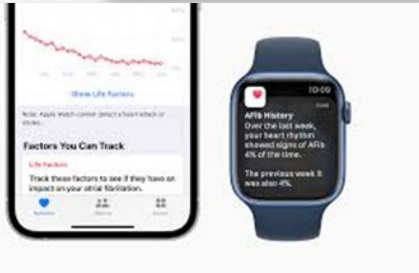
**53%**

of Americans own at least one wearable or connected device (Rock Health 2024)

# The Consumer Diagnostics Market is Evolving Rapidly

## SENSOR-BASED

Continuous or episodic physiological data from wearables & biosensors



## IN VITRO

Biochemical analysis of specimens (blood, urine, saliva) outside the body



## IMAGING

Smartphone cameras & AI to capture and analyze visual clinical data



# Comparing Testing Paradigms

	OTC <i>In Vitro</i> Diagnostic	At-Home Collection Test	Direct to Consumer Testing	Point of Care / CLIA Waived
<b>Sample collection</b>	Self-collection; instructions/platform designed for a lay user. <i>Typically self-pay.</i>	At home via test kit (stool, urine, oral fluid, fingerstick) and mailed to a partner lab. <i>Typically Rx and reimbursed.</i>	At home via kit or at a blood draw site. <i>Consumer orders directly, pays out of pocket.</i>	Collected by/under supervision of trained staff at a CLIA-waived facility. <i>Typically reimbursed by insurance.</i>
<b>Analysis</b>	At home	CLIA-Certified Lab (high-complexity)	CLIA-Certified Lab (high-complexity)	At the site of care (pharmacy, mobile unit, school, etc.)
<b>Follow-up</b>	🕒: <i>within minutes</i>	🕒: <i>days–weeks</i>	🕒: <i>days–weeks</i>	🕒: <i>within minutes</i>
	Consumer receives results directly and determines next	Results to consumer and/or ordering clinician. Clinician	Results returned digitally; Some offer optional clinician	Results delivered onsite. Follow-up typically available in the same

# Snapshot of the OTC Dx market

## Mature Core

- Pregnancy & fertility testing (*first OTC test cleared 1978*)
- Blood glucose monitoring (*biggest market share by value*)
- Drug-of-abuse testing
- Infectious disease (*COVID, flu, HIV*)

## Rapidly Growing

- STI home testing (syphilis, chlamydia/gonorrhea)
- CGMs for wellness use
- Wearable cardiovascular monitoring
- Hormone panels & reproductive health

## Emerging / Frontier

- Microfluidics & CRISPR-based diagnostics
- Smartphone-integrated spectroscopy
- AI/LLM interpretation layer

# A Large Overall Market...

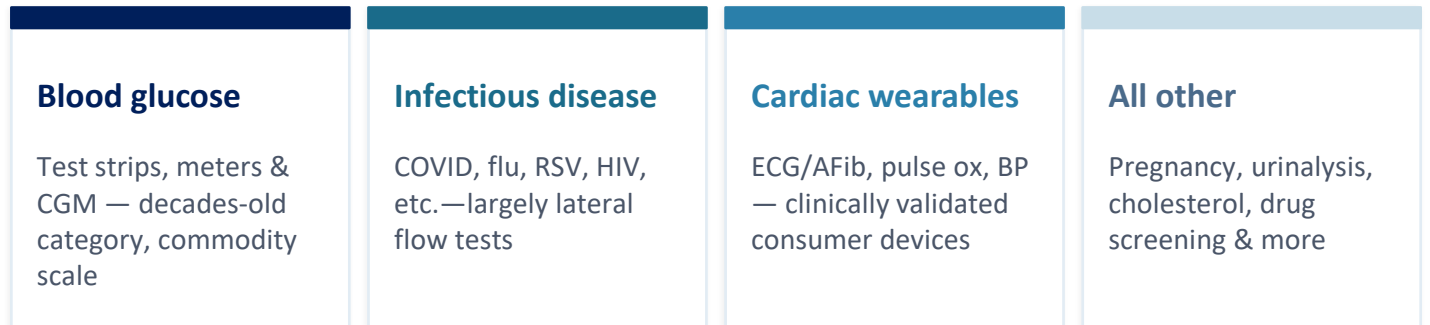
~\$50–60B

estimated global consumer  
diagnostics market (2024)\*

*OTC test kits + diagnostic wearables*

*Directional estimate combining multiple  
market research sources*

## ...DOMINATED BY A FEW WELL-ESTABLISHED CATEGORIES



*Segment proportions are directional / illustrative.*

# COVID Changed Expectations Permanently

**78x**

Telehealth surge  
in April 2020  
(McKinsey)

**38x**

Stabilized level  
by early 2021 vs.  
pre-pandemic baseline

**40%**

Americans planned  
to continue telehealth  
(up from 11% pre-COVID)

**66%**

Consumers were willing to  
share data with a provider  
(Rock Health 2024)

## Behavioral Legacy

**72%** of respondents report prior at-home test use (Rock Health 2023) — but **64%** exclusively took COVID tests, signaling room for ongoing education

**71.4%** of physicians report using telehealth in their practices weekly, up from 25.1% in 2018 (AMA 2024)

# What Consumers Value in At-Home Diagnostics

## Convenience & Speed

Test when and where desired; results in minutes; no appointment needed; smartphone integration

## Accuracy & Trust

FDA clearance matters to consumers; brand recognition plays a role; COVID testing built real-world confidence in lateral flow format

## Affordability

Price is a key barrier; free government programs (COVIDTests.gov) drove dramatically higher uptake

## Privacy & Discretion

Critical for stigmatized conditions (HIV, STIs, mental health); home testing reduces those barriers

## Integration with Care




Consumers want results to connect to follow-up — telehealth, prescriptions, referrals (NIH Home Test to Treat model)

## Data Privacy & Control

Growing wariness: self-reported willingness to share with health tech companies fell from 25% in 2020 to 14% in 2023 (Rock Health)




# Barriers—and opportunities—in OTC diagnostics development

## The Friction

-  Regulatory hurdles and gaps can be difficult to navigate
-  Reimbursement challenges persist
-  Digital access growing but unevenly distributed
-  OTC products not well-integrated into care delivery

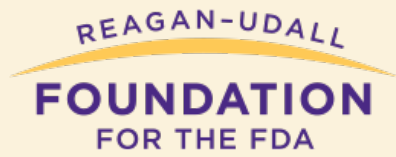


## The Momentum

-  FDA and CMS policy evolving (ACNU, 2026 wellness guidance, TEMPO, ACCESS)
-  Consumer interest and demand remains high
-  New technologies under development offer significant promise to address unmet need

**The market is evolving rapidly.  
Policy is moving.  
Consumer expectations are high.**

**What does the path forward look like?**



# Current Environment for OTC Diagnostics

## **PRESENTER:**

Courtney Lias, PhD  
U.S. Food and Drug Administration



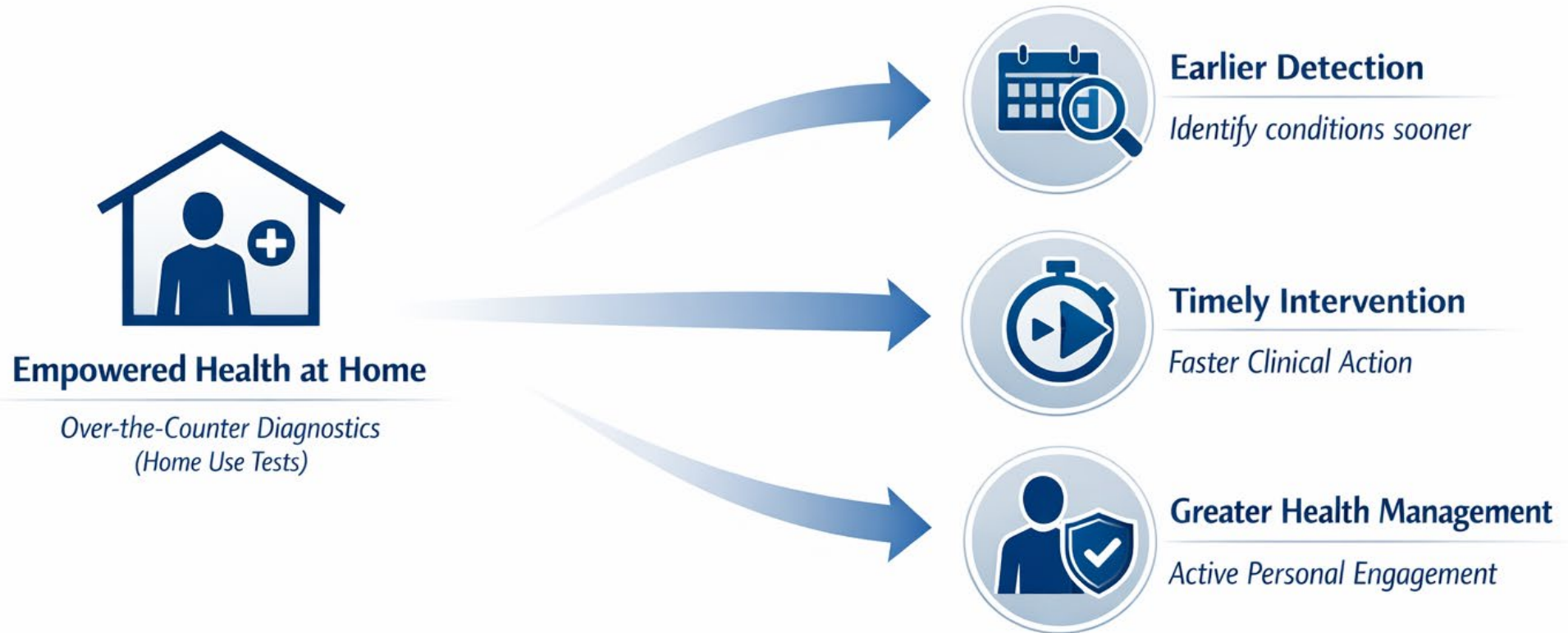
# Over-the-Counter Diagnostics: FDA Perspectives

## **Over-the-Counter Diagnostics: Advancing Home as a Health Care Hub**

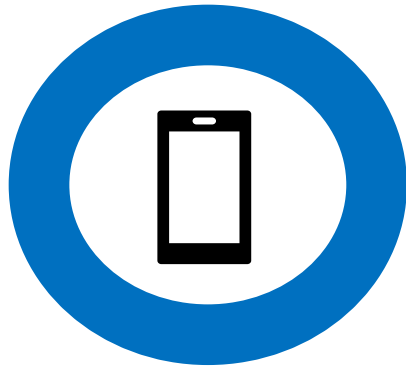
March 25, 2026

Courtney H. Lias, Ph.D.  
Office Director  
OHT7: Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality  
CDRH | Food and Drug Administration

# Home Use Tests

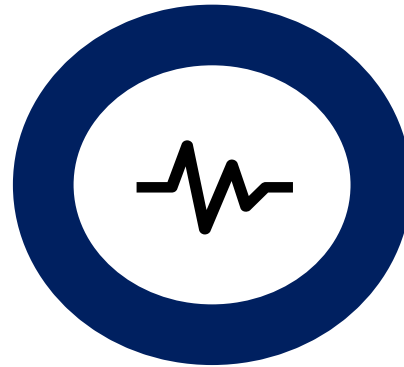


# Growing shift toward OTC availability for diagnostics & wearables



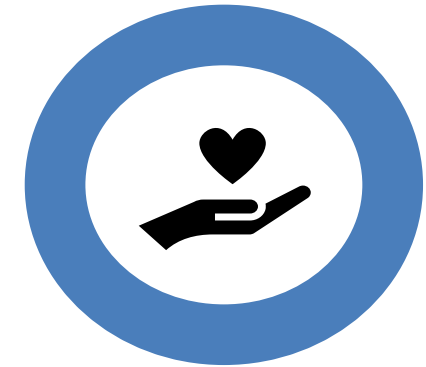
---

Increasing comfort with  
**self-monitoring**



---

Desire for **real-time**  
**health data**



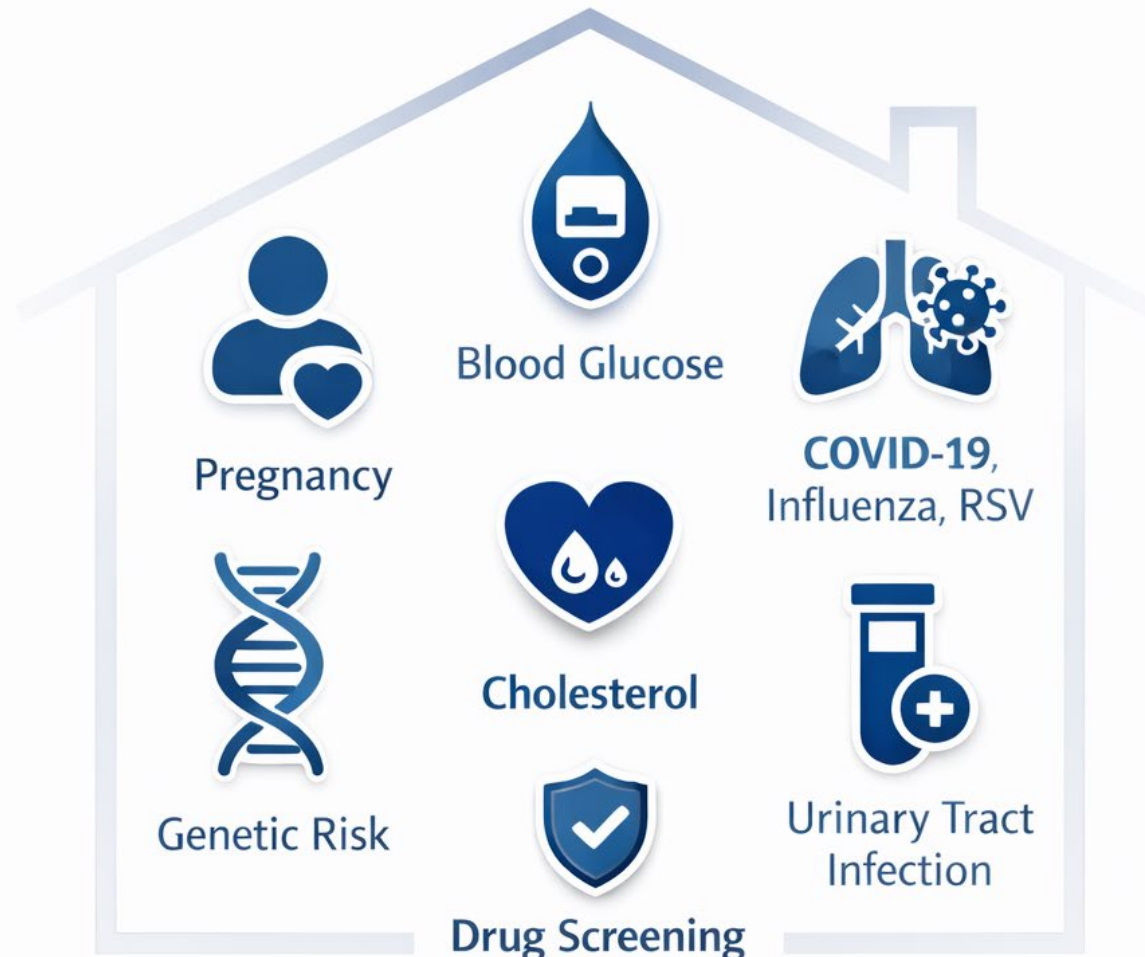
---

Stronger consumer  
focus on **prevention &**  
**wellness**

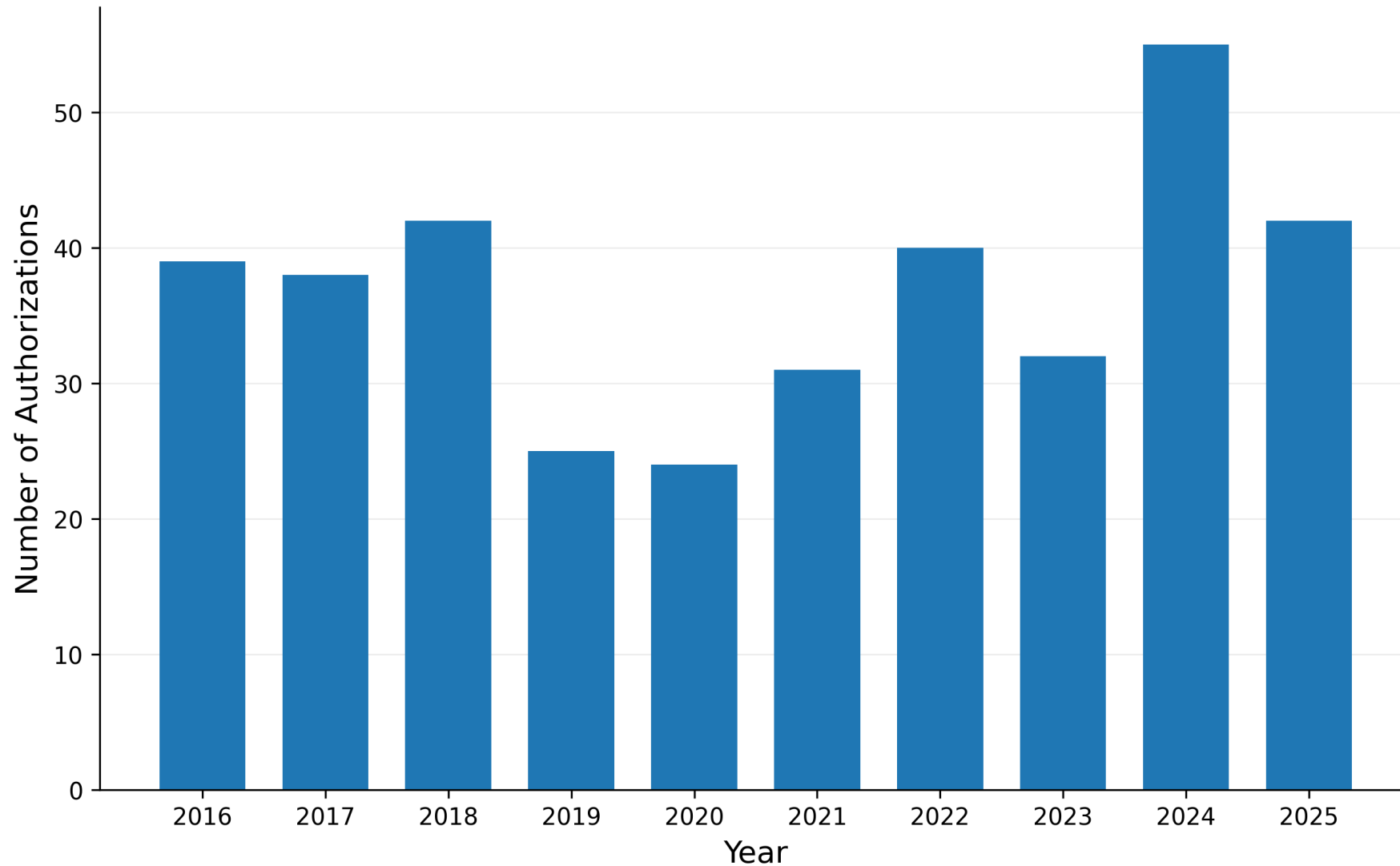
# Growing shift toward OTC availability for diagnostics & wearables



Nearly 400 authorized tests in the last decade



# Home Use Test Authorizations



# Infectious Disease Testing at Home



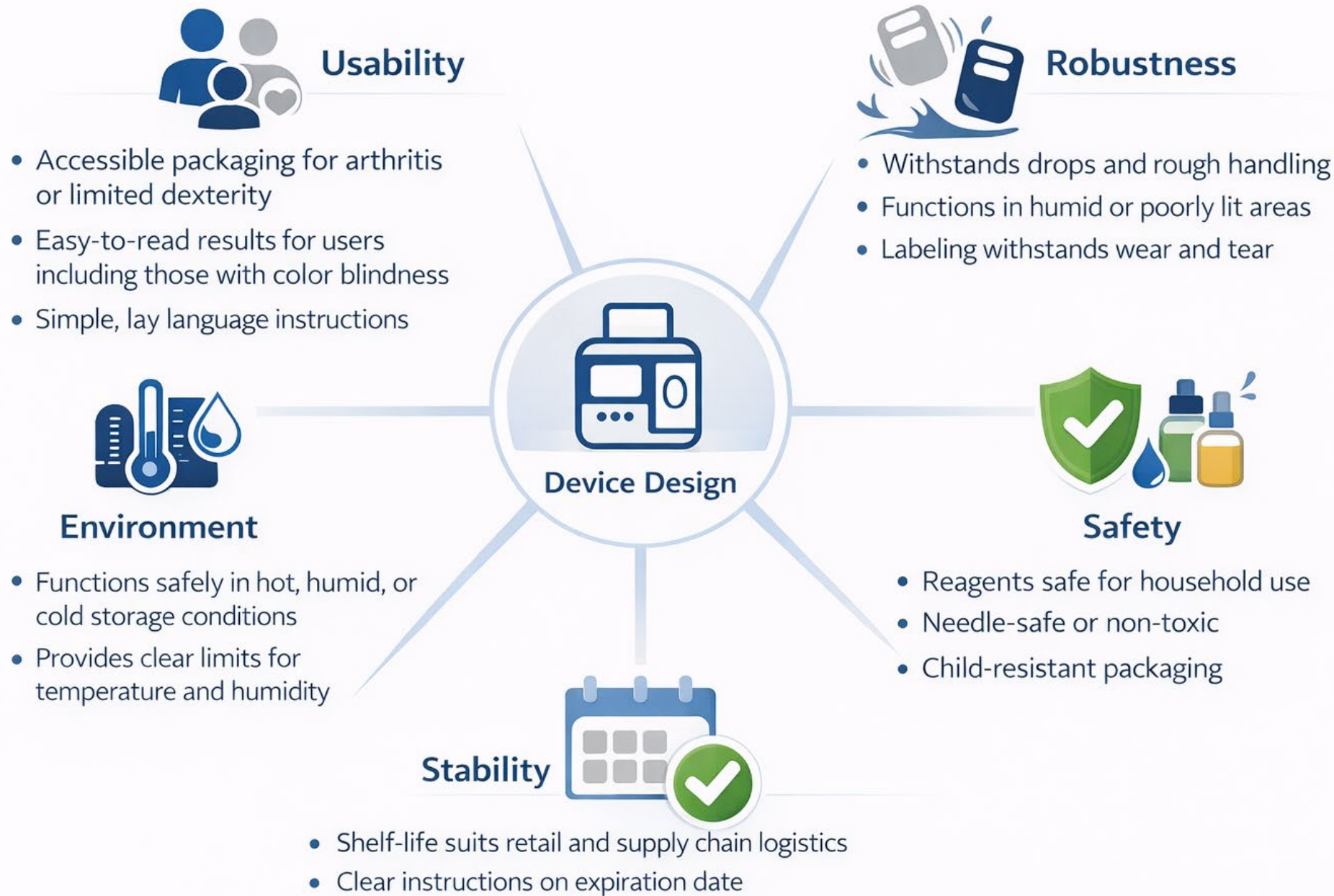
**COVID-19 Tests**



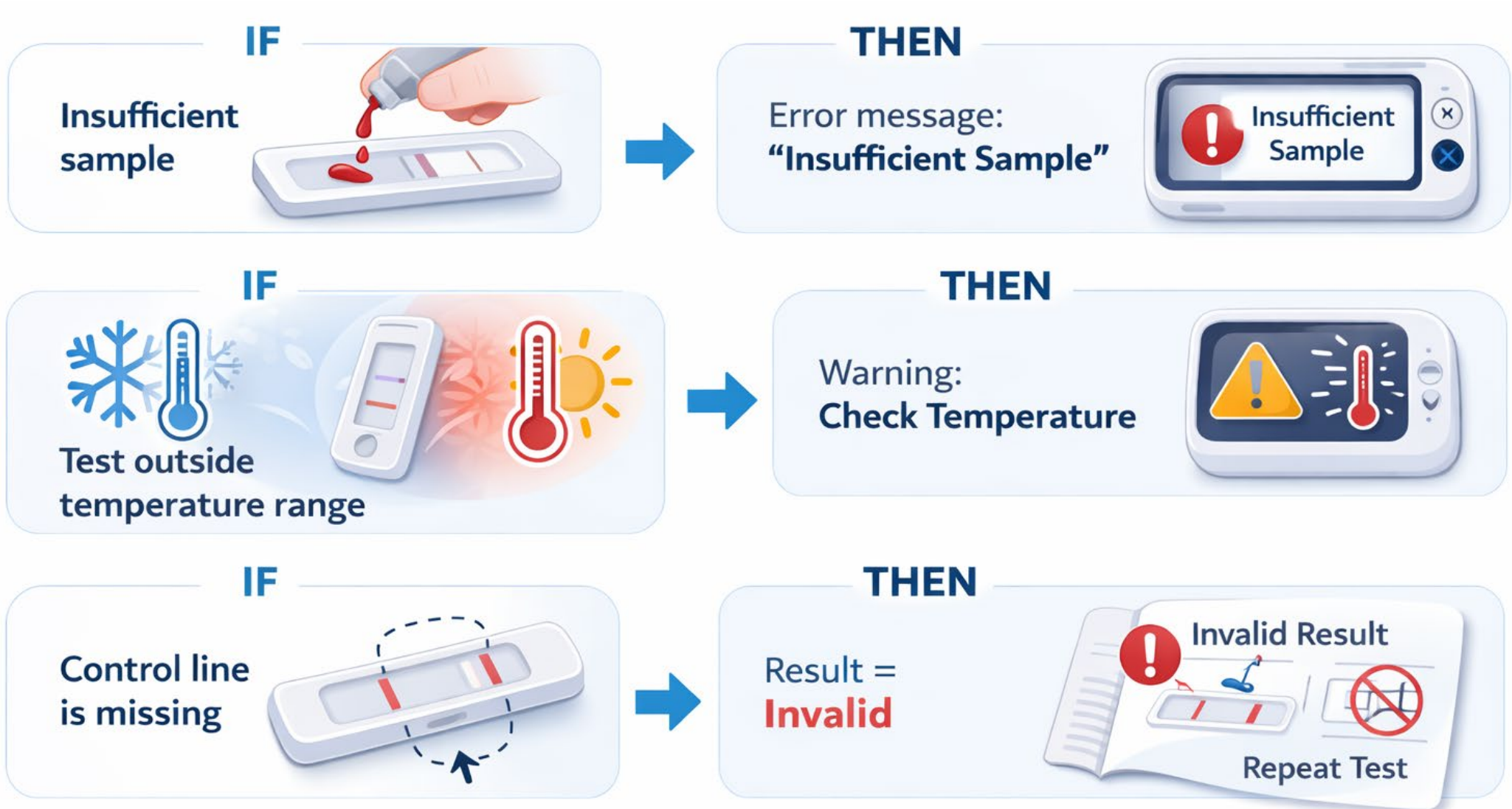
**Multianalyte  
Respiratory Panels**  
*(Flu, RSV, etc.)*



Growing availability of  
tests for HIV, UTIs, and STIs



# Can I break it?



# Home Use Specimens

Critical considerations for developing home-use medical devices

## Amount Needed



How much is required?

## Collection Interference



- Lotions on skin.
- Mouthwash for oral sample

## Collection Time



How long does it take?





## Impact of Errors



E.g, excessive pressure causing hemolysis



# Which Specimen Type?

	Urine	Capillary Blood	Dried Blood Spot	Oral Fluid
				
	✓ Easier	⚠ Tricky	⚠ Moderate	✓ Easier
<b>Ease of Collection</b>	<ul style="list-style-type: none"> <li>• Variable concentration</li> </ul>	<ul style="list-style-type: none"> <li>• Direct circulation access</li> </ul>	<ul style="list-style-type: none"> <li>• Good stability</li> </ul>	<ul style="list-style-type: none"> <li>• Lower concentration</li> </ul>
<b>Biomarker Availability</b>	<ul style="list-style-type: none"> <li>• Less stable</li> </ul>	<ul style="list-style-type: none"> <li>• Hemolysis risk</li> </ul>	<ul style="list-style-type: none"> <li>• Hemolysis risk</li> </ul>	<ul style="list-style-type: none"> <li>• Small volumes</li> </ul>
<b>Key Considerations</b>	<ul style="list-style-type: none"> <li>• Concentration varies</li> </ul>	<ul style="list-style-type: none"> <li>• Technique &amp; hemolysis risk</li> </ul>	<ul style="list-style-type: none"> <li>• Add reconstitution step</li> </ul>	<ul style="list-style-type: none"> <li>• Volume &amp; availability</li> </ul>

# Validating Home Use Tests



# Home Use Labeling



# Innovation



## Guidances & Templates



Clarifying Expectations

## ITAP Program



Independent Test Assessment Program

## Industry Outreach



Conferences & Workshops

## 1-on-1 Engagement



Q-Submission Program

## Federal Partnerships



Collaboration with NIH & CDC

# Home Use Tests – Resources

- **Websites:**

- [Over-the-Counter \(OTC\) Medical Devices: Considerations for Device Manufacturers | FDA](#)
- [Home Use Tests | FDA](#)
- [OTC – Over The Counter database for IVD Home Use Lab Tests \(Over The Counter\) Tests](#)

- **Guidance Documents:**

- [Design Considerations for Devices Intended for Home Use](#)
- [Applying Human Factors and Usability Engineering to Medical Devices](#)
- [Labeling Requirements – Over-The-Counter \(Non-Prescription\) Medical Devices.](#)
- [Guidance on Medical Device Patient Labeling](#)

**Thank You**

# Current Environment for OTC Diagnostics

**PRESENTER:**

Ramy Arnaout, MD  
Beth Israel Deaconess Medical Center



# Over-the-Counter Diagnostics: Advancing Home as a Health-Care Hub

---

**Ramy Arnaout, MD, DPhil**

Associate Director, Clinical Microbiology, Beth Israel Deaconess Medical Center (BIDMC)

Associate Professor of Pathology, Harvard Medical School

Division of Clinical Informatics, Department of Medicine, BIDMC



# About the Presenter

Arnaout Laboratory for Immunomics and Informatics

## Learning from COVID-19 Viral Loads

How viral loads vary—or don't—across patients can predict the performance of antigen tests in different groups

COVID-19 test results are usually reported simply as “positive” or “negative.” However, the amount of virus a person produces—the **viral load**—can vary. As clinical microbiologists responsible for COVID-19 testing at a major medical center, we **estimated** viral load for over **40,000 patients** who had a positive PCR test at our hospital from 2020-2023 so you can see how viral loads vary—or don't—across age, sex, and so on. **Please explore for yourself!**

[Explore groups >](#)

### Viral Loads In These 6 Groups

- The mean viral load across **~754 well appearing early variant era patients** was  **$1.1 \times 10^4$  copies/mL**.
- The mean viral load across **~1,136 sick appearing early variant era patients** was  **$4.6 \times 10^4$  copies/mL**.

OPEN ACCESS Freely available online

## The Landscape of Inappropriate Laboratory Testing: A 15-Year Meta-Analysis

Ming Zhi<sup>1</sup>, Eric L. Ding<sup>1,2,3</sup>, Jesse Theisen-Toupal<sup>1,4</sup>, Julia Whelan<sup>1,5</sup>, Ramy Arnaout<sup>1,4,7\*</sup>

1 Harvard Medical School, Boston, Massachusetts, United States of America, 2 Channing Laboratory, Department of Medicine, Brigham and Women's Hospital, Boston, Massachusetts, United States of America, 3 Massachusetts General Hospital, Boston, Massachusetts, United States of America, 4 Department of Pathology, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA, 5 Division of Clinical Informatics, Department of Medicine, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA, 6 Harvard Medical School, Boston, Massachusetts, USA, 7 Harvard Medical School, Boston, Massachusetts, USA

### Grade Inflation in Generative Models

Phuc Nguyen, Miao Li, Alexandra Morgan, Rima Arnaout, and Ramy Arnaout

Abstract—Generative models hold great potential, but only if one can trust the evaluation of the data they generate. We show that many commonly used quality scores for comparing generative models are biased, leading to inflated grades. We propose a new quality score, Equipoint, which is unbiased and more robust to model overfitting. We demonstrate that Equipoint is a more reliable quality score for comparing generative models.

### GEM-T: Generative Tabular Data via Fitting Moments

Miao Li<sup>1</sup>, Phuc Nguyen<sup>1</sup>, Christopher Tam<sup>1</sup>, Alexandra Morgan, Kenneth Ge, Rahul Bansal, Linzi Yu, Rima Arnaout<sup>1</sup>, Ramy Arnaout<sup>1\*</sup>

AMERICAN SOCIETY FOR MICROBIOLOGY | Journal of Clinical Microbiology®

### Cooperation under Pressure: Lessons from the COVID-19 Swab Crisis

Ramy A. Arnaout<sup>a,b,c</sup>

<sup>a</sup>Department of Pathology, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA  
<sup>b</sup>Division of Clinical Informatics, Department of Medicine, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA  
<sup>c</sup>Harvard Medical School, Boston, Massachusetts, USA

**ABSTRACT** The early months of the COVID-19 pandemic were marked by a desperate need for nasopharyngeal swabs to test for SARS-CoV-2, with demand far outstripping supply. April marked the anniversary of an unprecedented nationwide multibusiness/multihospital partnership that successfully met this need, a fitting occasion to review lessons learned. Here, I briefly recount the key events, constraints, and thought processes surrounding the effort in order to better inform responses to future crises. Overall, the experience was a strong validation of Joy's Law and illustrated the utility of recognizing opportunities to build in safety to ease the severity of unexpected, large-scale supply shortages.

pyproject.toml

## sentropy 1.0.5

pip install sentropy

Released: Jan 8, 2025

A Python package for measuring the composition of complex datasets

### Project description

Quantify datasets more reliably using elements' similarities

## sentropy

sentropy: A Python package for revealing hidden differences in complex datasets

python 3.9 | 3.10 | 3.11 | Tests: passcov

About | Key terms | How to cite | Installation | Basic usage | Shannon entropy | Shannon-type S-entropy | Multiple measures of | Passing a similarity function | Representativeness | Results as a pandas dataframe | Ordinariness | TorchGPU | More applications | Alternatives

Verified details

These details have been verified by PyPI

Maintainers

rhongphuc

Unverified details

These details have not been verified by PyPI

Project links

Bug Tracker

Homepage

Meta

- License: MIT License
- Author: Elliot Hill
- Maintainer: Alex Morgan
- Requires: Python >=3.9
- Provides-Extra: lint, ray, tests

Classifiers

License: OSI Approved :: MIT License

Operating System: OS Independent

Programming Language: Python 3

Report project as malware

Dataset 1

Both have 16 unique elements and thus identical traditional entropy, despite their clear differences

$D_1 = 16$

Dataset 2

$D_1 = 16$

Similarity matrix

$D_1^2 = 2.6$

$D_2^2 = 2.0$

In contrast, S-entropy sees that Dataset 2's elements all have red in them—similarities that give it lower S-entropy

<https://arnaoutlab.org/coviral> ; J. Vacc. Vaccin. 2025

# OTC Testing: Why It Matters

---

- Most health care is delivered **outside the hospital**
  - Early rule-in/rule-out → better, more cost-effective care
- **Common indications**
  - Infectious-disease (COVID-19, influenza, HIV)
  - Pregnancy & fertility
  - Glucose, cholesterol, drug-of-abuse screening
- **~500M–1B tests/year** in the US
  - Not counting glucometers
  - Compare to ~20B lab tests performed in the hospital
- **Results usually not stored**
  - Better for OTC data must become part of the patient's electronic health record (EHR)—not “dark matter” invisible to care teams



# What Counts as an OTC Diagnostic—and What Doesn't

---

- **OTC diagnostics**

- FDA-cleared, at-home tests that measure a biological analyte
- Common specimen types: nasopharyngeal secretions (swabs), blood, urine

- **Not OTC diagnostics**

- Wellness/health apps: track steps, heart-rate, sleep, activity
- Anything requiring a prescription

- **Borderline/gray area/evolving**

- Cardiac-related heart-rate & EKG monitors (yes)
- Hand-held ultrasound (not presently)



# How OTC Results Reach the EHR (When They Do)

- **Manual provider entry**
  - Patient tells clinician → clinician types result into EHR
- **Patient portal entry**
  - Patient logs into portal and manually records result
- ✓ **Image-capture & barcode scanning**
  - Photo or video of test + QR/barcode → app extracts result & pushes to EHR
- **Key challenge**
  - Each method requires activation energy from the patient
  - **Need friction-less UX for widespread data collection**



# Why Harness OTC Data?



## Caregivers

- Train AI-based decision support on anonymized OTC results
- Benchmark outcomes across regions to identify best-practice pathways
- Simulate rare-disease presentations with synthetic cases for education



## Regulators

- Train AI-based CDS on anonymized patient histories including OTC results
- Benchmark outcomes across regions to identify best-practice pathways
- Simulate rare-disease presentations with synthetic cases for education



## Test Developers

- Stress-test assay algorithms with synthetic specimens
- Perform *in silico* trials before development
- Benchmark against competitor data aggregated from public repositories



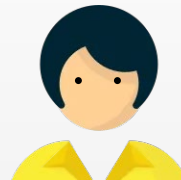
## Academia

- Use large datasets for hypothesis generation
- Validate epidemiological models using synthetic cohorts that preserve privacy
- Publish reproducible studies without needing IRB-approved patient data



## Payors

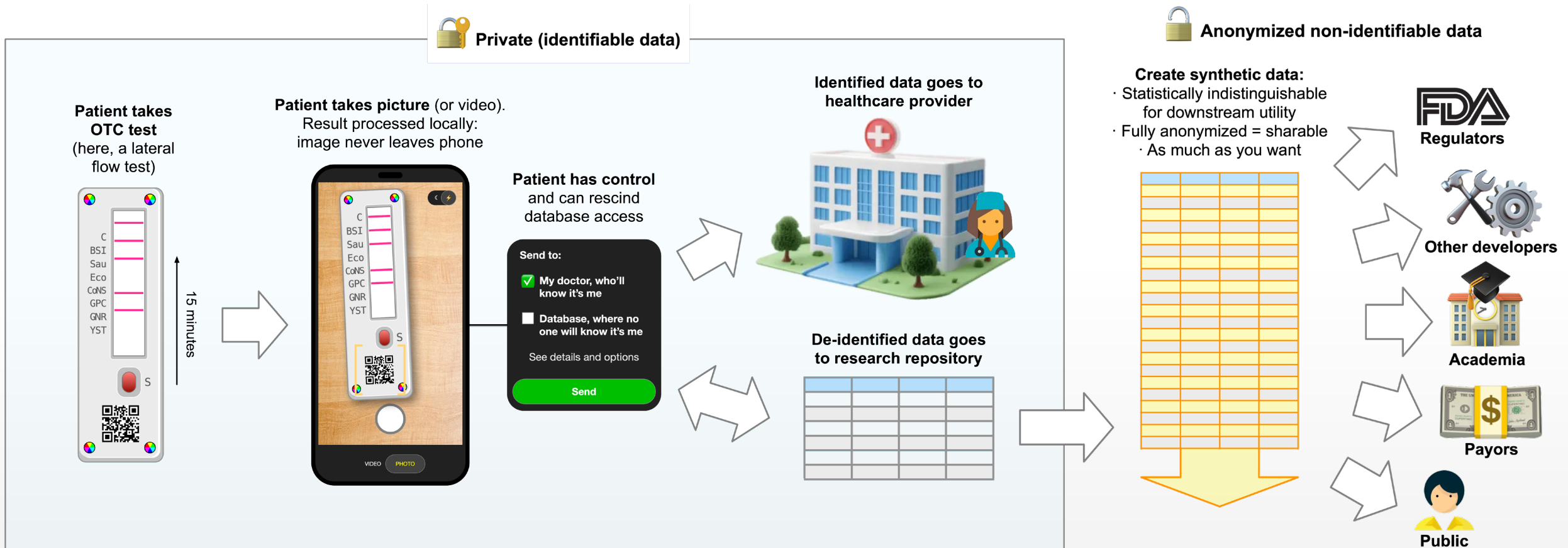
- Model disease incidence & test utilization to design value-based reimbursement policies
- Simulate cost-effectiveness of specific OTCs across demographic segments
- Detect fraud or misuse patterns



## Patients

- Faster, more accurate diagnosis
- Personalized care pathways
- Lower health-care costs
- Privacy-preserving participation
- Empowerment & engagement

# Vision: From OTC Test to Shareable Synthetic Data



# Challenges/Obstacles to Overcome

## • Patient incentives & trust

- “Don’t make me think:” data collection must be effortless for the patient
- Surveillance concerns → need transparent governance & consent

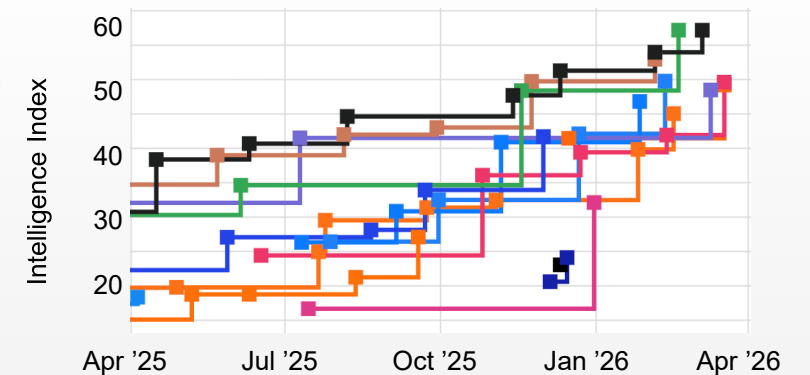
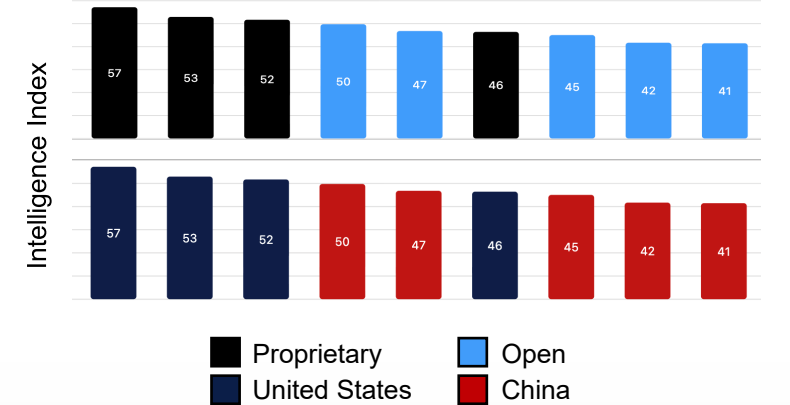
## • Technical collection hurdles

- Data-capture technology: barcode scan, local language-vision ML model, smartphone requirement
- What data to record? Line intensity, time-to-pos., environmental conditions...
- Synthetic data quality: how to benchmark, statistical vs. functional tests

## • Data-sharing infrastructure

- Who hosts the repository? Public vs. private governance model
- Incentivizing developers to contribute data
- Robust, standards-based anonymization pipelines

Top Artificial Intelligence Models, March 25, 2026



<https://artificialanalysis.ai/>

# Closing Thoughts

---

- OTC diagnostics are a **large, untapped data source that can improve care, research, regulation, and cost-effectiveness**
- Local-processing + patient-controlled sharing can **address privacy concerns**
- **Synthetic data** bridges the gap between useful analytics and strict privacy mandates
- **Overcoming incentive, technical, and infrastructure challenges** will help unlock the potential of the home-as-a-health-hub model

# Thank you



# Current Environment for OTC Diagnostics

## PANELISTS:

- Ramy Arnaout, MD, Beth Israel Deaconess Medical Center
- Julie Barnes, JD, Maverick Health Policy
- Courtney Lias, PhD, U.S. Food and Drug Administration
- Anita Nosratieh, PhD, Abbott
- Stacey Swartz, PharmD, Neighborhood Pharmacy of Del Ray

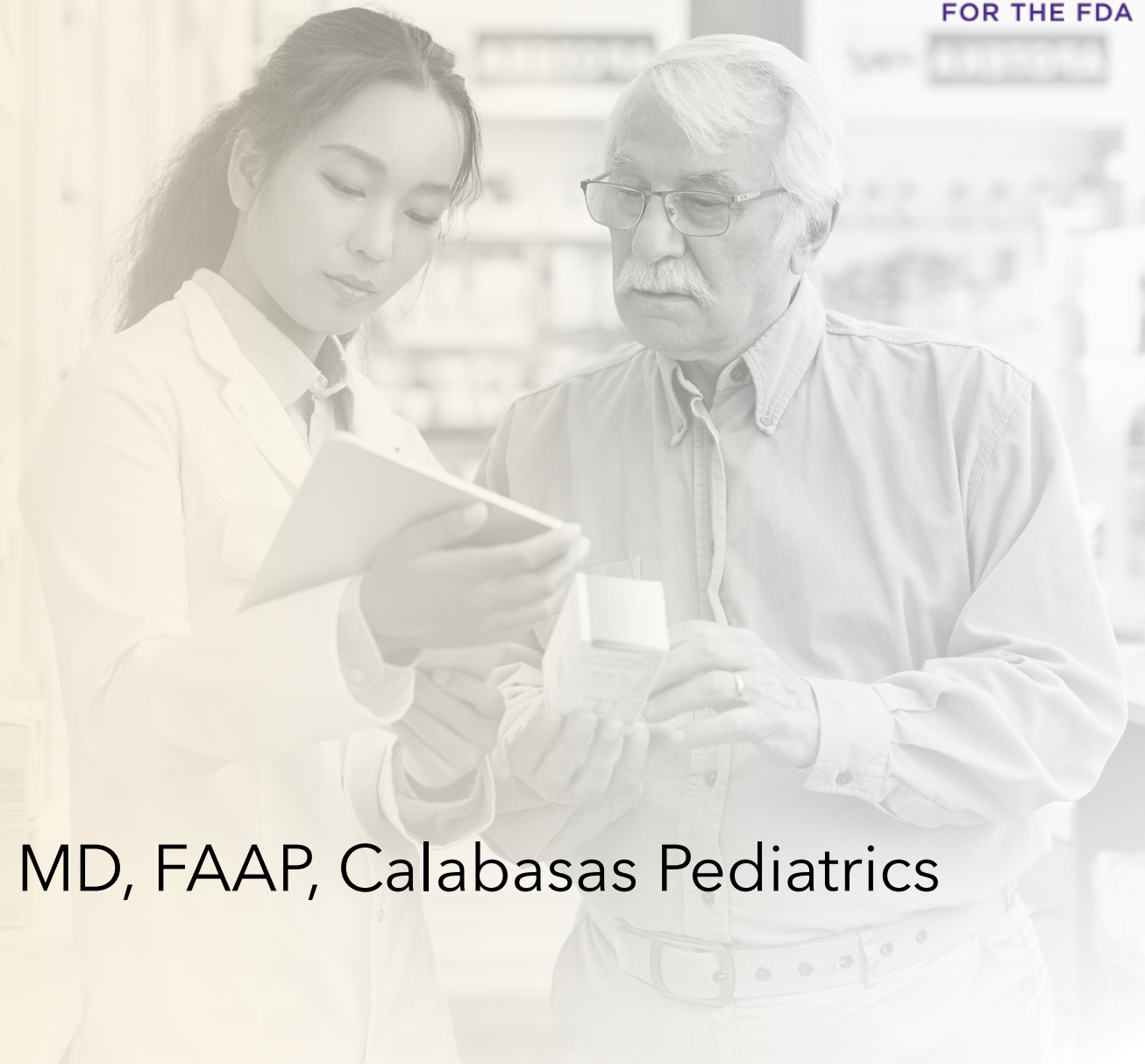
# Integrating OTC Diagnostics into Care Delivery

## PANELISTS:

- James Appleby, BSP Pharm, MPH, Gerontological Society of America
- Deborah Autor, JD, Hims & Hers
- Michael Umbleby, RPh, Walgreens
- John Whyte, MD, MPH, American Medical Association

# User Perspective

**SPEAKER:** Tanya Altmann, MD, FAAP, Calabasas Pediatrics



# Next Generation OTC Diagnostics

**PRESENTER:**

Paul Wardle, MA, MMath  
Klick USA Inc.



# Transforming Diagnostic & Medication Access

## Next Generation OTC Diagnostics

**DATE PRESENTED:** March 25, 2026  
**CONTACT:** Paul Wardle [wardle@klick.com](mailto:wardle@klick.com)

# Disclaimer

## The opinions shared today are mine They do not necessarily reflect the views of the FDA or my employer.

- Klick is a full-service life sciences commercialization partner. We support sponsors across prescription, nonprescription, devices, diagnostics and supplements.
- We also develop software as a medical device (SaMD) solutions in support of NDA applications for the new Additional Conditions for Nonprescription Use (ACNU) pathway
- Paul has led or supported many prescription-to-nonprescription NDA programs, including ACNU, across a wide range of therapeutic conditions
- Adjunct instructor at New York University in Statistics, Measurement and Analysis
- Masters degrees in Mathematics and Theoretical Physics from the University of Cambridge

**Transforming medication access:** A novel regulatory pathway for increasing direct-to-consumer access. RAPS JOURNAL OF REGULATORY AFFAIRS. 2026;1(1):25-36. Published online 12 January 2026. <https://www.raps.org/news-and-articles/News-Articles/2026/1/Transforming-medication-access-A-novel-regulatory>

**50th Year** **JRA** Journal of Regulatory Affairs

### Transforming medication access: A novel regulatory pathway for increasing direct-to-consumer access

  
Paul Wardle, MA, MMath

This article examines how technology can be leveraged to expand direct-to-consumer access to medications under the US Food and Drug Administration's (FDA) new regulatory pathway, which took effect in May 2025. Driven by unmet patient medical needs, shortages of healthcare professionals (HCPs), and technological advancements that can help reduce barriers to treatment, the FDA has introduced a new incremental NDA pathway that allows sponsors to propose alternative mechanisms to support appropriate medication access without the supervision of an HCP legally authorized to prescribe or administer the drug. This pathway has important potential benefits for branded prescription medicines, generic manufacturers, consumer healthcare companies, and most importantly, consumers or patients.

  
Aleks Lyons, BSc, BSc

**Keywords** – ACNU, consumer engagement, DTC, self-care, patient access, unmet needs

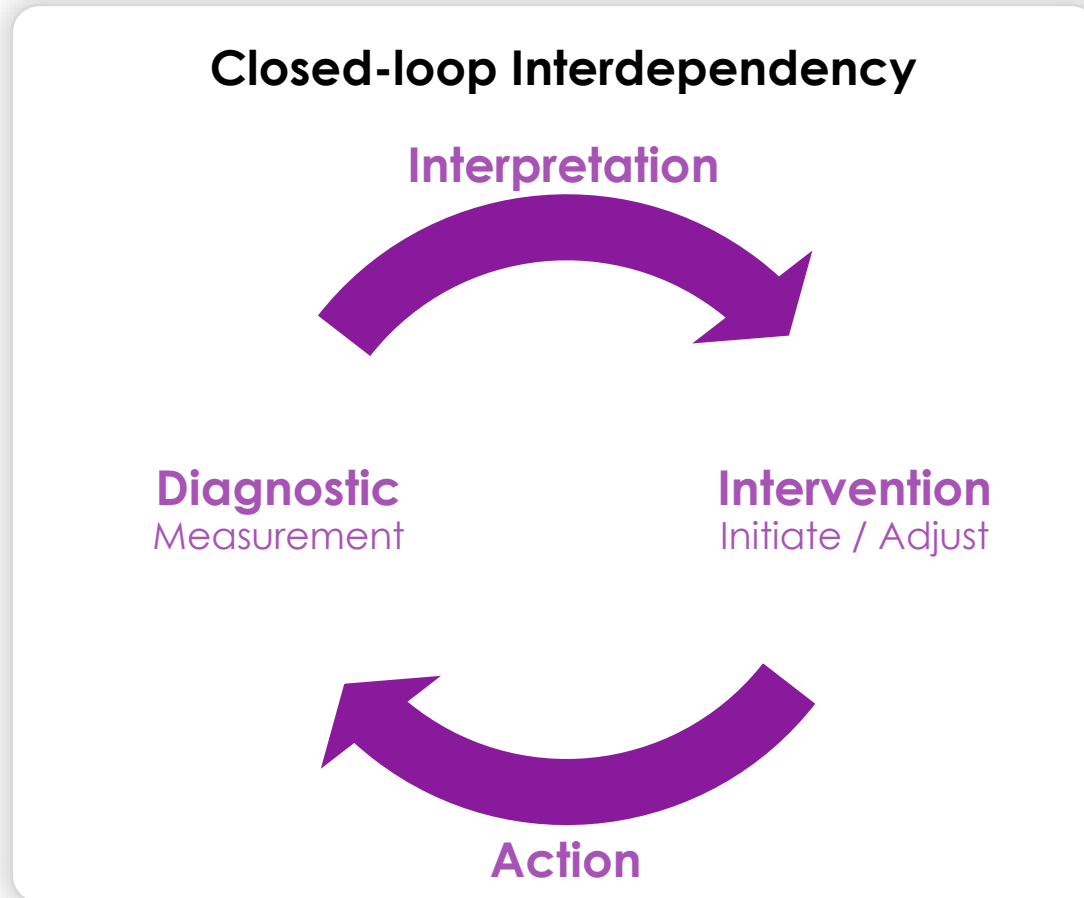
**Background and introduction**  
Despite widespread medical insurance, significant portions of the US population remain undertreated or untreated for their medical conditions. In addition, a multitude of circumstances can result in a multitude of barriers to treatment, including financial, geographical, physical, or psychological obstacles. Further, even if these barriers were overcome, there are insufficient HCPs to meet these unmet needs. To address these issues, effective May 2025 the FDA implemented a new regulatory pathway for new drug applications (NDAs) aimed at increasing medication access. The intent of this pathway is to encourage the development of innovative direct-to-consumer (DTC) access mechanisms that enable more convenient consumer access to medications while ensuring the safe and effective use of the drugs.

The new rule is also positioned to improve public health by expanding the types of drug products, including those for chronic conditions, that are accessible to qualified consumers. Any such mechanism approved under this ACNU [additional conditions for nonprescription use] NDA pathway must ensure appropriate access, where otherwise an HCP would have been necessary.<sup>1</sup> The distinction between prescription and nonprescription drugs is clear. When an HCP is necessary to guide the safe and effective selection and use of the product, it should be classified as a prescription drug; if an HCP is not necessary, the product should be approved as a nonprescription drug. With an ACNU drug, if, for example, a technology mechanism is used to ensure appropriate access to and safe and effective use of the product without an HCP prescription, then the ACNU drug would be nonprescription for those consumers who gain access with the mechanism or condition. When neither an HCP nor an alternative mechanism is necessary, and consumer labeling alone is sufficient to guide safe and effective drug selection and use, then the product may be approved as a

January–February 2026 | Volume 1 | Number 1 25

# Effective Healthcare Requires Access

## *Optimizing diagnostic & medication accessibility*



**MANY FACTORS TO CONSIDER** e.g.

- In-person vs. remote
- Individual vs. provider supported
- Accuracy & accessibility
- Timeliness & convenience
- Diagnosis vs. adherence or adaptive care
- Comorbidities
- Integration across the system
- Privacy & control
- Reimbursement & affordability
- Self-monitoring

# Our medical needs are extensive and varied

*National Health Interview Survey (NHIS) data<sup>1</sup>*

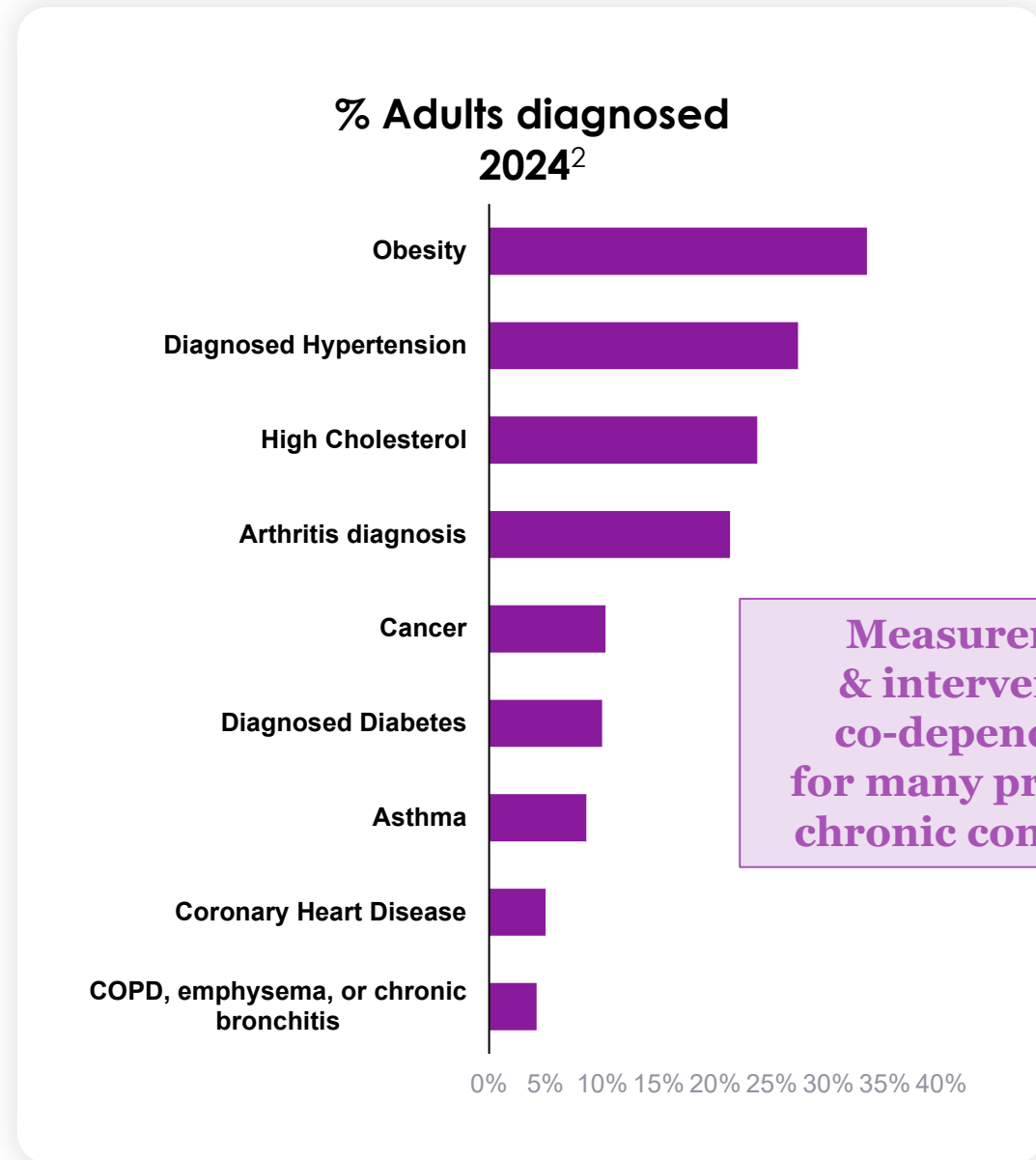
**51.8%**

of adults have at least one chronic disease<sup>1</sup>

**27.2%**

of US adults have multiple chronic conditions<sup>1</sup>

1. Boersma et al. Prev Chronic Dis 2020;17:200130
2. [https://wwwn.cdc.gov/NHISDataQueryTool/SHS\\_adult/index.html](https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index.html)



# Despite effective treatments, there remain *large unmet needs*

*illustrative*

**Gaps in diagnosis** e.g. diabetes<sup>2</sup> ~23%, hypertension<sup>3</sup> ~37%

**Patients not treating** e.g. cholesterol<sup>1</sup> ~45%, obesity<sup>6</sup> >50%

**Uncontrolled** e.g. hypertension<sup>9</sup> 77%, asthma<sup>7</sup> ~62%

**Non-adherence** e.g. hypertension<sup>4</sup>, cholesterol<sup>1</sup> ~50%

**Delayed treatment** e.g. mental health<sup>5</sup> ~11 years

**Medication access** e.g. food allergies: current epinephrine Rx<sup>8</sup> 24%

Sources:

1. JAMA Cardiol. 2019 Mar; 4(3): 206–213
2. <https://www.cdc.gov/diabetes/php/data-research/>
3. *American Journal of Hypertension*, Volume 34, Issue 9, September 2021, Pages 989–998
4. *BMJ* 2008; 336, 1114–1117; *J Am Soc Hypertens.* 2011; 5:56–63

5. <https://www.nami.org/about-mental-illness/mental-health-by-the-numbers/>
6. <https://pubmed.ncbi.nlm.nih.gov/35928911/>
7. <https://pubmed.ncbi.nlm.nih.gov/38013060/>
8. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720064>
9. <https://www.cdc.gov/high-blood-pressure/data-research/facts-stats/>

# Barriers to healthcare are *real and widespread*

- Many social determinants of health<sup>8</sup>
- Healthcare access challenges often exacerbated by nature of employment<sup>2</sup>
- Caregivers experience increased barriers to healthcare access<sup>5</sup>

1. <https://www.healthsystemtracker.org/>  
 2. <https://www.hhs.gov>  
 3. <https://www.hsph.harvard.edu>  
 4. <https://www.sciencedirect.com>  
 5. <https://psycnet.apa.org>  
 6. American College of Physicians

7. <https://www.ncbi.nlm.nih.gov>  
 8. <https://health.gov>  
 9. [https://assets.ctfassets.net/4f3rgqwzdznj/1XSI43I40KXMQiJUti0ilq/ad0070ad4534f9b5776bc2c41091c321/GoodRx\\_Healthcare\\_Deserts\\_White\\_Paper.pdf](https://assets.ctfassets.net/4f3rgqwzdznj/1XSI43I40KXMQiJUti0ilq/ad0070ad4534f9b5776bc2c41091c321/GoodRx_Healthcare_Deserts_White_Paper.pdf)



## OPPORTUNITY COST OF GOING TO THE DOCTOR<sup>1</sup>

too high for many who have to choose between work and healthcare<sup>3</sup>



## INDIVIDUALS WITH PHYSICAL DISABILITIES<sup>4</sup>

have an 85% higher odds of having unmet prescription medication needs<sup>1</sup>



## 75 M AMERICANS

live in an area with a **shortage of primary care doctors**.<sup>2</sup>  
 Over 41 Mmillion live in a pharmacy desert.<sup>8</sup>



## Delaying healthcare due to **procrastination or avoidance behaviors** is common<sup>6,7</sup>

# Consumers are interested in new ways *to manage their own health*

I am always looking for  
**new ways to manage  
my health on my own**

I wish it was **easier to  
access the medication**  
that I need to manage  
my health

**I prefer to use over-the-  
counter medicines first**  
... and only consult with  
my doctor if necessary

**AGREE**  
strongly or somewhat

63%

37%

35%

**DISAGREE**  
strongly or somewhat

14%

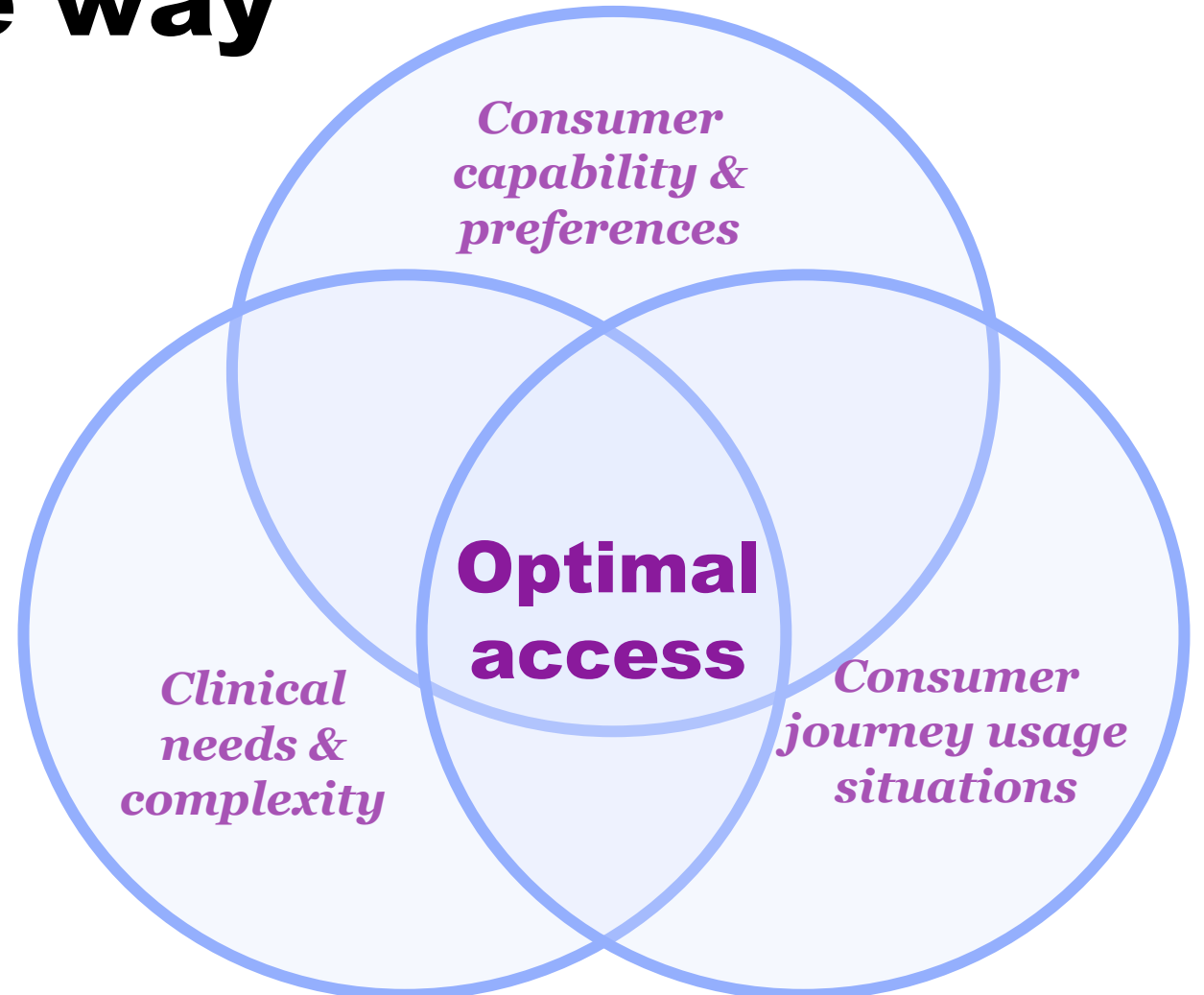
28%

41%

Klick online survey Q2: 2022, explored preferences and barriers across a range of chronic health conditions

# Should we *always* get access the same way *every time?*

- Historically prescription vs. nonprescription access has been defined by the product
- However, consumer needs for HCP interactions are situation dependent and often more nuanced
  - When might an HCP be appropriate?
  - When might self-directed care be better?
  - How best to address affordability?



# ACNU NDA – Increasing Medication Access

*Additional Condition for Nonprescription Use*

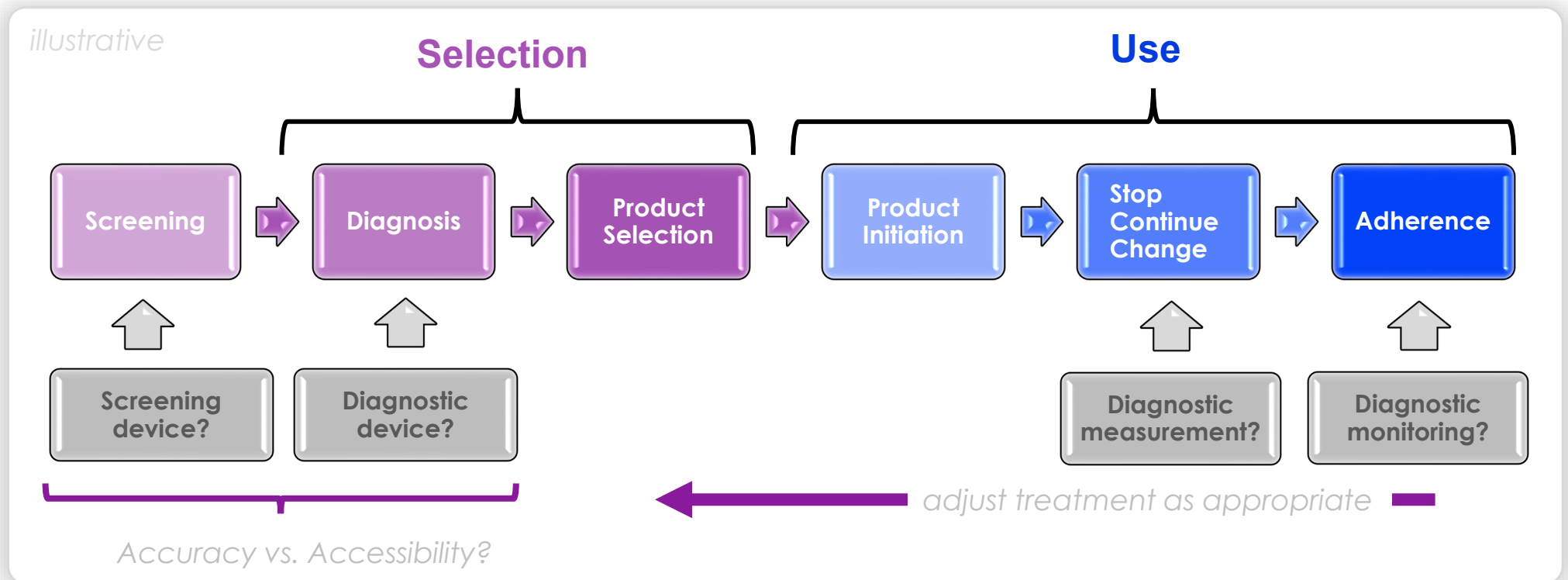
Enforced “criteria” to gain access



Nonprescription, because doctor is not required

# ACNU "condition" may necessary to support *selection, use or both*

## Diagnostic and Medication Interdependency



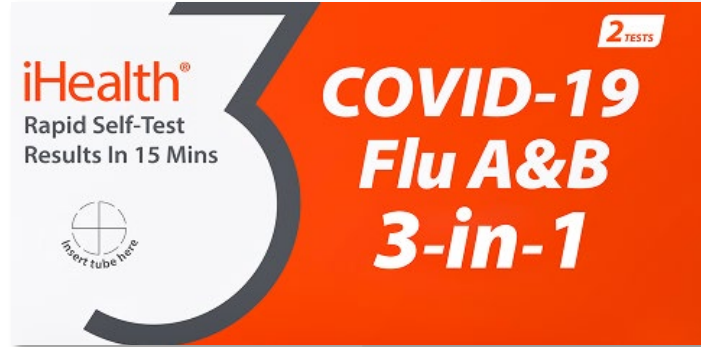
**Medication**

**Diagnostic Measurement**

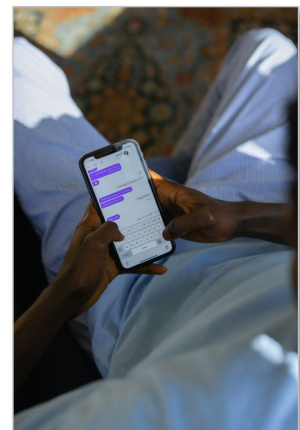
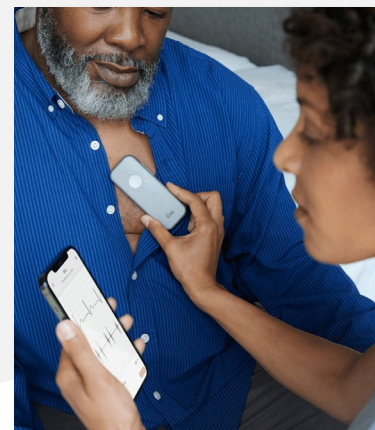
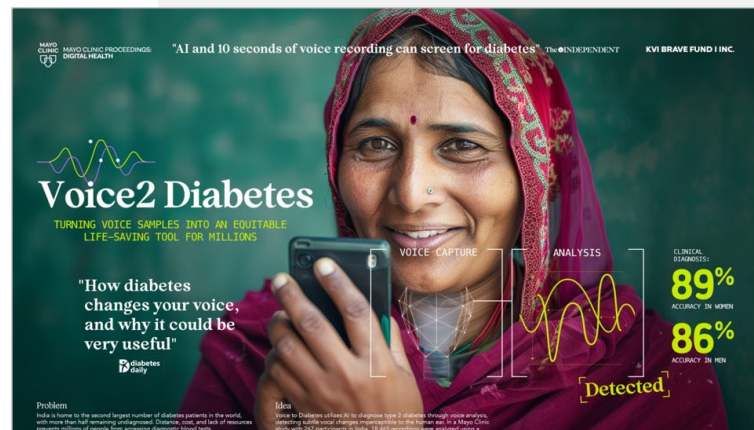
e.g. cholesterol, A1C, blood pressure

# Reimagining Diagnostic Access & Solutions

- Screening, diagnostic, measurement
- Accessible, remote, non-invasive
- Enabling action including medication



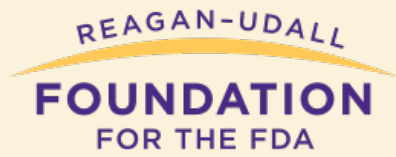
Trademarks & Visuals owned by respective companies. Voice2 Diabetes screening a Klick development activity



**There's  
something  
different here.**

**Paul A Wardle**  
SVP, Innovation Consulting





# Next Generation OTC Diagnostics

## **PRESENTER:**

Patty Post, BA  
Checkable



The logo for 'checkable' features the word in a teal, rounded sans-serif font. The letter 'k' is stylized with a teal checkmark shape integrated into its upper right portion. A registered trademark symbol (®) is located at the top right of the word.

checkable®

HOME STREP TEST

---



# Checkable® Home Strep Test

## \*Currently Under FDA Review

36M Pharyngitis Visits a Year  
26M Strep Tests Administered  
5.2M Prescribed an Rx

Checkable® Home Strep Test includes a backup test to ensure consumers can retest if needed or test a family member for added convenience and peace of mind.



Start to Finish in 10 Minutes

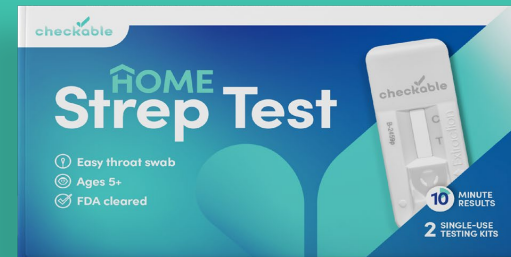


Clinically Validated Lateral Flow Technology



Designed for safe, guided use at-home

## Checkable® Home Strep Test



+Not Shown Dual Chamber Reagent



# Checkable® is Making Throat Swabs Safe - Simple - Scalable



Real Use



Guided Learning

Some sore throats are scarier than others.



Instructions Built Into Packaging



# Considerations for Expanding Testing Closer to Home

## Condition Suitability

Strong OTC candidates typically have

- ✓ Clear symptom presentation
- ✓ Established gold standard
- ✓ Straightforward interpretation
- ✓ Clear follow-up action

**OTC testing kits can meaningfully expand access and improve public health - if we align on a balanced, benefit-focused regulatory pathway.**

**Patty Post**  
Founder & CEO



## Regulatory Balance & Pathway Challenges

Are we focusing too much on risk, while minimizing public health benefits?

- ✓ A large majority of rapid OTC testing kits work exactly as they do in clinics and labs.
- ✓ Home testing expands access within our healthcare system, especially for those often missed.
- ✓ Benefits now clearly outweigh risk across specific conditions.
- ✓ Risk can be further mitigated with user-friendly design, intuitive labeling, and thoughtful stewardship.
- ✓ Pathway guidance must balance safety with access and impact, fostering regulatory clarity and guardrails for innovation.

# Next Generation OTC Diagnostics

**PRESENTER:**

Sam Surette, BS  
Apple



# Opportunistic Detection

Intelligent insights from wearables

Sam Surette, Regulatory Affairs Manager, Apple



# Opportunistic Detection

---

Detects signs of a chronic condition

Analyzes passive sensor data from consumer wearable

Returns a positive result only

Upstream from screening and diagnostics

# Regulatory Considerations

---

Operating points prioritize high specificity

Human factors and post-market surveillance demonstrate safe use in OTC population for pre-screening of irregular rhythms, sleep apnea, and hypertension



# Next Generation OTC Diagnostics

## PANELISTS:

- Kathryn Capanna, MBA, U.S. Food and Drug Administration
- Marcia Howard, PhD, CAE, Consumer Healthcare Products Association
- Michael Mina, MD, PhD, HTR Advisors
- Patty Post, BA, Checkable
- Sam Surette, BS, Apple
- Paul Wardle, MA, MMath, Klick

# Thank you for attending!

The recording and transcript will  
be posted on our website soon.  
[www.reaganudall.org](http://www.reaganudall.org)