Accessible by Design:
The Story of the NIH RADx Accessibility Initiative

June 10, 2026

RADx Background

- **Rapid Acceleration of Diagnostics** (RADx®): A new initiative of NIBIB, beginning in 2020
  - NIBIB funds research in biomedical imaging, bioengineering, and informatics, supporting the next generation of interdisciplinary researchers
- **Goal:** Speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing
  - Over 7 Billion tests/products
  - 45 FDA authorized tests
  - 1st Over-the-Counter test for use at home
  - >100 organizations supported
  - $1.7 Billion

2022:
Program Launch & Foundation

Program Background

January 2022

U.S. government begins large-scale distribution of COVID-19 home tests.

Q1 - 2022

Disability and aging advocacy organizations call for improved accessibility of home tests.

March 24, 2022: Listening Session

NIH convenes advocacy organizations and government agencies to identify accessibility barriers and priorities.

Advocacy Participants (8)

- Alliance on Aging and Vision Loss (AAVL)
- American Council of the Blind (ACB)
- American Foundation for the Blind (AFB)
- American Geriatrics Society (AGS)
- Independence Through Enhancement of Medicare Coalition (ITEM)
- National Disability Rights Network (NDRN)
- National Federation of the Blind (NFB)
- World Institute on Disability (WID)

Agency Participants (9)

- Centers for Disease Control
- Food and Drug Administration
- National Council on Disability
- National Eye Institute
- National Center for Medical Rehabilitation Research
- National Institute on Disability, Independent Living, and Rehabilitation Research/Administration for Community Living
- National Institute of Dental and Craniofacial Research
- National Institute of Nursing Research
- US Access Board

Funding is allocated to establish the RADx Tech Accessibility Initiative.

Research and Program Design

April 2022: Literature Review

We seek existing accessibility design standards for in vitro diagnostics and consumer medical products. No formal standards for non-digital product design are found.

April 2022: Manufacturer Recruitment (Original Program)

Test manufacturers are invited to participate from among RADx Tech industry participants. Ultimately 15 of 23 companies join the initiative.

April 2022: GT HomeLab Engagement

Georgia Tech's HomeLab accessibility laboratory is engaged to conduct systematic usability and accessibility evaluations.

Complete Testing Workflow

Striving for complete solutions from product acquisition through disposal

Purchase → Unboxing → Sample Collection → Sample Handling → Run Test → Read Results → Disposal

Plus general topics across all categories: Holistic Design, Regulatory, Design Control, Braille, Plain Language and Engaging End Users

Product Evaluation

May 2022: Product Accessibility Assessments Begin

HomeLab begins detailed evaluations of test kits.

About the process:

- The workflow is broken into a list of individual critical and non-critical tasks that span test box opening through disposal (averaging 40+)
- Each task is evaluated for accessibility for:
  - Blind users
  - Low-vision users
  - Individuals with limited dexterity
  - Aging populations
- Accessibility recommendations are developed for problematic steps.

HomeLab Report – Sample Task Analysis

Example tasks include:

- Open the outer box
- Consume instructions
- Remove seal from buffer tube
- Open swab package
- Dispense 3 drops of buffer into sample well on test device
- Close tube cap
- Interpret results

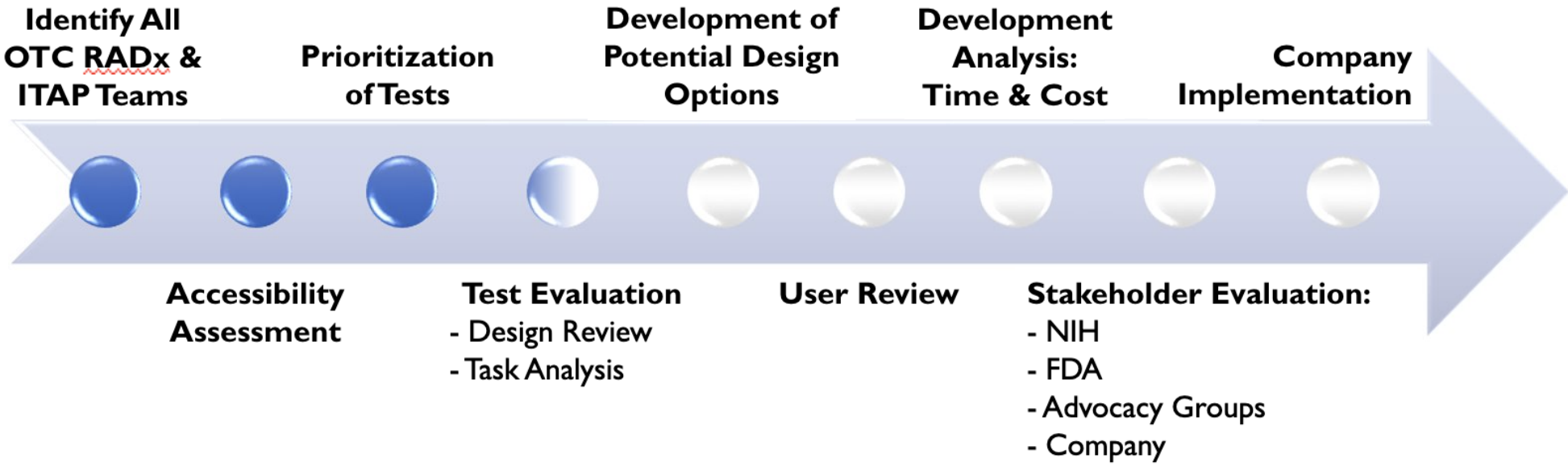
User Group	Number of inaccessible essential tasks	Number of inaccessible nonessential tasks
No vision	18	2
Low vision	5	1
Limited Dexterity	2	0
Older Adults	5	0

Stakeholder Engagement

May 11, 2022: Advocacy & Agency Meetings Begin

Monthly meetings launch to engage advocacy groups and federal partners.

Initial Process Diagram



Lessons Learned:

- Make information fully accessible
- Engage SMEs with lived experience ***continually*** throughout the evaluation and design process.

Subject Matter Experts (SMEs)

May 2022: SME Recruitment

Based on the advice of the advocacy partners, subject matter experts (SMEs), including individuals with lived disability experience, are recruited to evaluate products and provide design input.

- **Subject matter experts were critical to the success of the program**
- **19 program SMEs supporting RADx:**
  - Trace Research & Development Center @ University of Maryland
  - Non-visual Accessibility Analyst, National Federation of the Blind
  - Designers from blind population
  - Reviewers from aging population
  - Reviewers from motor impairment population

User Evaluation and Design Development

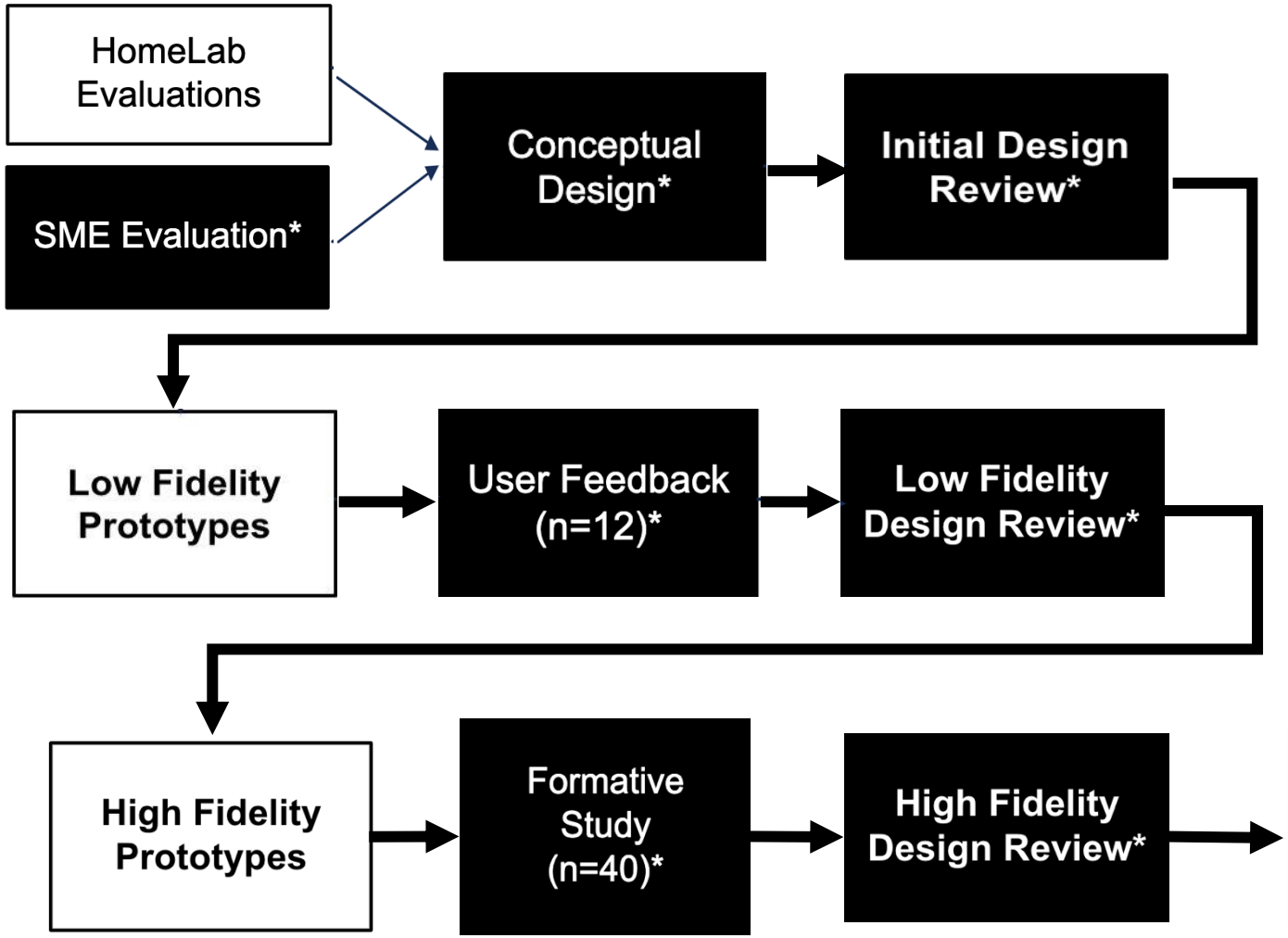
June 2022: SME Usability Studies Begin

SMEs conduct independent accessibility evaluations using HomeLab task lists and product kits.

June 2022: Design Firms Engaged

Two design companies begin developing accessible redesign concepts based on HomeLab and SME findings.

User Evaluation and Design Development Process



July 2022: Inclusive Design Process Implemented

RADx formalizes a redesigned development process ensuring continual engagement of users with disabilities throughout evaluation and design.

Learnings Documentation

July 2022: Best Practices Working Group Formed

Because many accessibility challenges were discovered to be common across products—and there is no existing guidance—RADx begins developing Best Practices for the Design of Accessible COVID-19 Home Tests.

Program Expansion

September 2022: RADx Tech III Solicitation Posted

New funding opportunity supports development of new tests in two tracks:

- More accessible diagnostic tests
- Higher-performance next-generation tests

Accessibility is embedded in both tracks. More SMEs are brought on to support the expanding work.

The solicitation itself (i.e., the hosting webpage, instructional content, and application form) was developed to be accessible.

Program Growth and Publication

Oct–Nov 2022: Tech III Application Reviews

Expert panels, including disability accessibility experts, evaluate submissions.

December 2022: Interim Best Practices Released

A preliminary version focused on packaging and instructions is published.

2023:
Implementation and Knowledge Dissemination

Implementation and Knowledge Dissemination

Jan–Feb 2023: National Webinars

Point-of-Care Technology Research Network (POCTRN) hosts webinars on accessible test design and the Best Practices guidance.

Jan-Mar 2023: Formative Studies implemented

Overview:

- 109 accessible design concept prototypes developed
- 5 User studies (94 participants) were completed to evaluate accessible design concept prototypes

Formative Studies

109 design concepts / prototypes evaluated

- Completed structured interviews
- Participants represented a mix of different accessibility user groups

Example 1: Test Tube Barrier

				
Large Grip Ring (M1,2,3,4)	Small Grip Ring (M1,2,3,4)	Large Tab (M1,2,3,4)	Small Tab (M1,2,3,4)	Off the Shelf Tab (M1,2,3,4)
Preferred	**Acceptable**	**Acceptable**	**Not Recommended**	**Not Recommended**

Formative Study Example

Example 2: Swab Pouch Opening

			
Folded End [V1]	Long Folded End [V1]	Notch Swab Package [V1]	Bubble Tab [M1,2,3,4]
Acceptable	**Not Recommended**	**Not Recommended**	**Acceptable**
			
Plastic Moon [M3]	Paper Moon [M3]	Opposed Tabs [M3]	Original [M3]
Preferred	**Acceptable**	**Acceptable**	**Not Recommended**

Program Progress

March 2023: Program Status Update

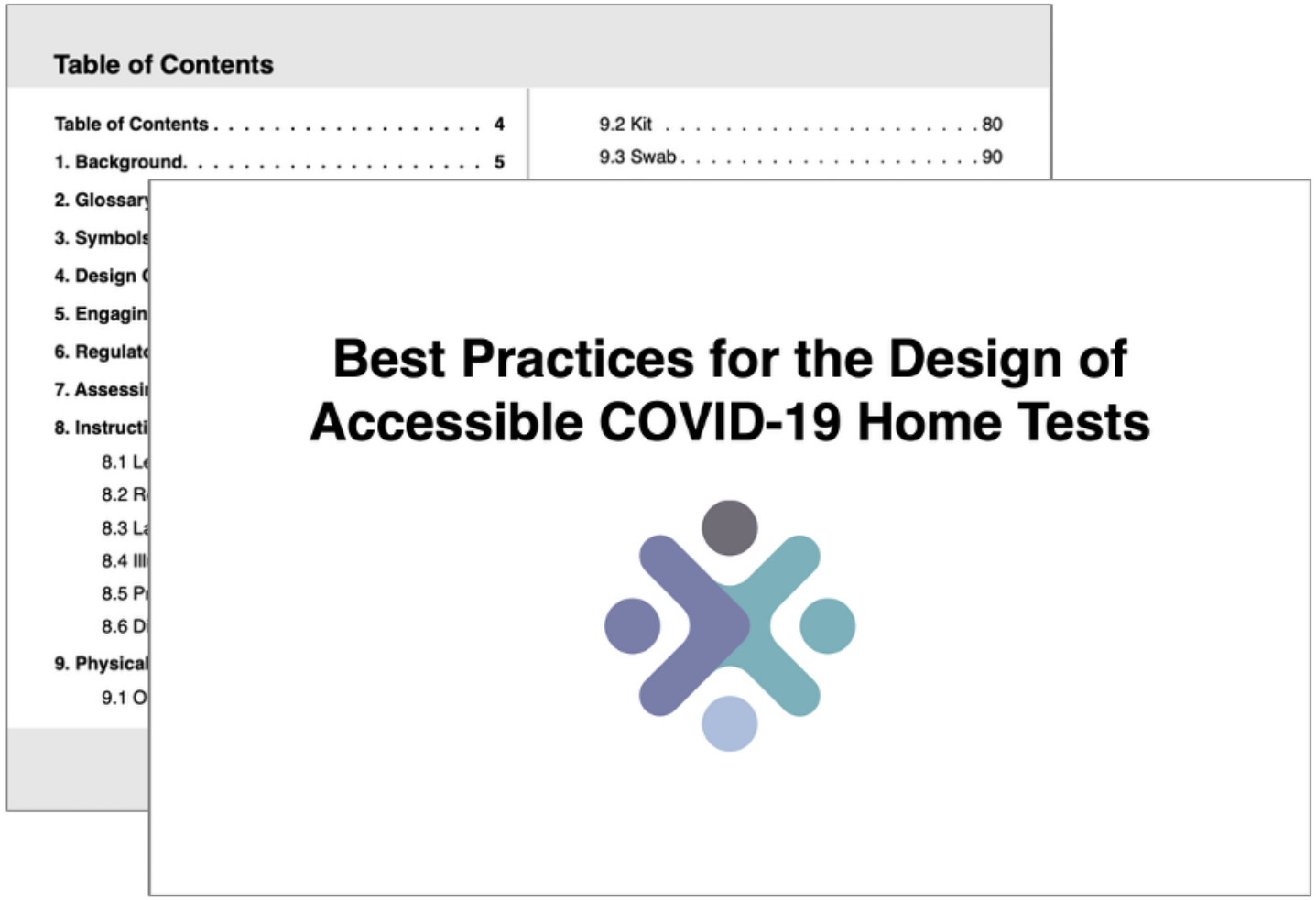
- 12 products remain in the Original RADx Accessibility Program addressing existing products.
- Began engaging with the 17 tests in the Accessible Test track of the RADx Tech III program (developing new test products).

Best Practices Publication

June 30, 2023: Best Practices Publication

The complete Best Practices for the Design of Accessible COVID-19 Home Tests are published on the U.S. Access Board website.

- **Objective:** Capture and leverage learnings and experience from the RADx Tech Accessibility Program for current and future tests.
- **Target Audience**: Commercial manufacturers and designers



Readers – Future Potential

Mar-Nov 2023: Universal Test Reader Investigation

- Test readers facilitate auditory, haptic, and more explicit visual feedback for users, but few test developers currently offer readers.
- **Met with 15 companies to review state of development 20 reader technologies**
- **Key Takeaways**
  - Most readers leverage smart technology (17/20)
  - All readers able to support multiplex tests
  - Most support colorimetric and fluorescence detection
  - Some readers able to support multiple LFA strips for multiplex testing

Cirrincione, M., Downing, M., Leite, K., Dolphin, S., Samuta, A., Schermer, M, Noble, K., & Walsh, B. (2024). Assessment of Reader Technologies for Over-the-Counter Diagnostic Testing. ***IEEE Open Journal of Engineering in Medicine and Biology***

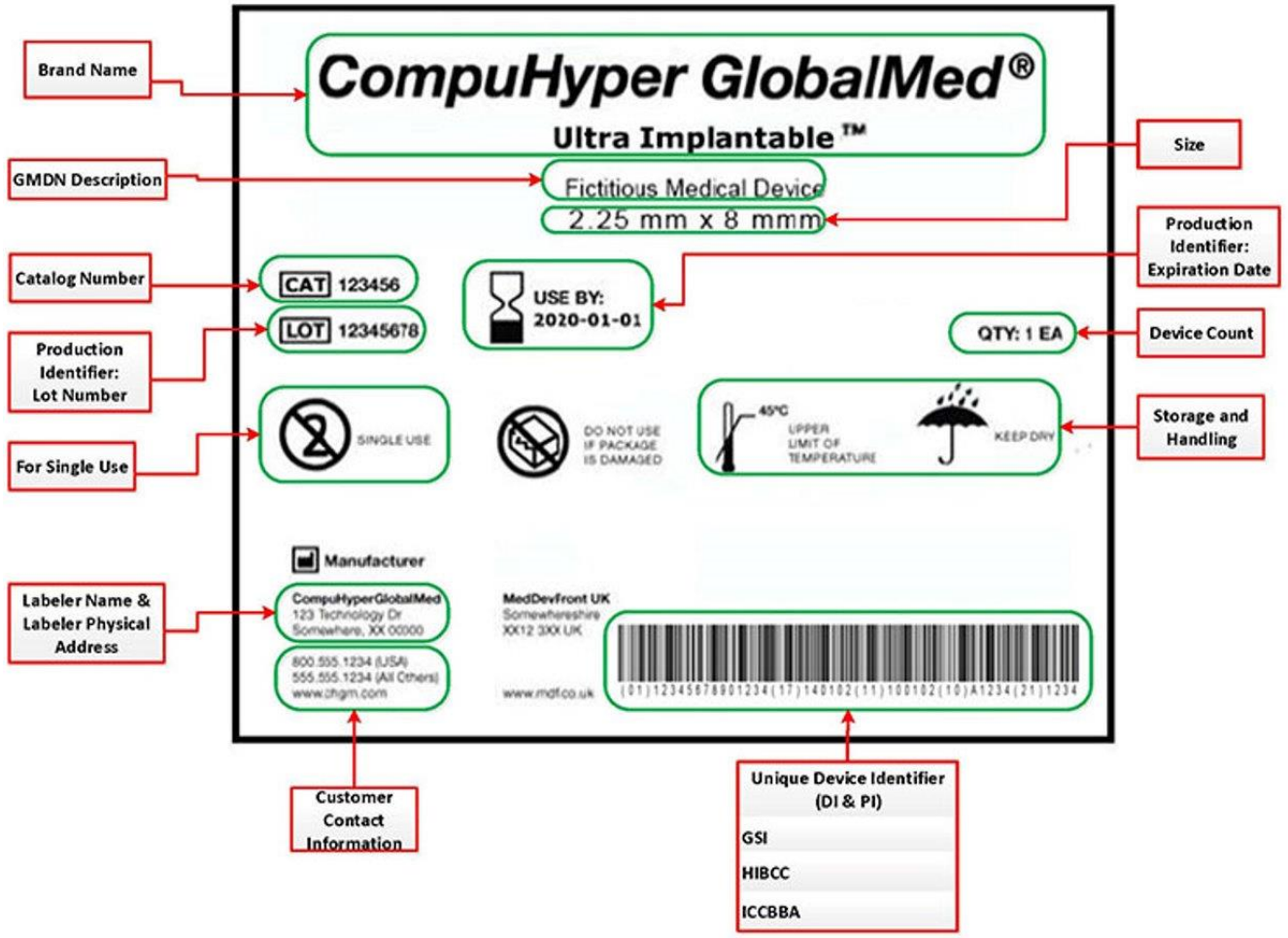
Parameter	Range
Non-Recurring Engineering (NRE)	$3k – $2M
Maturity	Prototype – Commercial
Time to Develop	2 – 24+ Months
Installed Base	0 – 100k
Detection Method	Camera, Sensor
Multiplex Capabilities	All
Dual Strip	Some
Technology	Colorimetric, Fluorescence
Current Use Case	POC, OTC
Regulatory Status	None, CE Mark, 510k

UDI / Medical Device Labeling

Explored improved accessibility of outer packaging through UDI/Medical Device Labeling

Current labeling/UDI requirements, which support icon-only presentation of information do not promote accessibility.

- **Google** – Lookout
- **Microsoft** – Seeing AI



Plain language

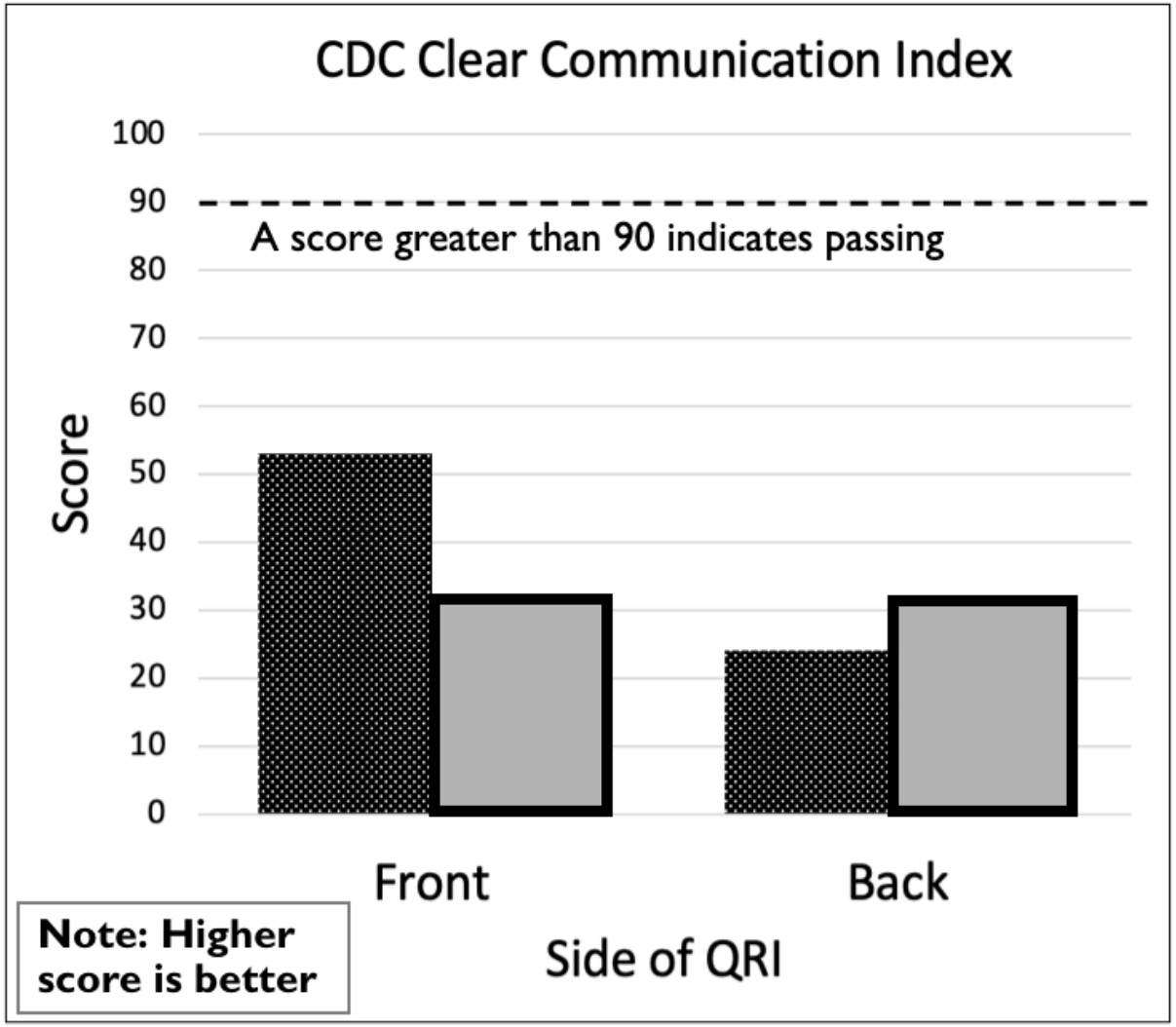
Nov 2023-May 2024: Plain Language Analysis

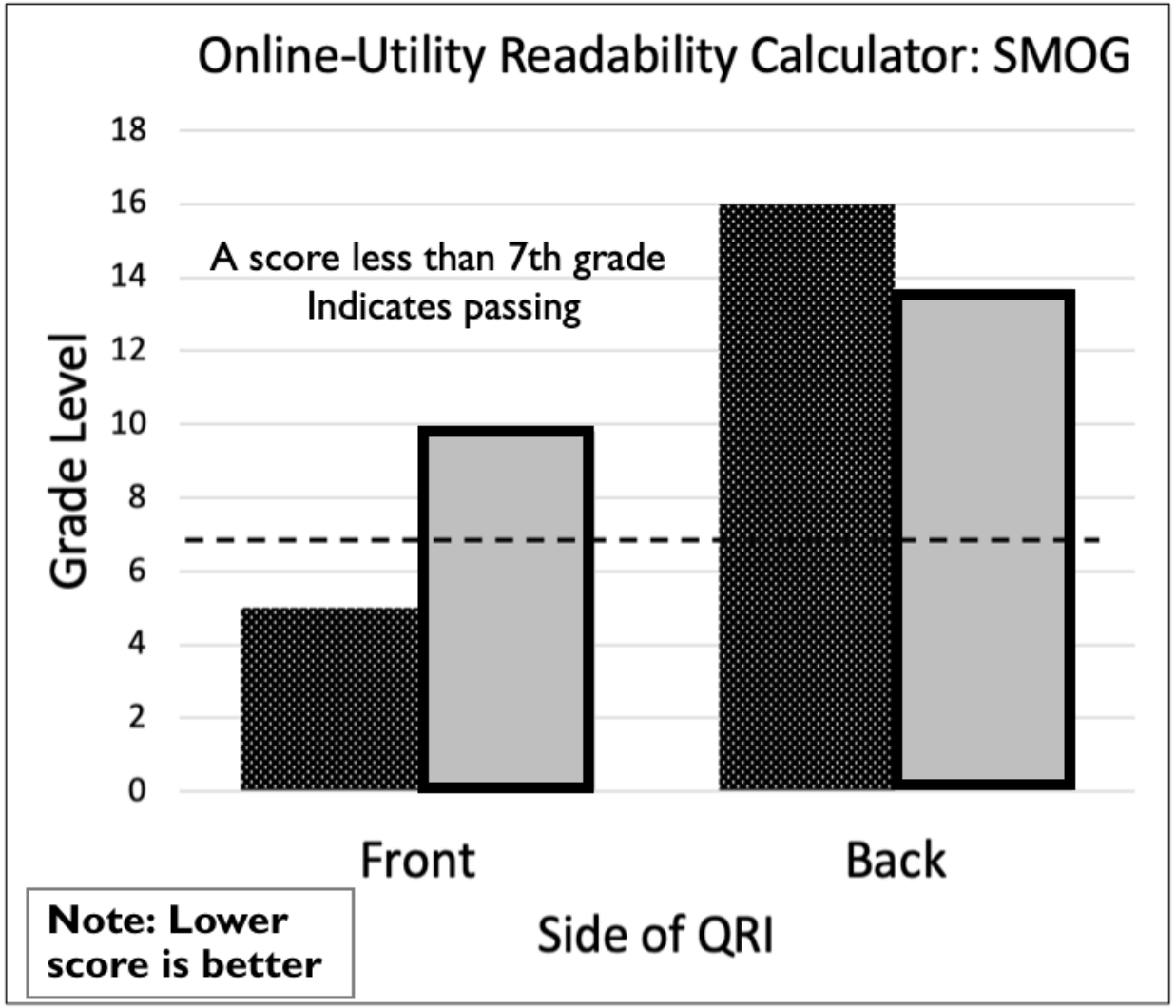
RADx undertook a study of plain language to provide compelling, scientific evidence of the benefit of instructional content in plain language.

Industry Accepted Scoring Tools:

- **Assessment Tools:** Assigns a score and indicates a threshold of passing
  - CDC Clear Communication Index
  - Patient Education Materials Assessment Tool (PEMAT)
  - Suitability Assessment of Materials (SAM)
- **Readability Calculators:** Assigns a grade level as a score to indicate level of readability
  - FRY
  - SMOG

Plain Language Study Examples





2024:
Standards, Research, and Global Collaboration

Global Outreach and Digital Materials

Jan–Apr 2024: Standards and Industry Engagement

RADx engages organizations including:

- Standards bodies
- Manufacturing groups
- Large-scale acquirers
- Global health organizations

January 2024: In Vitro Diagnostics Digital Accessibility Initiative

Systematic review begins of digital materials associated with diagnostic tests, including:

- Websites
- PDF and HTML instructions
- Video content

Research Publications and Global Collaboration

January 2024: Reader Research Published

Assessment of Reader Technologies for Over-the-Counter Diagnostic Testing article is published in the peer-reviewed journal, *IEEE Open Journal of Engineering in Medicine and Biology.*

February 2024: Braille Research Published

Information Accessibility in the Form of Braille article is published – also in the *IEEE Open Journal of Engineering in Medicine and Biology.*

March 2024: Collaboration with WHO

WHO works toward adapting the RADx Best Practices into a global guidance for home test design.

World Health Organization

Federal Programs and Standards

June 2024: Support for other Federal Programs

RADx Accessibility team provides input for:

- ASPR test procurement strategies
- Independent Test Assessment Program (ITAP)

July-Oct 2024: Standards Development with AAMI begins

The Association for the Advancement of Medical Instrumentation (AAMI) invites RADx to propose a Technical Information Report (TIR) on accessible test design in July and approves our proposal in late October. This report will broaden the scope of the RADx Best Practices to address all home tests and position these recommendations to be adopted as AAMI standards or FDA guidance in the future.

2025:
Publications and Broadened Adoption

Status of Programs

January 2025: RADx Tech III Program Status Update

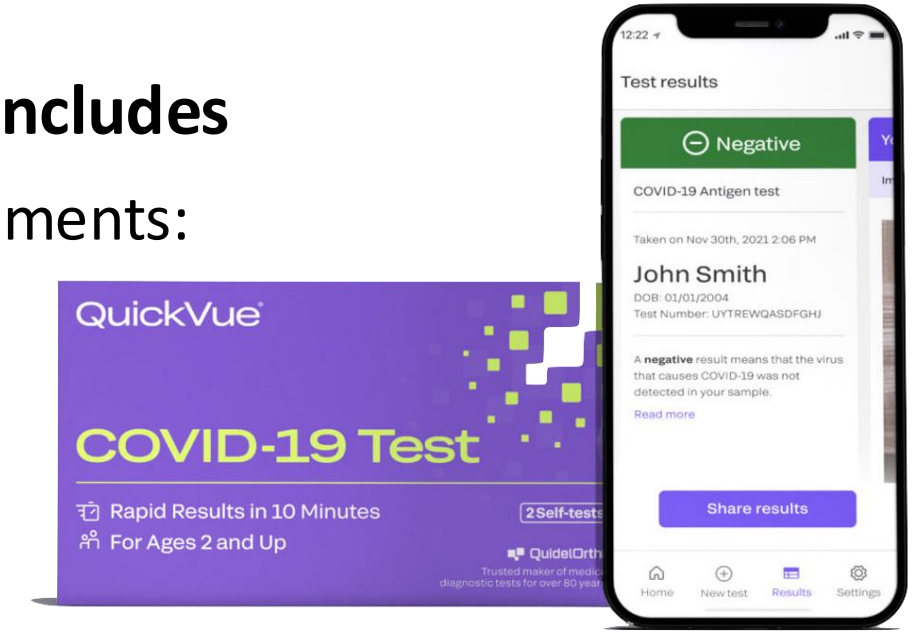
20 active projects – Most projects have completed final accessibility assessments.

The next stage is an expert panel to request funding for implementation.

April 2025: Original RADx Accessibility Program Concludes

Three companies complete funded accessibility improvements:

- QuidelOrtho QuickVue
- GADx COVI-Go
- Maxim ClearDetect



Program Expansion and Publication

May-June 2025: Multiplex Independent Test Assessment Program (ITAP) Solicitation

NIH publishes a new solicitation supporting development of multiplex tests (detecting multiple illnesses such as COVID-19, Flu A, Flu B, and RSV). The RADx Accessibility team will provide support for program finalists.

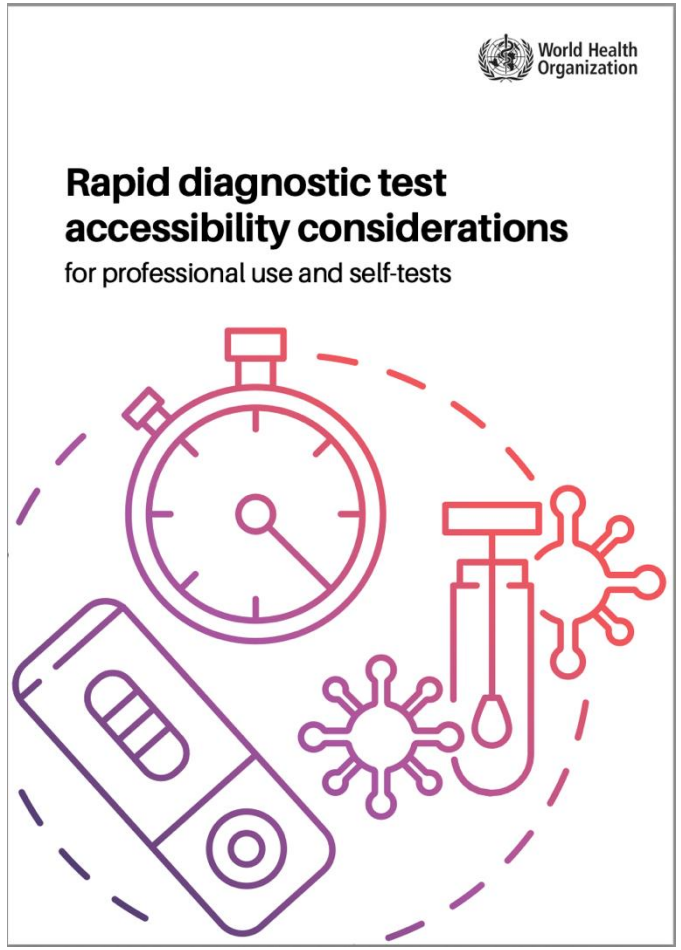
June 22, 2025: Background and Program Design Published

An article on the background and process undertaken for the RADx Accessible Tests Initiative, Confronting the Public Health Challenge of Inaccessible COVID-19 Home Tests: Insights from the RADx® Tech Accessibility Initiative is published in the peer-reviewed journal, *Frontiers in Public Health.*

Additional Best Practices Publications

July 20, 2025: WHO Guidance Published

The World Health Organization publishes their international guidance, taking a wholistic approach to apply the Best Practices' principles broadly to IVD tests (e.g., malaria, pregnancy, HIV).



December 2025: AAMI Technical Information Report Published

AAMI releases TIR130:2025 – Best Practices for Designing Accessible At-Home Diagnostic Test Kits, available to AAMI members and for purchase.

2026:
Program Legacy

Documenting and Winding Down

January 2026: Supplemental Guidance Development Begins

Work begins on additional guidance to supplement the Best Practices, reflecting lessons learned from the RADx program and providing practical guidance on improving the accessibility of digital materials accompanying consumer test products.

May 2026: Accessible Tests Project Status

- The last three projects complete their milestones to “graduate” the program.

Program Engagement - Stakeholders

Advocacy Groups

- National Federation of the Blind (NFB)
- American Council of the Blind (ACB)
- World Institute on Disability (WID)
- Alliance on Aging and Vision Loss (AAVL)
- American Foundation for the Blind (AFB)
- American Geriatrics Society (AGS)
- Perkins School and Library
- Independence Through Enhancement of Medicare Coalition (ITEM)
- National Disability Rights Network (NDRN)
- World Blind Union (WBU)
- Royal National Institute of Blind People (RNIB)
- American Association of Retired Persons (AARP)
- G3ict

Government Agencies

- The White House
- National Institutes of Health
- National Institute of Biomedical Imaging and Bioengineering
- US Access Board
- Food and Drug Administration (FDA)
- National Institute on Disability, Independent Living, and Rehabilitation Research/ Administration for Community Living
- General Services Administration (GSA)
- Centers for Disease Control (CDC)
- National Eye Institute
- National Council on Disability
- National Library Services (NLS)
- National Center for Medical Rehabilitation Research
- National Institute of Dental and Craniofacial Research
- National Institute of Nursing Research
- Administration for Strategic Preparedness and Response

Industry

- Georgia Tech HomeLab
- Veranex Solutions
- SMEs (No/low vision)
- SMEs (Dexterity)
- SMEs (Aging)
- SMEs (Academics)
- Rook Quality System
- Plainli
- Gener8
- Howe Innovation Center
- Microsoft
- PDT Astronics
- TPGi
- Video Production Specialists
- Test Reader Companies
- Braille Display Manufacturers
- Braille Printing Houses
- Beta Breakers
- Meadows Design
- Universities with RERC funding
- Individuals and orgs with expertise at the intersection of AI and accessibility

Other Entities

- University of Maryland Trace Center (Research)
- FIND Diagnostics (connector)
- Advanced Medical Technology Association (Trade org)
- Consumer Technology Association (Trade Org)
- World Health Organization (WHO)
- Association for the Advancement of Medical Instruments (AAMI, Standards)
- Institute of Tropical Medicine (Research)
- American National Standards Institute (ANSI, Standards)
- International Medical Device Regulators Forum (IMDRF, Regulator)
- MedTech Europe (Trade org)
- Medical Device Innovation Consortium (MDIC)
- Teach Access (programmatic)

Making Tests COVID Tests Accessible

Completed initiatives:

- **Mini Accessibility Program**, reworking existing tests (addressed 15 products)
- **Legacy Independent Test Assessment Program (ITAP)** – improving existing tests (12)
- **Tech III (Fast Track) Program**, new test development (100 applicants; 24 engaged)

56 products reviewed

- Resource intensive to rework test: 8+ product iterations, 100s hours
- Faster and cheaper to design in accessibility from the start

RADx Accessibility Initiative Measures

Programs & Products

- **3** programs: Original RADx, RADx Tech III, ITAP
- **56** products received accessibility evaluations and recommendations
- **24** reader technologies evaluated

Publications/Broadened Awareness

- **3** Best Practices documents published (plus another pending): US Access Board, WHO, AAMI
- **3** peer-reviewed journal articles published (plus another pending)
- **8** conference presentations and invited talks (including POCTRN, ACB, NFB, Plain Language Summit)
- **Countless** stakeholders engaged across advocacy groups, government agencies, industry, and others

Government impact

- NIH engages accessibility resources beyond dedicated accessibility programs
- ASPR considers accessibility of products for future distribution

Program Legacy

2026: Sustaining the Work

Conversations have taken place (or are underway) with agencies, nonprofits, universities, and potential funders to identify pathways for sustaining the Accessibility Initiative's work, including organizations that could continue current efforts or support future projects.

- FDA
- NIDILRR
- Georgia Tech
- Olin College of Engineering
- Teach Access
- VentureWell
- NIH Office of the Chief Information Officer (OCIO)

Thank You