



COVID-19 Accessible Testing - Best Practices

Rapid Acceleration of Diagnostics Tech (RADx)

February 28, 2023



Presenters

- **Brian Walsh**, RADx Accessibility Program Manager, Deployment Core Team Lead
- **Clair O'Donovan**, RADx Team Lead
- **Emily Kennedy**, RADx Project Facilitator
- **John Blackwood**, RADx Team Lead

RADx Accessibility Team

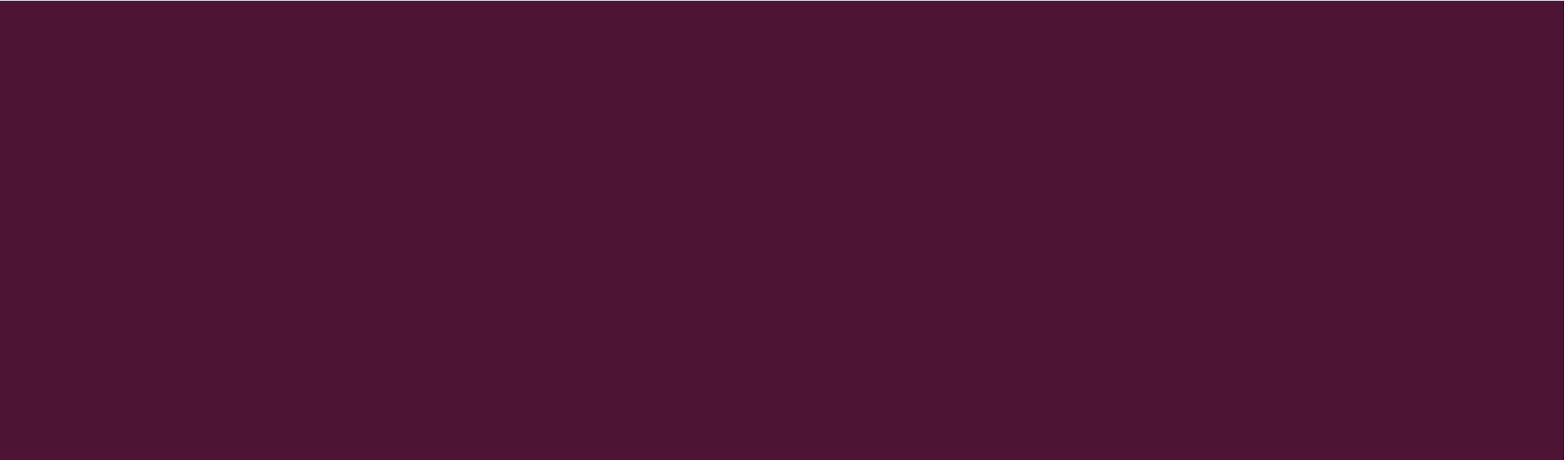
- **Clair O'Donovan**, RADx Team Lead
- **Mia Cirrincione**, RADx Project Facilitator
- **Sam Dolphin**, RADx Project Facilitator
- **Maren Downing**, RADx Project Facilitator
- **Emily Kennedy**, RADx Project Facilitator
- **Kevin Leite**, RADx Director Commercialization Support
- **Shaun Moshasha**, RADx Project Facilitator
- **Kim Noble**, RADx Communication Lead
- **Adam Samuta**, RADx Project Facilitator
- **Sal Strods**, RADx Team Lead

Overview

- RADx Program Overview
- Testing Workflow
- Best Practices
- Instructions & Digital Design
- Company Perspective



RADx Program Overview



NIH's Rapid Acceleration of Diagnostics (RADx)

Goal: Speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing

- Over 4 Billion tests/products
- 45 FDA authorized tests
- 1st Over-the-Counter test for use at home
- >100 organizations supported

Reference: <https://www.nibib.nih.gov/covid-19/radx-tech-program>

Listening Session...The Beginning

March 2022

Goals:

- Understand challenges to the accessibility of at-home tests
- Discuss potential improvements, including their potential timescale
- Open lines of communication for ongoing discussion

■ **Key User Populations:**

- No-vision and low-vision
- Fine motor skill difficulties
- Aging population

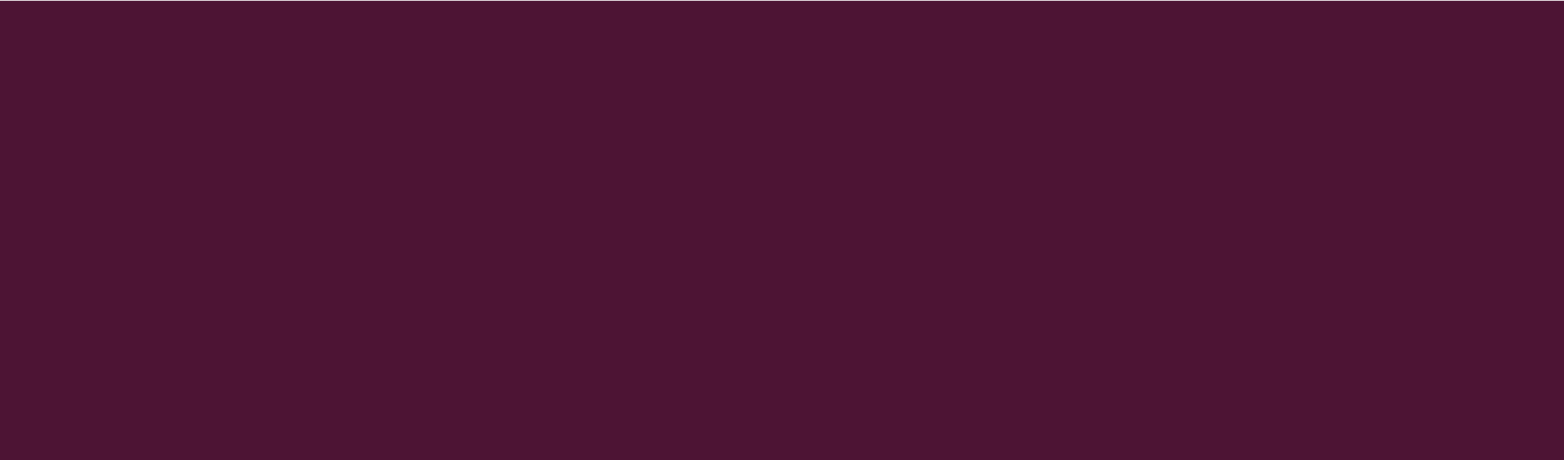
Advocacy Attendees:

- 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)

Accessibility Best Practices

- **Extremely limited standards or guidance**
- **Rich information & learnings emerged from RADx Tech Accessibility Program**
- **Learnings would perish when the program expires**
- **Best Practices Initiative**
 - **Objective:** Capture and leverage learnings and experience from the RADx Tech Accessibility Program for current and future tests
 - **Provide a roadmap for industry to build more accessible products**
 - Document learnings & process
 - Validation of design concepts
 - Execute process and resources to ensure effectiveness
 - **Target Audience:** Commercial manufacturers and designers

Best Practice Content and Testing Workflow



Testing Workflow

Strive for complete solutions from product acquisition through disposal



PURCHASE	UN-BOX	SAMPLE COLLECTION	SAMPLE HANDLING	RUN TEST	READ RESULTS	DISPOSAL
• Labeling • Packaging	• Labeling • Packaging	• Swabs and sample collection • Liquid containers • Packaging • Instructions	• Liquid transfer • Cassette/ Test Reader • Packaging • Instructions	• Cassette/ Test Reader • Instructions • Connecting components digitally • Test analysis	• Test analysis • Communicating results • Cassette/ Test Reader • Connecting components digitally	• Disposal of components • Instructions
General topics across all categories: Holistic Design, Regulatory, Design Control, Braille, and Engaging End Users						

Packaging: Identification

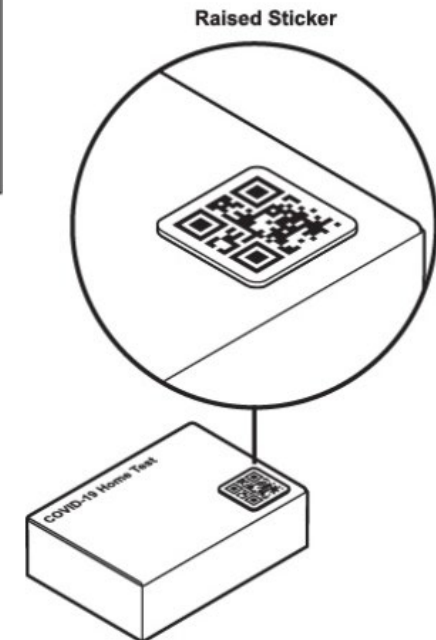
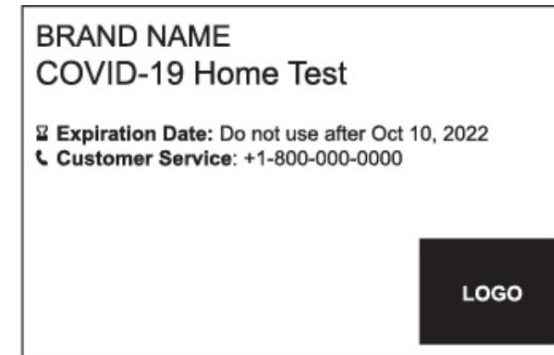
➤ *Outer box device packaging is the initial introduction to the User.*

■ Issues

- Much of standard packaging is filled with random information
- QR codes are often missing or insufficiently sized
- No tactile features

■ Recommendations

- Key information includes brand name, device type, expiration date, links to instructions, and customer service phone number
- QR codes should be easily identifiable
- Provide a means to tactilely find encoded information (e.g., a raised sticker, or raised outline)



Packaging: Accessing Contents

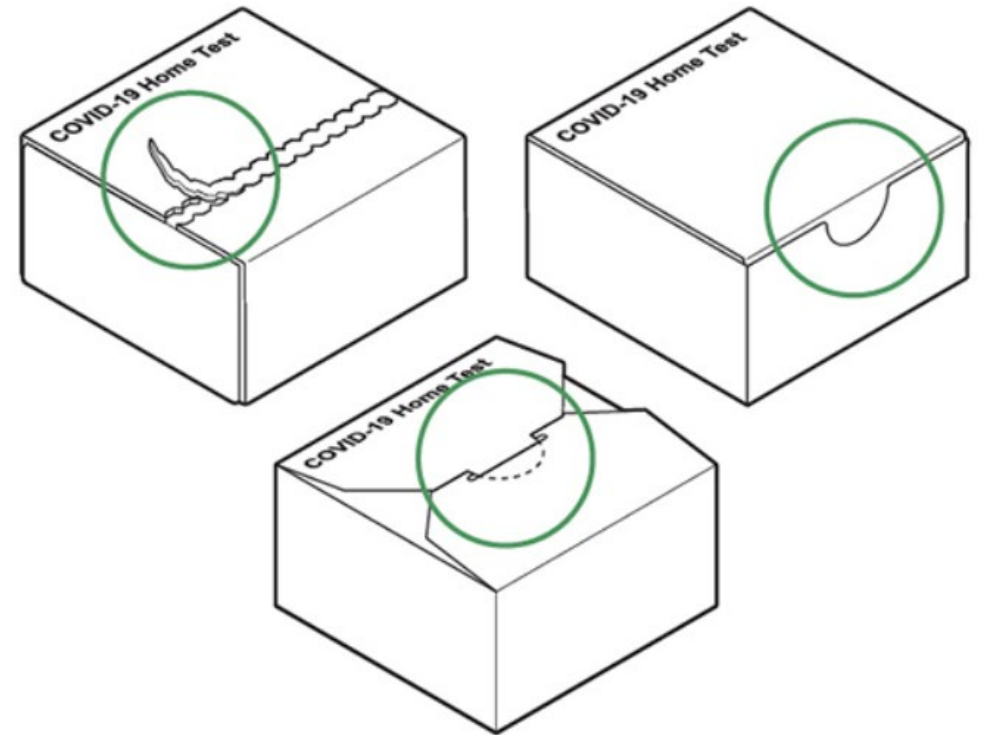
➤ ***Contents must be accessible to Users***

■ **Issues**

- Too much force is required to open
- Hard to access contents
- Tamper-proof labels
 - Many users resort to external tools such as scissors, knives, etc.

■ **Recommendations**

- Do not require user to apply in excess of five pounds force
- Top of box should open wide for easy access to contents
- Provide familiar tactile cues on the packaging



Note: Make packages resealable if >1 test is included

Sample Collection

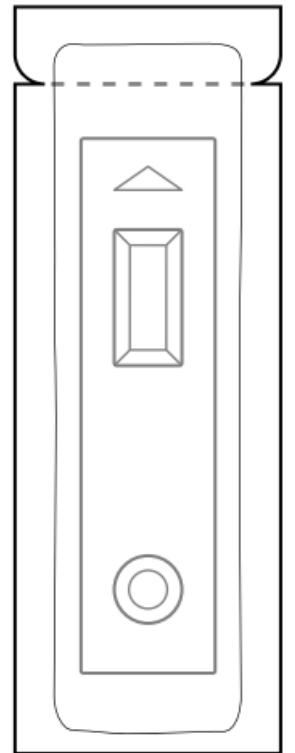
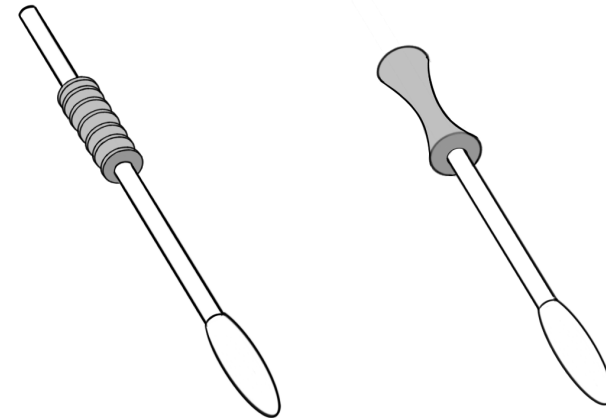
- **Swabs for sample collection are a universal opportunity for improvement**
- **Cost sensitive: Off-the-shelf standard parts from large-scale manufacturers**
- **Must balance short-term and long-term solutions**

- **Issues**

- Is it obvious which end to open?
- Packaging may inadvertently open the sterile end of the swab
- Swabs with no clear indications for handling may be misused

- **Recommendations**

- Swabs should have identifiable features (e.g., colors, shapes, textures) so that the user knows where to grasp, preventing sample contamination



Liquid Containers

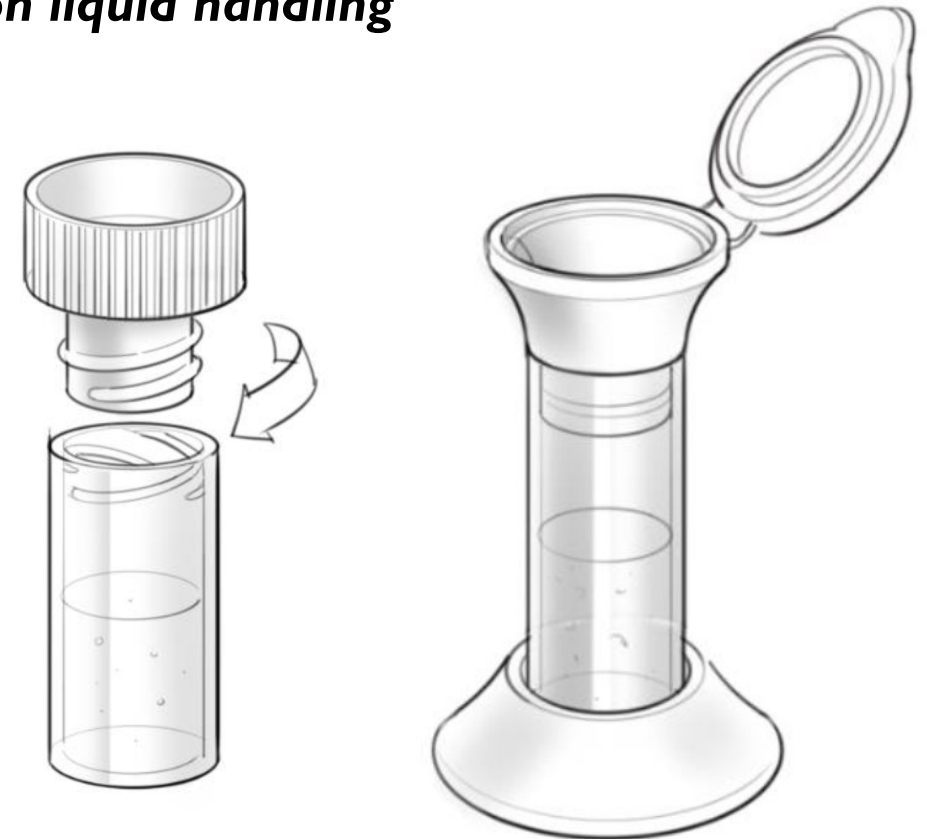
- *Vials are multi-purpose - hold liquid as well as receive the swab and sample*
- *Facilitates docking and provides means for gross or precision liquid handling*

■ Issues

- Caps are small and can be easily misplaced
- Caps can be difficult to remove
- Liquid vials can be easily tipped over

■ Recommendations

- Attach the cap to the liquid vial
- Incorporate a stand for stability or a freestanding tube with wide base
- Vial opening should be large enough to receive sample



Liquid Transfer

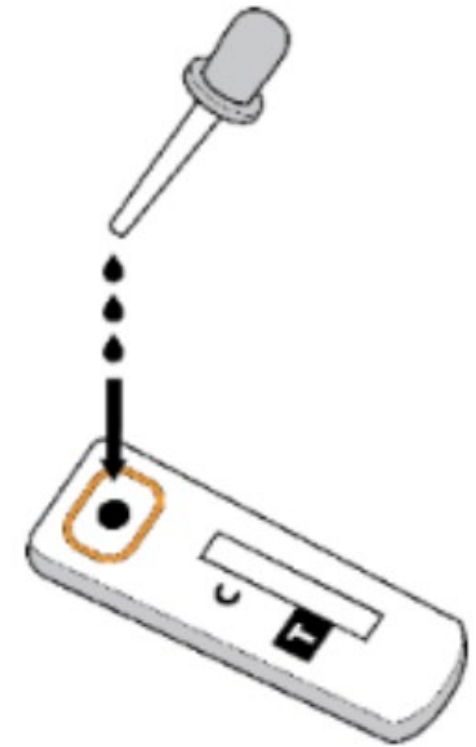
➤ *Accurate liquid transfer is critical to successful assay function*

■ Issues

- Liquid transfer from one location to another creates a spill risk
- Error-free counting of drops for sample preparation is challenging

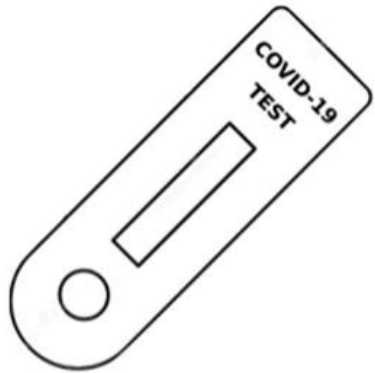
■ Recommendations

- Eliminate precision liquid transfer when possible
- Design the test to use the entire contents of the fluid vial
- Consider docking of parts where possible
- Focus on instructions

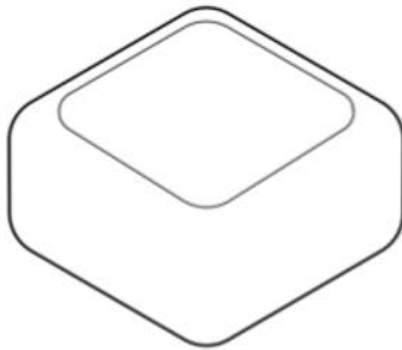


Cassette and Test Reader (1 of 2)

- Some tests are self-contained
- Some tests use reader technologies – stand-alone readers, smartphones, or readers paired to smartphones
- Words matter – terms used interchangeably cause confusion (Analyzer vs. Reader)



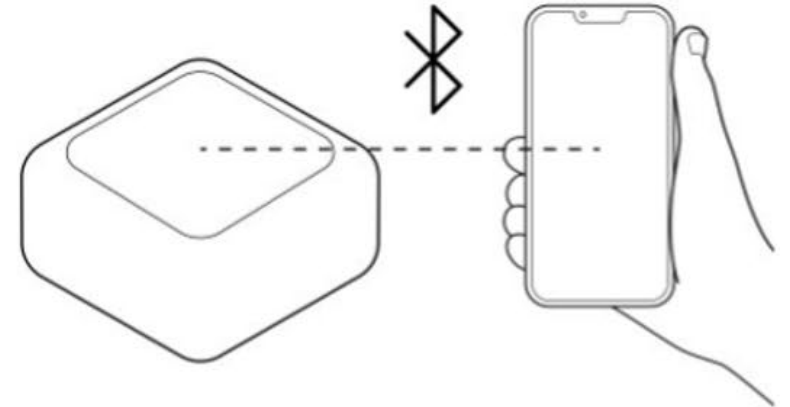
Test Cassette



***Stand-alone
reader***



***Stand-alone
smartphone***

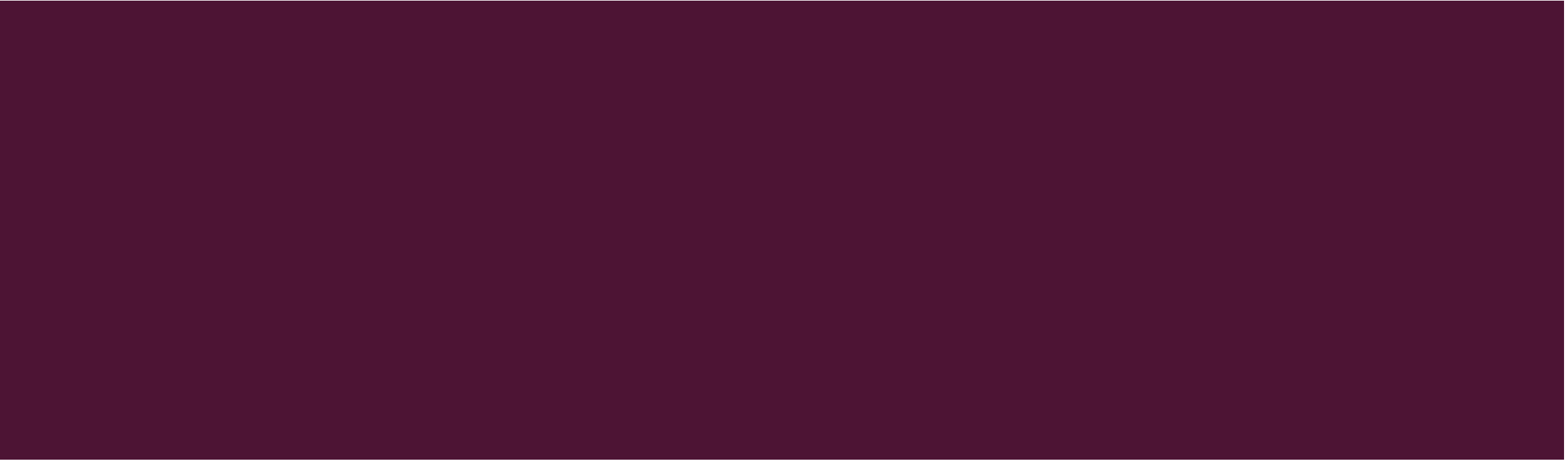


***Reader with
smartphone***

Cassette and Test Reader (2 of 2)

- **Readers may use nonvisual indicators to help guide test taking & results reporting**
 - Examples: audible beeps, audible voice, haptic feedback
 - Generally audible voice and haptic feedback is optimum solution
- **Using smartphones as the only reader**
 - Not everyone has a smartphone (e.g. aging population, economically disadvantaged)
 - Orientation for taking photos is important
 - Use technology that already exists (i.e., "familiar")
 - Provide auditory/haptic device positioning and camera visibility feedback (e.g., "test identified"; "failed - move closer"; "failed - increase brightness")
 - Standalone readers with optional smart technology preferred

Instructions & Digital Design



Georgia Tech HomeLab Usability Analysis

- **All products had issues related to instructions**
- **Instructions was the greatest area of deficiency (48% of recommendations)**

HomeLab Task Analysis

Product	Total Tasks	Essential Tasks	Inaccessible Essential Tasks
A	36	30	17 (56.7%)
B	38	29	12 (41.4%)
C	64	51	18 (35.3%)
D	41	31	20 (64.5%)
E	45	37	20 (54.1%)
F	42	33	16 (48.5%)
G	74	66	22 (33.3%)
H	36	32	16 (50.0%)
I	43	32	19 (59.4%)
J	44	39	13 (33.3%)
K	44	34	16 (47.1%)
L	42	35	16 (45.7%)
M	76	61	20 (32.8%)
N	42	34	16 (47.1%)
O	43	32	16 (50.0%)

HomeLab Recommendations

Product	Total Recommendations	Instructions Related Recommendations
A	18	14 (77.8%)
B	16	12 (75.0%)
C	25	15 (60.0%)
D	23	13 (56.5%)
E	16	8 (50.0%)
F	26	13 (50.0%)
G	20	10 (50.0%)
H	22	10 (45.5%)
I	14	6 (42.9%)
J	21	9 (42.9%)
K	17	7 (41.2%)
L	28	11 (39.3%)
M	20	7 (35.0%)
N	23	7 (30.4%)
O	10	3 (30.0%)

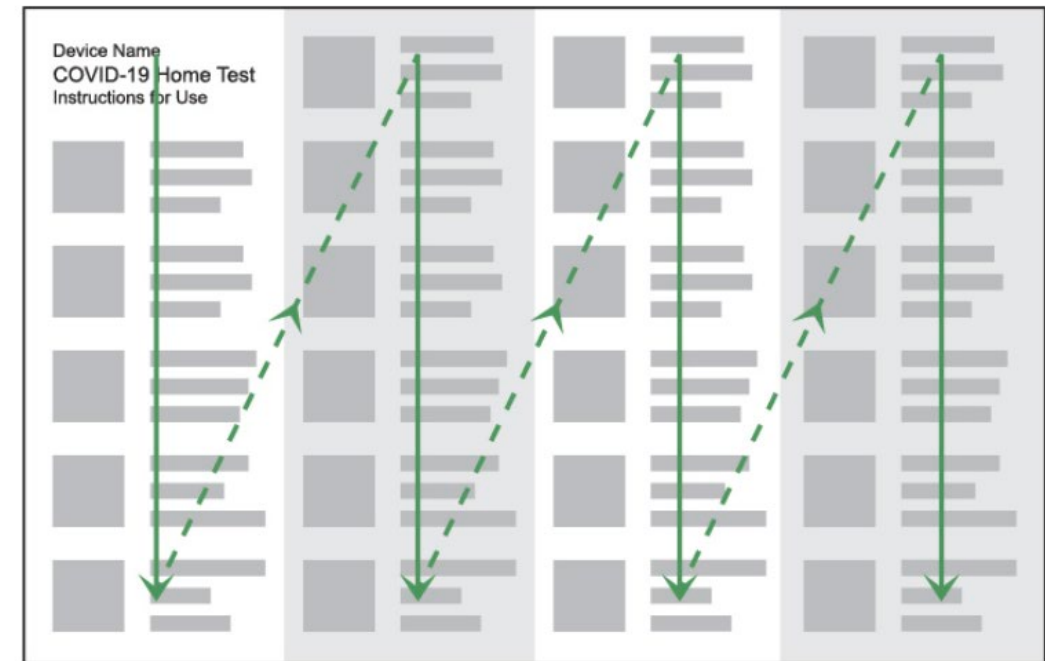
Instructions - Printed

■ Issues

- Text features (size, font type, italics, and color contrast) are critical
- Steps requiring multiple actions are challenging to follow.
- Blocks of text are sometimes shown in different layouts.

■ Recommendations

- Use sans serif font, minimize italics, minimum size 14 font, use appropriate contrast ratio and line thickness
- Provide a single, actionable task for each step
- Use a consistent layout. A column style layout works best



Text

Black on White

Text

Black on Yellow

Text

Red on White

Text

White on Blue

Instructions – Digital

- **Digital instructions screen reader compatibility**

- Screen Reader – software program or application enabling no-vision or low-vision users to convert text displayed on a computer screen, tablet or phone into synthesized speech or refreshable braille display.
 - Windows – JAWS & NVDA
 - MacOS, iOS, tvOS – VoiceOver
 - Android phones, tablets, and kiosks – TalkBack

- **All images must have meaningful, descriptive alternative ('alt') text**

- E.g., describing test components such that they can be discerned from one another non-visually

- **Web Content Accessibility Guidelines (WCAG) 2.1 AA and PDF/UA standards**

- Section 508 and WCAG 2.1 AA compliance is the legal requirement

Digital Design

Smart Technology

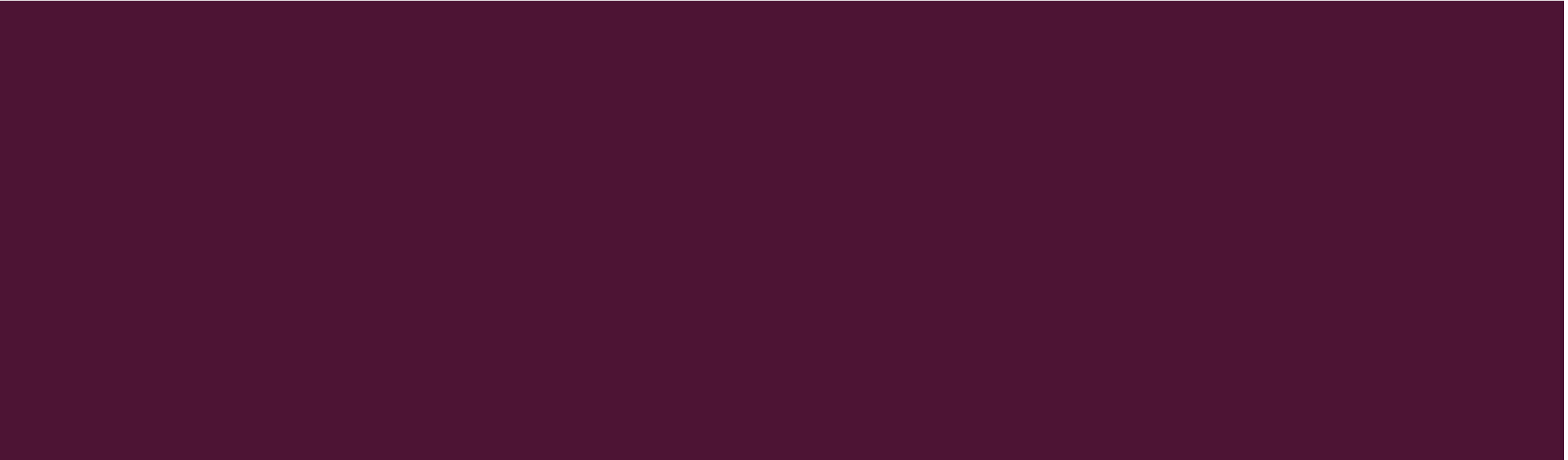
- **User interfaces (UI) significantly impact usability - small improvements have major impacts**
 - Provide options to review content in both landscape and portrait orientations.
 - Errors, warnings, and success messages do not automatically disappear until user acknowledges message
- **Operating system (OS) compatibility**
 - Content must be recognized & understood by computer, smartphone, and tablet OS & accessibility tools.
 - Ensure application recognizes and supports built-in device OS accessibility settings

Other Modalities

- **Audio instructions - human voiceover is preferred or clear text-to-speech (TTS) engines**
- **Audible phone instructions - IVR systems connect users to instructions through a phone call**
- **Video instructions with multilingual closed captions**



Company Perspective



Different Reactions from Different Types of Organizations

Company willingness to engage with the RADx Accessibility Program – Responses differ depending on type of organization

- Multinational Publicly Traded Diagnostics Company
- Privately Held Small Company with Limited Portfolio
- Start Up Entity with Technology that Could A True Advance in Accessible Testing

Multinational Publicly Traded Diagnostics Company

- **Meeting #1** - “We are interested to learn more”
- **Meeting #2** - “We want to be responsive but give us some time to review with management”
- **Meeting #3** – “This is interesting. We already build into our products a lot of Accessibility features”
- **Meeting #4** – “You know. We unfortunately have other things we need to spend our time and money on right now and while this is interesting and important; we must decline”

Multinational Company



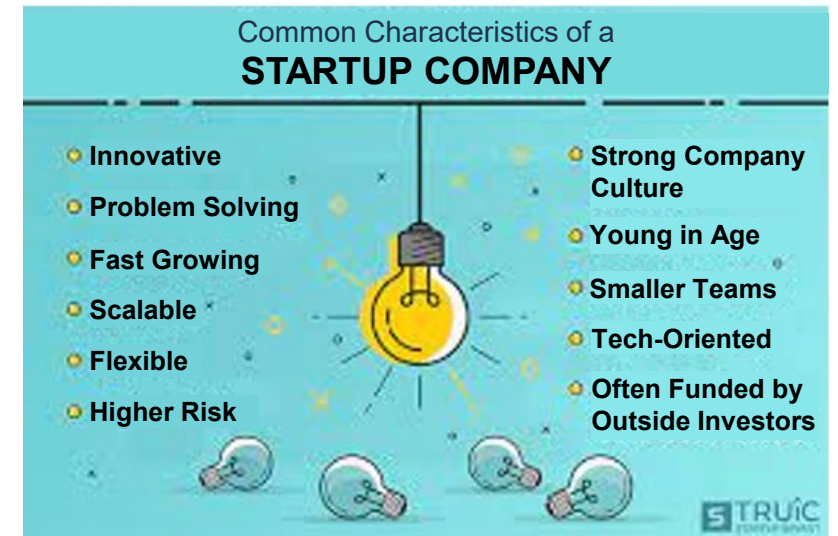
Privately Held Small Company with Limited Portfolio

- **Meeting #1** – “This is excellent – tell us more”
- **Meeting #2** – “When can we send you documents and materials to review”
- **Meeting #3** – “We are ready, willing and able to adapt our product so that it is as highly accessible as we can make it.
- **Meeting #4** – “Let’s proceed with recommended changes. The only caveat is that if a change would lead to a ‘form, fit or function’ design change we want to be careful not to trigger the need for a new clinical trial. That is the line we have to be careful not to not cross by accident. But we are open to it if it make sense. Everything else is good to go”



StartUp Entity with Technology that Could Make A True Advance in Accessible Testing

- **Meeting #1** – “We could have applied for Advanced Testing, but our intuition was that this is uniquely suited for Accessibility”
- **Meeting #2** – “Thanks for taking us through the program and guiding us. We really want to make this a product that can serve those with challenges using other types of products
- **Meeting #3** – “We want to succeed and are willing to adjust our project. We are not experts in everything that goes into Accessibility Design - will need help.





Summary



Key Takeaways

- **Accessible design extends through the entire product experience from acquisition to disposal**
- **Requirements for an accessible design are best developed in cooperation with those from the target populations**
 - For example, wearing an eye mask is not a good surrogate for understanding the needs of the no-vision/low-vision populations
- **Consistent with good design process, accessible design begins at the requirements phase**
- **Pursue an "accessible" solution that is consistent with a mainstream solution – accessible design adds value for all users**

Best Practices Status

- **First iteration focused primarily on packaging and instructions**
 - This document is now available on the U.S.Access Board website
 - Approximately 1200 website visits in last 60 days
- **Comprehensive version is scheduled for publication in June 2023**
- **Documents available both accessible online HTML and PDF**



Thank You



References

- ADA Standards for Accessible Design. (2010). US Department of Justice Civil Rights Division.
- ANSI/AAMI HE75:2009(R)2018 Human Factors Engineering - Design of Medical Devices. (2018).
- Applying Human Factors and Usability Engineering to Medical Devices. (2016). U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluation
- Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices. (2020). US Food and Drug Administration.
- Design Considerations for Devices Intended for Home Use. (2014). US Food and Drug Administration.
- Do It By Design - An Introduction to Human Factors in Medical Devices. (1996). US Food and Drug Administration.
- Federal Plain Language Guidelines. (2011). In [PlainLanguage.gov](https://www.plainlanguage.gov/).
- Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation. (1997). US Food and Drug Administration.
- Web Content Accessibility Guidelines (WCAG) 2.1 W3C Recommendation. (2018).