
Best Practices for the Design of Accessible COVID-19 Home Tests

Table of Contents

Introduction	3
Glossary	5
Physical Components	7
1.1 Instructions/Accessing Information	8
1.2 Package Design	29
1.3 Kit Design	41
Digital Design	49
2.1 Instructions/Accessing Information	50
2.2 Test Procedure	71
References	74

Introduction

The National Institutes of Health (NIH) launched the Rapid Acceleration of Diagnostics (RADx®) initiative to speed innovation, development, commercialization, and implementation of COVID-19 testing technologies. The RADx Tech program, one arm of the initiative, was specifically designed to compress the customary technology development timeline from years down to just months. While these programs have increased testing capacity in the U.S. by billions, there is a continuing need to develop at-home COVID-19 tests that are accessible to all users including populations that have no vision or low vision, a reduced range of dexterity or motor skills, and those that are aging.

Within RADx Tech, the RADx Deployment Core has focused on increasing accessibility of at-home COVID-19 tests. As first steps, research was conducted to locate pre-existing accessible product design guidelines and engineering design groups were consulted. One of the immediate and surprising insights to come from these efforts was the lack of

comprehensive in vitro diagnostic (IVD) guidelines or standards for accessible design of IVD products for manufacturers and engineers. Advocacy groups and foundations that have a deep knowledge of the experience and needs of people with these types of challenges were engaged.

Due to the lack of fully accessible at-home COVID-19 tests, a research funding program was created with the purpose of developing more accessible tests. Through this effort, members of advocacy groups continue to be engaged to help provide feedback on device usability and troubleshoot design challenges for these populations. RADx Tech experts are actively working with manufacturers to address device design, packaging, and modes of instruction, among other challenges.

Through knowledge garnered from all the above actions, a comprehensive, practical and useful set of Best Practice Recommendations was created to

help fill a critical need in the design community. It is intended that this document will be used primarily by manufacturers for designing more accessible IVDs. While the goal of the document is to provide recommendations for making an at-home diagnostic kit accessible to aging populations and/or users with visual/motor disabilities, many of the recommendations will improve the overall usability and will likely result in universal access to the test kit.

When this work began, it was recognized that there was a need to provide information to the manufacturing and engineering communities as soon as possible. This document is an abridged version of Best Practice Recommendations, and covers topics prioritized for early release. A more complete version is expected to be posted in the first half of 2023.

Glossary

Cartridge – Device where a sample is added, processed, and a result is communicated visually or by a test reader.

Dropper – Device usually intended to contain the buffer fluid into which the sample is introduced and transferred to the cartridge. May be integrated into a fluid vial.

Fluid Vial – Container of fluid intended to be dispensed into another container (e.g., dropper).

Haptic Feedback – Feedback that creates a touch experience for the user through application of force or motion. Tends to be related to dynamic physical features (e.g., phone vibration) (See also tactile feedback).

Lateral Flow Assay (LFA) – (Also referred to as a lateral flow device, a rapid test, or a lateral flow immunochromatographic assay) A device intended to detect the presence of a target substance in a liquid sample without the need for specialized and costly equipment.

Optical Character Recognition (OCR) – Software that converts non-editable document formats such as PDFs, images or paper documents into machine-readable formats that are editable and searchable.

Quick Response (QR) Code – A type of matrix barcode that can be read easily by a digital device, which stores information as a series of pixels in a square-shaped grid.

Quick Reference Guide (QRG) – (Also referred to as Quick Reference Information (QRI)) A short version of the test instructions. It is intended for untrained operators and contains the step-by-step instructions needed to perform the test with a negligible likelihood of erroneous results.

Responsive Web Design – (Also referred to as responsive design) An approach to web design that aims to make web pages render on a variety of devices and window or screen sizes from minimum to maximum display size to ensure usability and satisfaction.

(Continued on next page)

Screen Reader – A software program or an application that enables no-vision or low-vision users to convert text displayed on a computer screen, tablet or phone into synthesized speech or to a refreshable braille display. A screen reader is the interface between the computer's software and the user. It enables users to perform any operation on a computer (e.g., JAWS and NVDA on Windows; VoiceOver on macOS, iOS, iPadOS, and tvOS; and TalkBack on Android phones, tablets, and kiosks).

Swab – The sample collection device with one part intended to be held in the hand and another part placed into the nostril.

Tactile Feedback – Feedback that is perceptible by touch. Tends to be related to static physical features (e.g., a button that is higher than the device surface) (See also haptic feedback).

Test Reader – Device which accepts cartridges and/or analyzes a sample and provides a test result.

Tube Holder – Device which holds a fluid vial in an upright position.

Chapter 1

Physical Components

1.1 Instructions/Accessing Information

1.2 Package Design

1.3 Kit Design

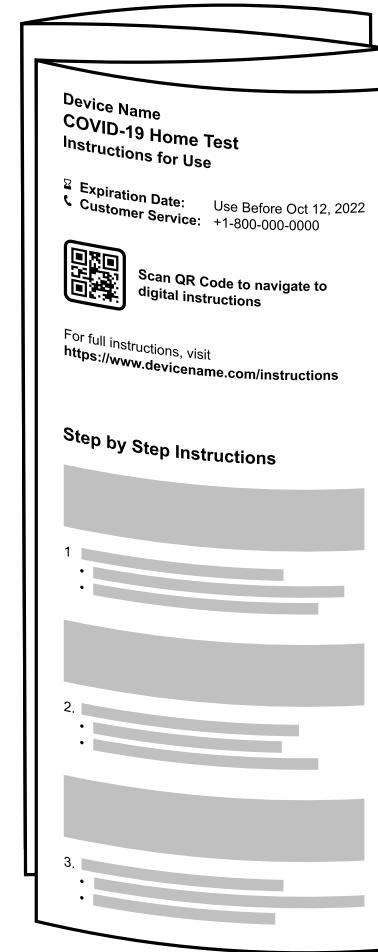
1.1 Instructions/Accessing Information

- **Text Perception**
- **General Readability and Layout**
- **Physical Embodiment**
- **Graphics, Images and Symbols**
- **Language**

Instructions/Accessing Information • Text Perception

Text Perception

Physical instruction in the form of text is one important way to convey information, as it can be provided directly on packaging or on a separate component inside packaging.



Instructions for use

Instructions/Accessing Information • Text Perception

Issue

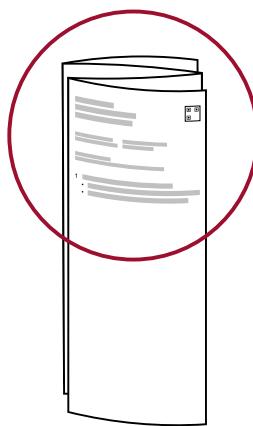
- Some instructions include the use of hard-to-read fonts, italics, underlining, or other text features that increase the level of reading difficulty.
- Instructions are also challenging to read when multiple fonts and typefaces are used.

Recommendation

- Consistently use a sans serif font that is easy to read such as Arial, Verdana, Helvetica, Calibri, etc.
- Minimize italics
- Do not use all capital letters
- Avoid/minimize underlining

Instructions/Accessing Information • Text Perception

Issue



Device Name
COVID-19 Home Test
Instructions for Use

Expiration Date: 10/12/2022
Customer Service: +1-800-000-0000

For full instructions, visit
<https://www.devicename.com/instructions>

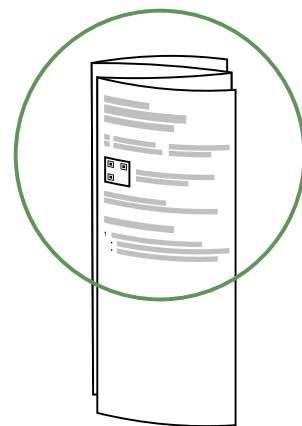
Step by Step Instruction

1. Step Title Text Goes Here
 - Action Item 1 Goes Here
 - Action Item 2 Goes Here

Key information hard to distinguish

- Content is displayed such that it is challenging to distinguish key and supporting information.
- Expiration dates and QR codes are small (one-half inch square or less) and difficult to locate.
- Expiration date is presented as a number string (e.g., YYYY-MM-DD or MM/DD/YYYY) only, which OCR applications do not recognize as dates.

Recommendation



Device Name
COVID-19 Home Test
Instructions for Use

Expiration Date: Use Before Oct 12, 2022
Customer Service: +1-800-000-0000

Scan QR code to navigate to digital instructions

For full instructions, visit
<https://www.devicename.com/instructions>

Step by Step Instruction

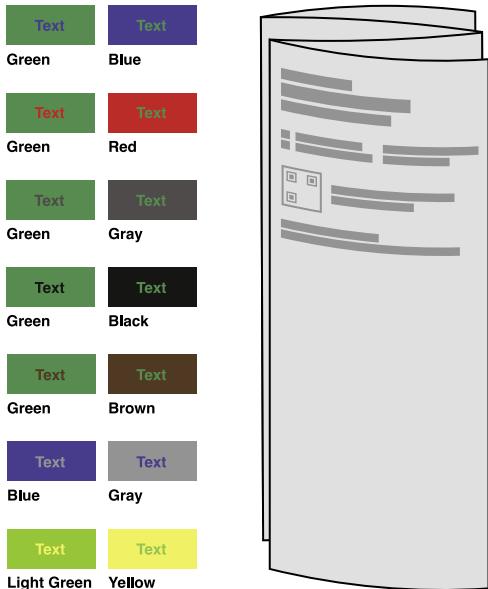
1. Step Title Text Goes Here
 - Action Item 1 Goes Here
 - Action Item 2 Goes Here

Key information stands apart

- Present key information in large and/or boldface type. (Use minimum of 14 pt).
- Provide QR codes measuring larger than one-half inch square.
- Present expiration date with abbreviated or spelled out month, numerical day and year (e.g., Oct 12, 2022), as well as in unique device identifier (UDI) format (e.g., 2022-10-12). Ideally, state: ‘Use before <date>’ or ‘Do not use after <date>’.

Instructions/Accessing Information • Text Perception

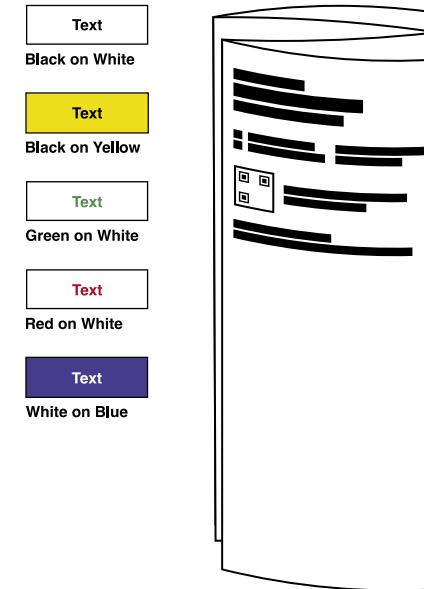
Issue



Poor color combination; instructions with poor legibility

Information can be provided with poor color contrast.
It can be challenging to perceive key information.

Recommendation

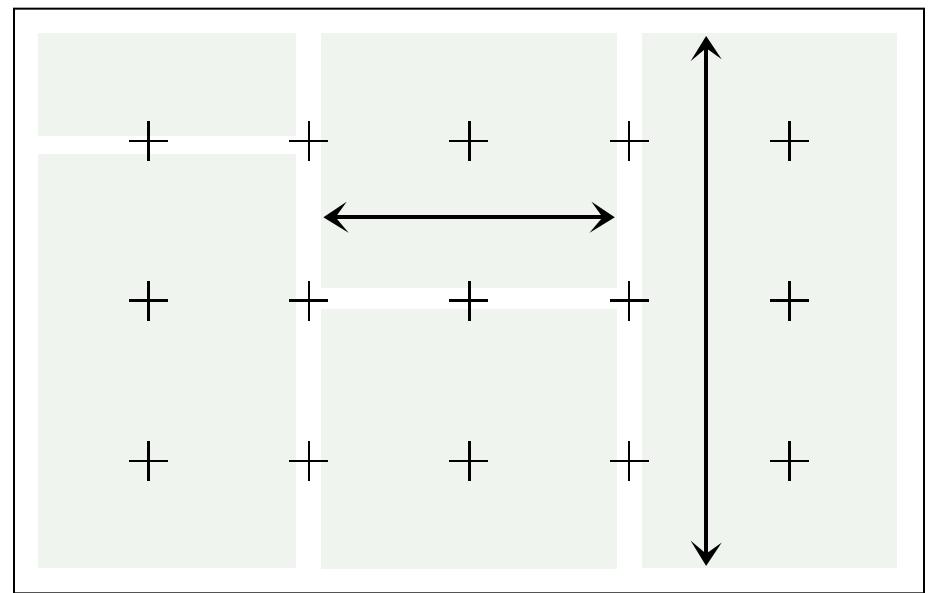


Recommended color combination; legible instructions

Color contrast needs to allow for better differentiation between the text and background. Provide a minimum contrast ratio of 4.5:1 for 14 pt or smaller and 3:1 for larger text. Contrast ratio compares relative luminance of text and background color and can be measured using free color contrast checker tools like The Paciello Group Interactive's (TPGi's) Colour Contrast Analyser (CCA).

General Readability and Layout

Users' ability to find and follow instructions can be greatly affected by how information is organized and displayed. Key information can either pop out or can be lost in a sea of text and graphics. Likewise, these layouts can make information inaccessible to those using digital technologies such as OCR applications.



Layout considerations for readability

Instructions/Accessing Information • General Readability and Layout

Issue

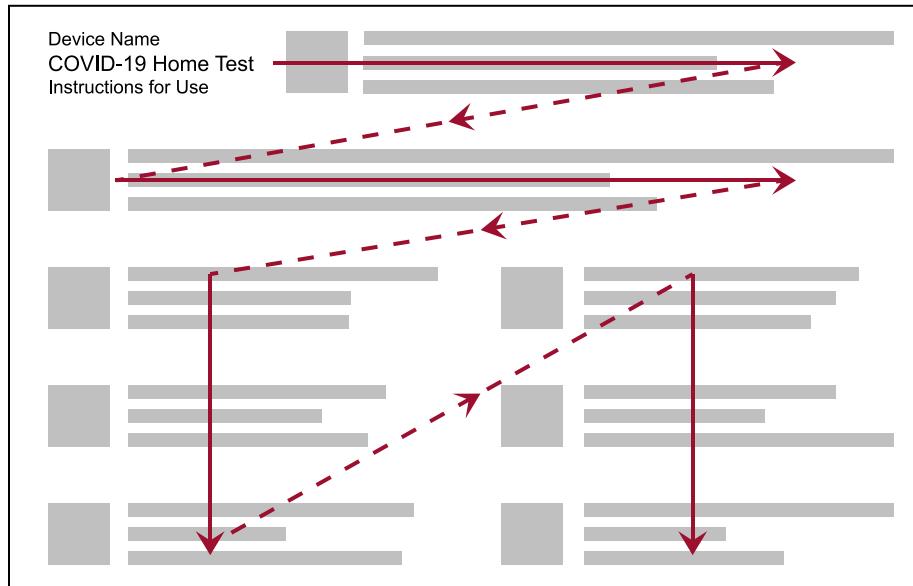
- Too much information can be presented in a format that is difficult to follow. It can be difficult to understand what is meant to be read and in what order.
- Steps requiring multiple actions or tasks are challenging for all to follow. Multiple steps that take up different amounts of page ‘real estate’ are difficult to scan for low-vision users.

Recommendation

- Provide a single, actionable task for each step.
- Break text into block paragraphs using bullet points when possible. As a best practice for all lay users, write short sentences at a 7th grade reading level.

Instructions/Accessing Information • General Readability and Layout

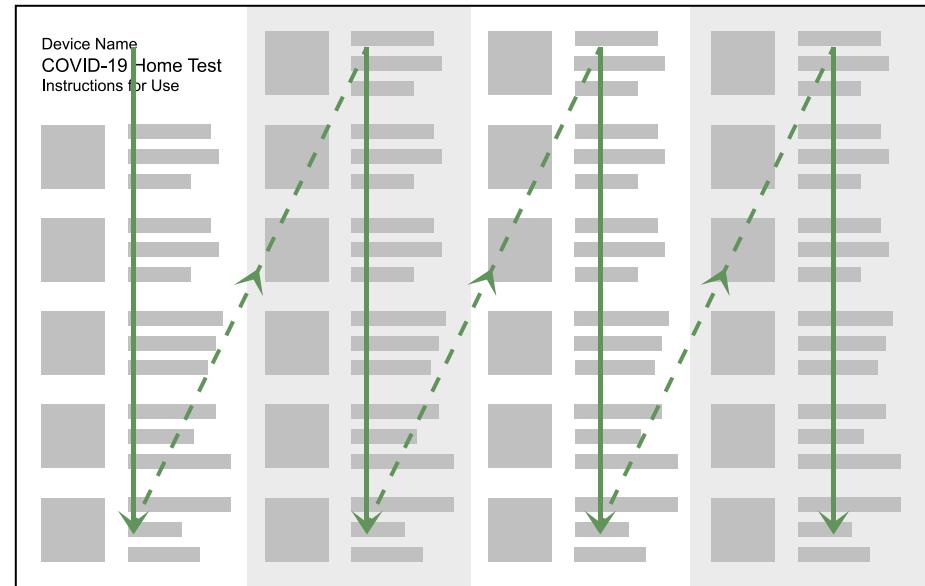
Issue



Text layout with inconsistent information flow

- Blocks of text are sometimes presented in different layouts, some left to right and others top to bottom, making following along cumbersome.
- Lack of breaks in large blocks of text make the information difficult to digest and wide columns can make low-vision users dizzy.

Recommendation



Recommended text layout and information flow

- Use a consistent layout. A columnar layout works best. Use the flow scheme shown above. Blocks are arranged in columns; columns are arranged left to right. Use narrow columns.
- Present document in landscape format if possible.
- Include a margin of at least three pixels between rows and columns.

Instructions/Accessing Information • General Readability and Layout

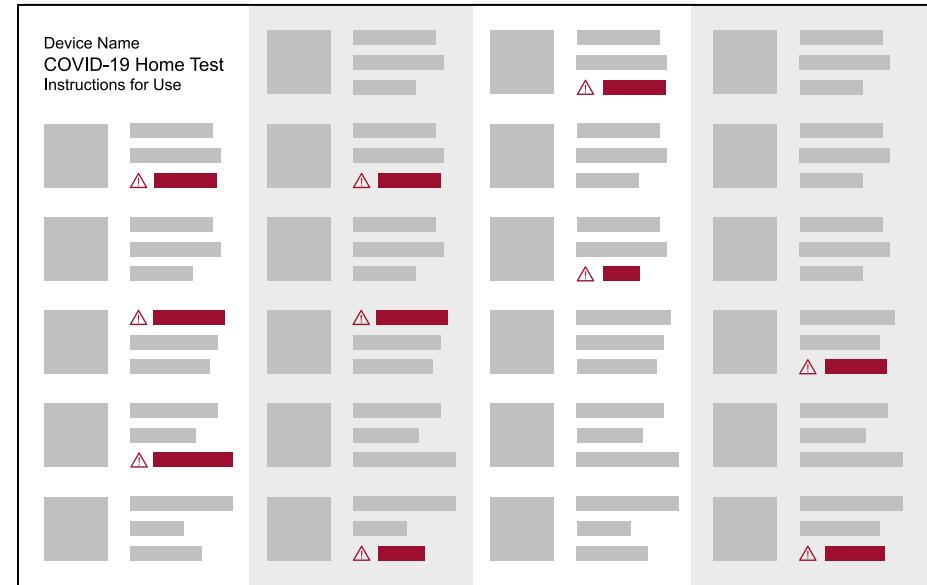
Issue



Numerous warnings embedded in copy

Multiple warnings are presented inconsistently making it hard to locate them or allow the truly important warnings to attract the appropriate amount of attention.

Recommendation



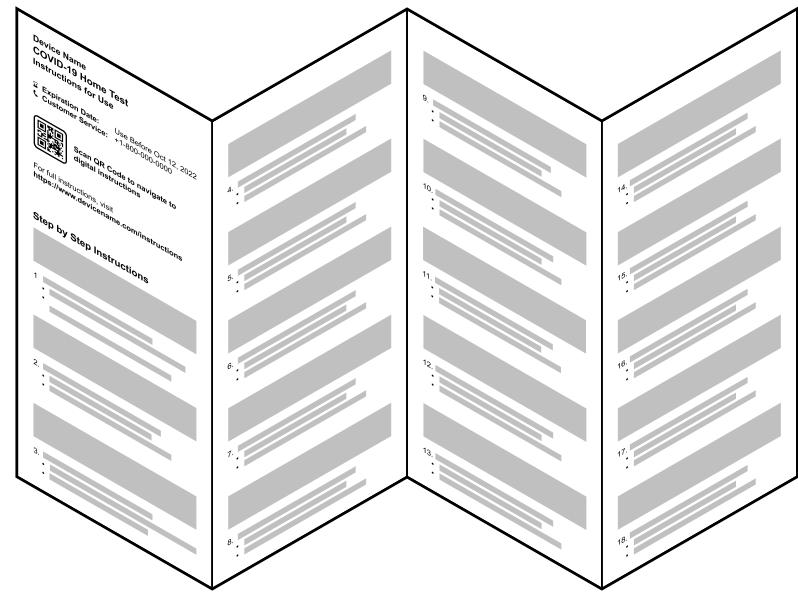
Targeted warnings, visually differentiated from plain copy

Essential warnings (e.g., those where use error is associated with the greatest risk of an invalid test result) should be communicated in a consistent manner (e.g., bold, red font).

Instructions/Accessing Information • Physical Embodiment

Physical Embodiment

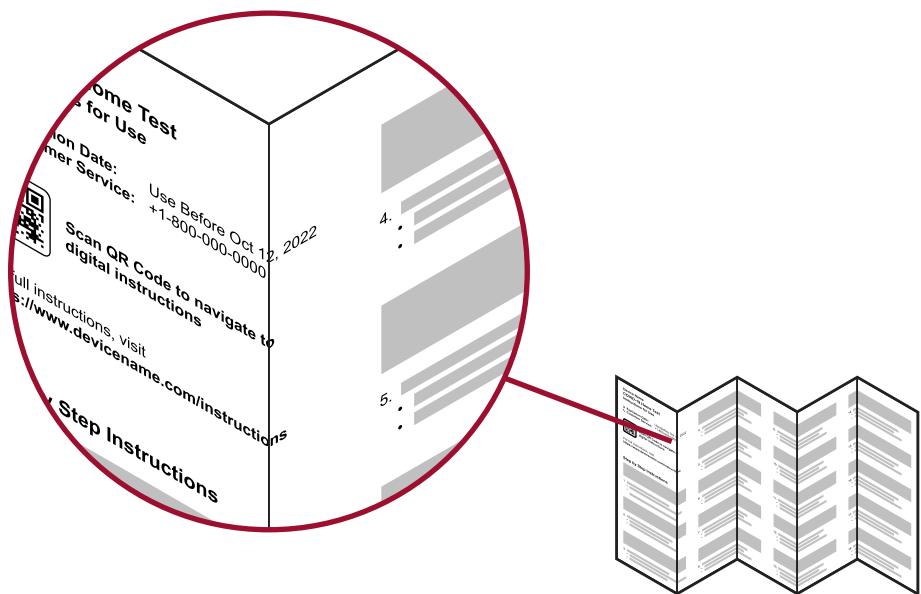
Instructions can be provided in a number of ways: on a card, on paper, on a fold out, or in a booklet. The mode in which physical instructions are provided can impact readability and usability.



Instructions for use

Instructions/Accessing Information • Physical Embodiment

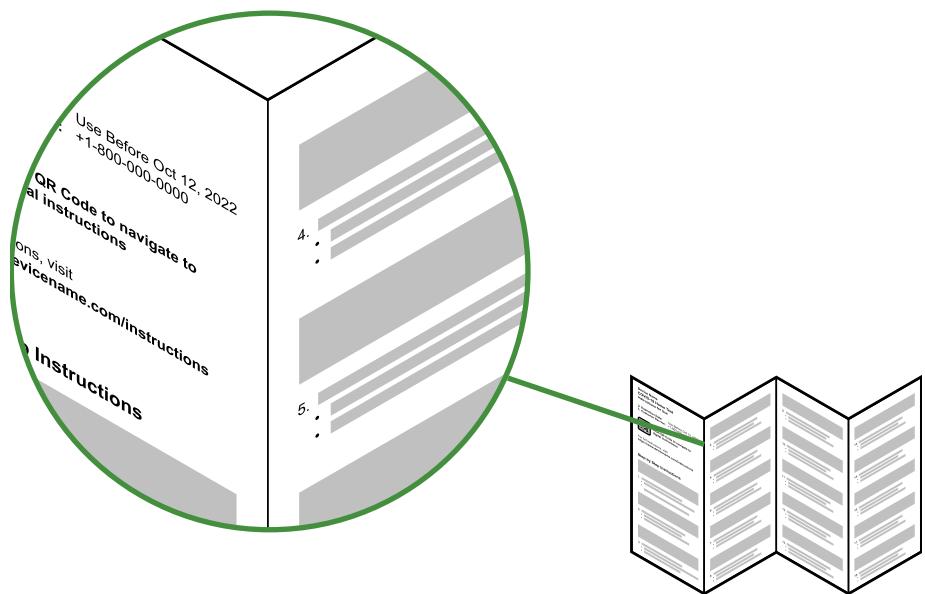
Issue



Information split along paper fold

Large instruction panels with folds can result in text crossing over folds. Same-topic information may be split across front and back panels, resulting in reduced readability.

Recommendation

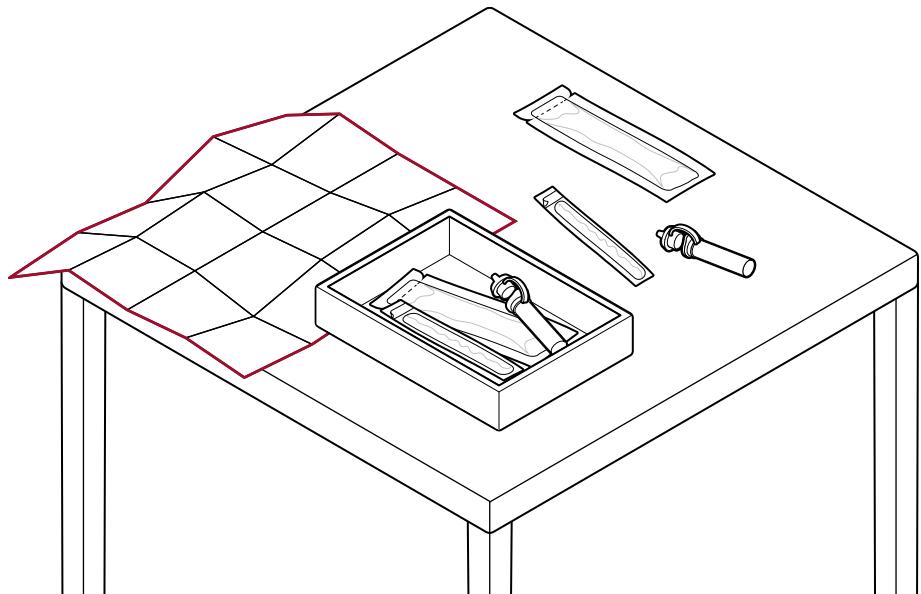


Information contained within folded panels

- Ensure paper creases only appear in the margins of text columns. Text columns should be equal width.
- Including text column gutters on folds may make it easier to scan parts of a folded document for OCR.
- Place all information needed to run the test on one side of the paper or card. The other side can be used for supporting information.

Instructions/Accessing Information • Physical Embodiment

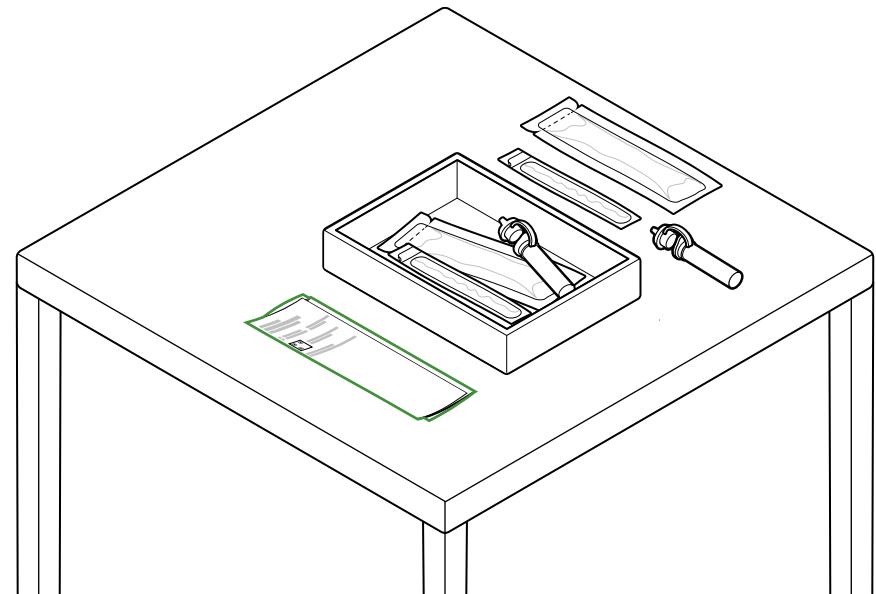
Issue



Instructions that require full unfolding

- It can be difficult to physically place instructions adjacent to the components due to size or material making them difficult to reference while using the test.
- Tests with fluid can result in spills which can deteriorate less robust instructional materials.

Recommendation

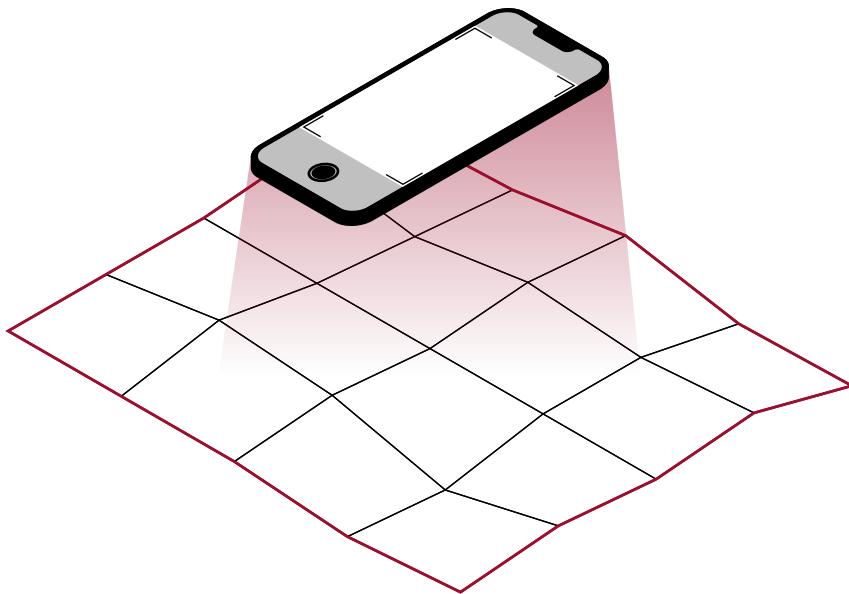


Instructions that can be unfolded by section

- Provide instructions in a manner that they can be placed adjacent to a test kit on a table.
- Consider that lighter paper weights allow instructions to lay flat. Use materials which can withstand some amount of liquid spill. If coatings are used, limit reflectivity.

Instructions/Accessing Information • Physical Embodiment

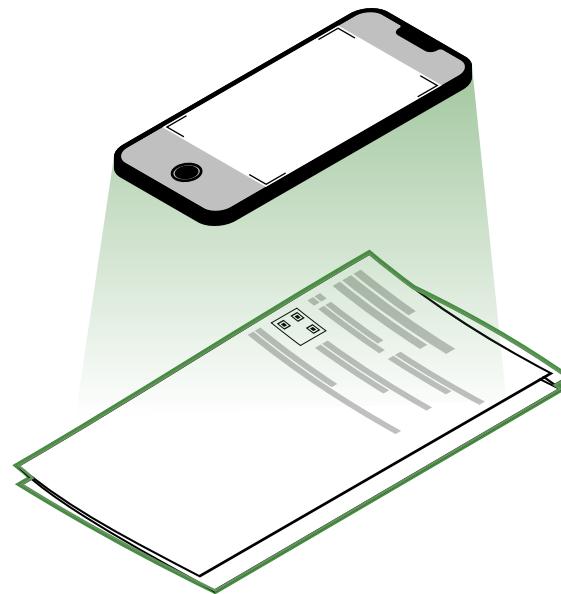
Issue



Instructions are too large for scanning

Paper (or similar) documents may be provided in an incompatible format for assistive technologies. Pages or panels may be too large for flatbed scanners and smartphone OCR. Multiple panels without numbering make it difficult to navigate from page to page.

Recommendation

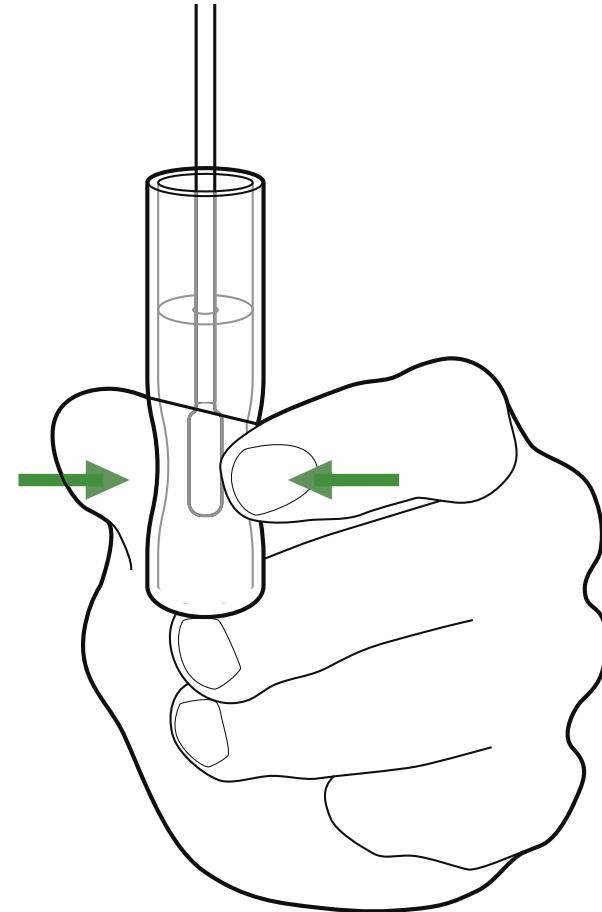


Instructions are an appropriate size for scanning

- Provide paper (or similar) documents in panels no larger than letter paper dimensions (8.5" x 11").
- Use page numbers for multiple panels on the front and back.

Graphics, Images and Symbols

Graphics, images, and symbols can be an effective way for users to quickly perceive and understand information.



Arrows show user interaction with product

Instructions/Accessing Information • Graphics, Images and Symbols

Issue



Photo backgrounds distract from product

Photos contain extra, unnecessary information making them difficult for low-vision users to perceive.

Recommendation

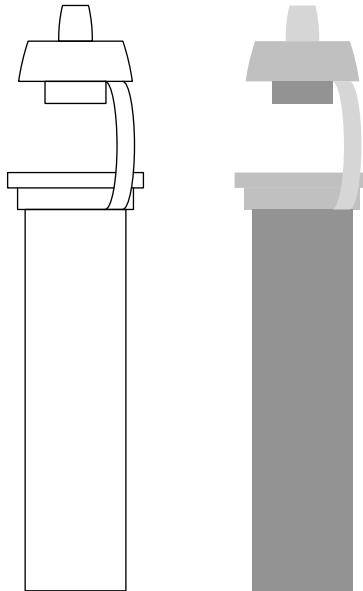


Line drawings improve comprehension

- Use high-quality, high-contrast, thick line drawings with perspective instead of photos.
- Use varying line weights to distinguish detail and accent features (e.g., 0.5 pt – 1.5 pt for lines and 3 pt – 4 pt for accent features).

Instructions/Accessing Information • Graphics, Images and Symbols

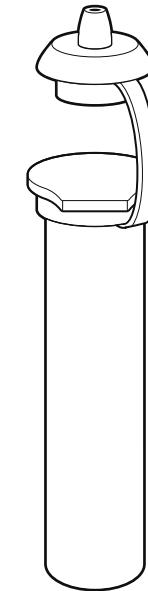
Issue



2D thin line and low-contrast drawings

It can also be difficult to interpret 2D drawings, especially those with thin lines, low contrast, or lower image quality or sharpness.

Recommendation

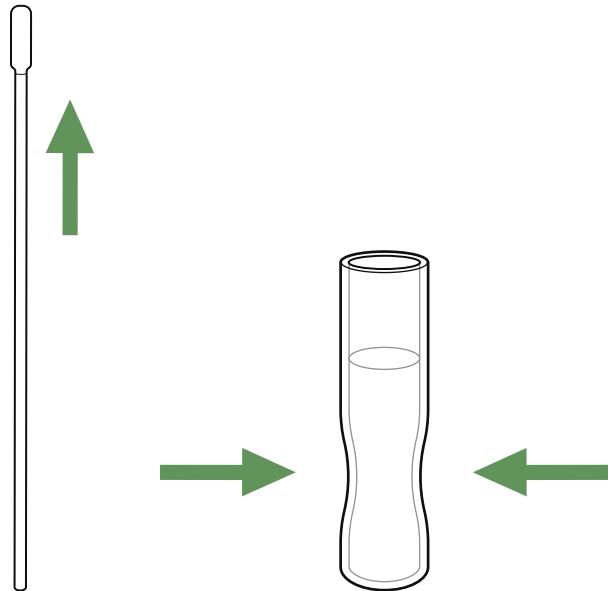


3D drawing with appropriate line thickness

Where possible, use 3D renderings with perspective and solid colors.

Instructions/Accessing Information • Graphics, Images and Symbols

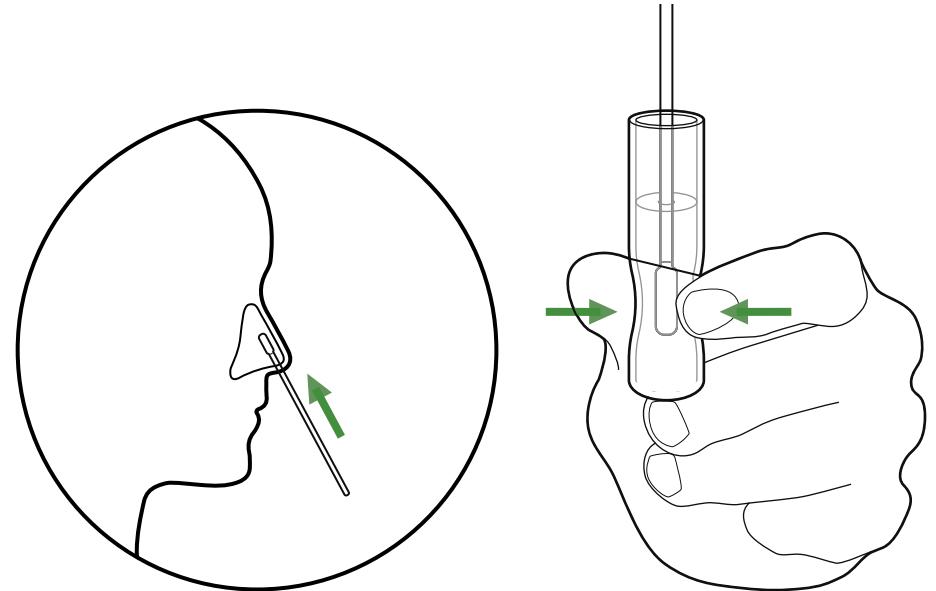
Issue



Images without context

- Images without context do not inform readers about relative component size.
- They force the reader to guess where and how components are to be utilized.

Recommendation



Images with context

- Make use of graphics that provide physical context for the reader (e.g., include hands, noses).
- Use only enough detail on features to clarify their purpose (e.g., a drawing of a head does not need to include hair).

Instructions/Accessing Information • Graphics, Images and Symbols

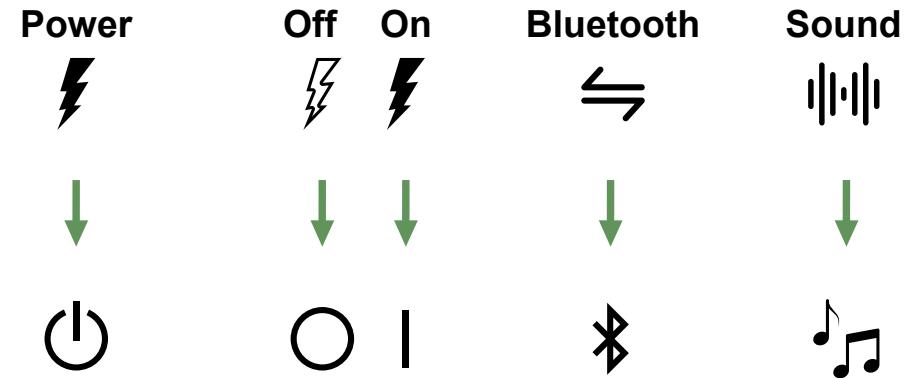
Issue



Non-standard symbols

Symbols are hard to understand if they are arbitrarily chosen or region-specific. Their meaning may not be obvious to the reader.

Recommendation



Standard symbols

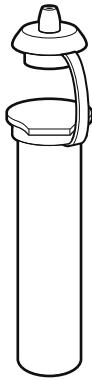
Use unambiguous and globally accepted symbols. Include a symbol key that is findable and near the symbol or include text labeling immediately adjacent to it. Follow the International Organization for Standardization (ISO) 15223 standard for symbols used on medical device packaging.

Instructions/Accessing Information • Graphics, Images and Symbols

Issue



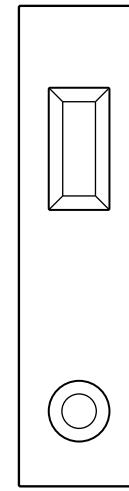
Actual
Vial



Vial
Illustration



Actual
Cartridge

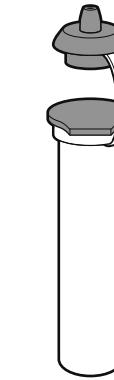


Cartridge
Illustration

Recommendation



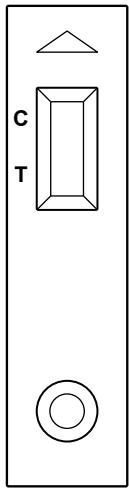
Actual
Vial



Vial
Illustration



Actual
Cartridge



Cartridge
Illustration

Drawings without realistic detail

Graphics that are not presented with details that match the actual components may cause confusion.

Drawings with realistic detail

- Make sure graphics/images match the actual appearance of the components (e.g., if a cap is gray, do not illustrate in white; if the cartridge has text or other markings on it, include these in graphics).
- Use grayscale sparingly and retain outlining of gray features.

Language

The vocabulary used in instructions is key to a user's ability to understand what is required. Presenting information in plain, clear, concise language is critical to ensuring a user's understanding of how to use the test kit.

Instructions/Accessing Information • Language

Issue

- Presenting critical information without text labels creates issues with OCR interpretability (e.g., 1-800-000-0000 without a ‘Customer Service Phone’ text label is read as a number string).
- Instructions sometimes refer to components and features inconsistently, which can make finding and following information difficult.
- Certain practices create unnecessary ambiguity, such as referring to components or features generally as “this” or “that”; and using abbreviations/acronyms.

Recommendation

- Text label critical information such as the product website, customer service phone number, and customer service email so they are recognized as such by OCR applications (e.g., Customer Service Phone Number: 1-800-000-0000).
- Use the same name for a component or feature throughout the instructions and labels on components or packaging.
- Provide non-visual descriptive indicators when describing components or features.
- Avoid use of abbreviations or acronyms. If it is necessary, clearly define the abbreviation or acronym at first instance and use consistently thereafter.

1.2 Package Design

- Identification
- Accessing Contents

Package Design • Identification

Identification

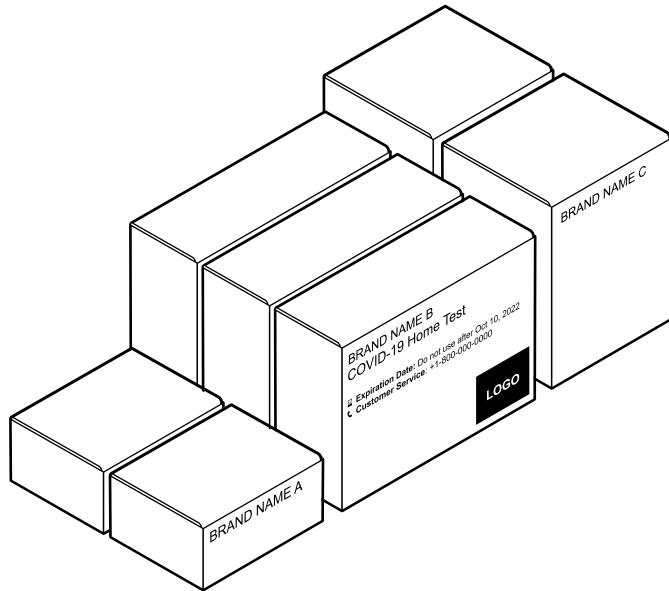
Outer box packaging is the initial introduction to any device. It can directly convey information through standard text, braille, or other novel means. It can indirectly convey information through shape, material, folds, breaks, and links to codes.



Box with examples of good identification features

Package Design • Identification

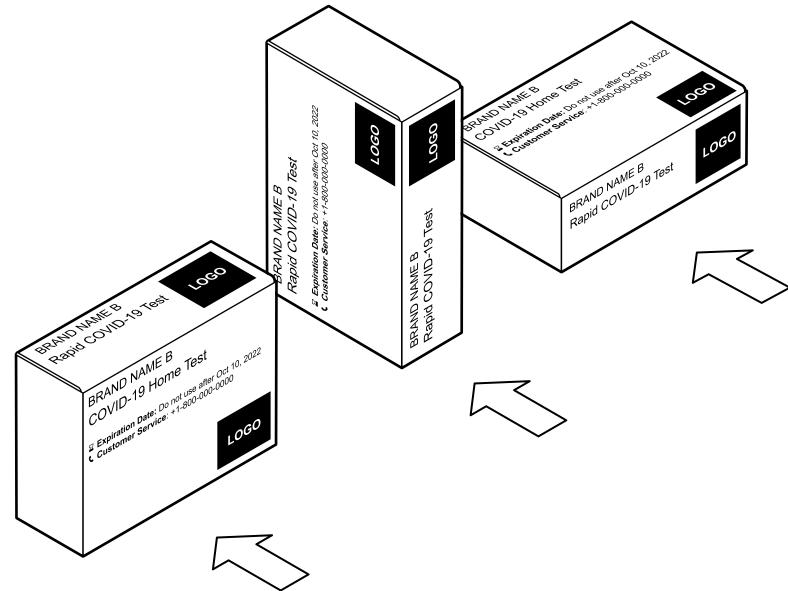
Issue



Box labeling viewable in only one orientation

Packages are often inadequately labeled. Boxes with nondescript panels may need to be rotated to ascertain contents.

Recommendation

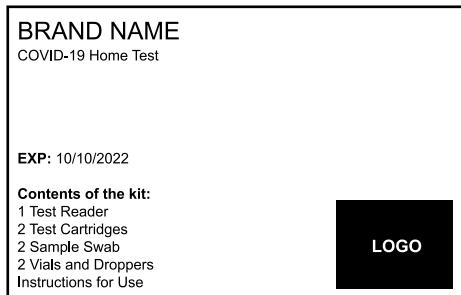


Box labeling viewable in multiple orientations

Consider how the package might be displayed (e.g., on a shelf) and what information the user might find most useful to perceive in different orientations in that setting.

Package Design • Identification

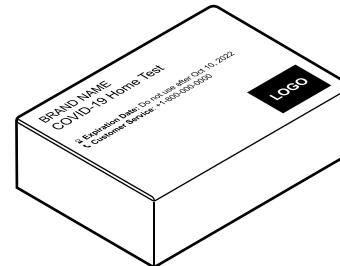
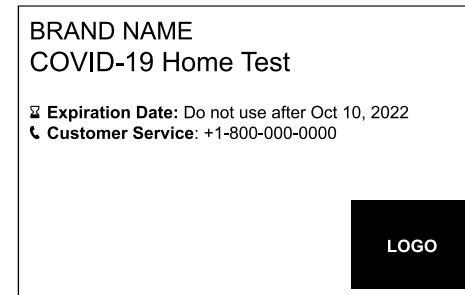
Issue



Box labeling with poor legibility

Much of standard packaging is filled with lots of information in a small (less than 14 pt) font.

Recommendation

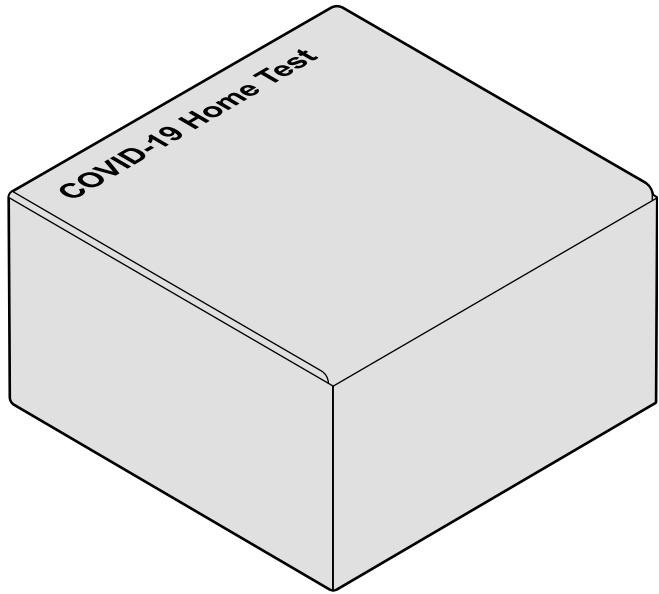


Box labeling with improved legibility

- Provide key information in large (14 pt minimum) sans serif font that is easy to read (e.g., Arial, Calibri, etc.). Do not use decorative fonts (e.g., Script, Slab).
- Key information includes brand name, device type, expiration date, links to instructions, and customer service phone number. Manufacturers should assure that labeling complies with regulatory bodies.

Package Design • Identification

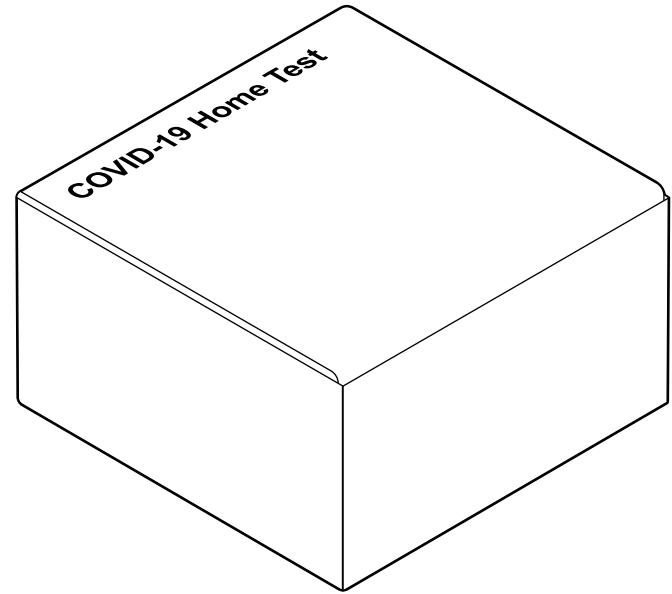
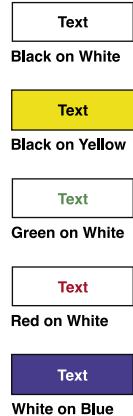
Issue



Poor color combination; packaging with poor legibility

Much of standard packaging is filled with lots of information with poor color contrast.

Recommendation

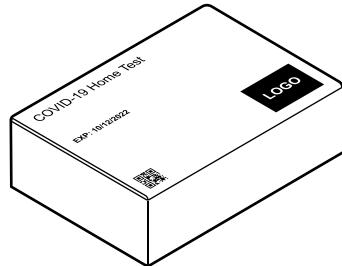
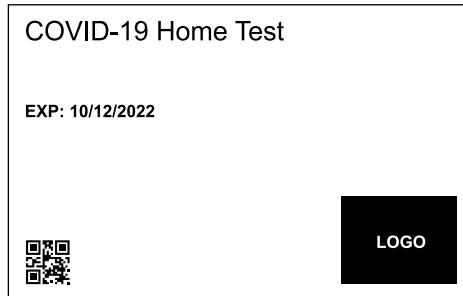


Recommended color combination; legible packaging

Use effective color contrast on outer packaging (refer to pg. 12 for design considerations).

Package Design • Identification

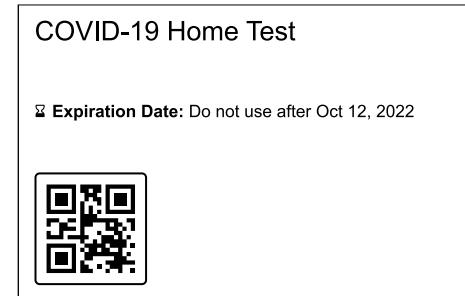
Issue



QR code is too small to easily locate

- QR codes are often missing or insufficiently sized (one-half inch square or less).
- Expiration date format is not recognizable by common OCR applications (refer to pg. 11 for more detail).

Recommendation

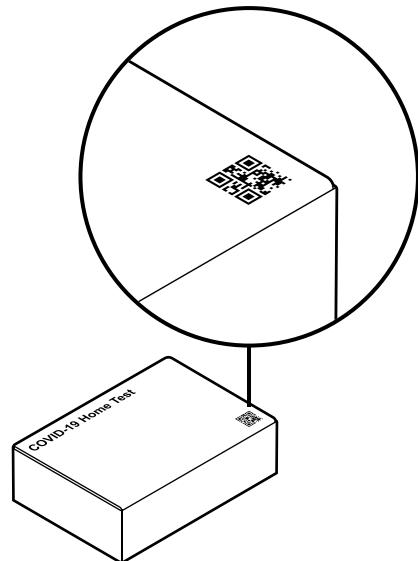


QR code is large and readily discoverable

- Present QR codes in size larger than one-half inch square.
- Refer to pg. 11 for guidance on expiration date formatting.

Package Design • Identification

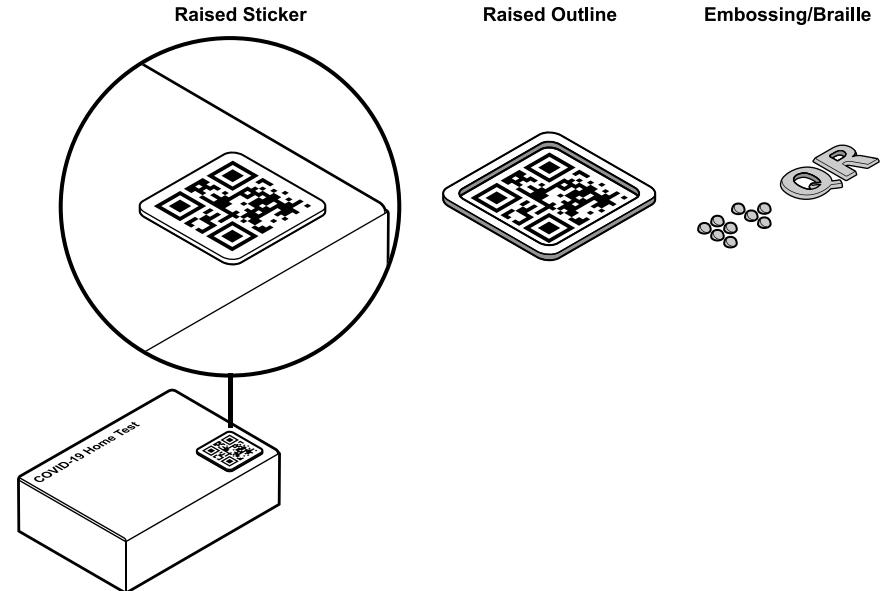
Issue



Example of a flat QR

There are generally no tactile features on the surfaces of standard boxes, which would otherwise allow for a no-vision or low-vision user to identify package contents, either through a QR code or through braille.

Recommendation



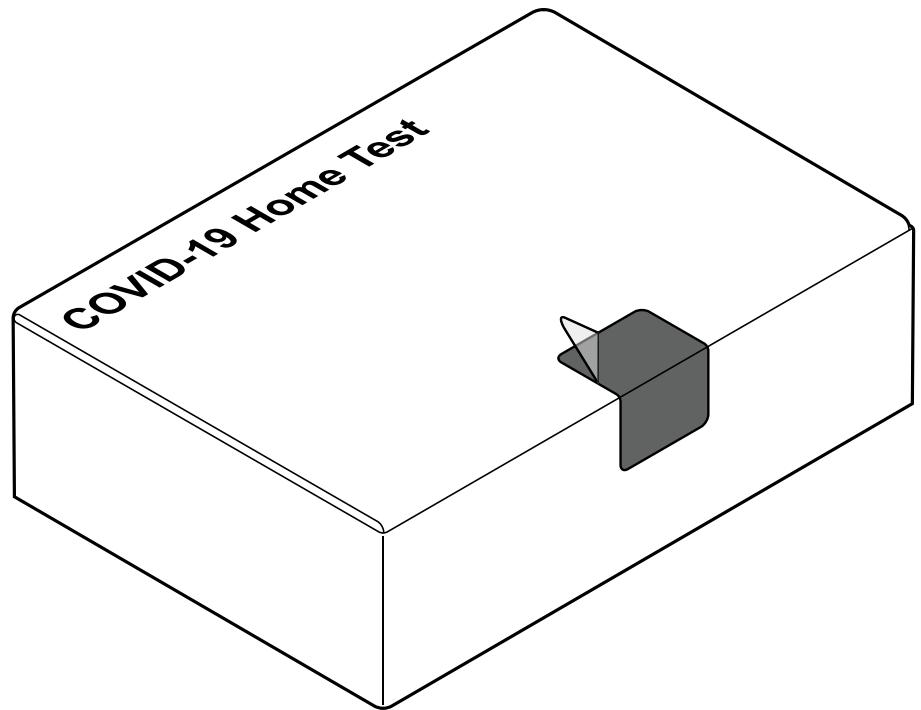
Alternatives to flat QR codes

Provide a means to tactiley find encoded information (e.g., a raised sticker, or raised outline). A QR code should be the primary way for a user to obtain information; braille and embossed lettering are appropriate secondary methods.

Accessing Contents

Opening and accessing packaging requires a balance of competing needs:

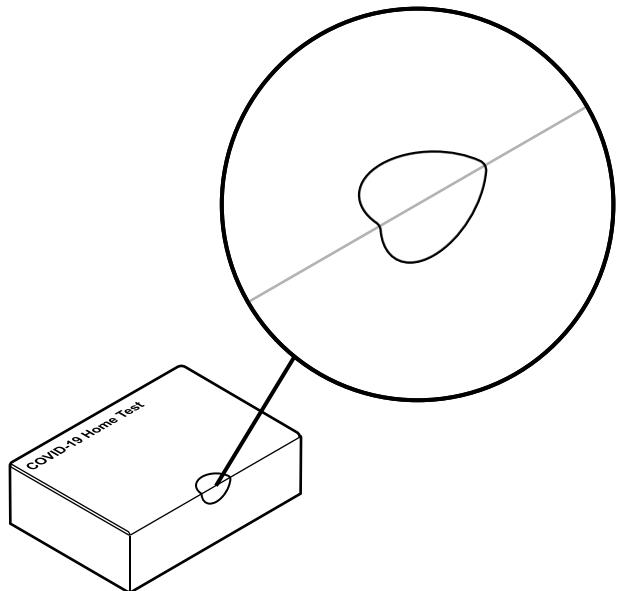
- Preventing unauthorized users from tampering with contents
- Ensuring the package is easy to open
- Minimizing jostling of internal components



Package with tamper-proof seal

Package Design • Accessing Contents

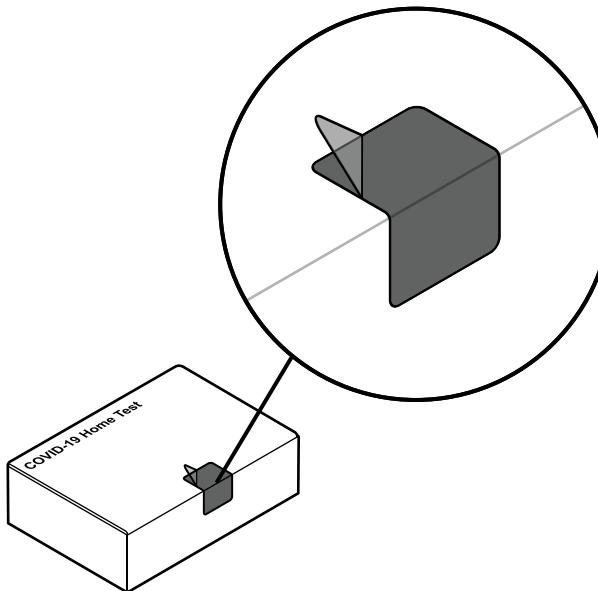
Issue



Difficult to remove tamper-proof seal

- Tamper-proof seals are often small, round adhesive stickers that can be challenging to find and to remove, especially for low-dexterity users.
- Tearing open a package without removing the sticker frequently results in the package being damaged and contents being disorganized and potentially misplaced.

Recommendation

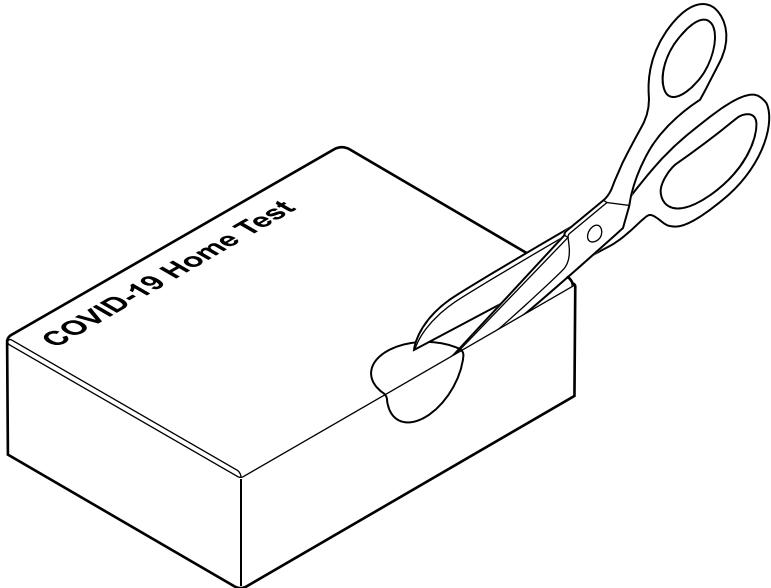


Easy to remove tamper-proof seal

- The grasp surface on the tamper-proof seal should be adequate for fingers to grasp, allowing users with low dexterity to easily remove it. If a feature to grasp is being provided, provide at least one-half inch square of graspable area.
- Force to remove a label or open a pouch/package should not exceed five pounds.

Package Design • Accessing Contents

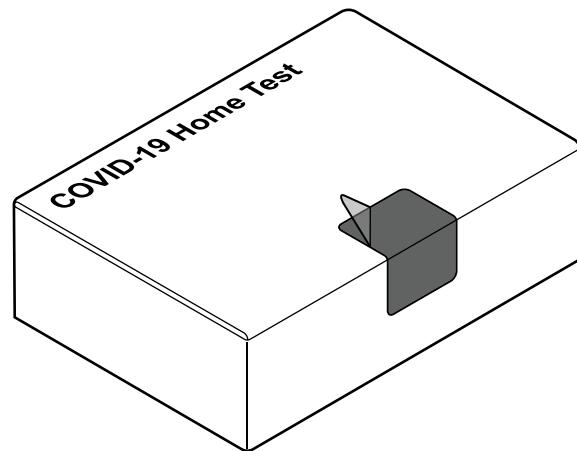
Issue



Difficult to remove tamper-proof seal

- When faced with this tamper-proof seal, many users resort to external tools such as scissors and knives to open the package, which may result in damaging contents.
- Many tamper-proof seals are clear, making them challenging to find for low-vision users.

Recommendation

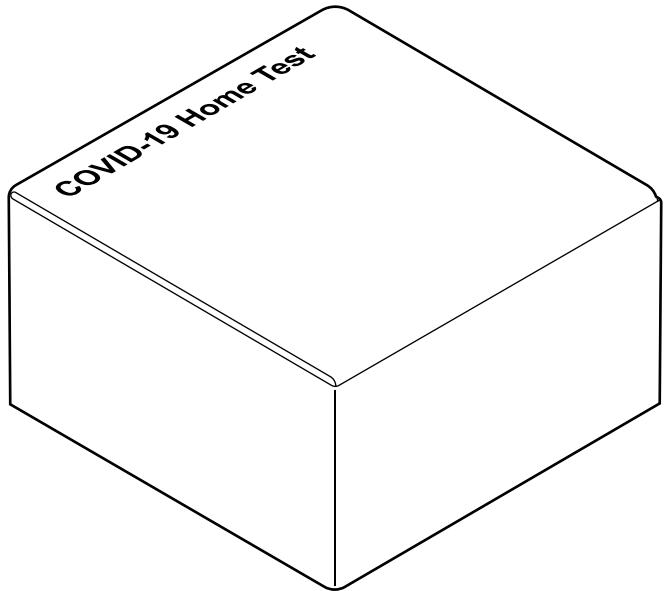


Easy to remove tamper-proof seal

- Provide a tamper-proof seal that is easy to find and easy to remove for everyone. Allow users to grasp features easily and complete the action required to remove without the need for external tools.
- The tamper-proof seal should be a contrasting color to the rest of the package.

Package Design • Accessing Contents

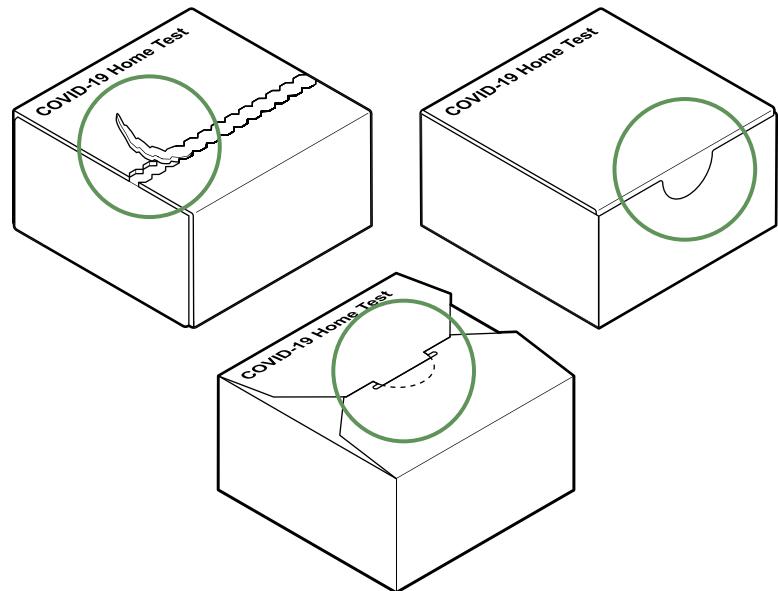
Issue



Package without intuitive opening

It can be challenging to understand how to open a package (e.g., How does the lid open? Is there a place where the top and bottom separate?), especially for no-vision and low-vision users, when the only indication regarding top, bottom, front, and back is through visual, printed labeling.

Recommendation

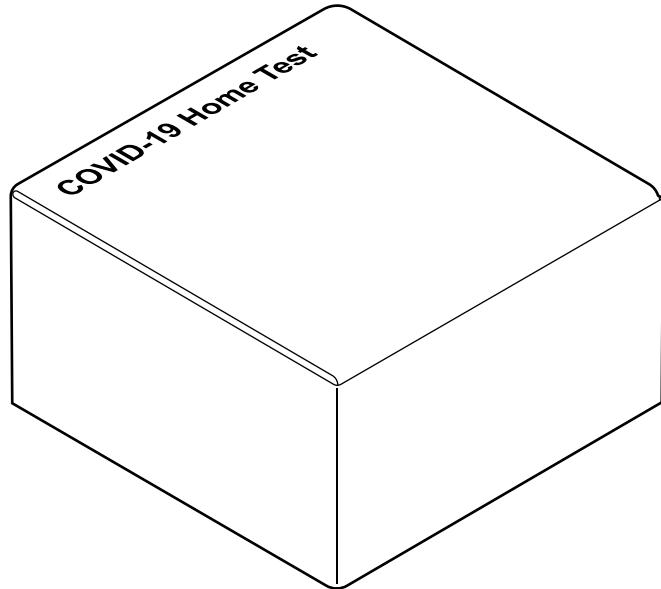


Packages with opening cues

Provide familiar tactile cues on the packaging indicating which part is meant to be moved, removed, or separated (e.g., perforated tear tab, thumb cutout, overlapping flaps).

Package Design • Accessing Contents

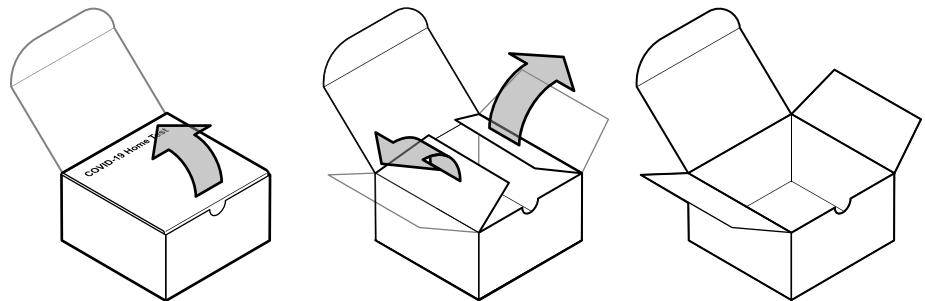
Issue



Plain box with no divots

It can be challenging to physically open a package when there are no affordances provided to grasp and pull or push.

Recommendation



Boxes with divots and flaps

Include features for opening the package which accommodate users' fingers and a variety of hand sizes to ensure opening methods require low force.

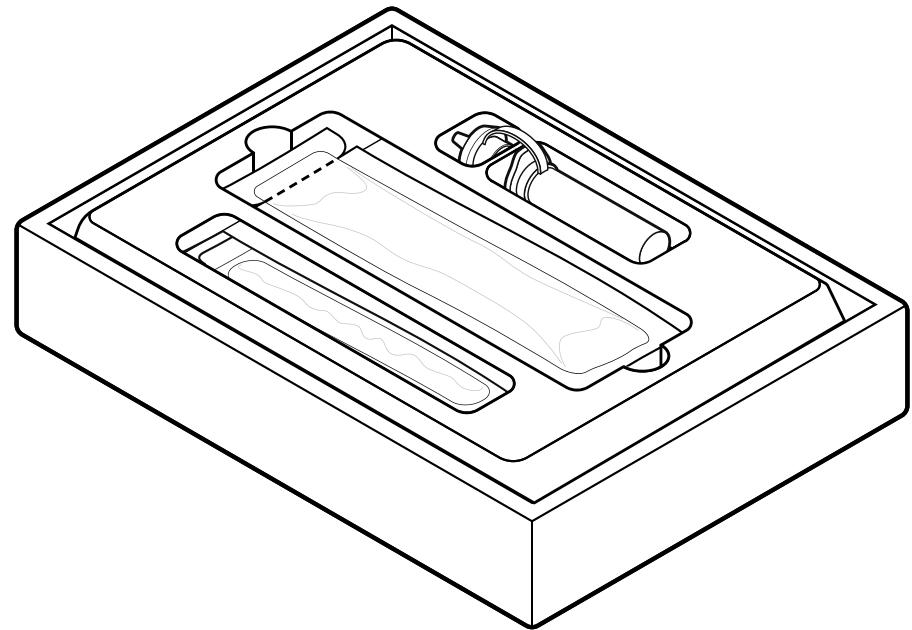
1.3 Kit Design

- Organization of Contents
- Identification of Contents
- Opening Internal Packages

Kit Design • Organization of Contents

Organization of Contents

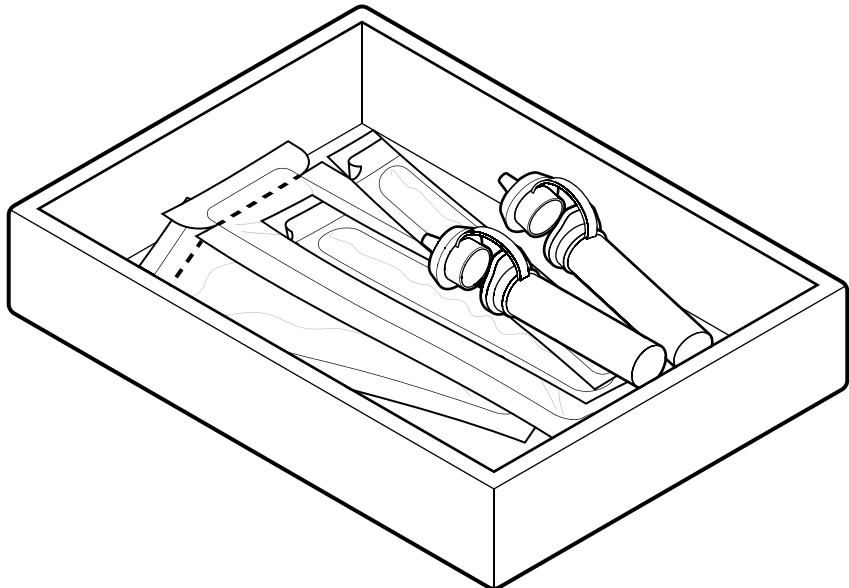
Test kits containing multiple components must identify the components, secure small components, and provide information on the order in which the components are to be used. Organizing contents thoughtfully can greatly enhance the user's ability to complete the test.



Kit contents

Kit Design • Organization of Contents

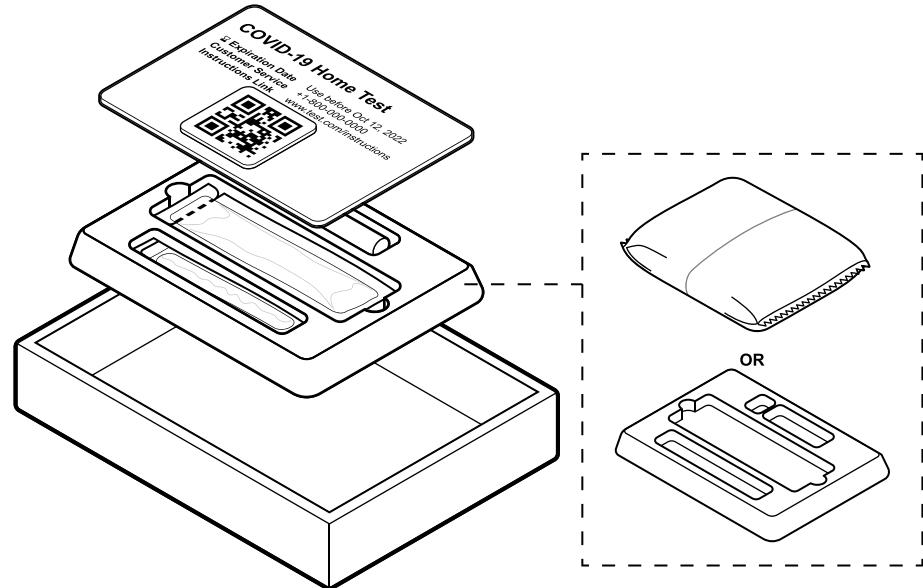
Issue



Loose contents inside box packaging

- Internal instructions and key information are not presented to the user in a manner that is easy to find and users do not know what to reference first.
- Packages can have a number of components and interior packages loosely placed inside. When opened, the contents can fall out rendering them hard to identify, manage, and track. It can be difficult to understand which interior package or component is meant to be handled and when.

Recommendation



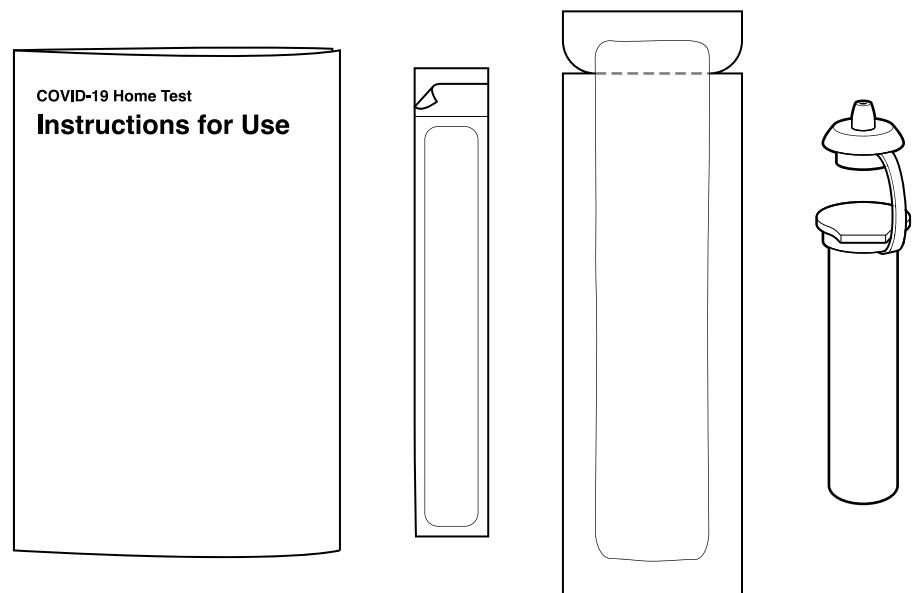
Contents neatly organized within box

- Provide legible (pg. 10) instructions (i.e., QRG) face up as the first thing users encounter. Include a tactile means to locate QR code, linking to digital instructions and test information, including test type, expiration date, and customer service phone number.
- Place contents in an organized and fixed manner (e.g., tray, card, dividers, etc.), in clear order of use. This helps users identify components, delineate order of use, and keep components secure.

Kit Design • Identification of Contents

Identification of Contents

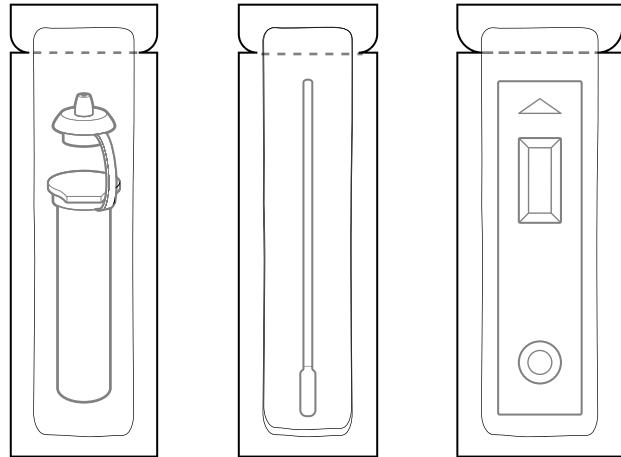
Contents in a package need to be identifiable so that users know when to open or use each individual package. It is also important to keep track of what is provided in a package to determine if there are missing components.



Instructions for use and kit contents

Kit Design • Identification of Contents

Issue



Foil



Foil

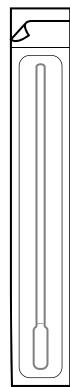


Foil

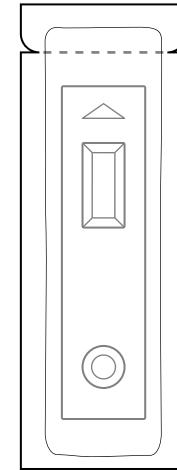
Parts are packaged in foil pouches with the same form factor

Component packages that are similar in size and shape to one another are difficult to distinguish.

Recommendation



Peel-apart



Foil



Plastic

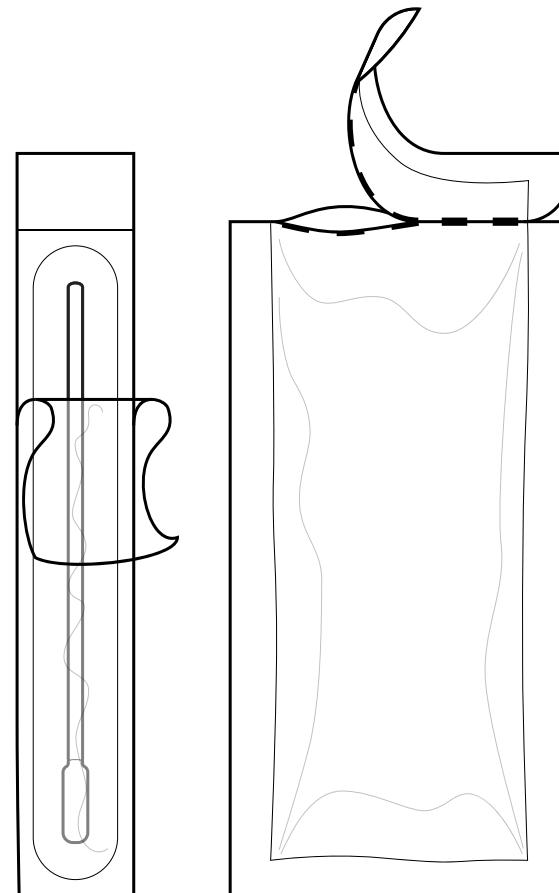
Parts are packaged with distinct materials and form factors

If components have interior packages, ensure that each component is tactiley discernible from others so users can use touch to identify contents. For example, a user could be instructed to feel for a component shape inside the interior package. Alternatively, the kit could provide distinct shapes of the interior packages that can be described to and felt by no-vision or low-vision users.

Kit Design • Opening Internal Packages

Opening Internal Packages

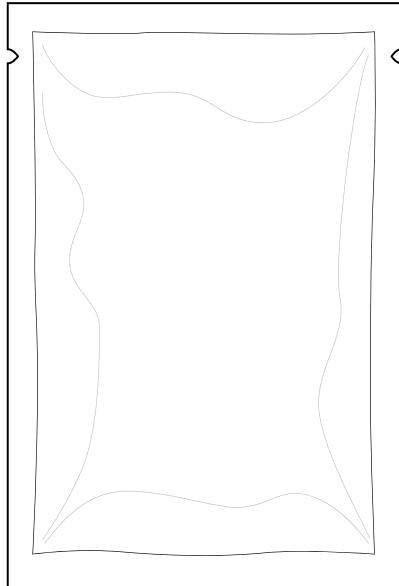
Accessing components frequently requires opening a sealed package. The user should be able to easily identify where to open the package. They should be provided with sufficient area to grasp the package. The force required should not exceed five pounds.



Internal packages

Kit Design • Opening Internal Packages

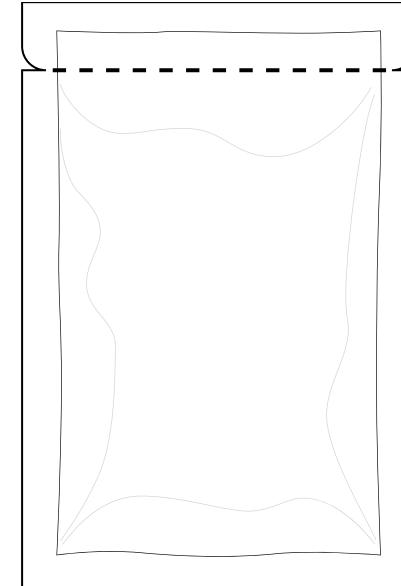
Issue



Pouch without clear indication for tear location

It can be difficult to understand how to open a pouch. Locating the correct place to tear is often challenging.

Recommendation

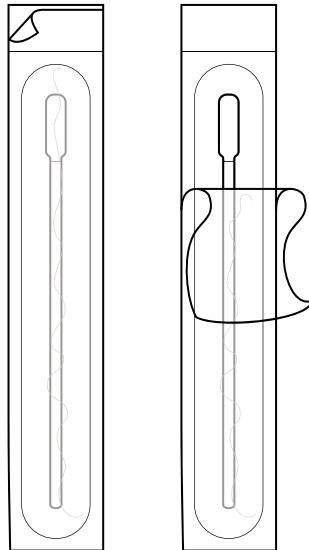


Pouch with evident tear location

Provide multi-modal methods to inform the user how to open package. For example, include both a line with high contrast of where a tear should happen along with a notch that is findable by touch.

Kit Design • Opening Internal Packages

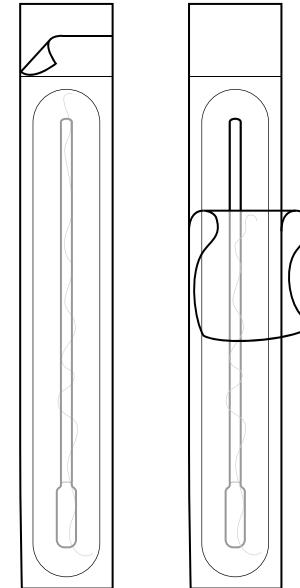
Issue



Swab packaging with swab tip near small peel tab

Interior packaging may present a method for opening which exposes an area to contamination through touch.

Recommendation



Swab packaging with swab handle near big peel tab

Ensure the opening exposes the component portion that would be preferred to touch (e.g., peel feature near swab handle rather than swab tip).

Chapter 2

Digital Design

2.1 Instructions/Accessing Information

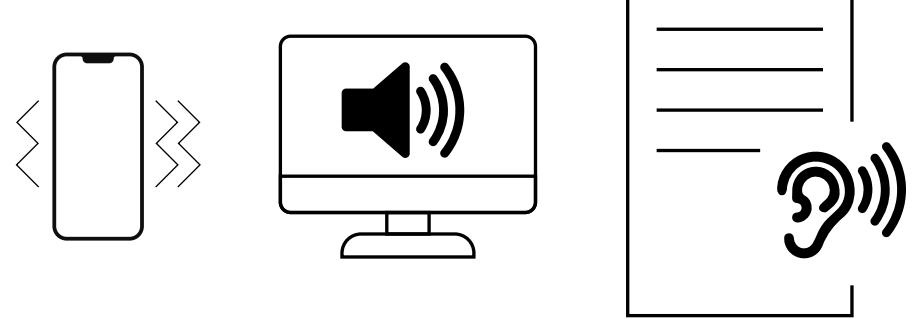
2.2 Test Procedure

2.1 Instructions/Accessing Information

- **Modality**
- **Assistive Technology Compatibility**
- **User Interface Features**
- **Operating System Compatibility**
- **Audio Instructions on a Website or Application**
- **Interactive Voice Response (IVR) System**
- **Video**
- **Language in Digital Formats**

Modality

Digital instructions are a great way to convey information and are especially useful for no-vision, low-vision, and older users. However, merely providing digital instructions does not mean that they are actually accessible to each of those user groups.



Digital modalities

Instructions/Accessing Information • Modality

Issue

Instructions are solely provided in print or accompanied by an image-only PDF making them inaccessible to users with no vision, low vision, dexterity challenges, or older users.

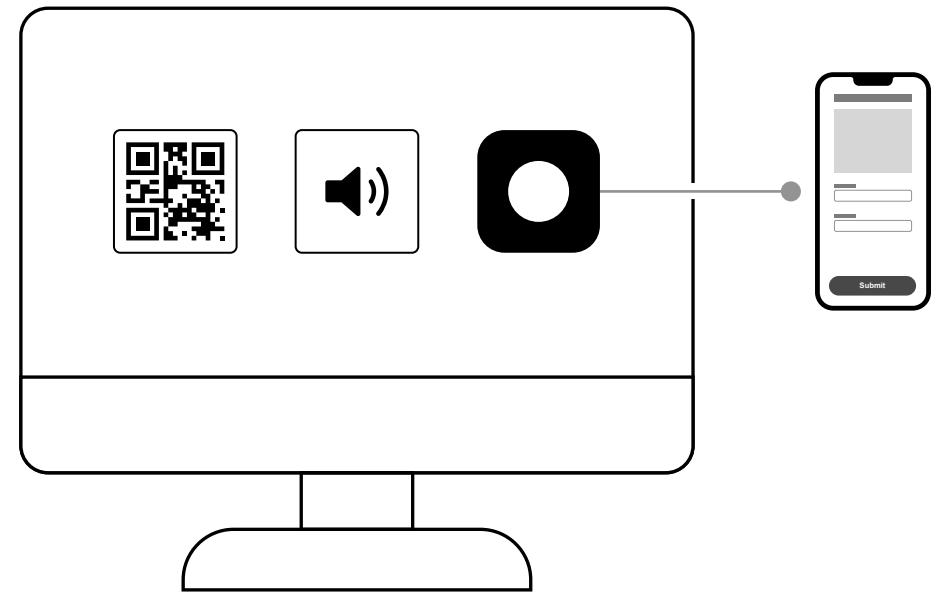
Recommendation

Offer instructions in alternate modalities conveying identical information such as:

- Digital instructions compatible with a screen reader and conforming to Web Content Accessibility Guidelines (WCAG) 2.1 AA and PDF/UA standards (e.g., HTML format on a web page)
- Large print and braille
- Audio format (MP3, etc.)
- Toll-free IVR telephone system
- Video with audio description, captions, and transcript

Assistive Technology Compatibility

Digital instructions should be provided on a website that conforms to WCAG 2.1 AA standard, and one that has been rigorously tested with assistive technology such as screen readers and voice dictation software. The website should be accessible via QR code and a plain text URL. Test-specific companion applications are another method for users to access digital instructions. Many people are familiar with the process of downloading an application.



Assistive technologies

Instructions/Accessing Information • Assistive Technology Compatibility

Issue

Instructions are provided in a format that is not compatible with use on a smartphone or computer and/or that cannot be utilized by an accessible tool such as operating system (OS) accessibility features.

Recommendation

- Digital instructions should be on a web page (not just as a downloadable PDF) that applies responsive web design.
- Audit the web pages with assistive technology used by experienced digital accessibility professionals.
- Reference and implement best practices for making application content accessible:
[Web Accessibility](#)
[Mobile Accessibility](#)
- Ensure the QRG is available as a PDF that conforms to Section 508, WCAG 2.1 level AA, and PDF/Universal Accessibility (UA) standards.
- Ensure all images have meaningful, descriptive alternative ('alt') text, particularly when describing test components such that they can be discerned from one another non-visually.
- Ensure all form fields have accessible names/labels.

(Continued on next page)

Recommendation (continued)

- Consider providing a Digital Accessible Information System (DAISY) format of the QRG with sections and subsections defined in the file (See also Physical Components • Instructions/Accessing Information pgs. 8-28).
- Provide a link or button on the web page that leads the user to a full digital version of the instructions and allow users to request a large-print or braille copy be mailed to them at no charge.

Instructions/Accessing Information • Assistive Technology Compatibility

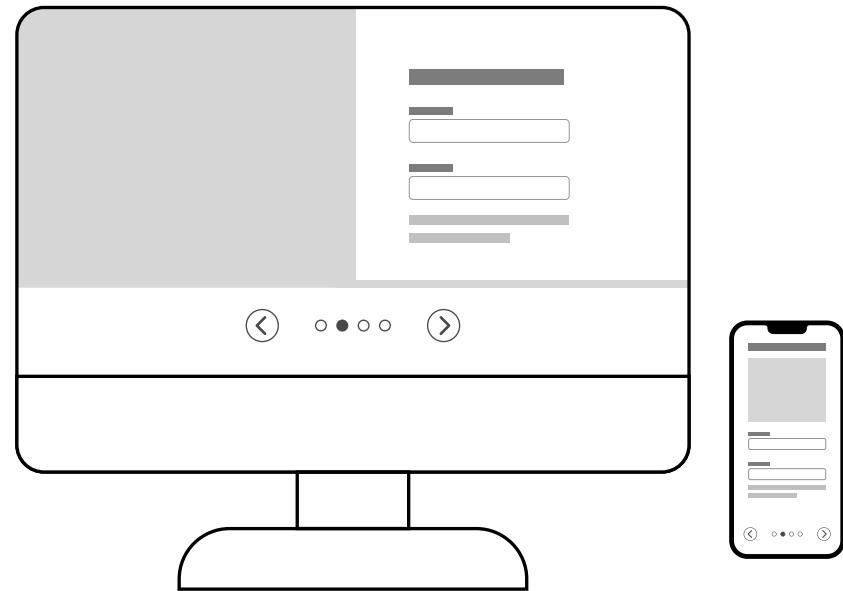
Issue



Formatting incompatible with screen reader

Not all digital instructions are compatible with screen readers. Key elements are often coded incorrectly or in a format that screen readers cannot detect, meaning content may be out of order, incomplete, or incomprehensible. Instructions may be provided in a format that is not compatible with use on a smartphone or tablet or that cannot be perceived by an accessible tool such as OS accessibility features.

Recommendation

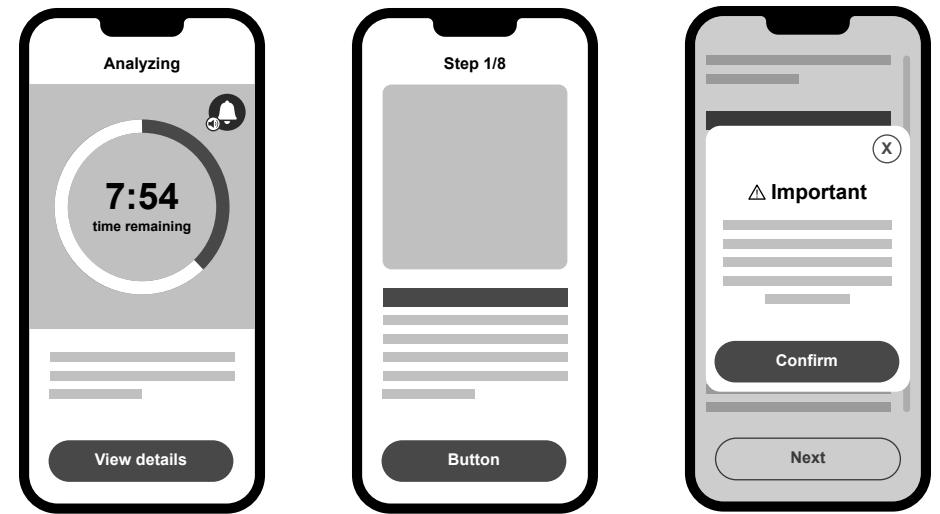


Formatting compatible with screen readers

Ensure digital instructions are compatible with all commonly used screen readers. Confirm both computer and mobile screen reader compatibility of each and every screen element (e.g., images, fields, buttons).

User Interface (UI) Features

The presence or absence of features in an application or web design can significantly impact usability and user satisfaction with the test. A small improvement in UI design can have a major impact on the entire user experience.



User interface considerations

Instructions/Accessing Information • User Interface Features

Issue

- Some applications are limited to only one mode of orientation, which makes it difficult for low-vision users and those with phones that are mounted in a particular orientation to access information.
- Some devices require specific placement using visual cues only (e.g., camera alignment using only screen markers for reference) and it can be challenging or impossible to locate or correctly orient the component in the camera frame for no-vision and low-vision users.

Recommendation

- Provide options to review content in both landscape and portrait orientations.
- If a device is required to be placed in a specific location in relation to a component (e.g., lining up one's phone over a feature):
 1. Provide auditory/haptic device positioning and camera visibility feedback to user (e.g., "test identified" or "failed – move closer"; or "failed – increase brightness").
 2. Consider implementing automated image correction.

Instructions/Accessing Information • User Interface Features

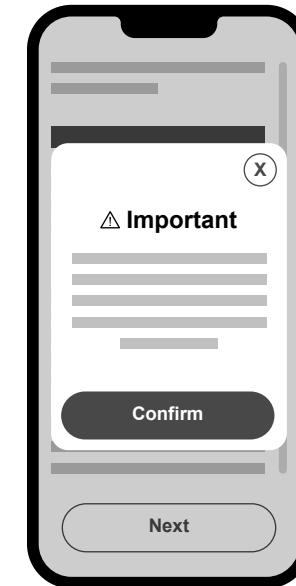
Issue



Important information integrated into text

Some important content can be missed with the use of a digital user interface if the content is not appropriately segmented.

Recommendation

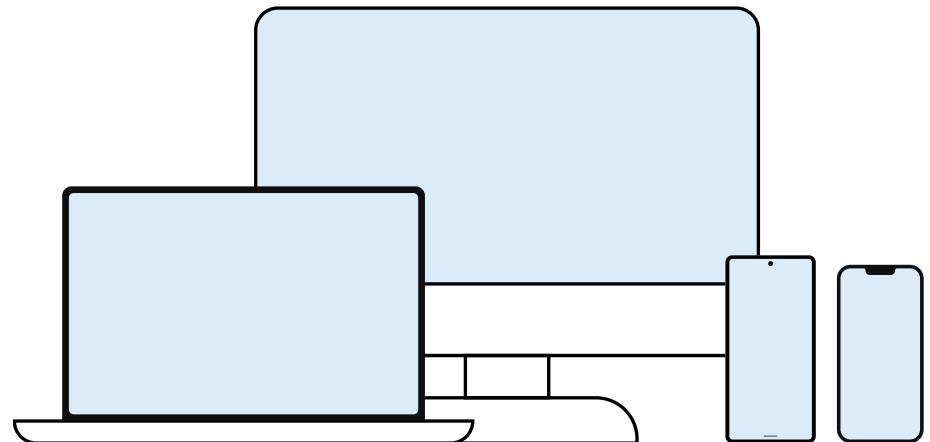


Important information presented in pop-up

- Provide pop-up messages for important content that remains on screen until user provides input to acknowledge the message.
- Errors, warnings, and success messages should not automatically disappear until the user acknowledges the message.

Operating System Compatibility

The ability for content to be recognized and understood by computer, smartphone, and tablet OS and accessibility tools is vital for no-vision and low-vision user access to information about the test.



Device operating systems

Instructions/Accessing Information • Operating System Compatibility

Issue

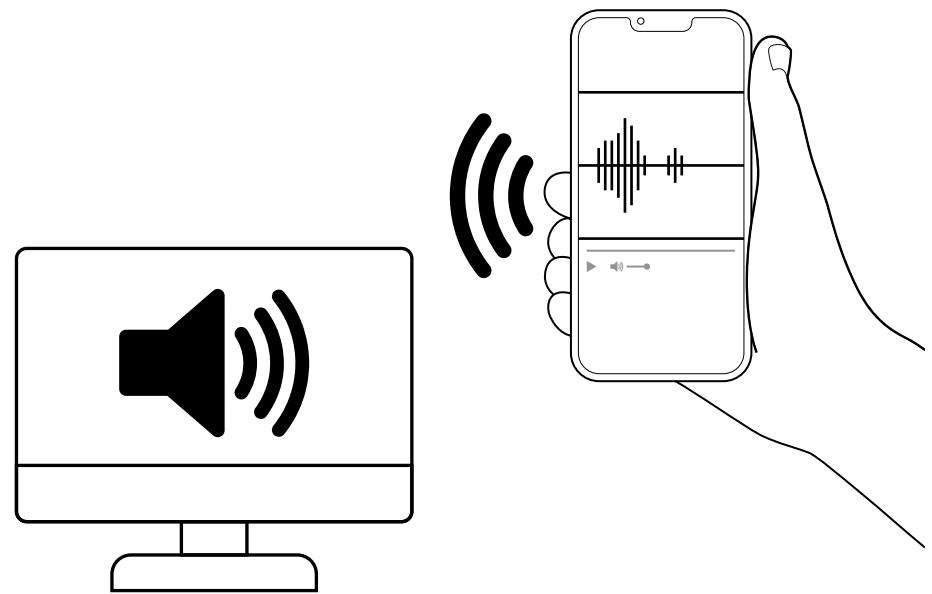
- Instructions are provided in a format that is not compatible with computer, smartphone, or tablet OS and accessibility tools.
- Some features which provide feedback (e.g., auditory and haptic) can compromise user's privacy and others (e.g., bright mode) can be disruptive if users are working with them in the dark.
- Applications sometimes require users to enter data to sign in before providing access or allowing users to receive test results.

Recommendation

- Ensure application recognizes and supports built-in device OS accessibility settings.
- Recognize and apply the user's system-wide auditory/haptic feedback preferences and provide an in-application option to turn auditory/haptic feedback on or off.
- Enable dark mode support.
- If the application requires data entry for sign-in / results reporting:
 1. Enable auto fill; enable single sign-on (SSO) through Google, Facebook, etc.
 2. Clarify which data entry fields are required vs. optional.
 3. Save partial data (e.g., create a user profile) so user does not have to input data again for repeat testing.
 4. Ensure that all data entry fields are assigned screen readable labels.

Audio Instructions via Website or Application

Audio may be the primary mode for some no-vision and low-vision users to receive instructions independently. Designing the audio content is critical to providing a comprehensive understanding of the product.



Multiple platforms supporting audio content

Instructions/Accessing Information • Audio Instructions

Issue

Audio instructions, which may be the preferred modality for some populations, are not always available.

Recommendation

Audio instructions should be available in easy-to-navigate formats and should utilize the text-only instructions as the script. Use of professional human voiceover is preferred to create the audio, but clear text-to-speech (TTS) engines may be used as an alternative. File formats include:

- A downloadable podcast type file (M4A) with sections of the QRG included as timestamped chapters or episodes. Alternative open file types that support metadata and navigational features may be used.
- DAISY audio book file with sections of the QRG included as chapters.
- Downloadable MP3 files for each section as well as a master file of all sections together.

Interactive Voice Response (IVR) System

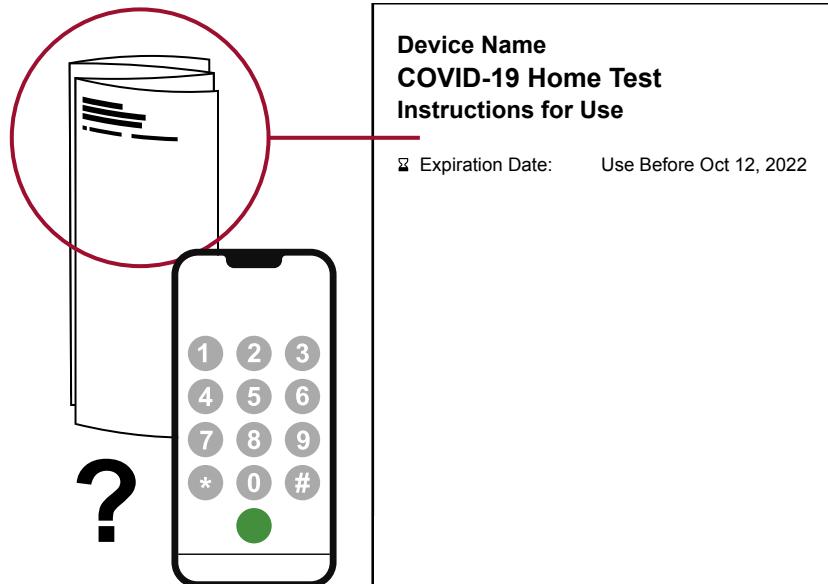
IVR systems can be used to connect users to instructions through a phone call. This is particularly useful for users with lower familiarity with using web or mobile applications. Connecting users to instructions via telephone allows them to use a well-known, expected, and sometimes expedited instruction format.



Interactive Voice Response (IVR) System

Instructions/Accessing Information • IVR System

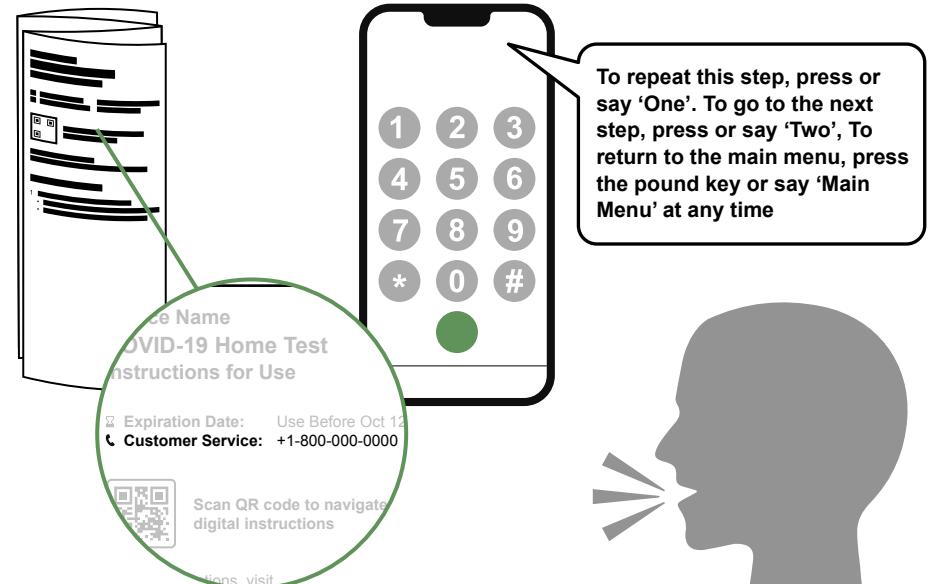
Issue



Instructions without IVR availability

Instructions are not always available by phone which is challenging to some users.

Recommendation



Instructions with IVR availability

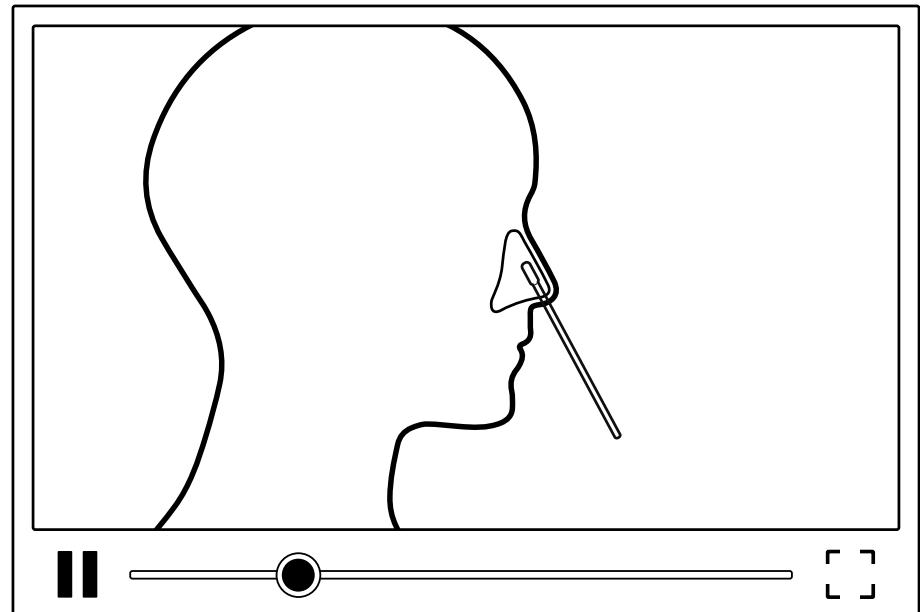
Provide audio instructions via IVR system capable of:

- Navigating instructions in the same manner as the downloadable file types.
- Responding to inputs via button presses associated with actions (e.g., progress to next step, repeat current step, return to previous step, return to main menu, connect the user to a live agent as needed).

Instructions/Accessing Information • Video

Video

Videos can be an effective way to inform users about the product and how to use it. They can provide a dynamic demonstration to learners who prefer to process information visually and audibly.



Video demonstration of test procedure

Instructions/Accessing Information • Video

Issue

- Video is not always provided on websites or applications.
- Videos are not always accessible or as audibly descriptive as they are visually descriptive. Where provided, audio description may not cover all steps.
- Some videos do not provide the ability to pause, rewind, or forward in discrete chunks or increments, making it challenging to jump to the step a user is trying to review.
- Visuals with actors completing steps can be challenging for low-vision users to follow due to issues with lighting and contrast.
- Abbreviated versions of a longer video tempts users to skip the complete video and miss important steps.
- Users may miss some steps only described in audio.
- Users may not always want to refer to video, especially for repeated uses of a test.
- Automatically looping videos can be distracting.

Recommendation

- Make video tutorial instructions available via the product website.
- Confirm video player is accessible (see WCAG 2.1 AA guidance).
- Provide the ability to control video playback including pause/play, rewind, forward, replay from the beginning, scroll through time or advance incrementally, and switch to full screen mode.
- Do not use visuals with actors completing steps, instead use high-contrast animations.
- Do not provide an abbreviated version of a longer video.
- Audio and visual content should each be independently sufficient for a user to understand the video's content.
- Allow skipping the video after it has been viewed once.

(Continued on next page)

Recommendation (continued)

- Avoid looping videos with no ability to pause.
- Include timestamps on the player for easy navigation to specific sections (e.g., getting started, workflow, interpreting results). Utilize common device OS system video controls.
- Label control buttons by function with large text and outline them with a two-pixel, lighter shade edge to suggest a bezel.
- Include multilingual closed-captions.
- Consider implementing a user profile recognition function to make video viewing required for the first test but optional for subsequent tests.

Language in Digital Formats

The vocabulary used in instructions impacts a user's ability to understand what is required of them throughout the test process. Presenting information in plain, clear, concise language is key to the user's understanding of how to perform the test.

Instructions/Accessing Information • Language in Digital Formats

Issue

- Digital instructions can provide language which is not descriptive enough for a no-vision user (e.g., “Grasp the yellow swab package and tear open.”). Tactile descriptions are not consistently provided in digital instructions.
- There are also component references that can create ambiguity for no-vision users working with screen readers, such as referring to components as “this” or “that.”
- Instructions sometimes refer to components and features inconsistently, which makes finding information or following along difficult.
- Audible content is not always as fully descriptive as visual content. If provided, audio descriptions are sometimes not provided in detail for all steps.

Recommendation

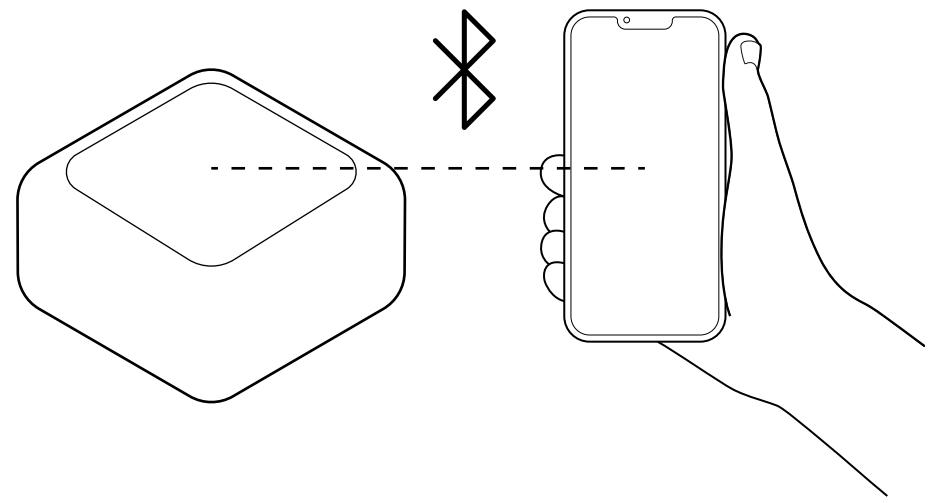
- Provide concise, descriptive language of tactile differentiation for each component, especially for components which are highlighted visually in instructions (refer to pg. 28 for more information).
- Provide clear instructions to conduct the test by feel alone so that no-vision and low-vision users can identify, orient, and use the test components correctly. This should include:
 1. How to discern inner packages from one another (e.g., the two parts of a dropper in separate pouches)
 2. A clear non-visual physical description of each kit component including shape, size, and feel (versus color) (e.g., “Open the package that is a rectangle with a pull tab at the end.”)
 3. How components interact with each other
 4. Translating visual content with clear and non-physical audio descriptions

2.2 Test Procedure

- Connecting/Bluetooth Pairing

Connecting/Bluetooth Pairing

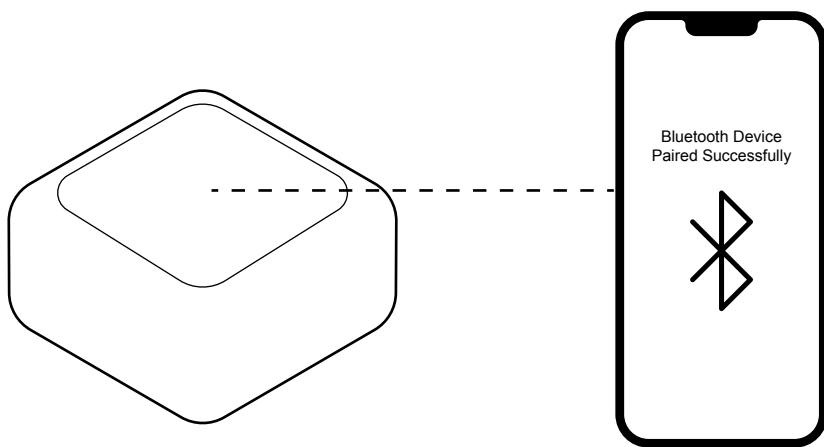
Some tests may require Bluetooth pairing (connecting a smartphone and another device) to read and communicate results. Pairing devices involves having two components in proximity to each other, initiating a pairing sequence, receiving feedback when pairing has been completed successfully (or not), and understanding what that feedback signifies.



Phone connecting via Bluetooth

Test Procedure • Connecting/Bluetooth Pairing

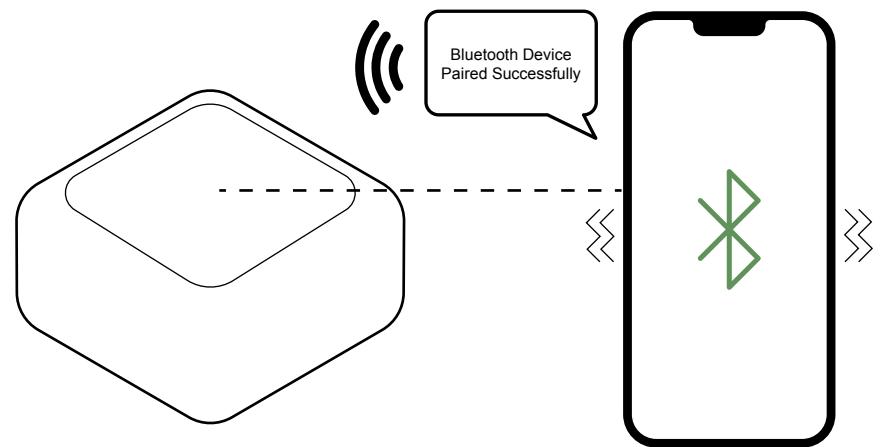
Issue



Phone connecting via Bluetooth with visual cues

- Common pairing methods only provide visual feedback on pairing status (e.g., lights on the device).
- Some pairing requires components to be placed a specific distance away from a component and the user is not aware when the two are in range of each other.

Recommendation



Phone connecting via Bluetooth with audio cues

- Provide multi-modal, clear feedback on pairing status (e.g., audible and/or tactile feedback).
- If a device is required to be placed a specific distance from a component, provide device positioning recognition to the user.

Connecting/Bluetooth Pairing

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 www.plainlanguage.gov. 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).