Rapid Diagnostic Test Accessibility Considerations: for professional use and self-tests – DRAFT

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1 Acknowledgements

This considerations document was drafted by Lara Vojnov (independent consultant) with the leadership and guidance of Kaloyan Kamenov (Department of Noncommunicable Diseases, Disability and Rehabilitation, WHO) and significant support from Mercedes Perez Gonzalez (Research for Health department).

WHO gratefully acknowledges the contributions of many individuals and institutions to develop and review this considerations document.

These include WHO colleagues: Ana Aceves Capri (Access to Medicines and Health Products), Chad Centner (Antimicrobial Resistance), Matteo Cesari (Ageing and Health), Jane Cunningham (Global Malaria Programme/Health Emergencies), Deirdre Healy (Regulation and Prequalification), Raul Iraheta (Health Emergencies), Cheryl Johnson (Global HIV, Hepatitis and STI Programme), Agnes Kijo (Regulation and Prequalification), Alexei Korobitsyn (Global TB Programme), Carl-Michael Nathanson (Global TB Programme), Irena Prat (Regulation and Prequalification), Anita Sands (Regulation and Prequalification), Ute Ströher (Regulation and Prequalification), Yuka Sumi (Ageing and Health).

The external advisory group was made up of the following individuals: Paolo Barbarino (Alzheimer's Disease International), Courtney Carson (Pandemic Action Network), Kim Charlson (Perkins Library/World Blind Union), Sam Dolphin (RADx), Samantha Flax (National Federation of the Blind), Klara Henderson (Department of Foreign Affairs and Trade, Australia), Diana Hiscock (HelpAge International), Bern Jordan (University of Maryland), Sarah Malaier (American Foundation for the Blind), Anafi Mataka (African Society for Laboratory Medicine), Jason Meddaugh (A. T. Guys), Joseph Murungu (Pangaea), Kim Noble (RADx), Corbb O'Connor (National Federation of the Blind of Minnesota/Level Access), Clair O'Donovan (RADx), Maria Paz (PAHO), Seth McGovern (Population Services International), Elena Rotarou (San Sebastian University), Marcie Roth (World Institute on Disability), Amba Salelka (International Disability Alliance), Gayatri Sekar (International Disability Alliance), Kenly Sikwese (AfroCAB), Theodoor Visser (Clinton Health Access Initiative), Brian Walsh (RADx).

Considerable content for this considerations document comes from the Rapid Acceleration of Diagnostics (RADx) Tech Program's *Best Practices for the Design of Accessible COVID-19 Home Tests*. WHO acknowledges and appreciates the work that went into development of that document and permission to reproduce some of the key elements, considerations, and illustrations.

Declaration of interest forms were signed by all external experts and no conflicts of interest were found.

Funding: this project has been funded in whole or in part with federal funds from the NIBIB, National Institutes of Health, Department of Health and Human Services (United States), under Contract No. 75N92022D00013-75N92023F00002.

2 Intended audience

The intended audience for this document is diagnostic technology developers and manufacturers, regulatory agencies, procurement agencies, implementing partners, and donors and funders of diagnostic research and diagnostic innovations.

3 Methodology

This considerations document is the result of a consultative process among many stakeholders in the global health and scientific community. Through an extensive document review process and internal WHO and external stakeholder consultations, the WHO department of Noncommunicable diseases, Disability and Rehabilitation and the WHO Emerging Technologies, Research Prioritization & Support unit of the Science division jointly developed a draft version of the considerations document. Thereafter, an iterative approach was taken to obtain inputs over several rounds of feedback and a public consultation from more than X experts and key stakeholders, including public health system practitioners, representatives of health ministries and national programmes, civil society, organizations of persons with disabilities, end-users, diagnostics experts, donors, and manufacturers. The draft document was also published online for public feedback on the WHO webpage for X days.

Within the extensive document review process, a number of related and relevant published documents were identified, reviewed, and adopted or adapted within this final considerations document (1-16).

4 Abbreviations

(Abbreviations to be completed upon completion of text)

G6PD: glucose-6-phosphate dehydrogenase deficiency, a test beneficial during the treatment for malaria
HIV: human immunodeficiency virus
IFU: instructions for use
IVD: *in vitro* diagnostic medical device
IVR: interactive voice response
LED: light-emitting diode
LFA: lateral flow assay
OCR: optical character recognition
OS: operating system
QR code: two-dimensional matrix barcode
QRI: quick reference instructions
RDTs: rapid diagnostic tests
RFID: radio frequency identification
SSO: single sign-on
TTS: text-to-speech
UDI: unique device identifier

5 Glossary

To be developed if clear need from colleagues
Advocacy groups
Capillary tubes
Civil society
Instructions for Use:

Labeling:
Lancet
OCR interpretation

6 Symbols guide

Symbols are a graphical representation that appear on the label and/or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people. Symbols quickly communicate a visual concept to the user in a way that, if used properly, can transcend language or literacy differences. The symbol can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters (11). Using internationally recognized symbols can aid visual communication. There are a number of internationally recognized symbols for certain IVD characteristics (e.g. storage temperature limits, identification of in vitro diagnostic use and manufacturer information) (17). These symbols are especially useful when printed materials are generated in multiple languages, when users are not familiar with the language in which the IFU is written, or when literacy might be limited.

Symbols, however, must not be used in isolation. They must always be accompanied by text, since symbols cannot be interpreted by assistive technologies. This ensures accessibility for those engaging visually and non-visually with the product.

The symbols should be explained in a symbol key in the IFU and should appear on the last page of the IFU.

Key symbols to include (11,17,18) (to be inserted during design layout):

- Off
- On
- Power
- Audio
- Sound
- Phone
- Caution
- Warning
- Biohazard
- QR code
- Do not eat or drink before testing
- Bluetooth
- Haptic or vibration
- Manufacturer
- Use by date or expiration
- Batch code
- Catalogue number
- Serial number

- Do not use if package is damaged
- Keep away from sunlight
- Keep dry
- Do not re-use
- *In vitro* diagnostic medical device

7 Background

The COVID-19 pandemic accelerated development and interest in diagnostics (*in vitro* diagnostic medical devices (IVDs)), with considerable numbers of new products coming to the market and clearer understanding of testing needs and practices by lay people. However, whether it be HIV professional use rapid diagnostic tests (RDTs) used by healthcare professionals, SARS-CoV-2 self-tests, or pregnancy tests, it is rare for manufacturers to understand and incorporate considerations that allow for their products to be accessible and used by all users, including persons with disabilities, physical or cognitive impairments, or people with low health literacy, amongst others.

Accessibility is about a service or product being designed in an equitable way with people with disabilities in mind so that any person can easily understand, use, and manage it. In the healthcare system, accessibility is fundamental to a range of elements, such as physical infrastructure, communication and health information, service delivery, medicines, medical products, and diagnostic tests.

When persons with disabilities or other marginalized population groups, such as older adults, people with low health and/or digital literacy, or where alcohol and drug use may have led to chemical impairments are not able to access the services they required, they are left behind. These population groups represent a significant proportion of the global population. Persons with disabilities, for example, comprise 1.3 billion people in the world – 1 in 6 of us – who often experience health inequalities, such as premature death of up to 20 years earlier than the life expectancy rate and higher disease risks (19). Often, these health inequities are due to unfair yet avoidable factors within and beyond the health system. While persons with disabilities have long-term impairments, anyone can find themselves in situations or circumstances where they are temporarily impaired and could benefit from accessibly-designed systems. For example, a person may be in a poorly lit location, might be managing an uncooperative young child, or may not be thinking clearly because of disease symptoms. Importantly, health care workers supporting clinical services in many settings, including those in low- and middle-income countries, may also have a disability or challenge that requires accessibility considerations.

Minimal global guidance exists to support manufacturers to develop more accessible rapid diagnostic tests, across diseases. Therefore, this document aims to provide considerations for manufacturers in developing or adapting their products to ensure accessibility for all users. The ultimate goal of this document for rapid diagnostic tests would be to achieve *universal design* – “the design and composition of an environment [or product] so that it can be accessed, understood, and used to the greatest extent possible by all people regardless of their age, ability or disability” (20). The seven principles of *universal design* are: equitable use, flexibility in use, simple and intuitive use, perceptible information, tolerance for error, low physical effort, and size and space for approach and use (21).

The scope of the document encompasses professional use and self-testing rapid diagnostics tests including, but not limited to, HIV, *P. falciparum/vivax* (malaria), tuberculosis, SARS-CoV-2, syphilis,

hepatitis B, hepatitis C, urine dipstick, G6PD, pregnancy, etc. Additionally, the considerations would also apply to multiplex tests, that is those that can test for two or more pathogens or conditions at the same time. For example, a rapid diagnostic test that can test for SARS-CoV-2 and influenza on the same test strip and with the same specimen.

8 Design considerations for general accessibility

Improving the accessibility of all health products should be a primary goal of manufacturers as doing so can improve the usability for all potential end users. Some guiding principles exist that support universal design of rapid diagnostic tests. These include:

- Engage end users, civil society, and advocacy groups early and at every stage
- Simplify workflow
    - Fewer steps are easier to document, manage, and execute
    - Fewer components are easier to identify and handle and are less likely to be misplaced
    - Simple, intuitive, and familiar design elements and nomenclature reduce ambiguity
- Provide multi-modal test instructions
    - Provide both physical and digital test instructions
    - Provide digital test instructions on an accessible webpage, as a downloadable document, and in a closed-captioned video tutorial with audio description
- Eliminate the need for precision, where possible
    - Steps that require precision (e.g. liquid transfer, counting drops, etc.) may cause barriers to independent completion and increase potential for user error
- Avoid small components
    - Larger components (with hollow plastics that maximize contact space and minimize material volume would support environmental sustainability efforts) are easier to manipulate and see and are less likely to be misplaced
- Incorporate simultaneous non-visual and visual cues
- Illustrations should be simple, high-contrast, shaded line drawings with alt text

9 Assessing access and usability

Assessing the accessibility and usability of any health product, including rapid diagnostic tests is critical. This should be done along the entire product development pathway and ideally well before product design lock in order to understand what is acceptable and accessible for end users. Such assessments should encompass the full end-to-end workflow and ensure a seamless experience for end users, whether professionals or not. In particular, people with disabilities should be prioritized for inclusion in evaluation and development processes.

Engaging with user groups, civil society, and advocacy groups during development, including persons with disabilities, healthcare workers, older persons, and adolescent populations, is essential to ensure accessibility of IVDs for the targeted populations. Civil society and advocacy groups can add particular value to the development process through engaging their networks and insights of end users that often represent the broader community's impressions. Regular and consistent engagement and assessments by end users, civil society, and advocacy groups through user feedback and usability studies will improve the final design of a test. Product designs should be assessed by end users, civil society, and advocacy groups representing a broad range of capabilities and disabilities.

End users, civil society, and advocacy groups can support product design through:

- Expediting the learning process
- Confirming or removing assumptions around product use and potential misuse
- Identifying user needs, preferences, and pitfalls in design
- Assessing designs for accessibility and usability
- Providing what disabled people want, need, and expect for a product

10 Essential principles of testing – creating an enabling and safe environment

There are several essential principles to diagnostic testing that should always be implemented to ensure a safe, welcoming, and respectful environment. Enabling individuals to make an informed and healthy choice to access testing and engage in follow-up care is a core public health function. Outside the health sector, the implementation of laws and policies that support human rights and foster access to and uptake of services is crucial to public health impact. Examples of policies that may encourage the uptake of testing are policies that protect patient consent and confidentiality, protections against mandatory or coercive testing, laws and policies that address stigma and discrimination against people on the basis of race, colour, national origin, age, disability, sex, or sexual orientation. For adolescents, persons with significant cognitive impairment, or those unable to express consent to testing, consent policies are needed that enable them to test without consent from a legal guardian (22).

Policies and laws are also needed to implement effective and decentralized approaches, including testing by lay providers (policies enabling task sharing), network-based testing services (policies addressing confidentiality), access to self-testing (policies addressing use of medical devices) and use of virtual interventions and telehealth (policies to allow self-care options and home delivery of commodities and services). Emphasis on self-care options can help overcome barriers associated with conventional services, such as stigma, discrimination and confidentiality concerns. By enabling individuals to test in the privacy of their own homes or to collect their own specimens, self-care options can encourage those who may be hesitant to access testing services for these reasons (23).

Furthermore, testing should be implemented in accordance with the “5 Cs”: patient Consent and Confidentiality, pre-test information and post-test Counselling, Correct results, and Connection (linkage to care). Services should be delivered in safe and acceptable spaces that offer protection and privacy from the effects of stigma, discrimination, violence, or the release of confidential information. Individuals, their families and partners, should be able to comfortably and freely express any concerns. Providers should demonstrate patience, understanding, acceptance, and knowledge about the choices and services available. They should support clients with the utmost privacy – utilizing the 5 Cs as a guide to testing services provided. Likewise, national governments should ensure the tools, policies, and standard operating procedures are in place to protect the privacy and confidentiality of all as well as the safety and security of their health care data, including any transmitted using digital technology, phone devices, telehealth, and other virtual interventions.

11 Relevance of this document for WHO prequalification and post-market surveillance

Rapid advances in development of medical devices are generating challenges in quality assurance for manufacturers and regulators, and in both quality assurance and product selection for procurers. Launched in 2010, WHO prequalification of IVDs provides a valuable service to each of these groups and is coordinated through the WHO department of Regulation and Prequalification.

Procurers can buy prequalified IVDs secure in the knowledge that these products are not only quality-assured by meeting WHO requirements on quality, safety, and performance, but also appropriate for their intended setting of use. Manufacturers who attain prequalification of their products will be able to offer those products for supply to procurement agencies and organizations that apply quality assurance policies to all health product procurement. For manufacturers, obtaining prequalification also provides an opportunity to review and even enhance their quality of production. For regulators in low- and middle-income countries — where medical device regulation continues to evolve — WHO prequalification provides complementary and valuable regulatory support. It participates in development of international standards for medical device regulation, applies these standards during product assessment and works with LMIC regulators to incorporate these standards in their own regulatory activities.

But the most important benefactors of IVD prequalification are healthcare workers and patients, for whom quality-assured IVDs are vital for effective diagnosis, linkage to care, monitoring of therapeutic efficiency and disease progression, transmission prevention, and the prevention of the development of drug resistance.

WHO prequalification of IVDs is a comprehensive quality assessment of individual IVDs through a standardized procedure aimed at determining whether the product meets WHO prequalification requirements (24).

Ideally, because of the benefits outlined above, manufacturers of RDTs currently eligible for submission for prequalification will commit to submitting an application for WHO prequalification. Manufacturers are encouraged to consider the recommendations laid down in this document and implement the respective changes to their IVD. Manufacturers with prequalified IVDs should submit a change request to WHO for approval before implementing such changes.

Once a product is prequalified and authorised for use, the manufacturer is obliged to conduct post-market surveillance. Post-market surveillance is the process to collect and analyze experiences with a product after it has been placed on the market. The IVD manufacturer must review experiences, including any product problems, and determine if the product can continue to be used or if corrective action needs to be taken – by asking “has the benefit-risk profile changed?”

Post-market surveillance actions might include:

- updated labelling (warnings, test procedures, etc.),
- return or destruction (~recall) of the affected lots,
- advice on clinical management (re-testing, etc.), or
- removal of product from the market.

WHO recommends that users (lay providers, health care professionals, laboratory personnel) contribute to post-market surveillance by reporting any problems as soon as they notice them. Product problems may be indicative of poor design or inadequate design for the intended use; these can be rectified.

12 General labeling, including instructions for use

12.1 Legibility

Challenge
Using mixed or hard-to-read typefaces, fonts, and other text features can result in hard to read test instructions.

In entirely capitalized words and phrases, letters are similar in size and shape, making them difficult to distinguish visually, especially for those with low vision. All caps may also be communicated by screen readers letter-by-letter, making interpretation challenging.

Considerations

- Consistently use an easy-to-read, sans serif typeface for all text, such as Arial, Calibri, Helvetica, Verdana, etc.
- Do not use italicized text, which reduces legibility for some users.
- Do not capitalize entire words.
- Avoid underlining, except for clickable links.
- Emphasize important content using boldface text or using text labels (e.g. ‘Warning’, ‘Note’).
- Workflow text should ideally be 14-18-point font, but a minimum of 10-point font, with a space between the lines of at least 3mm.

Accessible digital instructions should always be available, in particular and most importantly when workflow text is 14-point font or smaller.

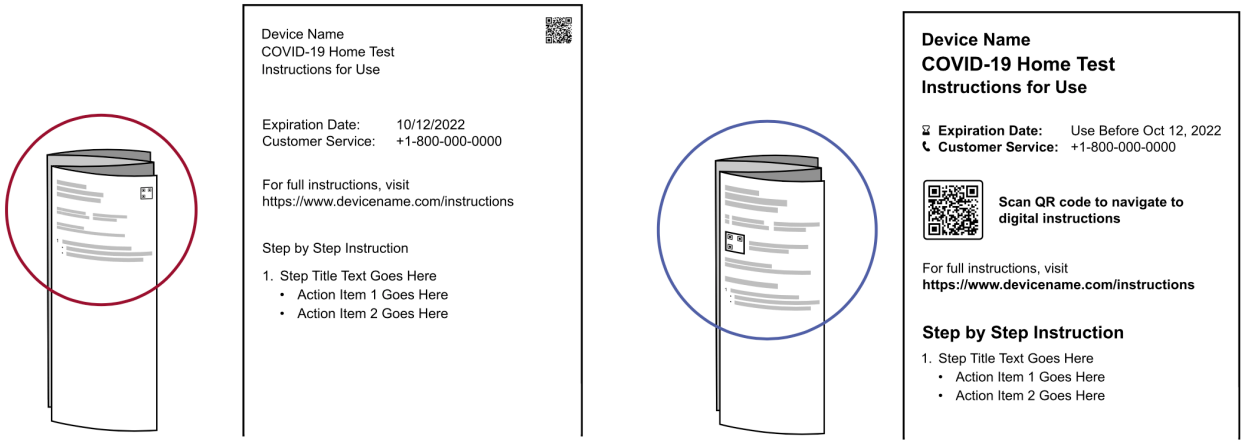

Figure 1. Challenge (left) and consideration (right) in preparing key information in the instructions for use.

Challenge
The design and layout of the instructions for use can be displayed such that it is challenging to distinguish key and supporting information (
Figure 1).

Expiry dates and QR codes are small and difficult to locate.

Presenting critical information without text labels creates issues with OCR interpretation (e.g. an expiry date presented as a number string may not be recognized as a date).

Considerations

Present key information in large and/or boldface font (minimum 14 point, ideally 18 point or larger) (Figure 1).

Include a data carrier/bar code that can be decoded by common smartphones (i.e. QR code) linking to digital instructions sized 20.3 mm (0.8 inches) square or larger to align with current industry practice.

Present expiry dates with abbreviated or spelled-out numerical day, month, and year (e.g. 12 Oct, 2025) as well as in unique device identifier (UDI) format (e.g. 2024-10-12).

Identify expiry date via text label (ie. 'Expiration date' or 'Use before').

Use a visual hierarchy (using elements like font size, weight, colour, spacing, and alignment) to present and organize information. In digital materials, use heading labels (e.g. H1, H2, H3) so that screen readers can recognize them.

Include critical information, such as the manufacturer's address and contact details, product website, customer service phone number, and customer service email with text to provide context to users employing OCR applications.

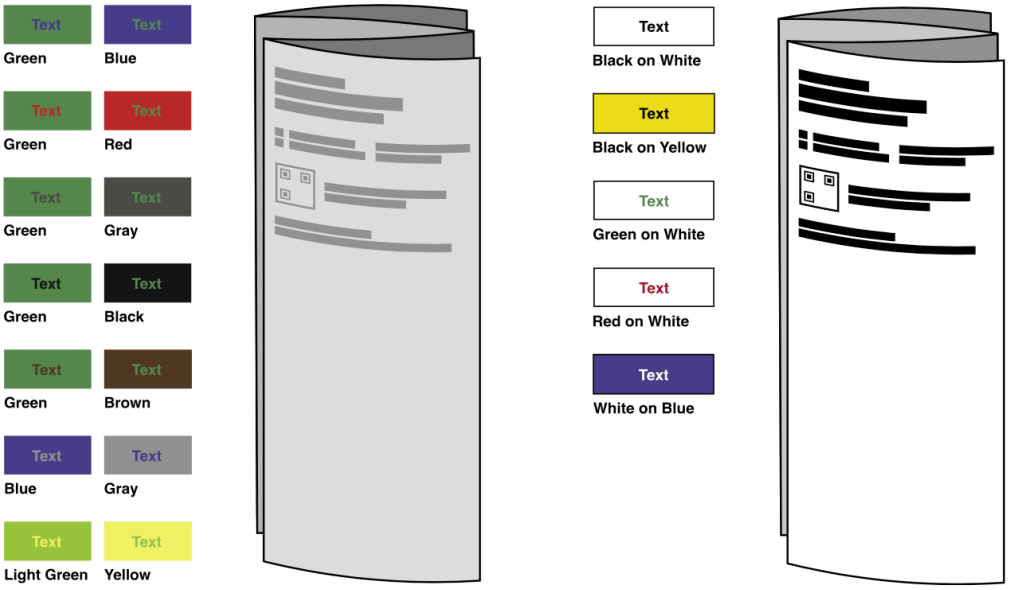

Figure 2. Challenge (left) and consideration (right) for ensuring appropriate colour contrast.

Challenge

Presenting text in poor colour combinations/contrasts that can challenge a variety of end-users, in particular those who are colour blind, have colour vision deficiencies, or low vision (Figure 2). Furthermore, poorly selected colour combinations or contrasts can make perceiving information challenging.

There are a number of different types of colour vision deficiency, including monochromacy or achromatopsia (where colours do not register for a person), tritanopia (impaired blue and yellow vision), deuteranopia (inability or difficulty identifying green colours), and protanopia (inability or difficulty distinguishing red hues).

Consideration

Colour contrast should allow for clear differentiation between the text and background (Figure 2). There should be a minimum contrast ratio[1] of 4.5:1 for 14 point or smaller font and 3:1 for larger font, per WCAG 2.2 AA compliance (25). This should support those who are colour blind or have colour vision deficiencies to also understand any drawings or figures in colour. Additional materials, such as contrast checkers (e.g. TPGi's Colour Contrast Analyser (26)) or colour blindness guides, exist and can be referred to in order to ensure appropriate colour combinations are used for text, drawings, and figures.

12.2 Readability and layout

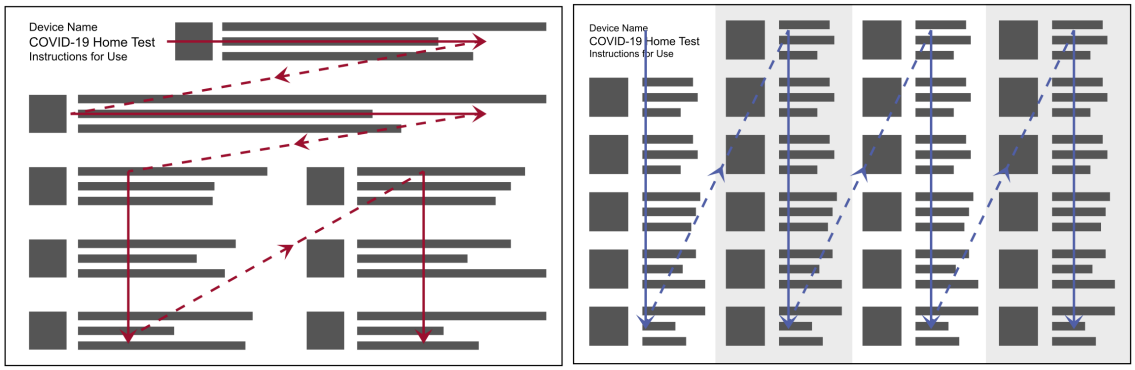

Figure 3. Challenge (left) and consideration (right) to improve readability and layout of instructions for use.

Challenge

Blocks of text presented in different layouts, with some sequences of blocks reading left to right and others top to bottom, make following along cumbersome (Figure 3). Large, unbroken blocks of text make digesting information difficult, while wide columns make some end users physically dizzy and can make it difficult to visually track from line to line.

Consideration

The readability and layout of the instructions for use should be developed to allow for clear comprehension. To improve the readability and layout and to improve OCR scanning, use the flow scheme shown in Figure 3, with columns arranged left to right (or the reverse for right-to-left languages). The number of columns per page will depend on the size of paper used and page orientation (e.g. four columns on A3 or 11x17 inches paper in landscape). The text columns should be equal width and include proportioned column gutters.

[1] Contrast ratio compares relative luminance of text and background colour and can be measured using free colour contrast checker tools.

Challenge
Individual steps requiring multiple actions or tasks can be challenging to comprehend and follow. Likewise, too much information can be presented in a format that is difficult to follow with individual steps consuming variable amounts of page space.

Consideration
Each step should be a single, actionable objective. Limit each step to no more than three interrelated tasks (e.g. tear open the swab package using the tear notch at the top and remove the swab). Break text describing each step into individual text blocks or lines for distinct actions in that step, using bullet points and white space where relevant.

Use no more than one independent clause in a sentence. If a sentence is simple enough (and written with appropriate grammar and punctuation), it should sound natural when read aloud.

Before each set of steps, tell the reader how many steps are in the procedure. Number each step using Arabic numbers (i.e. 1, 2, 3…) and visually emphasize them in contrast to body text. In digital formats, set step number and/or titles as semantic headings.

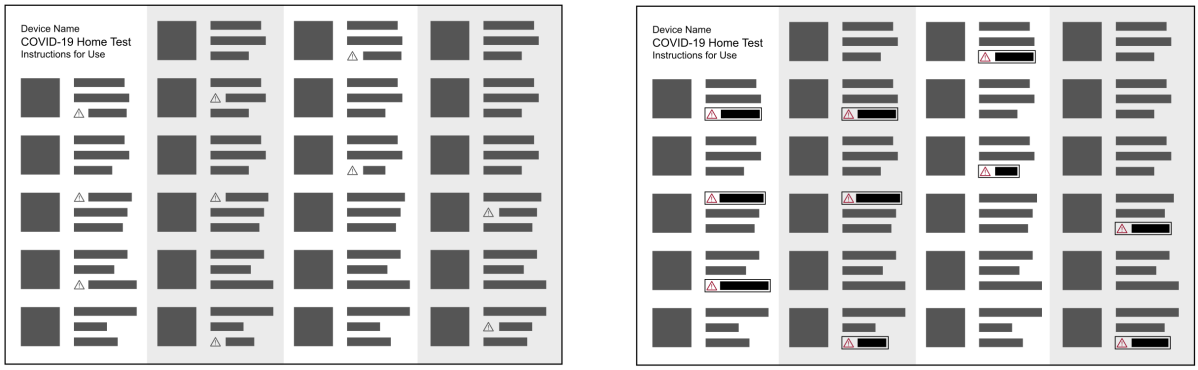

Figure 4. Challenge (left) and consideration (right) for displaying warnings within the instructions for use.

Challenge
Including warnings within the instructions for use is critical for the safety of end users and performance of the test; however, presenting them inconsistently can make it hard to locate them or allow the critical warnings to attract the appropriate amount of attention (Figure 4).

Consideration
Critical warnings should be communicated in a clear and consistent manner (e.g. with a red warning symbol and boldface font in a text box callout) (Figure 4). Warnings should be included early in the text before the action step in the procedure.

12.3 Language

Plain Language

Plain language involves creating communications, such as printed documents, webpages, or mobile application screens, that enable users to easily find what they need, understand it, and use it effectively (27). Plain language focuses on developing information suited to the user, encompassing aspects like purpose, structure, expression, design, and evaluation.

Instructions for use and labelling should be written in terms readily understood by the intended user using simple words with few syllables. A maximum Flesch-Kincaid grade six level should be considered.

Purpose: identify and describe the target users and the communication goals.

Establish clear information goals and choose document content with the intended audience in mind. Ensure that the structure and design of the content align with the needs, skills, and interests of the target users. When creating content, consider factors such as their native language, reading level, experience, and style preferences.

Structure: group and present content with a clear rationale to guide the user.

Organize the document for easy access, utilizing familiar structures to make navigation intuitive and relatable. Aim for a balance in information delivery: keep it concise enough to maintain attention while ensuring it's comprehensive enough to provide necessary context. Enhance document flow by grouping related content and using descriptive headers, and clearly and consistently dividing sections. Limit header levels to three or fewer, and present sequential items in a numbered list instead of using bullet points. Additionally, employ parallel structures for similar content.

Expression: select words, sentence structure, and overall organization for logic and empathy to promote comprehension and engagement.

Utilize terminology that is relevant to the end user and offer explanations for any unfamiliar or technical terms for lay users. Incorporate descriptive language where applicable and vary sentence length, aiming for 5 to 15 words per sentence. Start paragraphs with key information and ensure coherence by grouping related ideas, using transition words between sections as needed. Maintain a bias-free conversational tone that emphasizes positive outcomes and desired behaviors, while also including warnings to highlight potential negative consequences. Use consistent terms and words throughout as well as active voice. Finally, ensure that hyperlinked text corresponds accurately to the titles of the landing webpages.

Design: apply information design to enhance legibility, readability, and comprehension.

Make sure the design elements of the document enhance both the message and user comprehension. Utilize typography to improve legibility and layout to promote readability. Employ whitespace effectively to emphasize the organization of information. Incorporate clear and relevant illustrations to aid understanding, including depictions of desired behaviors and outcomes when applicable. Eliminate any unnecessary elements that could cause distractions.

Evaluation: develop and test wording, structure, and design with end users.

Gather input from target users, especially those presenting with specific challenges (e.g. physical or cognitive impairments) to identify their needs, preferences, usability, and satisfaction throughout the development of a document. Create content based on feedback from these users. Choose appropriate methods for assessing the clarity and actionability of the information. Evaluate the clarity, accuracy, and usefulness of the content with the target audience by asking them if it is clear who the information is intended for and what its purpose is. Additionally, request that users paraphrase key concepts and demonstrate how they would locate information within the document. Finally, compare the earlier and later versions of the information to verify improvements in plain language.

Descriptive Language

The language used should be descriptive, providing non-visual points of reference and instructions to enhance user comprehension. Generally, it's best to minimize word count while still delivering effective descriptions. Descriptive language should primarily appear in the body text of test instructions, but additional supporting information can be provided through alt text or 'More Info' redirects in interactive formats.

Challenge

Some practices can lead to unnecessary ambiguity, such as referring to components or features generically as "this" or "that" and using abbreviations or acronyms. Additionally, test instructions may sometimes refer to components and features inconsistently, and the descriptions of components often lack sufficient detail.

Consideration

Avoid using pronouns and refrain from abbreviations or acronyms, unless the abbreviation or acronym is as familiar as, or more familiar than, the expanded word (e.g. etc., FAQ, HIV). If you do use them, clearly define each one the first time it appears and use it consistently thereafter.

Maintain the same terminology for each component or feature throughout the test instructions and on labels for components or packaging.

Describe components with both tactile and visual references, focusing on aspects that differentiate them by feel, such as shape, texture, material, and weight. For example, descriptors for shape include rectangular, cylindrical, long, thin, wide, flat, narrow, and tall. Texture descriptors can be smooth, rough, soft, hard, or raised, while material references might include paper, plastic, foil, and metal. Weight descriptors can be heavy or lightweight.

Challenge

Colour is used and described in an ineffective manner.

Consideration

Colour should be utilized to indicate easily distinguishable areas, and any reference to colour should be accompanied by a non-visual descriptor (e.g., ribbed red dropper cap, rectangular silver pouch). Avoid relying on colours that might be imperceptible or indistinguishable. Additionally, describe each colour by name and, when relevant, include a reference to its relative tone (e.g., brighter). Refer to section 12.1 and considerations for people who might be colour blind or have colour vision deficiencies. Reviewing documents converted to grayscale can help to identify potential issues.

Challenge

The sequence of descriptive information may hinder users from accurately locating an item. Additionally, there is often no written description indicating the location of the results window or where the control and test lines will appear within it. Instructions may rely solely on illustrations to indicate to users how to orient test components for use.

Consideration

Begin with a brief description of how the feature feels, then provide details about its location, progressing from broad to specific to pinpoint a unique location. Conclude with a secondary visual

descriptor. For example: “The notch is a small slit in the edge of the flat, foil pouch on the long side near one end, marked with a black arrow.” The description can be broken down as follows: [feature name = notch], [feature tactile reference = small slit in edge], [highest level location reference = flat, foil pouch], [increasingly specific location = long side, near one end], [secondary visual descriptor = black arrow].

For interpreting results, describe the relative location of the result indicators. For instance: “The results window is located closest to the rectangular end of the cassette. In the results window, the control line is closest to the rectangular end, while the test line is nearest to the rounded end of the cassette.”

Describe how to orient the test components for use, using visual and tactile references.

Alternative Text

Alternative (alt) text is text included in the HTML code of webpages or in the tag structure of digital files to describe non-text media, such as graphs, charts, and non-decorative images. It ensures equal access for users who rely on braille displays or screen readers to access non-visual language and content. WCAG offers a variety of content to guide the development of effective alt text (25).

Challenge

Alt text may not adequately describe the content of an illustration or effectively convey the information presented in visuals. The length of alt text can vary, and it may sometimes be too technical, scientific, or vague. Critical non-visual cues should not be limited to alt text, since low vision users reading with magnification will not be able to benefit from these cues.

Consideration

Alt text should complement the accompanying text by translating visual content and providing additional detail without being redundant. Together, the alt text and instructional copy should allow users to understand and complete the test workflow without needing visual references. For example, instead of simply stating “an illustration of a swab breaking in half with the tip in a tube,” it would be more effective to say, “a swab tip rests in a tube, the swab is shown broken in half at a notch in the middle of the handle.”

Critical warnings shown in illustrations should be reiterated in the alt text if they are not included in the main copy or digital read order. Generally, alt text should consist of one to two sentences, although more complex visuals may require longer alt text descriptions. If the alt text is lengthy, consider integrating it into the body text of the test instructions instead. Additionally, alt text for a very simple image may be just a word or phrase. Correct grammar and punctuation should be used, where applicable, so that screen readers will convey the text accurately. Use present tense and active voice as much as possible.

Braille

Braille is a tactile reading and writing system where raised dots represent letters of the alphabet, numbers, and symbols (28). It offers a method for capturing and conveying the same level of detail found in text content.

Braille is an inherently physical medium traditionally produced using a braille embosser, a device that imprints braille on paper. It has a fixed minimum character size, roughly equivalent to 28-point font. One standard page of printed text typically translates into multiple braille pages, depending on the character

count and formatting. Dense, information-rich documents can result in significantly longer braille versions, particularly if they include complex elements like graphs, charts, or non-decorative images. Therefore, it is beneficial to provide paper braille instructions to customers upon request.

Most languages have both uncontracted (a.k.a., Grade 1) and contracted (a.k.a., or Grade 2) versions of braille code. Uncontracted braille spells out every word, while contracted braille uses abbreviations for common words and letter combinations. Uncontracted braille is primarily used by beginners, while contracted braille is used by more experienced braille users. Contracted braille takes up less space than uncontracted but can be read proficiently by fewer braille users. Manufacturers should understand the user requirements to establish the optimum braille format.

Braille can contribute to a comprehensive strategy for addressing product accessibility, but like most strategies, it is not a standalone solution. The majority of the no vision and low vision populations are not proficient in braille, so an overall strategy including braille might also include large text and digitally accessible information to address the broadest audience.

Creating web-based, digitally accessible content (e.g. HTML) or documents (e.g. PDF, .brf) is a cost-effective way for manufacturers to enhance braille access and access for non-braille users. Braille displays allow users to interact with digital content through braille rather than relying solely on audio, enabling them to access rich information embedded in text, including capitalization, typographical emphasis, spacing, and punctuation (28). A tactile or embossed data carrier/bar code that can be decoded by common smartphones (i.e. QR code), ideally available in multi-modal formats, would support introduction to digital content. Digital formats can be easily converted to braille using assistive technology:

- Accessible webpages with HTML content compatible with screen readers and braille devices are accessible to the broadest audience.
- Accessible PDF documents can be made available for download.
- Braille Ready Files (.brf) can be accessed without a computer or smartphone, through the use of a braille printer or display.

It is important for product labeling to adequately inform users about the available instruction formats and how to access them.

Additionally, to support result interpretation of rapid diagnostic tests, particularly in settings with limited internet connectivity, manufacturers could consider external readers or providing a low-technology free text-based result interpretation option.

12.4 Illustrations and symbols

Use of clear, simple, precise graphics can be useful, when large enough to be easily visible. These can guide the user through an order of operations or multiple decisions (e.g. interpretation of results). However, in user instruction manuals, tables and graphs are normally not appropriate and their use should be minimized. If a table or graph is necessary, include instructions on its use. Label each table or graph clearly (15).

Challenge
Pictorial representations or figures are poorly labelled or reference to text is unclear.

Consideration
Ensure that the pictorial representations and figures are near the text and match/refer to them in the text. Depict timing instructions by simple pictures of clocks showing start and end times with accompanying text. Include the number of drops required either directly as a drawing or by providing the numerical value next to the drops (e.g. 3x).

Figure 5. Challenge (left) and consideration (right) related to backgrounds.

Challenge
Photos often include excessive and unnecessary information, which can complicate interpretation, particularly when printed using a braille embosser.

illustrates how backgrounds in photos can divert attention from the product.

Consideration
Use line drawings with perspective rather than photos. Employing varying line weights can help distinguish details and highlight features, such as using 3- to 4-point lines for features that are closer in space or the focus of attention, and 1- to 1.5-point lines for features that are farther away or convey only contextual detail.

demonstrates how line drawings can enhance understanding.

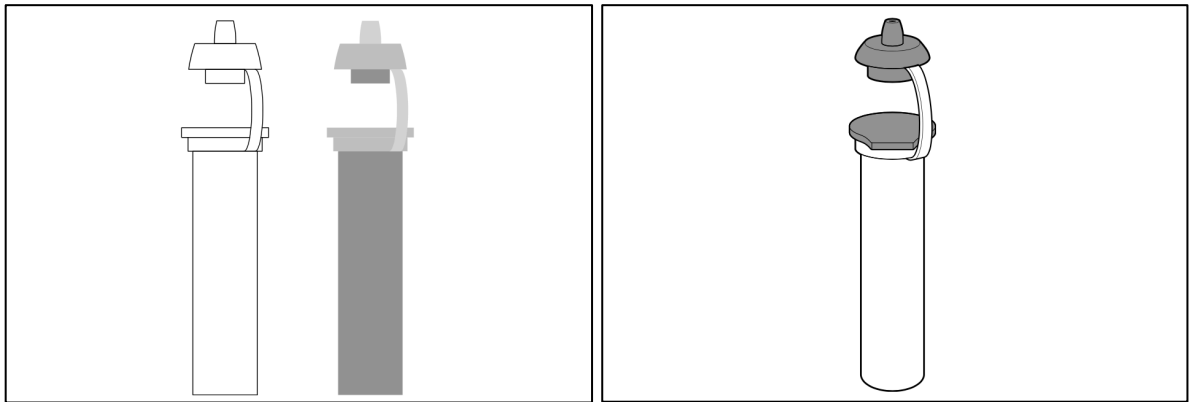

Figure 6. Challenge (left) and consideration (right) related to line thickness and contrast.

Challenge
Interpreting 2D drawings can be challenging, particularly when they feature thin lines, low contrast, or lower image quality and sharpness (Figure 6).

Consideration
Use high-quality, high-contrast line drawings with thick lines and appropriate shading (Figure 6).

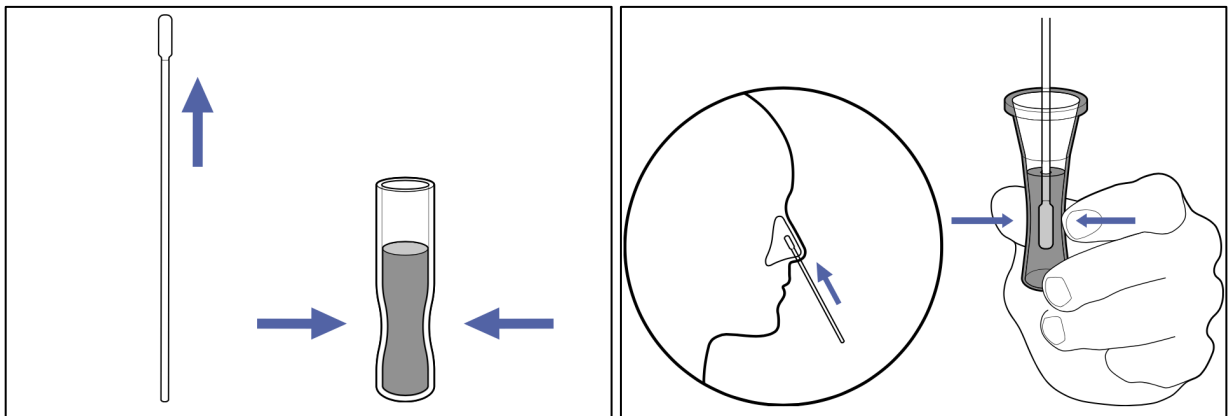

Figure 7. Challenge (left) and consideration (right) related to context in illustrations.

Challenge
Illustrations lacking context do not provide readers with information about the relative size of components, leaving them to guess how to use them (Figure 7).

Consideration
Incorporate illustrations that offer physical context for the reader, such as including hands or noses (Figure 7). Keep illustrations simple, providing only enough detail to clarify the features' purpose (for instance, a head doesn't need to have hair).

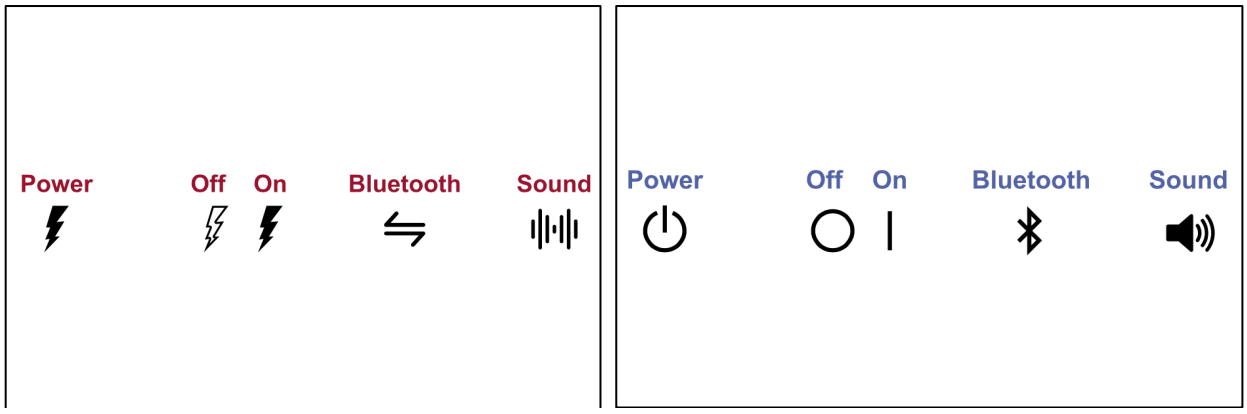

Figure 8. Challenge (left) and consideration (right) related to standard symbols.

Challenge
Symbols can be difficult to interpret if they are chosen arbitrarily or are specific to a particular region, as their meaning may not be clear to all readers (Figure 8).

Consideration
Utilize clear and universally accepted symbols, adhering to the ISO 15223-1:2021 standard for symbols on medical device packaging (17,18) (Figure 8). Include text labels directly adjacent to symbols (for example, 'Expiration Date' next to the hourglass symbol).

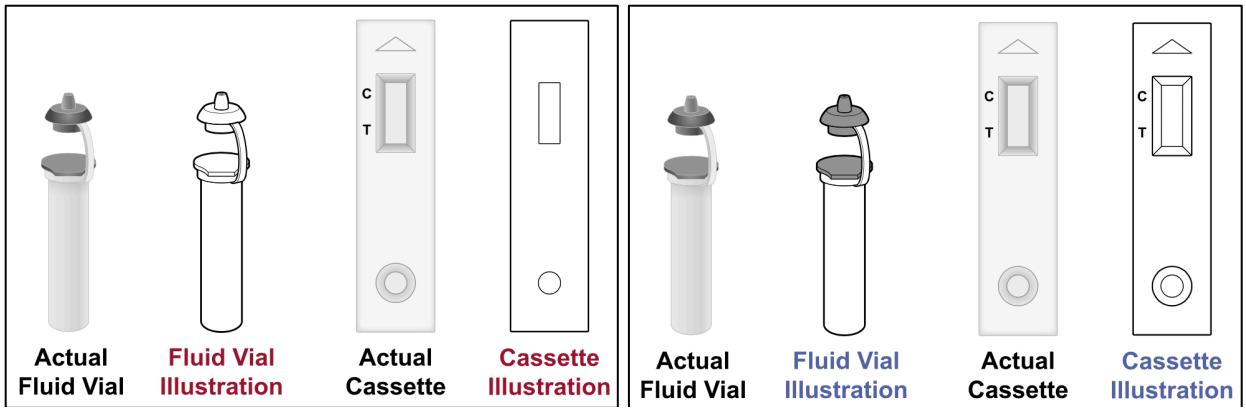

Figure 9. Challenge (left) and consideration (right) related to realistic details.

Challenge
Illustrations that lack realistic details matching the actual components can lead to confusion (Figure 9).

Consideration
Ensure that illustrations accurately reflect the actual appearance of the components; for example, if a cap is gray, do not depict it in white, and if the cassette features text or other markings, include these in the illustrations (Figure 9). If using grayscale, use representative colouring where possible to ensure adequate contrast is maintained and outlines are still apparent.

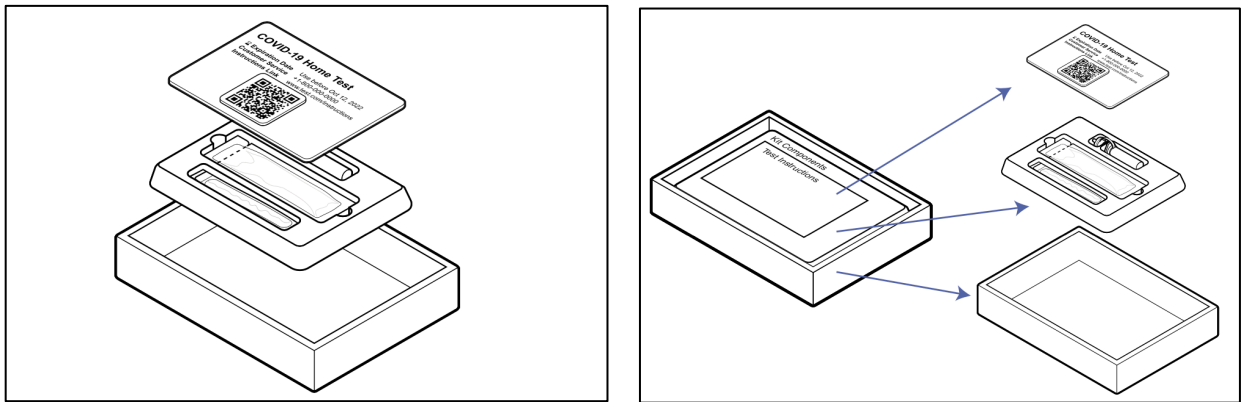

Figure 10. Challenge (left) and consideration (right) related to overlapping elements in illustrations.

Challenge
Illustrations featuring overlapping elements that seem to float in space without a composite reference can be hard to interpret (Figure 10).

Consideration
Simple illustrations can be interpreted by the broadest audience. If a more complex, exploded view is needed to convey an idea, include a composite reference image. Ensure that the exploded elements do not overlap and use arrows to indicate each element's position in the composite reference image.

Additionally, employ solid arrows between exploded elements to indicate stacking. Figure 10 illustrates a referenced exploded view image without overlapping elements.

12.5 Printed embodiment

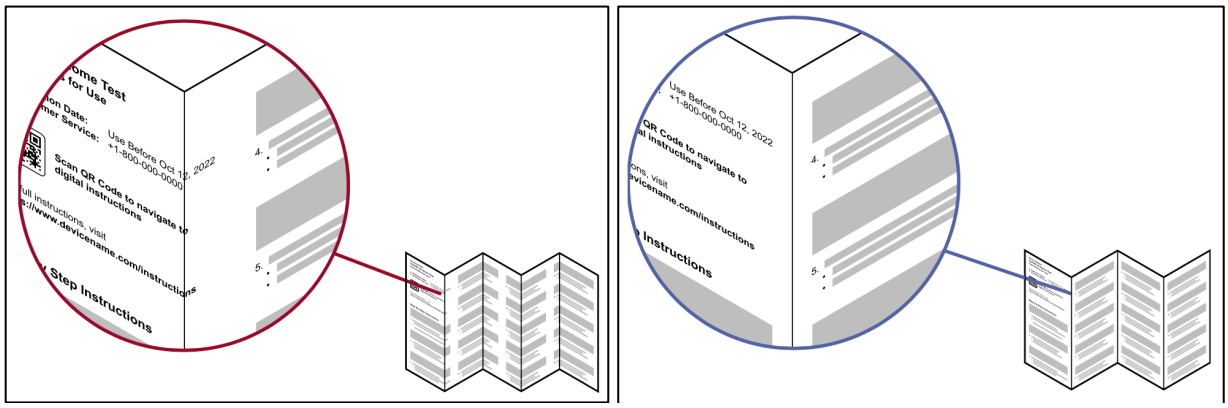

Figure 11. Challenge (left) and consideration (right) related to the location of information relative to paper folds.

Challenge
Large instruction panels with folds can lead to text crossing over the folds, causing same-topic information to be divided between the front and back panels, which reduces readability (Figure 11).

Consideration
Make sure paper creases are limited to the gutters of text columns to facilitate easier scanning of folded documents for OCR. Place all information required to conduct the test on one side of the paper or card, reserving the other side for supporting information. Figure 11 shows information contained within folded panels.

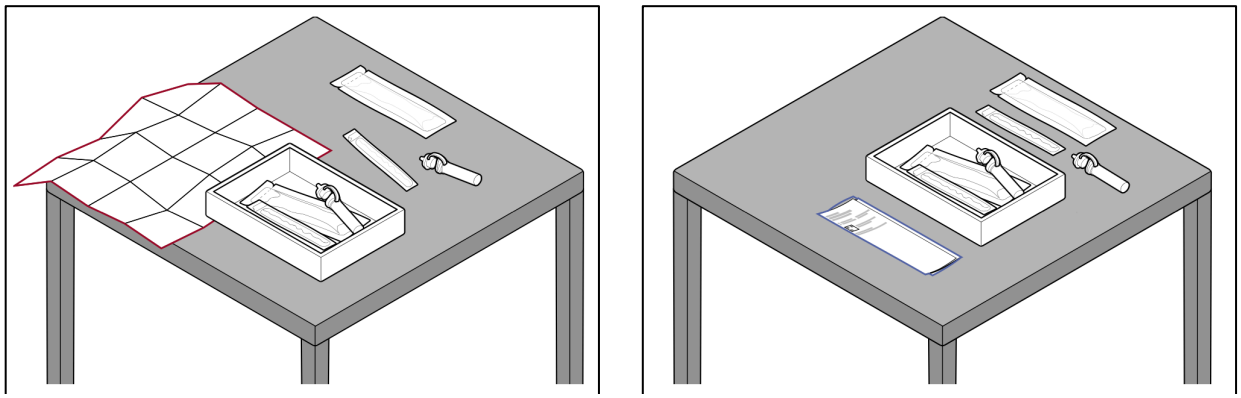

Figure 12. Challenge (left) and consideration (right) for instructions that require unfolding.

Challenge
Physically placing test instructions next to test components can be challenging due to their size or material, making it hard to reference the instructions while using the test. Additionally, tests involving fluids can lead to spills that may damage less durable instructional materials. Figure 12 illustrates test instructions that require full unfolding.

Consideration
Offer test instructions in a format that enables placement next to the test on a table. Lighter paper weights can help the instructions lay flat. Also consider using materials that can endure minor liquid spills. If coatings are applied, ensure they have limited reflectivity. Figure 12 illustrates test instructions that can be unfolded by section.

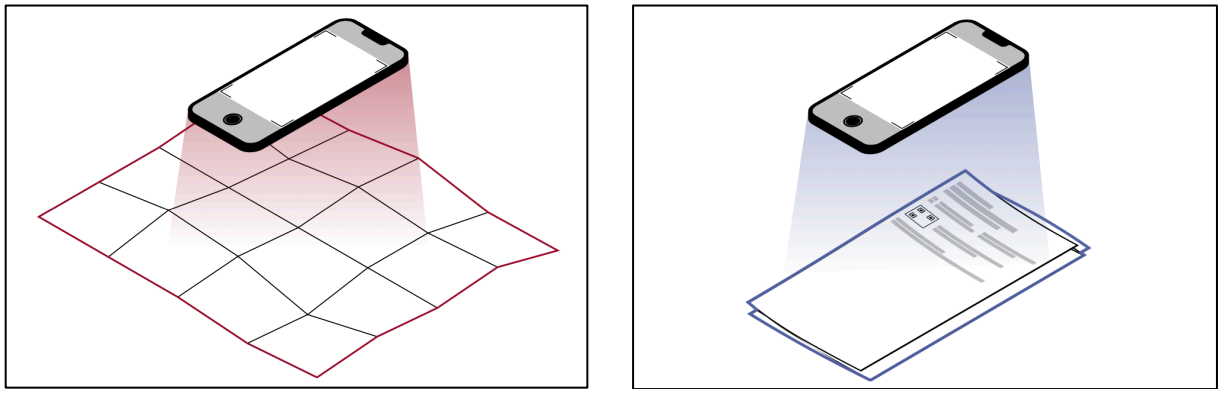

Figure 13. Challenge (left) and consideration (right) for the appropriate size of instructions to facilitate scanning.

Challenge
Paper (or similar) documents may be offered in a format that is incompatible with assistive technology. Pages or panels might be too large for flatbed scanners and smartphone OCR, and multiple panels lacking numbering can complicate navigation from page to page. Figure 13 demonstrates test instructions that are too large for effective scanning.

Consideration
Offer paper (or similar) documents in panels no larger than A4 (8.5 x 11 inches in U.S. letter size) to facilitate flatbed scanning. Include page numbers on both the front and back for multiple panels. Figure 13 illustrates test instructions that are appropriately sized for scanning.

12.6 Digital embodiment

Operating System Compatibility

It is essential for content to be recognized and understood by the operating systems (OS) of computers, smartphones, and tablets, including older ones, as well as by accessibility tools, to ensure users have access to information about the test.

Challenge
Test instructions may be offered in a format that is incompatible with the operating systems of computers, smartphones, or tablets, as well as with accessibility tools.

Some feedback features, such as auditory and haptic responses, can compromise user privacy, while others, like bright mode, may cause eye strain.

Additionally, applications may require users to enter personal information to sign in before granting access or allowing them to receive test results.

Consideration
Ensure that the application recognizes and supports the native accessibility settings of the device's operating system, (e.g. iOS VoicOver, Android TalkBack).

Custom video playback tools are not recommended. The app should also recognize and apply the user's system-wide accessibility preferences, such as font sizing or inverted colors, and include an in-app option to enable or disable auditory and haptic feedback. Additionally, a dark mode option should be available.

If the application requires data entry for sign-in or results reporting, it should:

1. Not require optional app users to provide more information than users must provide without the app. There should always be a “proceed as guest” option.
2. Enable autofill and/or single sign-on (SSO) options through services like Google, Apple, or Facebook.
3. Clearly indicate which data entry fields are required and which are optional.
4. Save partial data (e.g., by creating a user profile) to avoid requiring users to re-enter information for repeat testing.
5. Ensure that all data entry fields have labels compatible with assistive technology.
6. Ensure all text fields have valid autocomplete attributes that are supported by operating systems to avoid redundant typing.

Compatibility with Assistive Technology

Digital instructions should be available on a website that adheres to the WCAG 2.2 Level-AA (or better) international standard and has been rigorously tested with assistive technologies, including keyboard navigation, screen readers, voice dictation software, and magnification (29). The website should be available through a QR code and a plain text URL on the test box and package insert/instructions. Additionally, test-specific companion applications can provide another avenue for users to access digital test instructions.

Challenge
Test instructions may be presented in a format that is neither web nor mobile accessible and is incompatible with the accessibility features of the device's native operating system (OS).

Consideration
Digital test instructions should be hosted on a webpage that utilizes responsive web design. All relevant webpages should be audited for WCAG 2.2 AA compliance (29) by experienced digital accessibility professionals to ensure compatibility with assistive technologies. A follow-up audit should be conducted after any substantial updates to verify ongoing compliance. The remediated site should also be tested with assistive technology users.

Reference and implement best practices for ensuring both web and mobile accessibility of application content (30,31).

- Properly constructed HTML is the most widely accessible format.
- Any test instructions in PDF should conform to WCAG 2.2 AA and PDF/Universal Accessibility (UA) standards. This includes consideration of Section 508 in the US setting (32) and EN 301 549 in the European setting. It's important to note that while compliance to standards indicates an

accessible digital file format, it does not guarantee that the material is effective and accessible; content requires a separate and thorough review. Refer to section 12.3 for more information.

- All images in the digital instructions should include meaningful, descriptive alt text that supports nonvisual understanding of the information conveyed by the image (such as by shape, size, and feel). Refer to section 12.3 for more information.

Include a direct link on the product website to access a full digital version of the text instructions.

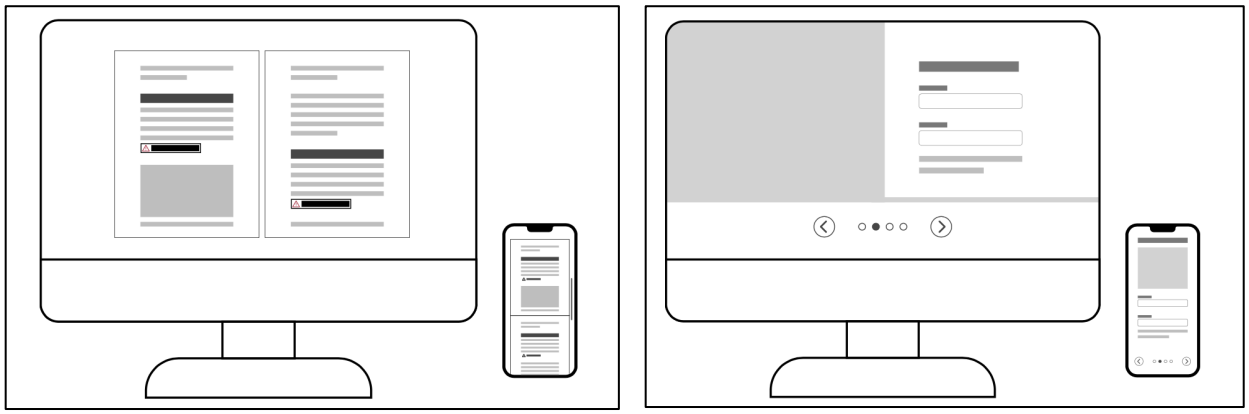

Figure 14. Challenge (left) and consideration (right) for screen reader formatting compatibility.

Challenge
Not all digital test instructions are compatible with screen readers, as key elements may be incorrectly coded or presented in a format that screen readers cannot detect (Figure 14). This can result in content being out of order, incomplete, or difficult to understand. Additionally, test instructions may be provided in a format that is not suitable for use on smartphones or tablets, or that cannot be processed by native operating system accessibility features.

Consideration
Ensure that digital test instructions are compatible with all commonly used combinations of screen readers and operating systems (Figure 14). Confirm the compatibility of every screen element, including images, fields, and buttons, with both computer and mobile screen readers.

User Interface and Experience Features

The presence or absence of features in an application or web design can greatly influence usability and user satisfaction with the test. Even a small enhancement in user interface design can significantly enhance the overall user experience.

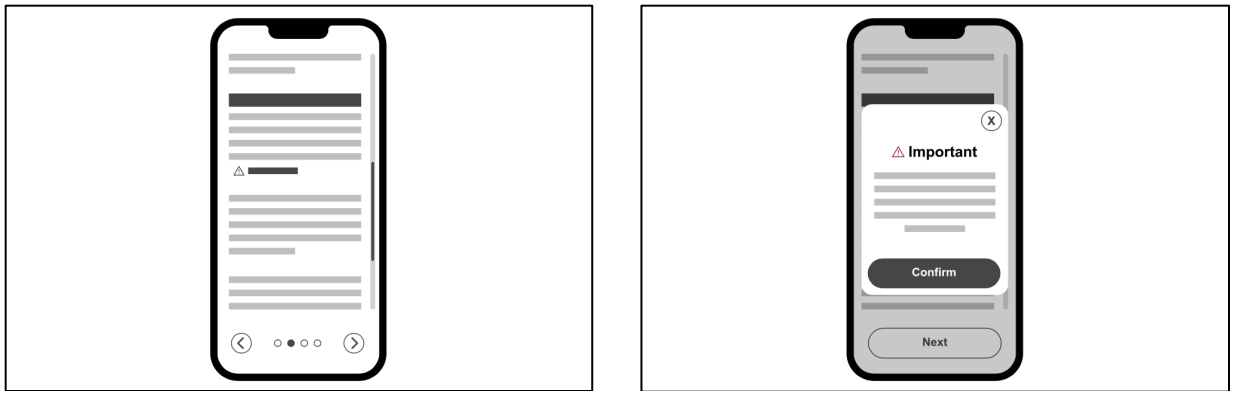

Figure 15. Challenge (left) and consideration (right) regarding the presentation of important messages.

Challenge

Important content can be overlooked when using a digital user interface if it is not properly segmented. Figure 15 illustrates how crucial information is integrated into the text.

Consideration

Implement messages for important content that remain on screen until the user takes action to acknowledge them (Figure 15). Errors, warnings, and success messages should not disappear automatically; they should remain visible until acknowledged by the user.

Interactive Voice Response (IVR) System

In settings with adequate infrastructure, IVR systems can facilitate access to instructions through phone calls, making them especially beneficial for users who may not be as comfortable with web or mobile applications. By providing test instructions via telephone, users can rely on a familiar and straightforward format for receiving information.

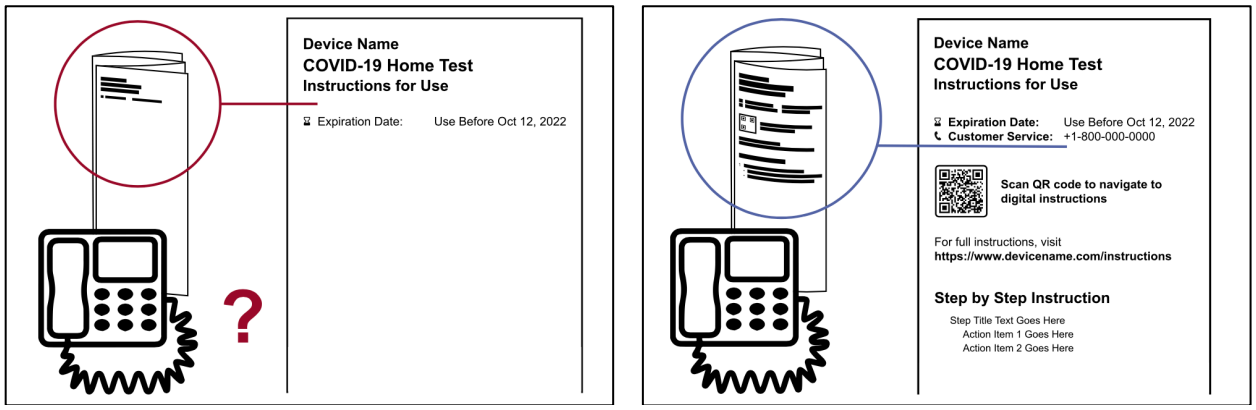

Figure 16. Challenge (left) and consideration (right) related to instructions with interactive voice response systems.

Challenge

Test instructions are not always available by phone, and when audio instructions are provided via this method, they often lack the ability to be navigated by section and step. Figure 16 illustrates the absence of IVR availability for test instructions.

Consideration
Audio test instructions should be provided via phone, utilizing an IVR system that allows callers to respond to prompts through button presses or spoken commands (Figure 17). This system should include options for navigation, such as continuing to the next step, repeating the current step, returning to the previous step, accessing the main menu, or connecting to a live agent.

The phone number to access the IVR system should be identified and displayed prominently near the top of the QRI and product page of the website for easy access.

Video Tutorial

Where infrastructure permits, videos can be an effective means of informing users about the product, offering dynamic demonstrations for those who prefer visual and auditory learning. When executed well, videos can enhance the audio instruction experience, often surpassing the effectiveness of screen reading digital instructions.

Challenge
Video test instructions are not always available on websites or applications. Additionally, some videos lack the ability to pause, rewind, or fast-forward in discrete increments, making it difficult for users to navigate to specific steps they wish to review.

Visuals featuring actors performing steps can be hard to follow due to issues with lighting, contrast, and overall visual complexity.

Offering an abbreviated version of a longer video may lead users to skip essential steps. Furthermore, automatically looping videos can be distracting and difficult to navigate.

Closed captions are often either absent or poorly synchronized. Audio descriptions—which convey the important visual elements of a video—may be lacking, hard to find, or insufficient in providing necessary nonvisual context.

Consideration
Make video test instructions available on the product website, ensuring that the video player is accessible (33,34). Users should have control over playback, including options to pause, play, rewind, fast-forward, increase or decrease playback speed, replay from the beginning, scroll through time, and switch to full screen mode.

Opt for high-contrast 2D animations that incorporate perspective, depth, and appropriate fill instead of live-action footage. Avoid providing abbreviated versions of longer videos, and refrain from using looping videos or audio without the ability to pause.

Ensure that closed captions are provided and properly synchronized with the video and audio content (35). Videos should include complete audio description. Provide audio description within the main audio, or preferably, as an option enabled by the user.

A descriptive transcript (i.e. The audio description script) should be provided along with any video.

If the video tutorial is embedded in an application, allow users to skip the video after their first viewing.

Include timestamps on the player for easy navigation to specific sections, such as getting started, workflow, and interpreting results, while utilizing native device OS video controls. Finally, ensure that on-screen buttons conform to the WCAG 2.2 success criterion 2.5.8 (25).

13 Physical Components

13.1 Outer packaging

Labeling

The outer box packaging serves as the first introduction to any device, making it crucial to carefully consider labeling and interaction with the packaging. Typically, packaging communicates information through text, images, and symbols, but it can also convey messages through its shape and provide links to external information, such as QR codes.

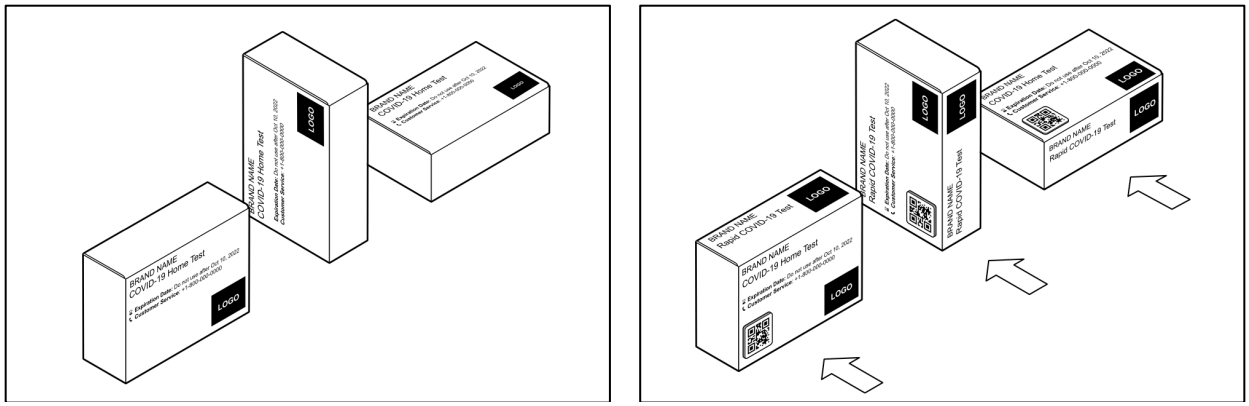

Figure 17. Challenge (left) and consideration (right) related to the orientation of box labels.

Challenge

Packages are frequently inadequately labeled and may lack essential information. For instance, Figure 17 illustrates a box with labeling that is only visible from one orientation.

Consideration

Consider how the package will be displayed, such as on a retail shelf or in a person's medicine cabinet, and what information will be most useful for the user. Figure 17 demonstrates a box with labeling that is accessible from multiple orientations. Consider embossing key information, like the product name, on the packaging in braille (see section 12.3, Braille).

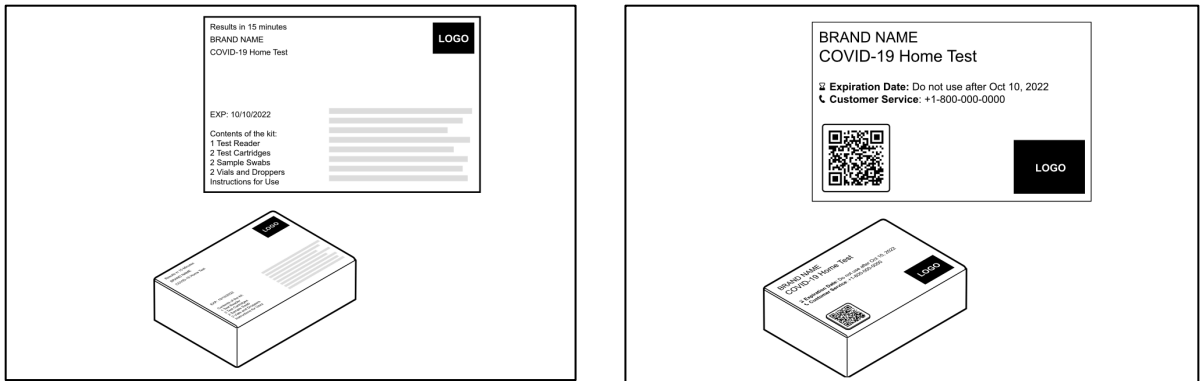

Figure 18. Challenge (left) and consideration (right) related to the legibility of labeling.

Challenge

The information on the outer box label may lack visual hierarchy and be cluttered with excessive details presented in a small font. Figure 18 illustrates a box label with poor legibility.

Consideration

Prioritize key information, such as the brand name, device type, expiration date, links to test instructions, and customer service number, by adjusting their size and position. Ensure that labeling adheres to the requirements set by regulatory bodies. Use a minimum font size of 14 points, ideally 18 points or larger, in a legible sans serif typeface (e.g., Arial, Calibri, Helvetica, Verdana). Avoid italics and decorative fonts (e.g., Script, Slab) and ensure effective color contrast (section 12.1). Figure 18 demonstrates box labeling with enhanced legibility.

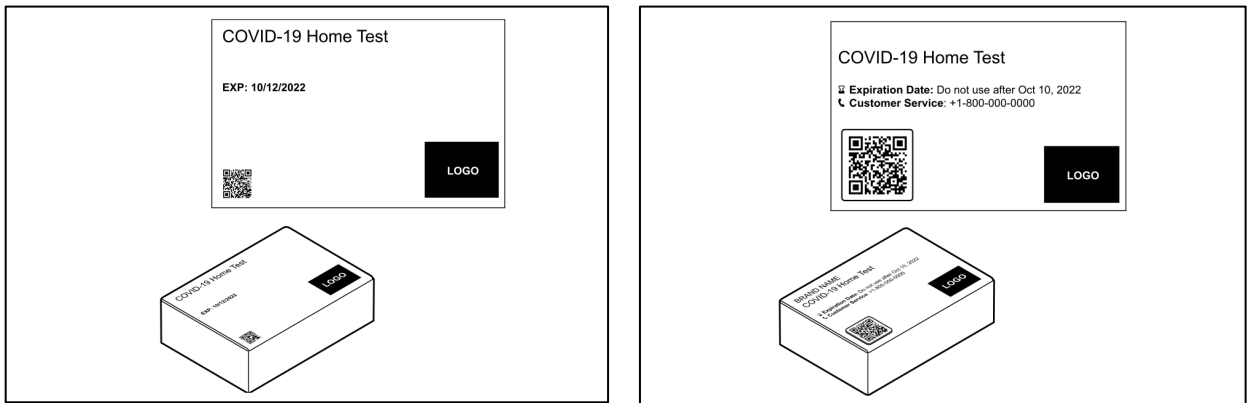

Figure 19. Challenge (left) and consideration (right) related to the size and location of QR codes.

Challenge

QR codes are frequently absent or inadequately sized, and the expiration date format may not be recognizable by common OCR applications. Figure 19 illustrates a QR code that is too small for easy identification.

Consideration

Ensure QR codes are presented at a size of at least 20.3 mm (0.8 inches) square to meet industry practice. Figure 19 demonstrates a QR code that is appropriately sized and easily visible. See section 12.1 for guidance on expiration date formatting.

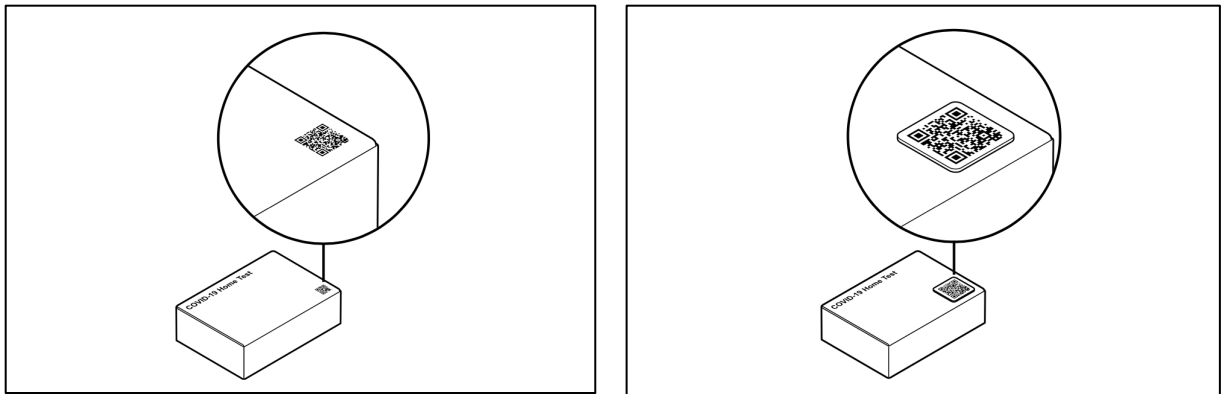

Figure 20. Challenge (left) and consideration (right) related to the ease of finding information such as QR codes.

Challenge
Outer packaging can sometimes hinder the ability to locate or access information easily. Figure 20 illustrates an example of a QR code printed directly on the box (left).

Consideration
Implement a tactile method for locating information, such as a QR code on a sticker or within a raised outline. Figure 20 illustrates a QR code printed on a sticker that can be tactilely identified (right).

Accessing Contents

Opening and accessing the contents of outer packaging requires balancing competing needs: preventing unauthorized tampering, ensuring ease of access for all users, and protecting the internal components.

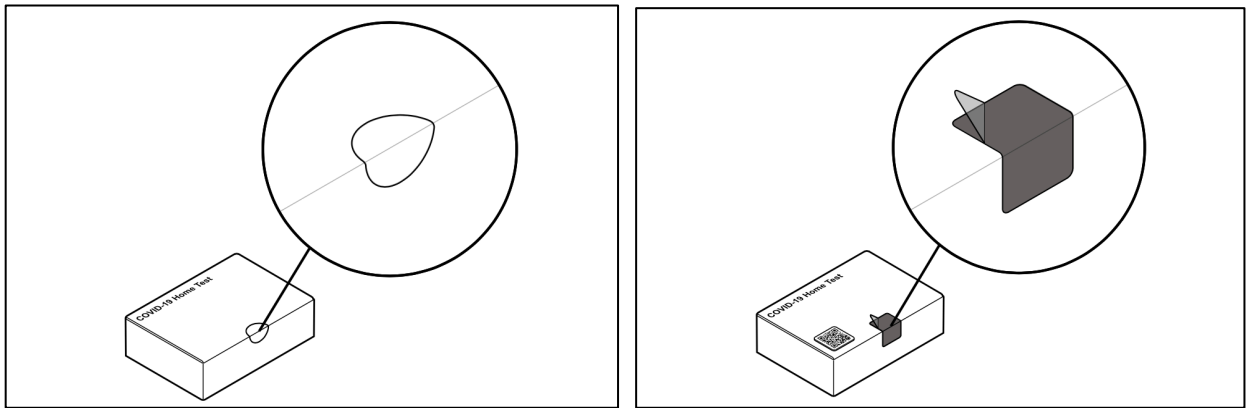

Figure 21. Challenge (left) and consideration (right) related to the removal of tamper-evident seals.

Challenge
Finding and removing small, clear tamper-evident seals can be challenging. Users may resort to using external tools, such as scissors, to open a difficult package, which can increase the potential for injury and lead to damage to the contents. Additionally, tearing open a package without fully removing the seal might cause damage to both the package and the fluid vial holder if it is integrated into the outer box. Figure 21 provides an example of a difficult-to-remove tamper-evident seal.

Consideration
The tamper-evident seal should be in a color that contrasts with the rest of the package to enhance visibility. It should also feature a grasp area that is at least 12.7 mm (0.5 inches) square to facilitate easy

removal without the need for external tools. Additionally, the force required to remove the seal should not exceed 2.2 kg or 5 lbs (22.2 N) (36). Figure 21 illustrates an example of an easy-to-remove tamper-evident seal.

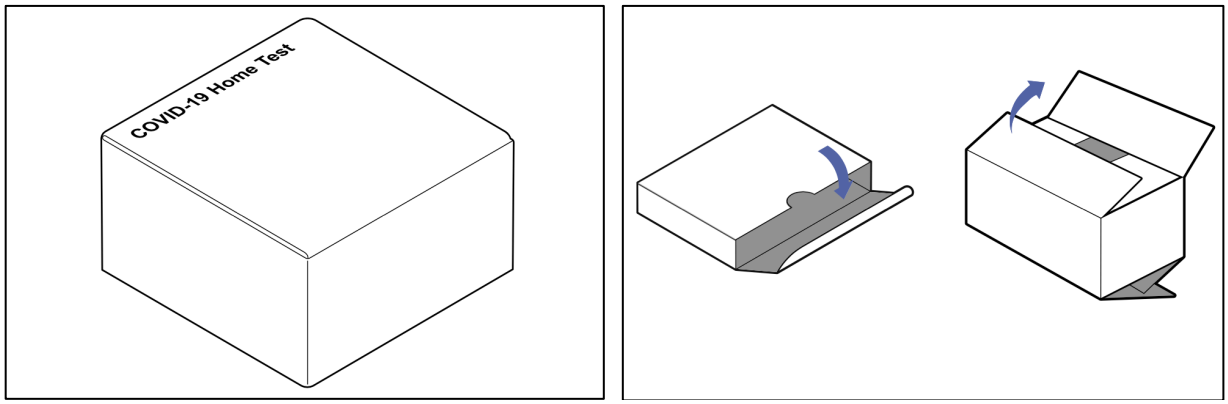

Figure 22. Challenge (left) and consideration (right) related to intuitive opening cues.

Challenge
Opening a package can be difficult when the only indicators for top, bottom, front, and back are visual, printed labeling. Figure 22 illustrates a package that lacks intuitive opening guidance.

Consideration
Packaging should feature familiar tactile cues to indicate where it should be opened, such as thumb cut-outs or overlapping flaps. Figure 22 displays packages that incorporate these opening cues.

13.2 Kit

Organization
Test kits with multiple components should clearly identify each component, secure small parts, and provide instructions on the order of use. Thoughtful organization of these components can significantly enhance the user's ability to complete the test. Including a tray as an optional accessory can further improve the user experience by helping to organize the components effectively.

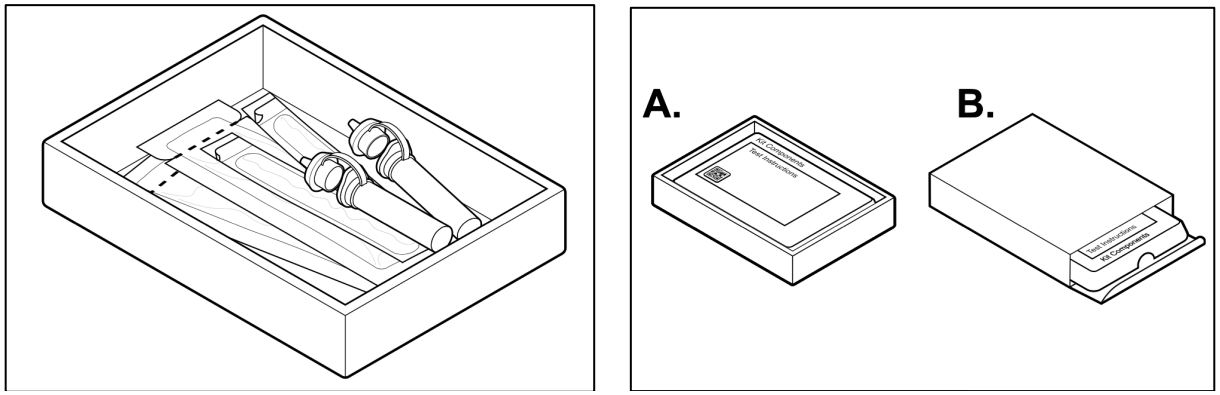

Figure 23. Challenge (left) and consideration (right) related to the organization of contents within a box.

Challenge
Finding internal physical test instructions and key information can be challenging, especially when components are loose within the box packaging (
).

Consideration
Ensure that legible test instructions are positioned face up as the first item users encounter.
demonstrates how contents can be neatly organized within the box.

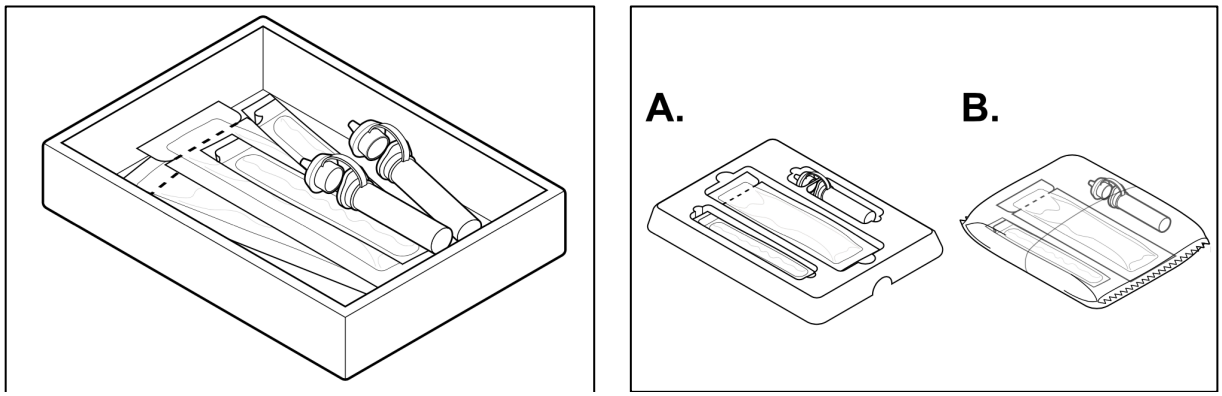

Figure 24. Challenge (left) and consideration (right) related to the organizations of contents in trays or pouches.

Challenge
Packages often contain multiple components and internal pouches that may be loosely placed inside (Figure 24). Upon opening, these contents can easily fall out and become misplaced, making it unclear in what order the internal pouches or components should be accessed.

Consideration
To enhance usability, contents should be arranged in an organized and/or fixed manner, such as using a tray, bag, card, or box dividers, clearly indicating the order of use. If a tray is included, it should provide sufficient finger clearance and gripping features, such as pull tabs, to facilitate easy removal from the box and access to the components. Figure 24 demonstrates contents neatly organized in a tray or tear pouch.

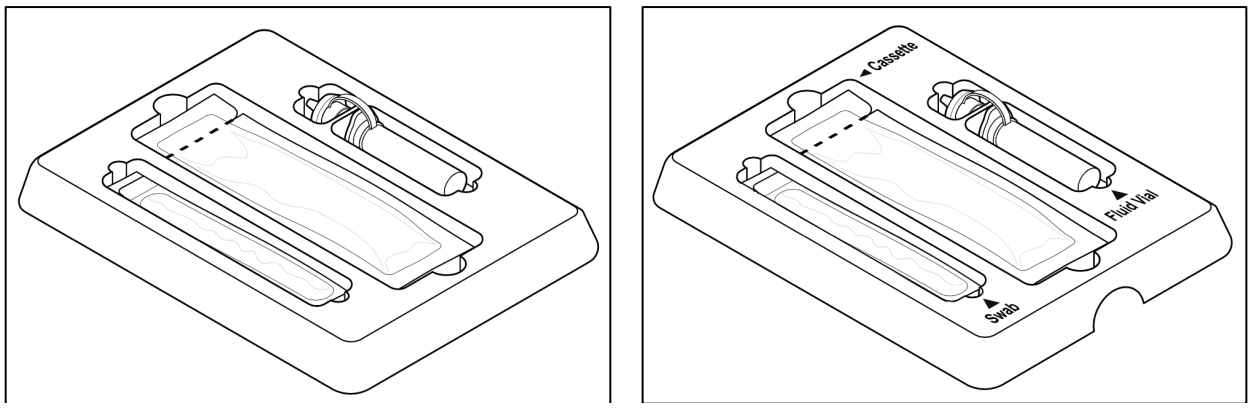

Figure 25. Challenge (left) and consideration (right) related to labels on internal trays.

Challenge
Components within an internal tray can be challenging to identify when they lack proper labeling. Figure 25 illustrates an internal tray that does not provide any labels for clarity.

Consideration
Incorporate high-contrast text labels on the internal tray to enhance visibility of components. Figure 25 illustrates an internal tray featuring such high-contrast labeling.

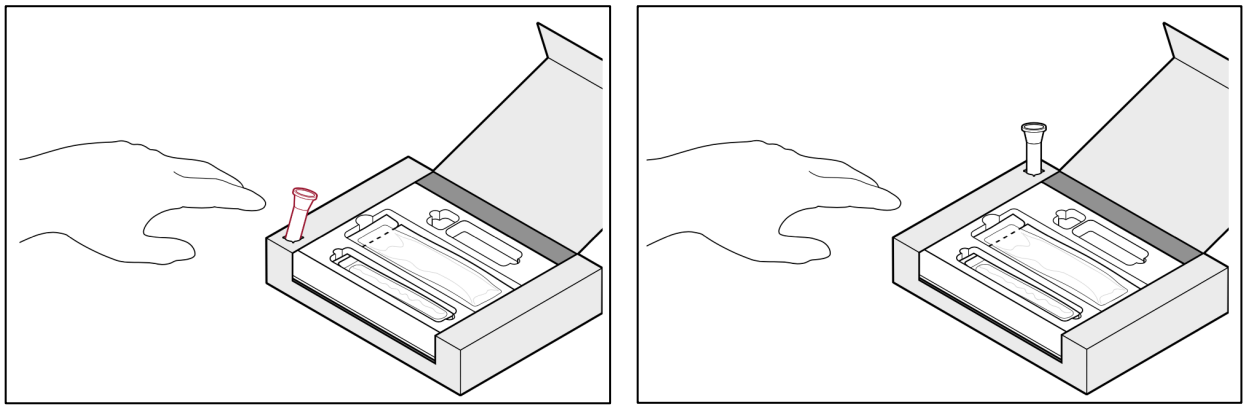

Figure 26. Challenge (left) and consideration (right) related to the location of fluid vial holders.

Challenge
Improper positioning of the fluid vial holder within a tray poses a risk of unintentional spillage. Figure 26 demonstrates how the location of the fluid vial holder can disrupt user workflow.

Consideration
The fluid vial holder should be strategically positioned in the tray to prevent unintentional disruption. Figure 26 illustrates how a better alignment of the fluid vial's location can enhance the workflow.

Internal Pouches

Accessing internal components often necessitates opening secondary packaging. Users should be able to easily distinguish between pouched components, identify where to open each pouch, and do so with less than 2.2 kg or 5 lbs (22.2 N) of force (36). Design features such as grip areas, visual cues, and labeling are crucial for enhancing the usability of these internal pouches.

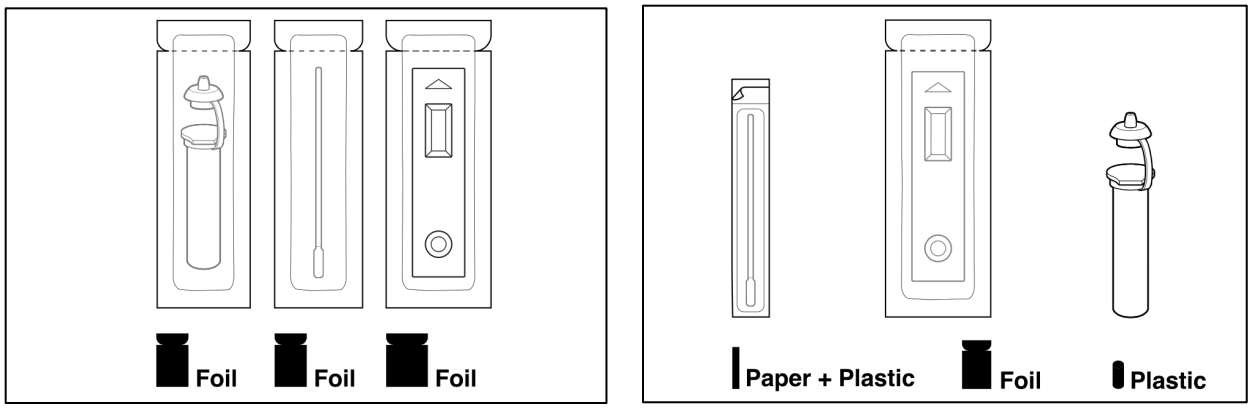

Figure 27. Challenge (left) and consideration (right) related to the form and composition of packaged parts.

Challenge
Internal pouches that are similar in size, shape, and material, or that lack adequate labeling, can be difficult for users to distinguish from one another. Figure 27 illustrates parts packaged in foil pouches that share the same form factor.

Consideration
To enhance usability, each pouched component should be tactilely distinguishable from others, such as by using distinct internal pouch shapes or sizes. Additionally, labeling internal pouches with component names or illustrations is essential. Figure 27 demonstrates parts packaged with distinct materials and form factors.

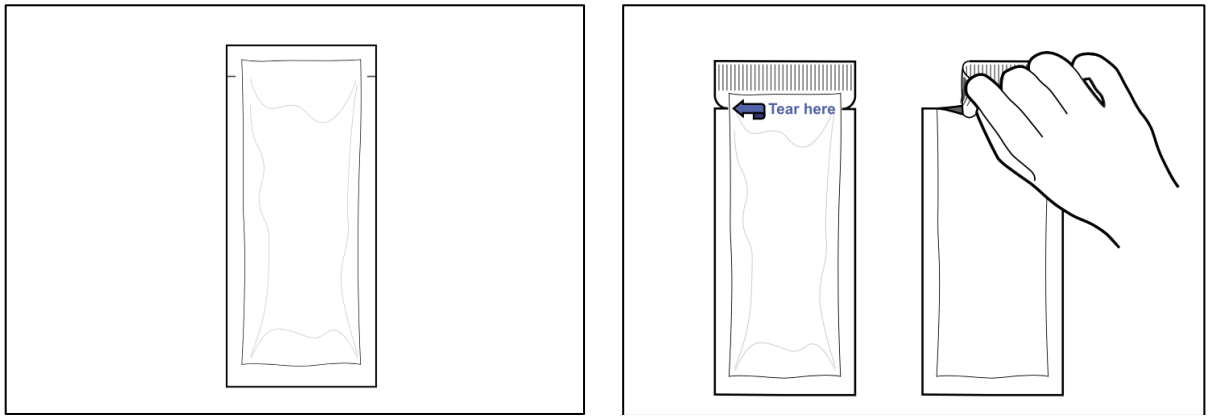

Figure 28. Challenge (left) and consideration (right) related to the ease of opening pouches.

Challenge
Internal pouches can be challenging to open, particularly when there is no clear indication of where to tear (
).

Consideration
Pouches should feature a notch marked with high-contrast text or an arrow to indicate the tear location. Additionally, incorporating textured grip areas can enhance usability. Figure 28 illustrates a pouch with clearly defined tear locations.

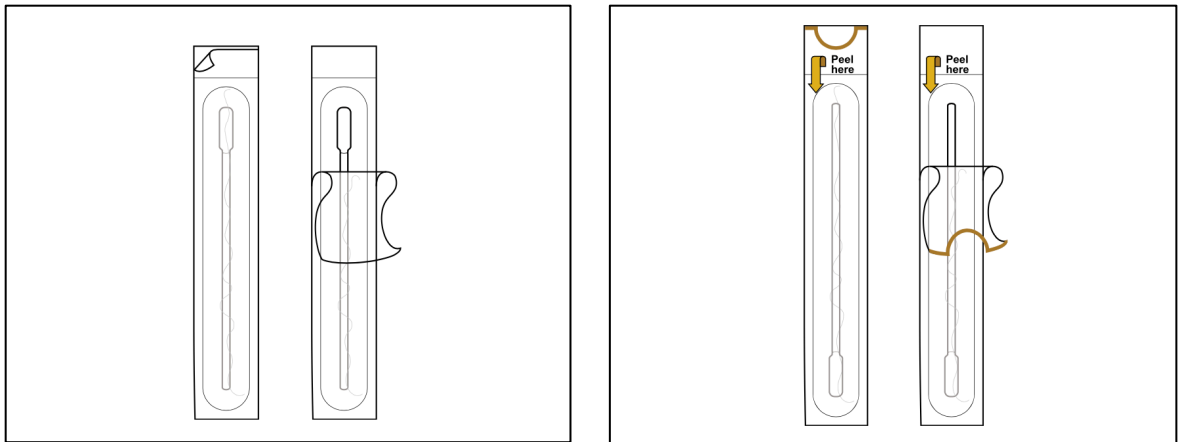

Figure 29. Challenge (left) and consideration (right) related to swab packaging.

Challenge
Peel-apart pouches often have layers that are difficult to differentiate and separate. Additionally, the internal packaging may have an opening method that exposes areas to contamination through touch. *Incorporate* a half-moon cut-out in one of the layers of the peel-apart pouch or a fold-over in one of the layers. Ensure that the opening exposes a component part intended for touch, such as positioning the peel feature near the swab handle instead of the swab tip. Figure 29 demonstrates swab packaging with the swab handle near the opening. illustrates swab packaging with the swab tip positioned near a small peel tab.

Consideration
Incorporate a half-moon cut-out in one of the layers of the peel-apart pouch or a fold-over in one of the layers. Ensure that the opening exposes a component part intended for touch, such as positioning the peel feature near the swab handle instead of the swab tip. Figure 29 demonstrates swab packaging with the swab handle near the opening.

13.3 Specimen collection

Challenge
Lancet may be difficult to manipulate and use. The lancet may require too much force for some users to use effectively.

Consideration
Any lancet included should be operable with either the right or left hand. The force required to use the lancet should not exceed 2.2 kg or 5 lbs (22.2N).

Capillary tube or swab
Any capillary tube or swab included should be operable with either the right or left hand.

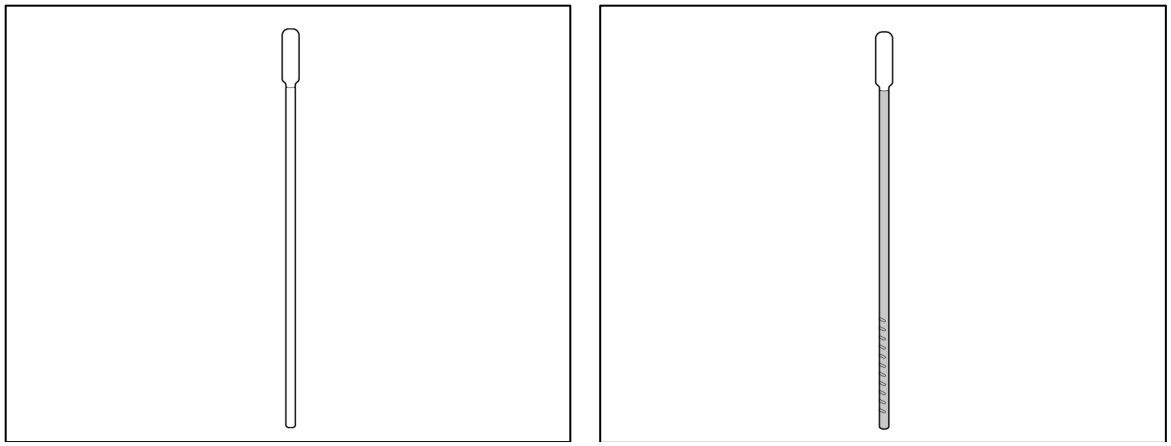

Figure 30. Challenge (left) and consideration (right) related to swab grips.

Challenge
Capillary tubes or swabs that lack clear indications for handling may risk contamination from touch. Figure 30 illustrates a swab without any clearly identifiable handling feature.

Consideration
The capillary tube or swab shaft should incorporate identifiable features, such as textures, to guide users on where to grasp it, helping to prevent specimen contamination. Additionally, using contrasting colours for the swab shaft and tip or capillary tip can enhance visibility. Figure 30 demonstrates a swab with a designated grip area feature.

Challenge
Stiff or difficult to use capillary tubes can result in errors or insufficient volume application to the cassette.

Consideration
Make capillary tubes more pliable, ensuring force to dispense liquid is less than 1.6 kg or 3.5 lbs (15.6 N). Construct capillary tubes of see-through materials to allow clear visualization of contents. Consider clear marking that indicates the correct volume.

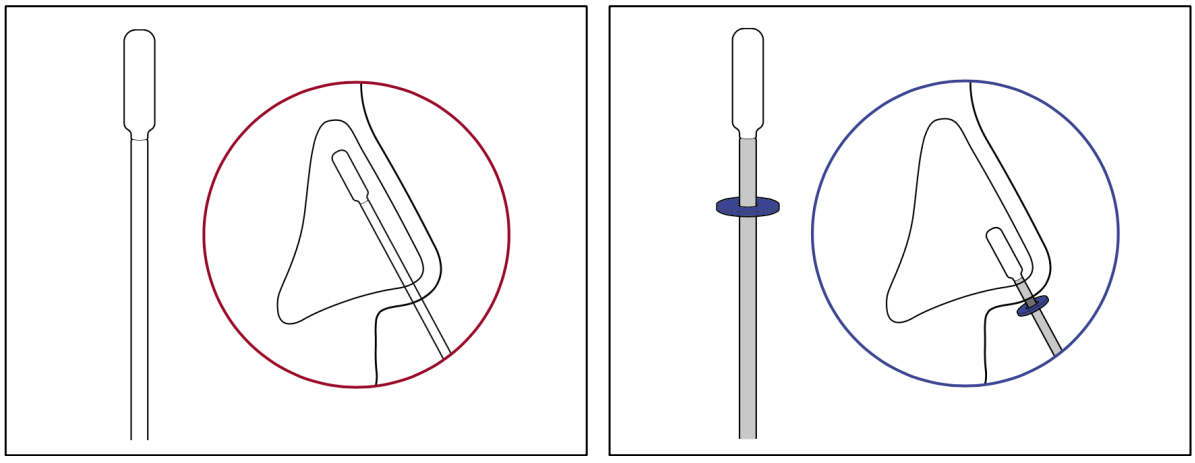

Figure 31. Challenges (left) and considerations (right) related to swab depth indications.

Challenge
Swabs lack clear indicators for the appropriate insertion depth in the nostril. Figure 31 illustrates a swab that does not provide depth guidance.

Consideration
Incorporate a tactile feature on the swab to guide the user on the required depth of insertion. Figure 31 illustrates a swab that includes this depth indication.

13.4 Fluid vials and specimen preparation

Any fluid vials or specimen preparation materials included should be operable with either the right or left hand.

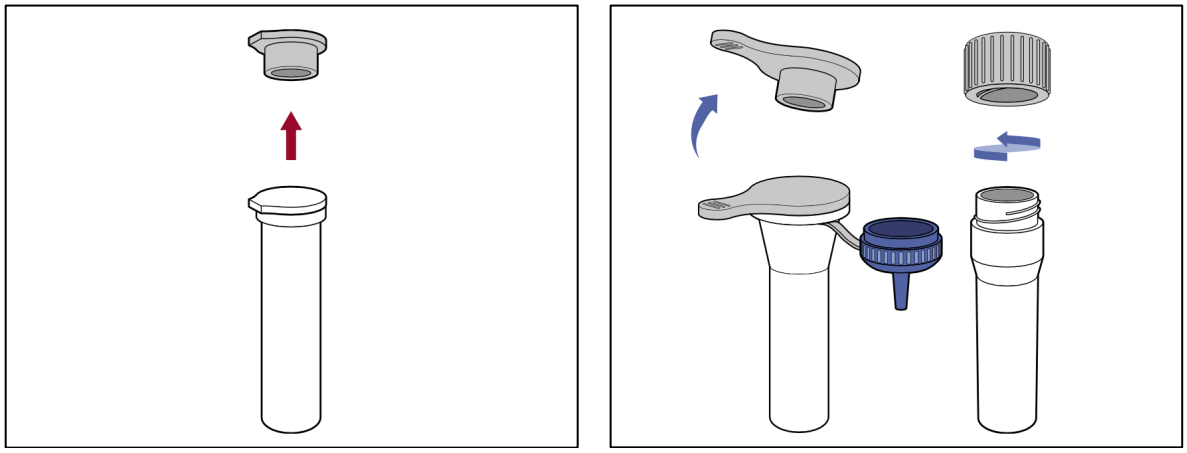

Figure 32. Challenge (left) and consideration (right) related to fluid vial caps.

Challenge
Small caps and vials can be easily misplaced and difficult to handle, increasing the risk of spills. Figure 32 depicts a vial with a cap that presents challenges during removal.

Consideration
Large caps and vials that incorporate identifiable features, such as distinctive colors or shapes, enhance handling. Additionally, attaching caps to the fluid vial using a living hinge can further facilitate ease of use. Figure 32 illustrates a vial with a cap designed to improve removal.

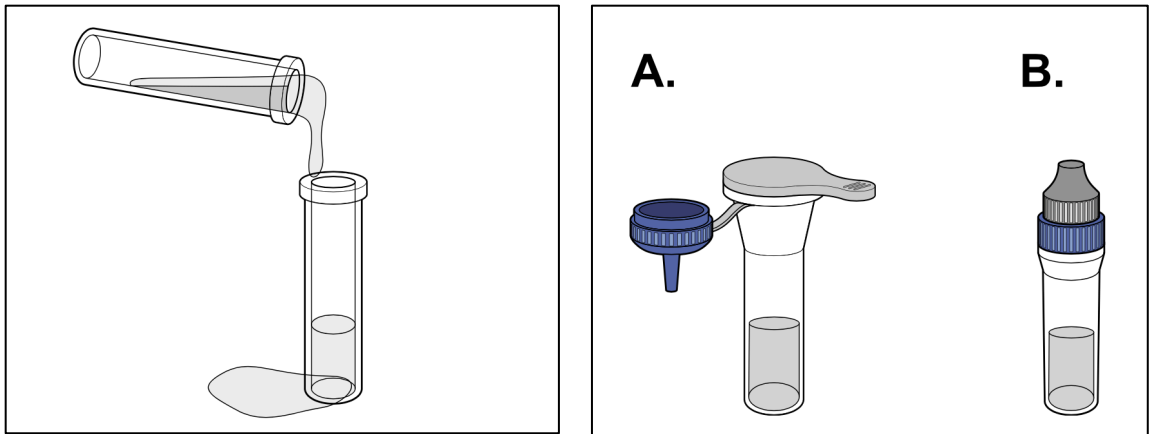

Figure 33. Challenge (left) and consideration (right) related to fluid transfer.

Challenge

Transferring liquids, such as buffer solution or other reagents, into the extraction fluid vial can elevate the risk of incomplete transfer and/or spills. Figure 33 depicts a configuration that may lead to such fluid transfer issues.

Consideration

To reduce the risk of spills, it's advisable to eliminate the need for transferring liquids when possible, such as by integrating a prefilled fluid vial with a dropper cap. Figure 33 illustrates an enhanced configuration that minimizes fluid transfer spills.

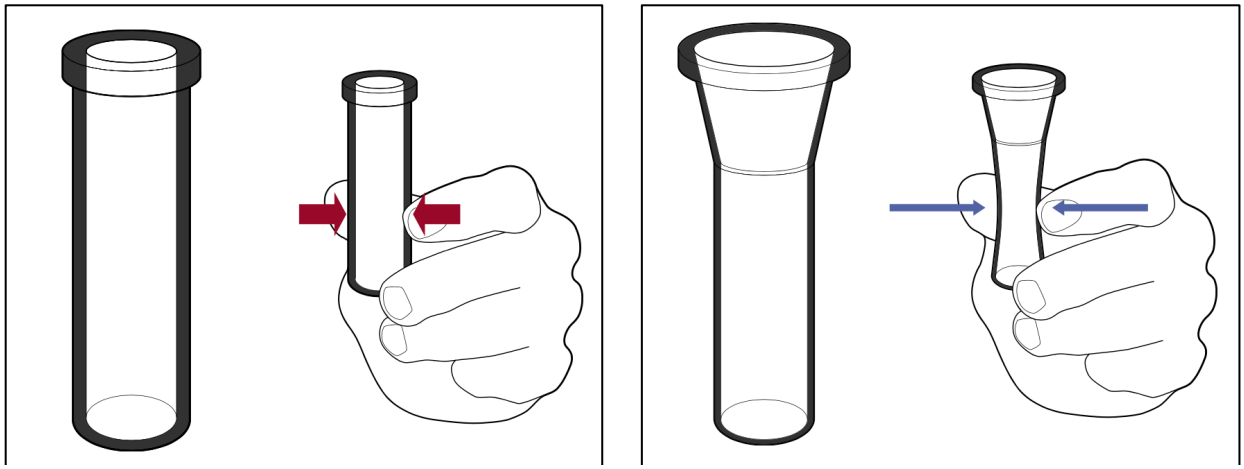

Figure 34. Challenge (left) and consideration (right) related to fluid vial walls.

Challenge

Fluid vials with stiff walls, such as those made of thick plastic, can make it challenging to dispense liquid by squeezing (Figure 34). Additionally, short fluid vials may be difficult to grip or manipulate effectively. The opacity of the material can also hinder the user's ability to visualize the liquid being dispensed.

Consideration

To improve usability, fluid vials should have thinner and more pliable walls, requiring less than 1.6 kg or 3.5 lbs (15.6 N) of force to dispense liquid (37). Additionally, the vials should be a minimum of 40 mm

(1.6 inches) long and constructed from transparent materials to allow for clear visualization of their contents (38). Figure 34 illustrates the preferred configuration of a thin-walled vial.

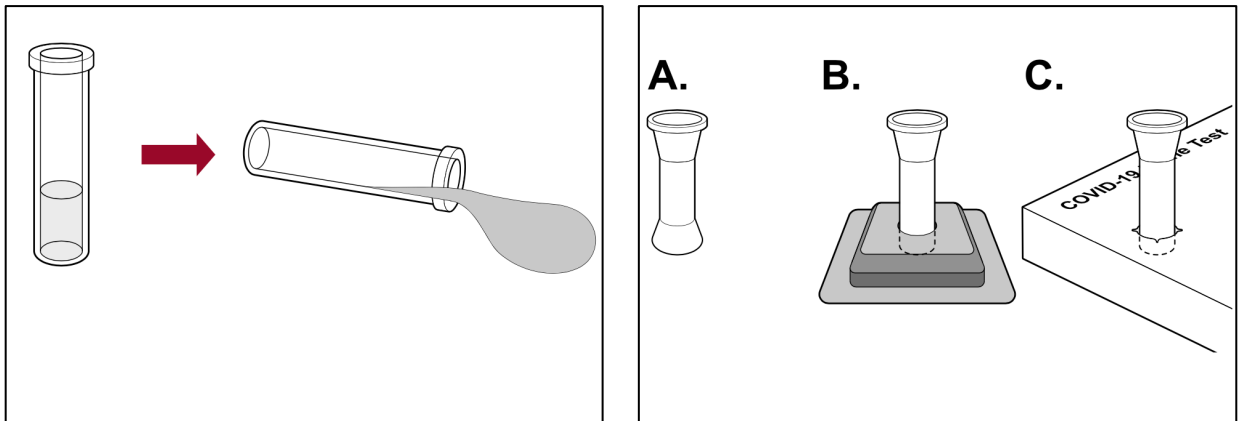

Figure 35. Challenge (left) and consideration (right) related to the stability of vials.

Challenge

Fluid vials can be unstable, which makes it challenging to set them down during the testing process. Figure 35 illustrates an unstable vial.

Consideration

To enhance stability, fluid vials should be designed to stand upright securely. This can be achieved through features such as an integrated vial base, a separate vial stand or a stand incorporated into a tray, if used, or a vial stand punch-out in the outer box. If opting for a punch-out, ensure that the force required to puncture it is less than 2.2 kg or 5 lbs (22.2 N), and use high-contrast labeling and a tactile outline to clearly indicate its location. The size should allow for a secure fit of the fluid vial, and the punch-out should be positioned in a way that does not interfere with the overall use of the box, preferably at the box edge (34). Figure 35 illustrates examples of vials designed for improved stability.

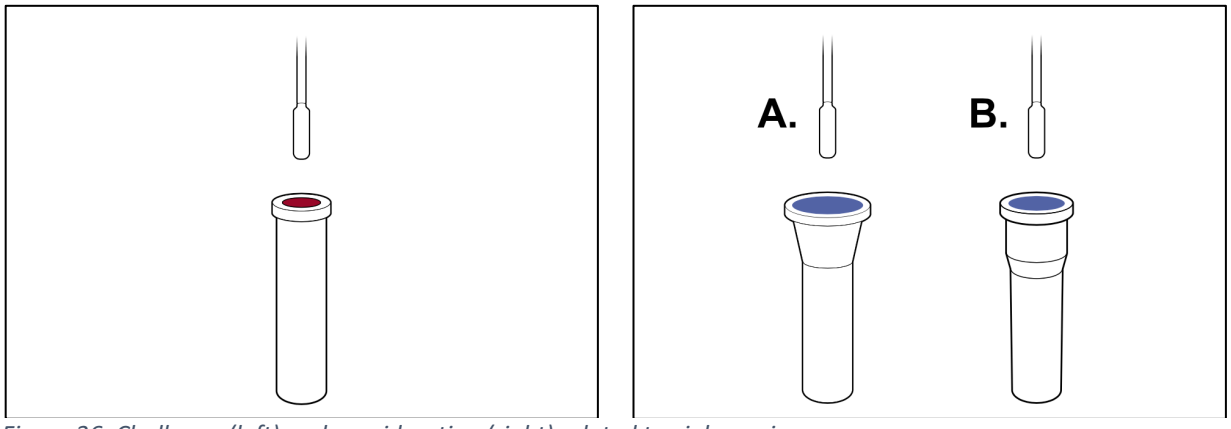

Figure 36. Challenge (left) and consideration (right) related to vial openings.

Challenge

Narrow openings can hinder the insertion of the swab into the fluid vial, increasing the risk of the swab tip being touched and contaminated during the process. Figure 36 illustrates an example of a vial with a suboptimal narrow opening.

Consideration
Widening or reshaping the fluid vial opening, such as using a funnel design, allows for easier and safer insertion of the swab. Figure 36 demonstrates improved tapered vial openings that facilitate this process.

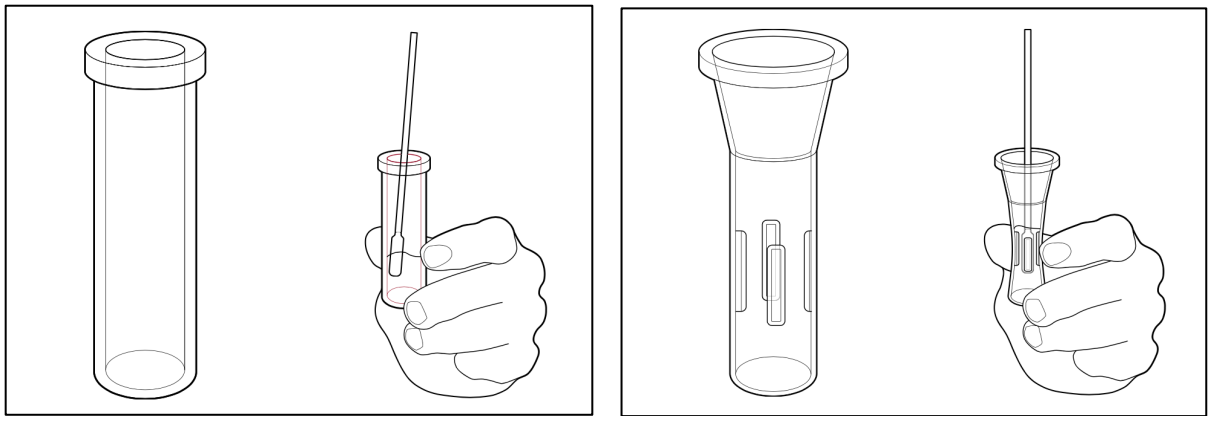

Figure 37. Challenge (left) and consideration (right) related to internal textures within vials.

Challenge
Tests may necessitate physically supporting the fluid vial during specimen agitation, which raises the risk of spills. Figure 37 illustrates a vial that lacks internal texture.

Consideration
Incorporate design features in the fluid vial that minimize the force required during specimen agitation or extraction, such as internal ribbing. Figure 37 illustrates a vial with this internal ribbing feature.

Challenge
Counting the drops delivered to the cassette specimen well can be difficult, leading to a higher risk of user error.

Consideration
Design the test to ensure that the entire volume in the fluid vial is utilized for analysis.

13.5 Cassette

The cassette included should be operable with either the right or left hand.

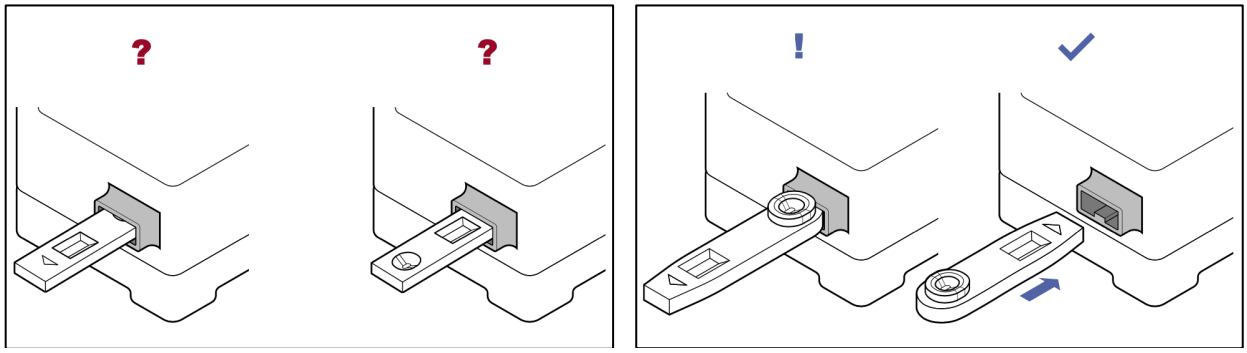

Figure 38. Challenge (left) and consideration (right) related to cassette orientation features.

Challenge
An indistinct cassette shape can make it difficult for users to correctly orient the device and identify key features, such as the specimen well and results window. Additionally, an unclear shape may hinder proper loading of the cassette into a test reader, if one is used. Figure 38 illustrates a setup that lacks orientation features.

Consideration
Design the cassette with distinctive features, such as colors, shapes, and textures, to facilitate easy identification and manipulation. Additionally, incorporate a keying feature that ensures the cassette can only be loaded into the test reader in the correct orientation. Figure 38 illustrates how mating features can indicate orientation.

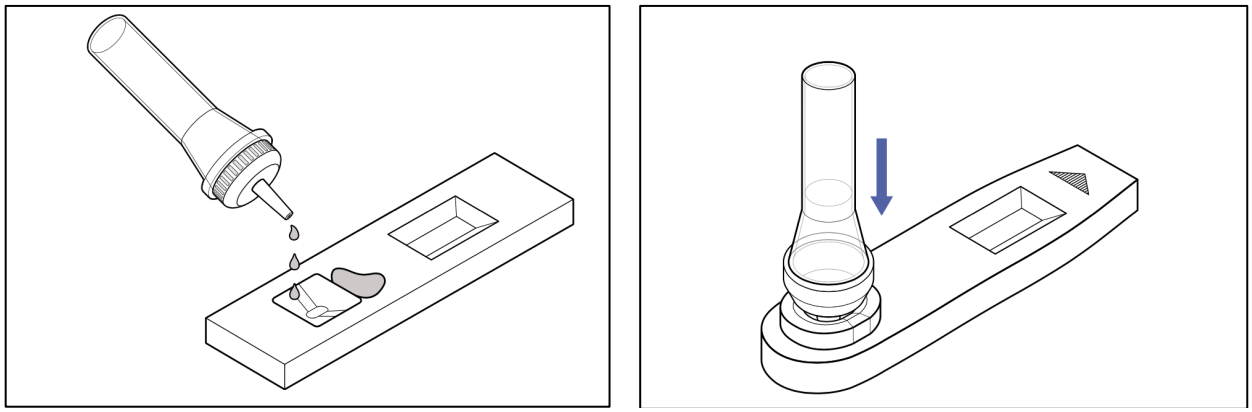

Figure 39. Challenge (left) and consideration (right) related to specimen wells versus results windows.

Challenge
The location of the specimen well and results window may be challenging to identify, particularly by touch, which can result in specimen spills. Furthermore, the specimen well and results window might be easily confused with each other. Figure 39 depicts a cassette lacking a distinguishable well location.

Consideration
To facilitate the transfer of specimen fluid, incorporate features on the cassette that aid in the alignment or docking of the fluid vial with the specimen well, such as locking features, raised edges, or contrasting colors for the specimen well. Additionally, ensure that the specimen well and results window are distinctly shaped and adequately separated from each other. Use clear visual and tactile reference points to describe how users can distinguish the specimen well from the results window. Figure 39 illustrates a cassette equipped with a docking feature.

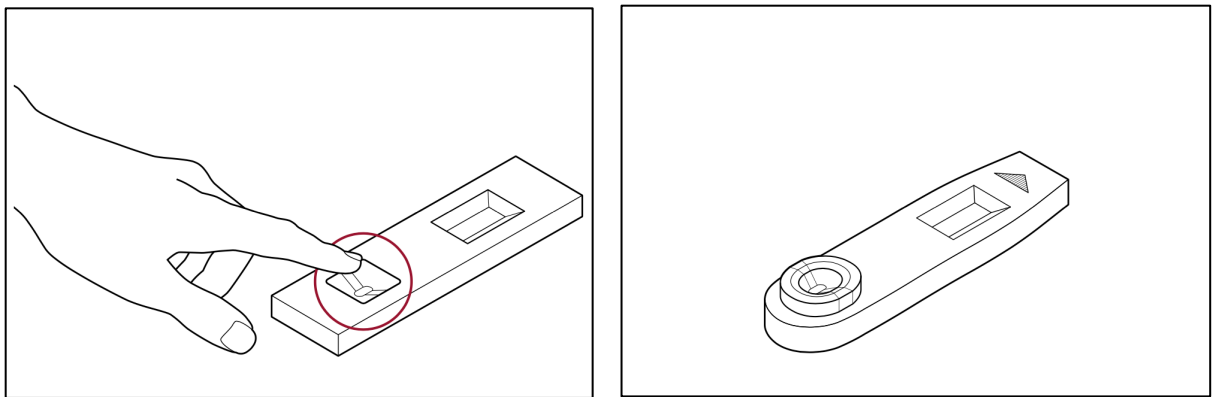

Figure 40. Challenge (left) and consideration (right) related to exposed versus protected specimen wells.

Challenge
An exposed specimen well heightens the risk of touch contamination, potentially impacting the accuracy of test results. Figure 40 demonstrates a cassette featuring an exposed specimen well.

Consideration
Incorporate features on the cassette that minimize the risk of touch contamination, such as raised edges around the specimen well. Figure 40 illustrates a cassette with a protected specimen well.

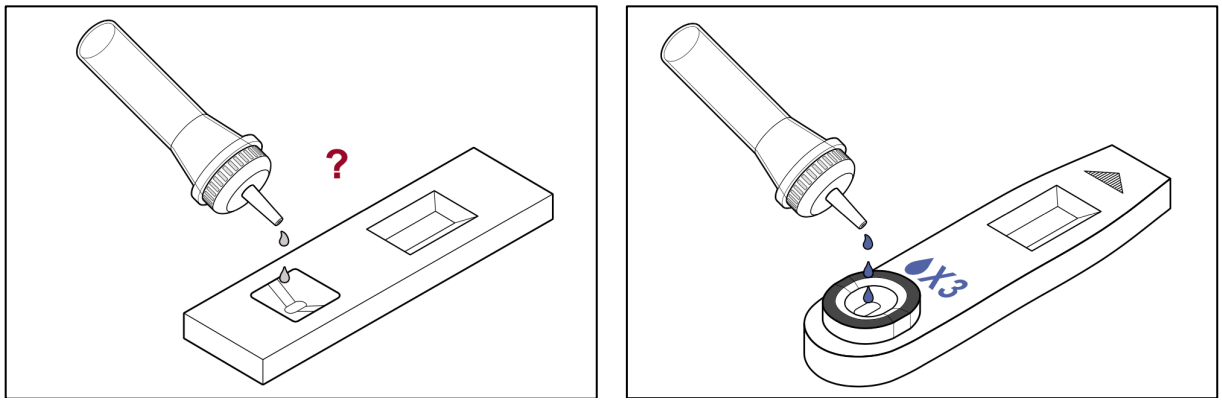

Figure 41. Challenge (left) and consideration (right) related to drop count labeling.

Challenge
Users might dispense an incorrect number of drops or place drops in the wrong location. Figure 41 depicts a cassette that lacks labeling for drop counting.

Consideration
If counting drops is necessary, a high-contrast label should be included on the cassette to indicate the required number of drops. To help identify the location of the specimen well, a raised edge of at least 3 mm (0.1 inches) and a high-contrast outline should be incorporated. Figure 41 illustrates a cassette with clear drop count labeling.

13.6 Test reader

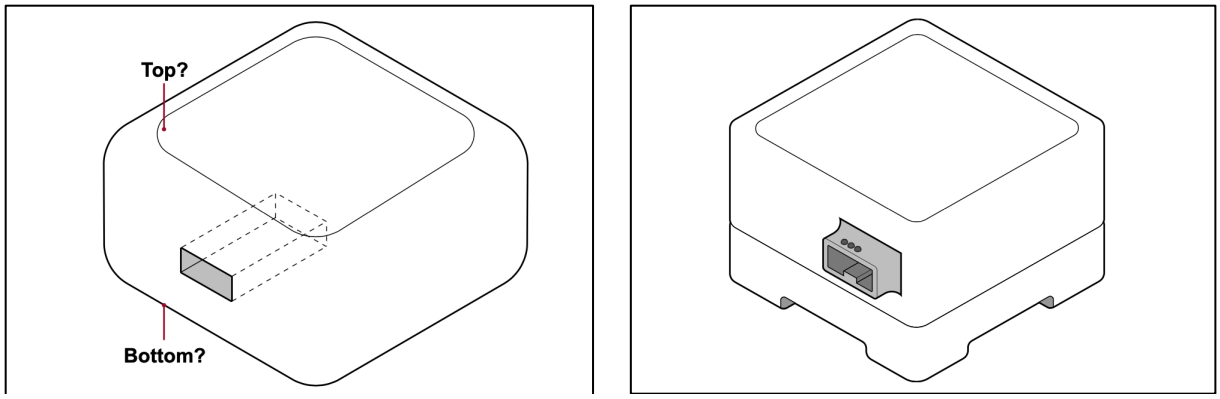

Figure 42. Challenge (left) and consideration (right) related to distinguishing features on test readers.

Challenge

The shape of the test reader may pose difficulties in orienting it correctly and identifying key features, such as the cassette insert area. Figure 42 depicts a test reader that lacks distinguishable features.

Consideration

The test reader should be designed with distinguishing features, such as varied colors, shapes, and textures, to facilitate easy orientation. Figure 42 illustrates a test reader that incorporates these distinguishable features.

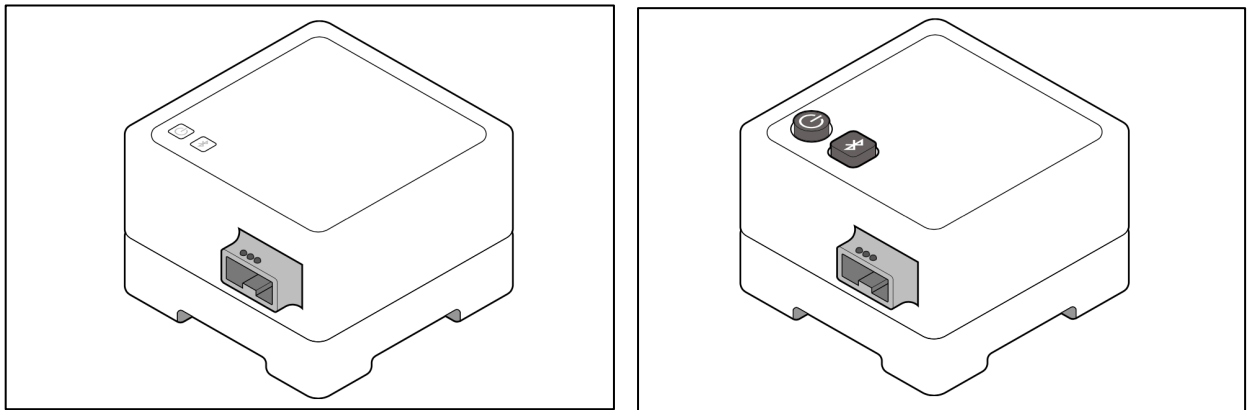

Figure 43. Challenge (left) and consideration (right) related to physical buttons on a test reader.

Challenge

Physical buttons on the test reader may be challenging to locate and activate, as illustrated in Figure 43, which shows a test reader with small button interfaces.

Consideration

To improve usability, physical buttons should be a minimum of 12.7 mm (0.5 inches) wide and spaced at least 17.8 mm (0.7 inches) center to center (39). Additionally, the features of the buttons, such as shape and edges, should be distinct. Figure 43 demonstrates a test reader with enhanced, larger button interfaces.

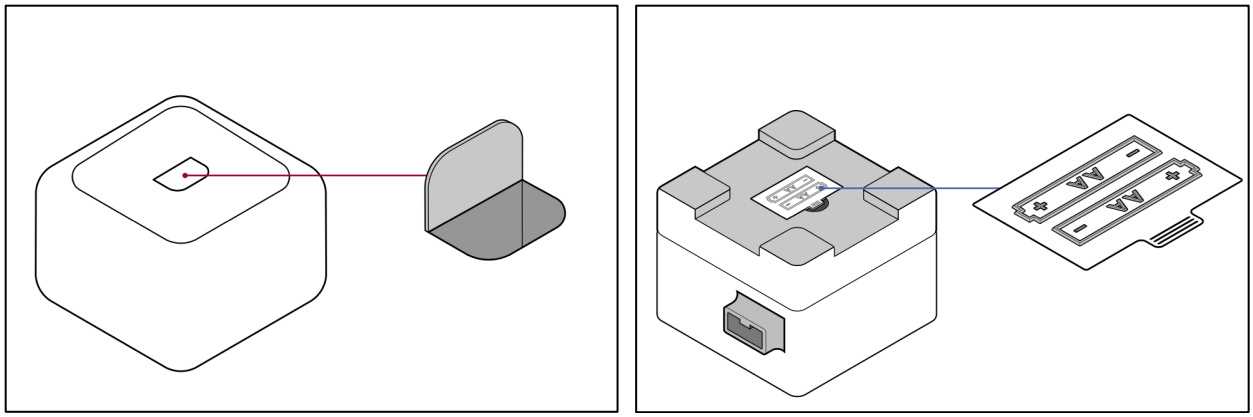

Figure 44. Challenge (left) and consideration (right) related to accessing the battery compartment.

Challenge

Test kits or instructions may not clearly indicate the location of the battery compartment, and batteries might be situated in an area that is challenging to access. If applicable, it's important to include an on-device label featuring a tactile symbol to indicate the battery location. Additionally, position the batteries in a way that allows for easy access. Figure 44 illustrates a test reader with a battery compartment that is straightforward to access. illustrates a battery compartment that is difficult to locate.

Consideration

If applicable, it's important to include an on-device label featuring a tactile symbol to indicate the battery location. Additionally, position the batteries in a way that allows for easy access. Figure 44 illustrates a test reader with a battery compartment that is straightforward to access.

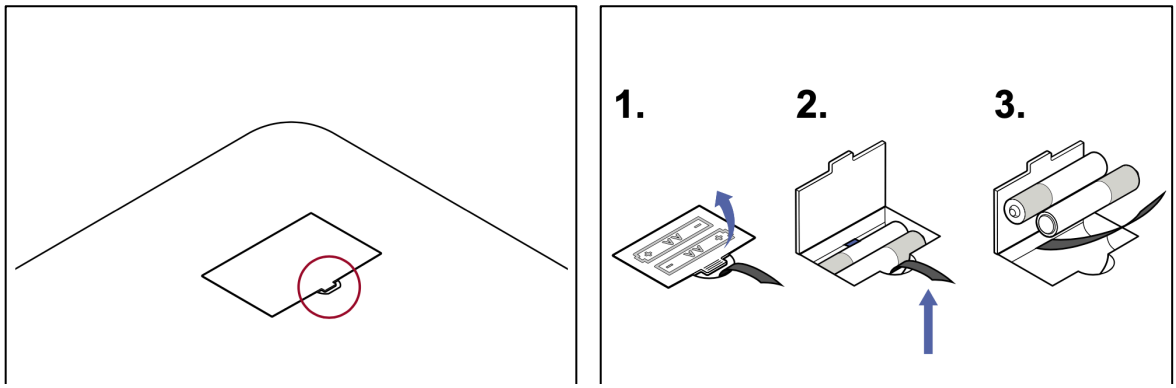

Figure 45. Challenge (left) and consideration (right) related to battery access features.

Challenge

Test kits or instructions often lack clear guidance on how to access and remove the batteries. Battery access doors can be challenging to open, especially when they feature small, hard-to-grip handles. Figure 45 depicts a battery access feature that is too small for easy manipulation.

Consideration

It is important to clearly label the battery access door to indicate the removal method, potentially using tactile features. Familiar battery removal methods should be implemented, and the design should

include elements that allow for manipulation without requiring fine motor skills, such as a pull tag or a larger divot. Figure 45 illustrates enhancements to battery access and removal features.

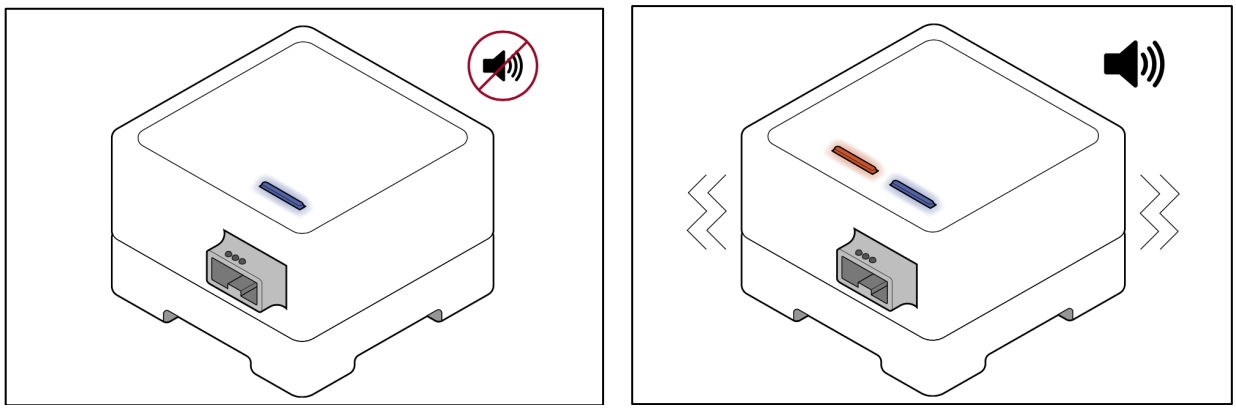

Figure 46. Challenge (left) and consideration (right) related to types of indicators for feedback on a test reader.

Challenge

Some test readers provide status updates—such as power, rechargeable battery level, and results availability—solely through visual indicators. Figure 46 demonstrates a test reader that relies exclusively on visual feedback.

Consideration

Consider incorporating nonvisual indicators, such as audible and/or haptic feedback, to communicate the test reader's status to users. If using LED lights to indicate status, multiple LEDs with spatial differentiation are preferable over a single LED that changes colors. Figure 46 illustrates a test reader equipped with visual, auditory, and haptic feedback.

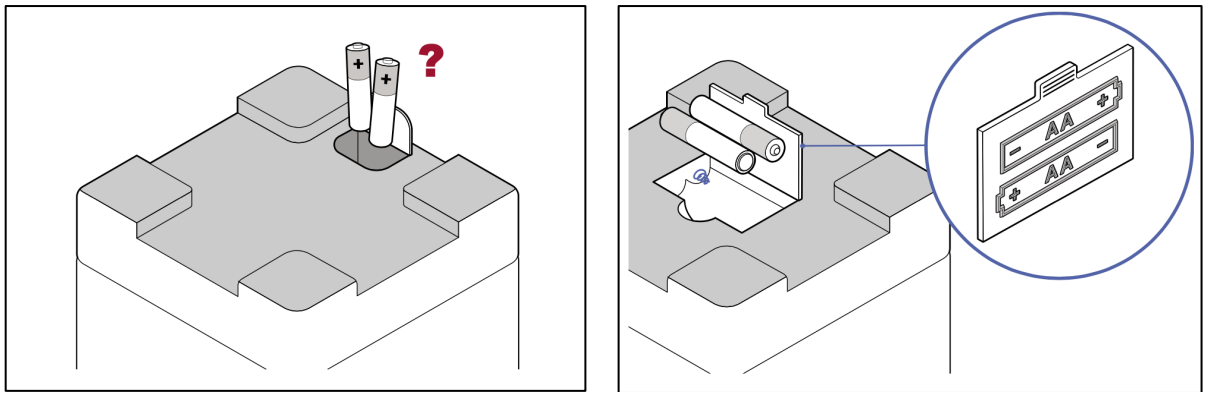

Figure 47. Challenge (left) and consideration (right) related to battery orientation cues.

Challenge

Battery-powered test readers may not provide clear guidance on the correct orientation for loading batteries, such as how to position the positive and negative terminals. Figure 47 illustrates a test reader that lacks orientation cues for battery installation.

Consideration

Consider pre-loading batteries for user convenience. Additionally, provide both visual and tactile indicators for the correct battery orientation on the access door and inside the compartment. Design

should align with common consumer mental models, such as placing the negative terminal on a spring. Figure 47 demonstrates a test reader with clear battery orientation cues.

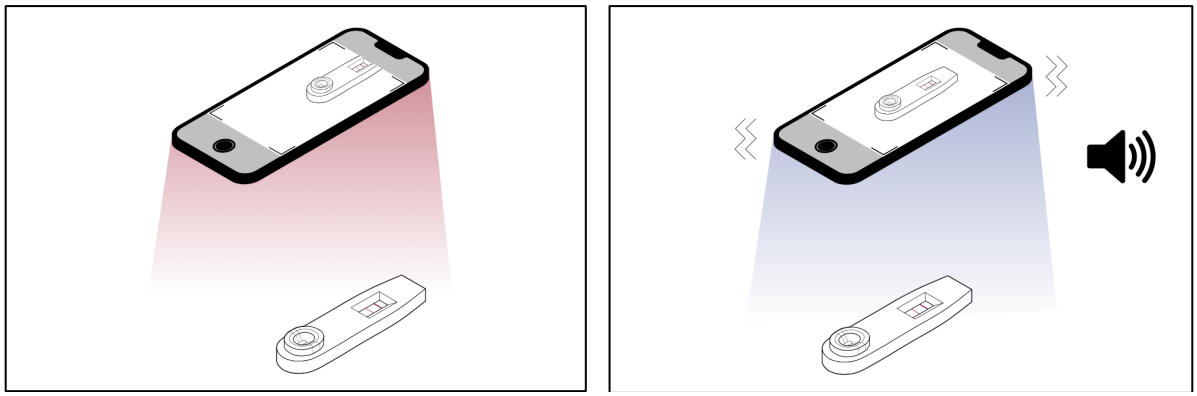

Figure 48. Challenge (left) and consideration (right) related to alignment of cassettes with smartphone-based readers.

Challenge
Smartphone-based readers often require precise placement of components, such as positioning within a camera frame, relying solely on visual cues like on-screen tracking markers. To enhance user experience, it is essential to provide auditory and haptic feedback for device positioning and camera visibility, such as messages indicating whether the test is identified or if adjustments are needed (e.g., "test identified," "failed - move closer," or "failed - increase brightness"). Additionally, incorporating automated image correction and utilizing the accessibility controls available in the native smartphone camera application can further improve usability. Figure 48 demonstrates a smartphone-based reader that is properly aligned with a test cassette. illustrates a smartphone-based reader that is misaligned with a test cassette.

Consideration
To enhance user experience, it is essential to provide auditory and haptic feedback for device positioning and camera visibility, such as messages indicating whether the test is identified or if adjustments are needed (e.g., "test identified," "failed - move closer," or "failed - increase brightness"). Additionally, incorporating automated image correction and utilizing the accessibility controls available in the native smartphone camera application can further improve usability. Figure 48 demonstrates a smartphone-based reader that is properly aligned with a test cassette.

For tests that require the user to place the cartridge or test strip on a card to interpret test results, the card should have a clipped corner so it can be oriented correctly by non-visual users. There should also be a visual and tactile outline to convey where on the card the cassette or strip should be positioned.

Challenge
Reusable test readers can accumulate dirt and grime in hard-to-reach areas, making them difficult to clean effectively.

Consideration
If the test reader is designed for reuse, it should prioritize cleanability. This can be achieved by minimizing crevices, allowing for easy wiping and maintenance.

13.7 Disposal

Challenge
Test kits often lack clear indications of which components are disposable, and they may not provide guidance on proper disposal methods, such as whether items should be discarded as household waste, recycled, or treated as hazardous waste. Additionally, devices containing batteries may not specify the necessity of removing batteries before disposal.

Consideration
Ensure that disposal labeling and instructions are clear. Additionally, if necessary, include explicit guidance for removing batteries prior to disposal.

14 Test analysis and result reporting

14.1 Bluetooth pairing

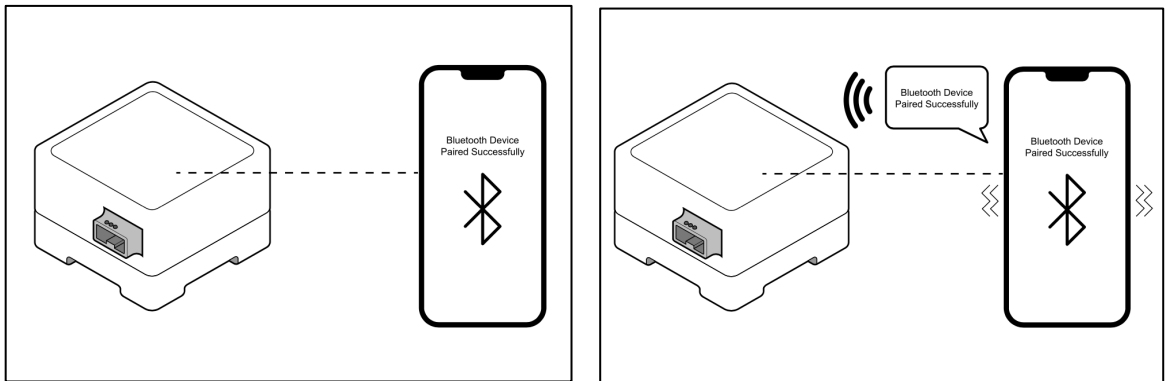

Figure 49. Challenge (left) and consideration (right) related to cues for Bluetooth pairing.

Challenge
Certain tests necessitate Bluetooth pairing between a smartphone and another device to analyze and communicate results. Common pairing methods typically offer only visual feedback regarding the pairing status. In some cases, devices must be positioned close to each other, but there is insufficient feedback to indicate whether they are within range. Figure 49 illustrates a phone connecting via Bluetooth with visual cues.

Consideration
Offer multi-modal and clear feedback on pairing status, such as audible and/or haptic signals. If devices need to be positioned at a specific distance from one another, include a feature that helps users recognize proper device placement. Figure 49 depicts a phone connecting via Bluetooth with accompanying audio cues.

Audible feedback can come from a number of sources (e.g. reader device, phone). If conveyed by the reader, voice prompts or beeps to indicate the power and pairing status can be effective. If the phone is used to convey pairing information, use the built-in accessibility tools to convey messages.

14.2 Test analysis

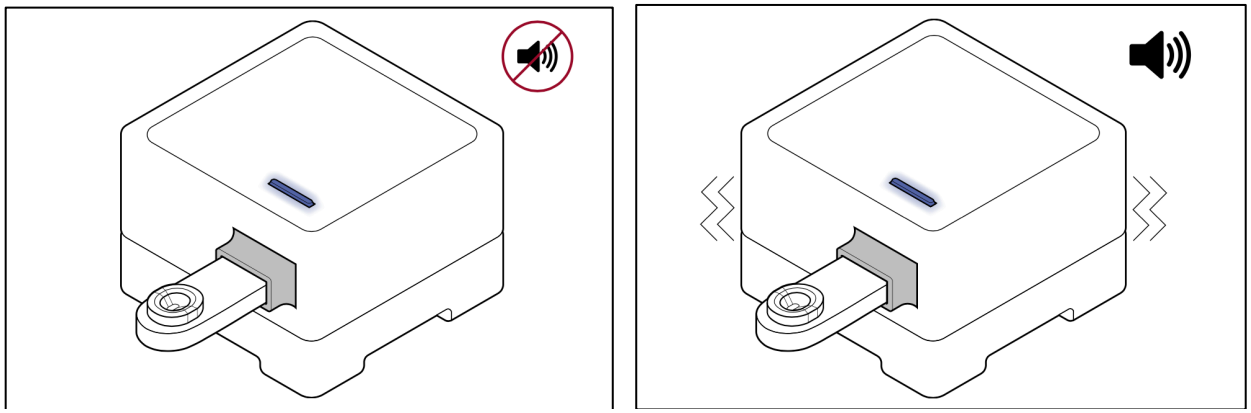

Figure 50. Challenge (left) and consideration (right) related to processing and feedback cues.

Challenge
There is no clear feedback, whether visual or otherwise, to confirm that the specimen has been successfully entered into the device and that test analysis is in progress. Most tests provide only visual confirmation once the specimen has finished processing and results are ready. Figure 50 illustrates a device that does not offer any processing cues.

Consideration
Incorporate visual, auditory, and/or haptic cues to inform users that the specimen has been successfully entered into the device and is currently being processed. Alongside visual indicators, consider including auditory and/or haptic feedback to signal when results are available. Figure 50 illustrates a device featuring both visual and auditory cues.

14.3 Results communication

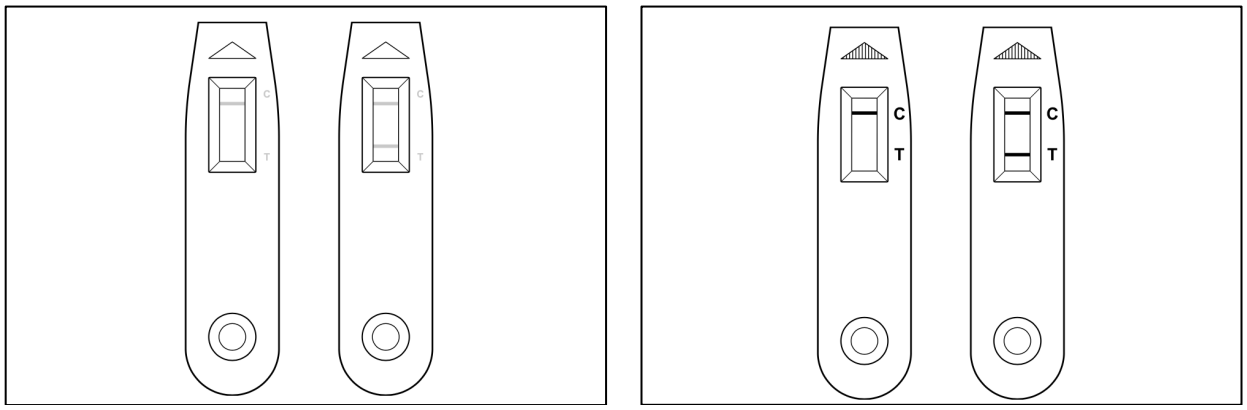

Figure 51. Challenge (left) and consideration (right) related to result lines and labeling.

Challenge
Control and/or test lines on the test strip within the cassette can often be quite faint or ambiguous. Additionally, the result labeling on the cassette may be too small or low in contrast or misaligned with the corresponding control and test lines in the results window.

Results can be displayed in a 'raw' format that may be misinterpreted by lay users (ie, 'C' indicating control could be misunderstood as 'C' indicating COVID-19).

When labeling appears in multiple orientations, users may need to rotate the cassette to read it properly.

A transparent shield over the results window can create optical difficulties.
illustrates faint result lines and unclear labeling.

Consideration
Optimize the chemistry in lateral flow assays (LFAs) to enhance the contrast and sharpness of control and test lines. Result labeling should adhere to guidelines for legibility (section 12.1), and it is important to ensure that cassette labeling aligns precisely with the positions of the control and test lines in the results window. Printing in indelible ink is preferred.

When possible, design the results status to be self-explanatory and easily interpretable without requiring a key or legend—such as spelling out "Control" and "Test" on the cassette. Abbreviations must be clearly defined in the test instructions. All cassette labeling should be oriented in the same direction. Ideally, all printing should be consistent with intended workflow with a single, unequivocal reading legend present on the right-hand side of the results window.

If the design includes a transparent shield over the result window, carefully consider how optical factors like refraction or reflection might affect the interpretation of results. Figure 51 illustrates bold result lines and clear labeling.

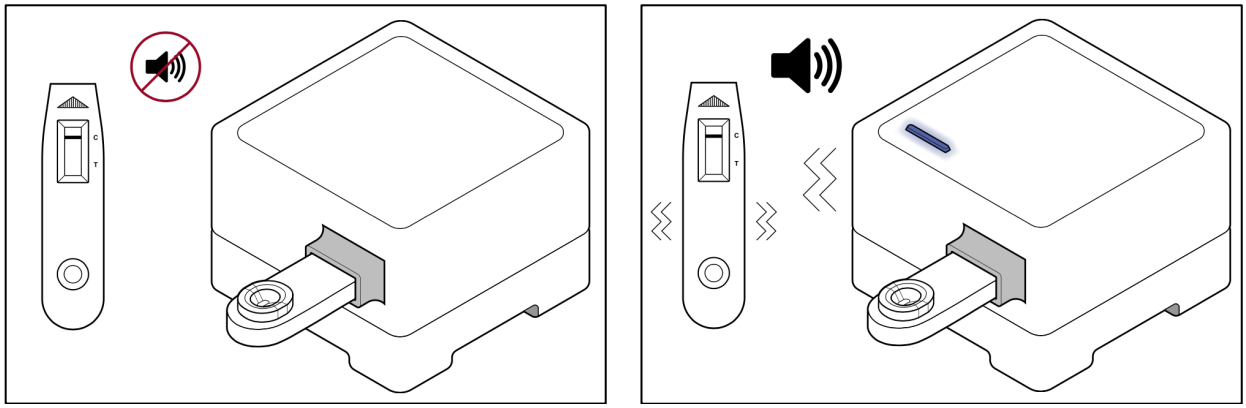

Figure 52. Challenge (left) and consideration (right) related to sensory feedback during results communication.

Challenge
Most tests primarily convey results visually. Figure 52 highlights the absence of sensory feedback.

Consideration
Consider incorporating non-visual cues, such as audible and/or haptic feedback, to convey results. Figure 52 presents options for visual, auditory, and haptic feedback.

15 Additional testing considerations

Though this document focuses on opening and performing rapid diagnostic tests, there are a number of additional critical steps that should be considered and supported, both pre- and post-test. In particular, any end users may need additional support in understanding what and when tests might be required for their care, how to handle the specimen type being considered, and how to interpret and act on the results.

Testing should always be done with informed consent from the individual.

National programmes should ensure that health care workers conducting rapid diagnostic tests are well-trained on case-finding and testing guidelines, who should be tested, any biosafety considerations for the specimen type required, how to read and interpret the test result as well as the understanding and being able to implement the required clinical follow-up(s) depending on the test result. In addition to training, job aides and other materials can support successful and reliable execution of clinical decision-making. WHO guidelines and national policies should be clearly developed indicating who should be tested, when, why, where, and how.

When considering self-testing, end users should be informed of the disease being tested for, the accuracy of the test, and any potential health associations. This could be done through national education campaigns as well as within testing materials supplied by the manufacturer. Additionally, a variety of specimen types can be incorporated for the use of rapid diagnostic tests, including urine, blood, saliva, nasal swabs, etc. Reading, interpreting, and acting upon any result are essential final steps. Suppliers should clearly note within the instructions for use how the test should be read and interpreted. Furthermore, upon receiving a test result, individuals should be provided with necessary access to the health care system and settings, if and when necessary.

Communities, families, and friends can be a support system to appropriately complete many of the test procedures and associated pre- and post-test considerations.

16 Considerations for implementing a biologically relevant internal control for rapid diagnostic tests

Traditionally, internal quality control mechanisms of rapid diagnostic tests focus on verifying the proper flow of reagents and the integrity of test components. The most common form is the control line, which typically appears regardless of the presence of the target analyte. This line confirms that the specimen has properly migrated through the test strip and that the labeled antibodies or antigens are functional. However, while this control verifies the test's basic operation, it doesn't necessarily guarantee that an adequate amount of human specimen was added.

To address the specific concern of ensuring adequate human specimen addition, more advanced quality control mechanisms can be incorporated:

1. Volume-dependent control lines: These are designed to appear only when a sufficient volume of specimen has been added. The control line could be formulated with reagents that require a minimum specimen volume to become visible.
2. Specimen-specific markers: For RDTs using human specimens, a control line could be designed to detect a ubiquitous human protein (e.g., albumin for blood tests) or human-specific anti-immunoglobulin antibodies, specific for the antibody in the particular conjugate. This would not only confirm proper test function but also verify the presence of human biological material in sufficient quantity.

Incorporating such mechanisms would significantly enhance the reliability of lateral flow tests by ensuring not just proper test function, but also adequate specimen input. This dual-control approach could greatly reduce false negatives resulting from insufficient specimen application, a common user error in point-of-care testing – both professional and self-testing.

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