



SUMMATIVE STUDY REPORT FOR LFD IFU REMOTE BASED USABILITY STUDY

26 November 2020

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Executive Summary

This report documents the results of a summative human factors study to evaluate the LFD COVID-19 virus test kit and IFU. The objective of this study is to validate that the LFD COVID-19 virus test kit and IFU is safe and effective to use by the intended user population in the intended use environment.

Due to the extremely tight time constraints this report is being generated in 3 days. As a result of this the report will not be as detailed as a conventional report. Whilst subjective data will be detailed this will be categorised into themes and will not attribute specific feedback to specific participants.

A total of n = 60 participants took part in the study (female n= 30; male n= 30). There were 4 user groups consisting of 15 participants per user group: Adolescents (aged 12-17 years old, Adults (aged 18 years and older), Adult caregivers for children (children under 12 years old) and Adult caregivers for adult dependents. The age of the participant administering the test was the age of the participant taken for the purposes of the study. Ages ranged from 12 to 78 years old, with the median age of 38 years old.

30 participants wore glasses/ contacts to read. 1 participant was colour blind. 10 participants had trouble gripping and holding objects. 14 participants had experience of using an in-home testing kit.

Participants were asked to conduct a simulated use of the LFD COVID-19 virus test kit using the IFU version 0.9.2. 18 November 2020. Participants received no training but were asked to use the IFU provided in the test kit. Participants were then asked follow up questions on their experience of using the device. Participants were asked a series of knowledge based questions and asked to refer to the instructions when answering the questions. Root cause analysis was conducted for all use problems encountered during the simulated use of the LFD COVID-19 virus test kit and for the knowledge based questions. Participants were also asked about additional support services they would want to access to assist them in using the test kit.

During the simulated use of the LFD COVID-19 virus test kit 55 participants successfully performed the test. Successfully performed the test has been defined as receiving a valid test result i.e. positive or negative test. 5 participants received an invalid test result. The reason for the invalid results may include the users putting the extraction tube fluid into the wrong part of the test strip, the user just having had a cup of coffee and also unknown cause

During simulated use of the LFD COVID-19 virus test kit the following steps encountered the most use problems:

- Clear, clean and dry a surface to place the home test kit on
- Holding the swab between your fingers, open your mouth wide and rub the fabric tip of the swab over both tonsils (or where they would have been). Do this with firm contact 4 times on each side
- Put the same swab gently into one nostril until you feel a slight resistance (about 2.5 cm for adults). Roll the swab firmly around in the inside of the nostril making 10 complete circles

During the knowledge based questioning the following questions asked encountered the most use problems:

- How often is it recommended to do the test?
- Once you have opened the test kit when should the test be started?
- What should you do if a child's symptoms are worsening?

Due to the criticality of the Covid-19 pandemic and for immediate need for mass public testing, observations from the study, leading to recommendation for IFU improvement have been incorporated into an updated version of the IFU. Recommendations and the recommended actions implemented in the new IFU Version 1.1.4 are detailed in the appendix.

1 Conclusion

End users could effectively use the LFD COVID-19 virus test kit and IFU. 55 out of 60 participants received a valid test i.e. either positive or negative. 5 participant had an invalid test.

The information in the IFU was not clear enough regarding the cleaning of the surface that would be used to prepare the test kit.

During simulated use participants found the swabbing the throat and nose the most problematic tasks to do.

Due to the criticality of the Covid-19 pandemic and for immediate need for mass public testing, observations from the study, leading to recommendation for IFU improvement have been incorporated into an updated version of the IFU. Recommendations and the recommended actions implemented in the new IFU Version 1.1.4 are detailed in the appendix.

2 Test Methodology

2.1 Background

The LFD COVID-19 virus in-home test kit is currently being developed for distribution to the general public within the United Kingdom.

A key feature in the successful undertaking of the test is the ability for users to understand the steps of use and to understand the general information contained within the IFU.

The DHSC therefore want to determine whether the IFU design enables safe and accurate test results to be achieved.

2.2 Objectives

The primary objective of this study was to validate that the LFD COVID-19 virus in-home test kit is safe and effective to use by the intended user population in the intended use environment.

2.3 Environment

2.3.1 Intended use environment

The LFD COVID-19 virus in-home test kit is intended to be used primarily in-home where standard lighting, room temperature, and noise levels are expected.

2.3.2 Study location and dates

Due to the current lockdown restrictions in the UK, this summative study was conducted as a remote study using the usability testing platform, UserZoom GO. Due to the extremely tight time constraints participants were recruited from the Cambridgeshire and Hertfordshire regions to ensure study materials could be hand delivered to participants homes guaranteeing that participants would have the necessary materials to be able to take part in the remote study. The study session were conducted from 19th November – 25th November 2020 inclusive.

2.4 Intended users

The intended users of the LFD COVID-19 virus in-home test kit are members of the general public. A self-test is expected to be performed from the age of 12. Tests on children below the age of 12 will be undertaken by an adult. Adult caregivers will also undertake the test on other adults who are unable to perform the test on themselves, Table 3.

Table 1 - Intended user groups

Intended User Groups	Experience
Adolescents (aged 12-17 years old)	Naive users to self-administer the test
Adults (aged 18 years old and above)	Naive users to self-administer the test
Adult caregivers for children	Naive users to administer the test on family members below the age of 12
Adult caregivers for adult dependants	Naive adult users to administer the test to other adults who are unable to self-test

2.5 Participants

A total of 60 participants took part in this study: 15 Adolescents (aged 12-17 years old), 15 Adults (aged 18 years and older), 15 Adult caregivers for children (children under 12 years old) and 15 Adult caregivers for adult dependents. Ages ranged from 12 to 78 years old, with the median age of 38 years old (Figure 1).

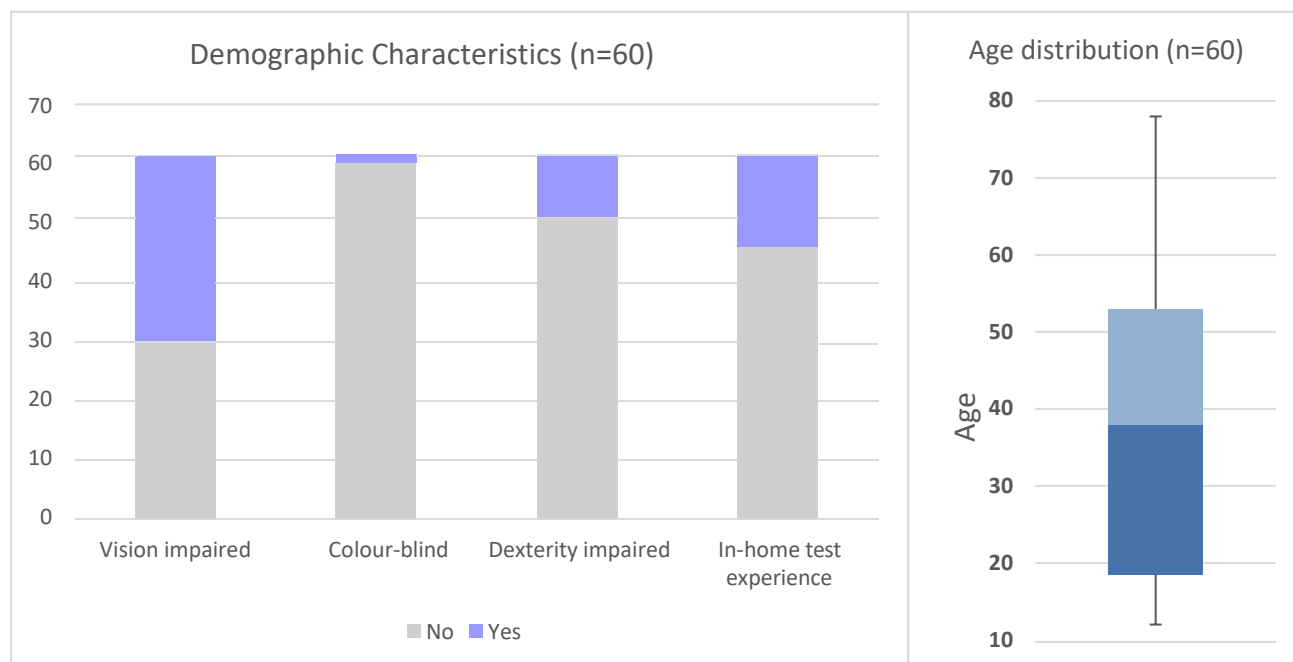


Figure 1 - Demographics

- 30 participants were male and 30 participants female.
- 30 participants wore glasses/ contacts to read. 1 participant was colour blind. 10 participants had trouble gripping and holding objects.
- 14 participants had experience of using an in-home testing kit.

One additional adult and one additional adult with child were seen due to two sets of Human factors teams working simultaneously due to the tight time constraints of this study. At the end of the 5th day it was established these two participants were surplus when the numbers for each users group were totalled. However the data for these two most recently interviewed participants has not been counted in the study results due to the requirement to stop when the quota of 15 participants was reached.

2.6 Session format

Each of the study sessions comprised a 60-minute remote based usability session.

2.6.1 Session introduction

Participants were asked to review and electronically sign the Informed Consent Form Ref Protocol ASJ-20-1313-D_A before the day of the study. After welcoming the participant, the moderator talked the participant through opening the study materials package and adjusting the webcam for optimal viewing of the session. The moderator then asked the participant questions about their personal background and experience with in-home test kits, see discussion guide ref Protocol ASJ-20-1313-D_A. The interviewer confirmed each individual's eligibility for participation and provided context for the study session.

2.6.2 Simulated use

Participants were introduced to the Covid-19 test and its purpose.

2.6.3 Simulated use steps and acceptance criteria: Adults/ adolescents self administration (taken from protocol ASJ-20-1313-D_A)

Participants were asked to imagine they had been sent the test kit and it was now time to perform the test on themselves. Participants were asked to refer to the instructions for use when conducting the test.

Table 2 details the use steps as detailed in the Protocol ASJ-20-1313-D_A.

Use Step	Acceptance criteria
Prepare your test area and check your kit contents	
Clear, clean and dry a flat surface to place the home test kit on.	Participant cleans the surface they are going to put the contents of the test kit onto and dries the surface
Wash your hands thoroughly for 20 seconds, using soap and warm water, or hand sanitiser.	Participant goes to wash hands or verbalises would wash hands. Note: Also assessed in Knowledge based questions
Take the test kit out of the foil packaging and place it onto the cleaned flat surface.	Participant unpacks contents of the test kit placing the items onto the cleaned surface.
Setup your test	
Use Step 1 Carefully twist or snap open the sachet	The user opens the sachet without spilling any of the fluid.
Use Step 2 Pour all of the fluid from the sachet into the extraction tube.	The user pours all of the fluid from the sachet into the extraction tube, without the two components touching each other.
Use Step 3 Place the filled tube in a cup or container to avoid spilling it while you use the swab	The user places the tube in a cup and does not spill any solution.
Use Step 4 Check the swab in the sealed wrapper in front of you	Note: Observing correct performance of this use step is challenging, therefore this task will be deemed a success if the user inserts the swab at the correct orientation in Use Step 8.
Use step 5 Gently blow your nose into a tissue.	Participant blows nose into a tissue.
Use step 6 Wash and dry your hands again (or use sanitiser if this is available).	Participant washes their hands.
Use Step 7 Open the swab package and gently take out the swab.	Participant opens the swab package without using any tools. Participant removes the swab from the packaging without touching the fabric/soft tip of the swab with their hand or any other surface.
Take your swab sample (or child's)	

<p>Use step 8</p> <p>Holding the swab between your fingers, open your mouth wide and rub the fabric tip of the swab over both tonsils (or where they would have been). Do this with firm contact 4 times on each side (use a mirror to help you do this). Carefully remove the swab from the back of your throat.</p>	<p>Participant opens their mouth wide and places the swab into the back of their mouth without touching any part of their mouth at this stage</p> <p>Participant rubs the fabric/soft tip of swab over both tonsils (or where they would be if they have been removed) with at least 4 observable directional movements.</p> <p>Participant removes the swab from their throat without touching any part of their mouth at this stage (not touching tongue, teeth, cheeks, gums etc)</p>
<p>Use step 9</p> <p>Put the same swab gently into one nostril until you feel a slight resistance (about 2.5cm up your nose).</p> <p>Roll the swab firmly around the inside of the nostril, making 10 complete circles.</p>	<p>Participant puts the same swab fabric/soft tip into one nostril about 2.5 cm up nostril.</p> <p>Participant rolls the swab around the circumference of their nostril in full circles at least 10 times.</p> <p>Participant then places the same swab fabric/ soft tip into the other nostril about 2.5 cm up nostril.</p> <p>Participant rolls the swab around the circumference of the other nostril in full circles at least 10 times.</p>
<p>Process the swab sample</p>	
<p>Use step 10</p> <p>Remove the extraction tube from the cup and place the fabric tip of the swab into the extraction tube so it is in the fluid.</p> <p>Press the tip against the edge of the extraction tube with force, while rotating it around the tube for 15 seconds.</p>	<p>Participant places the fabric/soft tip of the swab into the extraction tube.</p> <p>Participant presses the fabric/soft tip of the swab against the side of the extraction tube with force while rotating the swab around the extraction tube for 15 seconds.</p>
<p>Use step 11</p> <p>Pinch the tube as you remove the swab to make sure that all the fluid is removed from the soft tip of the swab.</p> <p>Place the swab in the plastic waste bag provided.</p>	<p>Participant takes out the swab whilst squeezing the extraction tube and fabric/soft tip of the swab (to squeeze as much fluid out of swab as possible).</p> <p>Participant puts the swab into a plastic bag and disposes of it into their household rubbish.</p>

<p>Use step 12 Press the nozzle cap tightly on to the extraction tube to avoid any leaks</p>	<p>Participant presses the nozzle cap tightly onto the extraction tube (to avoid leaks).</p>
<p>Use step 13 Gently squeeze the extraction tube to place 2 drops of liquid onto the specimen well on the test strip.</p>	<p>Participant tips the extraction tube to place 2 drops of liquid onto the test strip sample well.</p>
<p>Use step 14 Place the test strip on a flat and level surface Check the time or set a timer if you have one. Wait 30 minutes to read your result.</p>	<p>Participant places test strip on a flat surface</p> <p>Participant checks the time or sets timer for 30 minutes and leaves the test strip without touching it.</p> <p>After 30 minutes the participant reads the result.</p>

Table 2 – Use steps for self administration

2.6.4 Simulated use steps and acceptance criteria: Adults administering steps to a child or dependent (taken from protocol ASJ-20-1313-D_A)

Participants were asked to imagine they had been sent the test kit and it was now time to perform the test on their child/ family member. Participants were asked to refer to the instructions for use when conducting the test.

Table 3 details the variation in use steps for when adults are administering the test to a child or dependent as detailed in the Protocol ASJ-20-1313-D_A.

Use Step	Acceptance criteria
<p>Prepare your test area and check your kit contents As detailed in table x</p>	<p>As detailed in table x</p>
<p>Use Steps 1 through 7 As detailed in table x</p>	<p>As detailed in table x</p>
<p>Use step 8 (child/dependant) Ask the child to open their mouth wide, then rub the fabric tip of the swab over both tonsils (or where they would have been). Do this with firm contact 4 times on each side. Carefully remove the swab. If you cannot swab the tonsils, you can swab both nostrils.</p>	<p>Participant rubs the fabric tip of the swab over both tonsils with firm contact 4 times on each side, without touching any part of the child/ dependent’s mouth at this stage (not touching tongue, teeth, cheeks, gums etc).</p> <p>Participant removes the swab from the child/dependent’s throat without touching any part of their mouth at this stage (not touching tongue, teeth, cheeks, gums etc)</p>
<p>Use Step 9 (child/dependent) Put the fabric tip of the same swab gently into one of their nostrils until you feel some resistance. Roll the swab firmly around the inside of the nostril, making 10 complete circles and slowly remove it. If you could not swab their throat repeat in their other nostril.</p>	<p>Participant puts the fabric tip of the same swab gently into one of their nostrils</p> <p>Participant rolls the swab firmly around the inside of the nostril, making 10 complete circles and slowly removes it.</p>




	If the user could not swab the throat, they repeat in the other nostril.
Use Steps 10 through 14, As detailed in table x	As detailed in table x

Table 3 – Use steps for administering test to a child or dependent

2.6.5 Knowledge based questions

The following knowledge-based questions were asked to the adult participant who performed the test. Participants were advised they should refer to the materials available when answering the questions.

Question number	Knowledge based question	Acceptance criteria
1	How often is it recommended that you do this test?	Depends on circumstances and current national or local guidelines
2	Where can you find information on what to do if you have coronavirus symptoms or have a positive test for coronavirus?	NHS guidance online. nhs.uk/conditions/coronavirus-COVID-19
3	What are you advised to do if you have coronavirus symptoms and are deteriorating, or your symptoms last longer than a week?	User indicates one or all of following: Go online to: NHS 111 online coronavirus service, 111.nhs.uk . If you do not have internet access, call NHS 111. For a medical emergency dial 999.
4	What should you do if there is something missing or damaged in the kit?	User indicates one or all of the following: Do not use it. Call, using the numbers below, and ask for a new kit: - England, Wales and Northern Ireland: 119 (free from mobiles and landlines) - Scotland: 0300 303 2713 (charged at your standard network rate)
5	If while using the kit something breaks what in addition should you do?	Report the problem via the Coronavirus Yellow Card website, coronavirus-yellowcard.mhra.gov.uk
6	How should you ensure your hands are clean before you start using the test?	Wash your hands thoroughly for 20 seconds, using soap and warm water OR use hand sanitiser
7	Once you have opened the test kit when should the test be started	Within 30 minutes

8	What should you do if you touch the swab with your gum?	Get a new swab.
9	How long should you wait before reading the test result?	30 minutes.
10	What should you do if you leave the test to develop but get distracted and only come back to looking at the test after 1 hour?	If you leave the test to develop for longer than 35 minutes this will make the test result invalid.
11	<p>What does this test result indicate:</p> 	Two lines – even faint lines – indicate the test is positive.
12	<p>What does this test result indicate:</p> 	The test is invalid
13	<p>What does this test result indicate:</p> 	This indicates the test is negative.
14	How should you report a positive result?	<p>Answers can include:</p> <p>Report online www.gov.uk/covid19-self-test-help/</p> <p>Or scan this QR code with your smart phone to open the reporting website</p> <p>Report by telephone</p> <p>England, Wales and Northern Ireland: 119 (free from mobiles and landlines)</p> <p>Scotland: 0300 303 2713 (charged at your standard network rate)</p>

15	What should you do if a child's symptoms are worsening?	Visit NHS online www.111.nhs.uk or call 111
16	How should the test kit be disposed of after using?	Put all of the used test kit contents in the waste bag provided and place in your household waste

Table 4 – Knowledge based questions

2.6.6 Root cause analysis

Once participants had completed the simulated use, the moderator conducted follow-up questioning to investigate the root cause of any use errors, use difficulties, or close calls for the simulated use sessions and knowledge-based/scenario-based questions.

2.6.7 Subjective feedback

Participants were asked for their views on what could be improved with the IFU and testing process.


2.6.8 Debrief

After the interview the moderator thanked the respondent and concluded the interview.

2.7 User interface

Table 5 details the study material used.

In addition, participants were also sent a webcam to set up prior to the start of the session to enable an optimal view of the participant(s) and the table area they were using to perform the test.

Study material	Image	Description of study material
IFU		A5 IFU booklet Version 0.9.2
Test kit pack		LFD COVID-19 virus in-home test kit Clear Ziploc bag containing a swab, test strip in foil packaging, extraction tube, nozzle cap, extraction buffer sachet. Clear Ziploc bag also served as the waste bag.

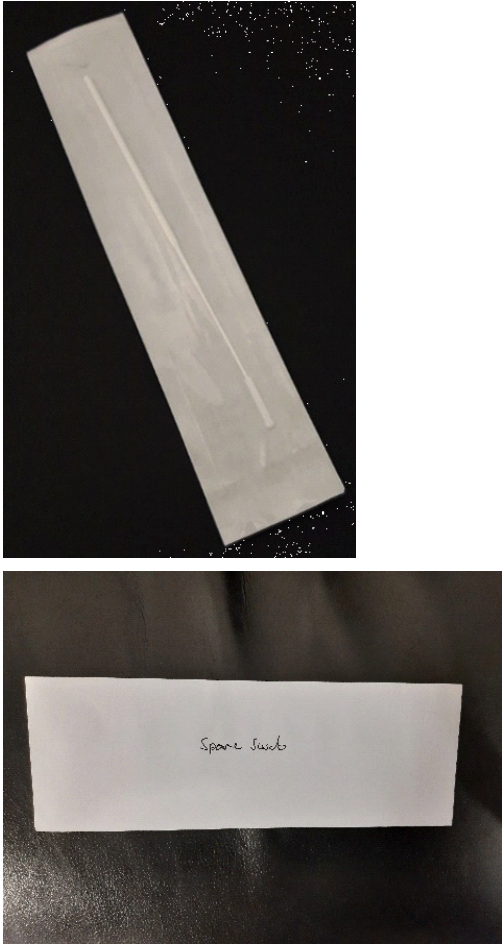

<p>Spare swab</p>		<p>Participants were also provided with a spare swab in an envelope labelled spare swab.</p>
<p>Hand sanitizer</p>		<p>Participants were provided with a bottle of hand sanitizer</p>

Table 5 – User interface

2.8 Data collection methods

All sessions were conducted remotely using the usability testing platform, Go Zoom. There were 2 sets of Human Factors teams conducting the study due to the tight time constraints. Study personnel included the 2 study moderators, who facilitated the study and interviewed the users, and 2 study observers, who observed the sessions. Study data was captured by the observer and directly inputted into the raw data file on an Excel spreadsheet. Video reviews were conducted where necessary to verify any results. The moderator took notes during the simulated use task on their moderator discussion guide to assist with root causing following the simulated use and knowledge-based questioning.

The following data was captured during each session:

- Task performance for each task (successes, use errors, close calls and use difficulties)
- Participant-reported root causes for use errors, close calls, and use difficulties.
- Users comments (non-verbatim)
- Users responses to subjective and open-ended questioning posed during the post-task interviews

- Moderator and observer observations

Outcome	Definition	Root Cause Investigation Required?	Method of Scoring Data
Success	Participant performs the task correctly on the initial attempt without assistance	No	Success Close Call Use Error N/A
Close Call	Any instance in which a participant makes a use error that could result in harm, but then takes an action to recover that prevents the harm from occurring.	Yes	Success Close Call Use Error N/A
Use Error	Any action or lack of action while using the system that leads to a different result than that intended by the manufacturer or expected by the user, including: <ul style="list-style-type: none"> A participant's inability to complete a task; A deviation from the IFU that leads to a device response that is different than intended by the manufacturer or expected by the participant; An instance where the participant requires assistance from study personnel to advance through tasks. <p>The following will not be considered use errors:</p> <ul style="list-style-type: none"> A malfunction of a medical device that causes an unexpected result; and Deviation from the IFU that does not lead to a device response that is different than intended by the manufacturer or expected by the participant (e.g., sub-steps are performed in a different order than listed in the IFU, but in an order that still allows successful progression to the subsequent tasks). 	Yes	Success Close Call Use Error N/A
Use Difficulty	Any observed difficulty on the part of the user while using the device, which does not result in a use error, but points to an underlying usability concern with the device's design, accompanying documentation, labelling, packaging, or training. Examples include (but are not limited to): <ul style="list-style-type: none"> The user verbally expresses frustration or facial expressions and body postures indicate frustration when using the device; The user re-reads the same section of the IFU during a task, in an attempt to comprehend a sequence of steps to take with the device; and The user is unable to apply the required amount of force to accomplish a task or 	Yes	Yes/No This metric is collected <u>in addition to</u> the observational score of Success/Close Call/Use Error

	step with the device, but experiences frustration or discomfort in the process of doing so.		
N/A	<p>If a task cannot be completed for a reason out of the control of the participant, the task should be scored as N/A. While root cause investigation is not required, notes need to be collected to indicate the reason for scoring N/A. N/A category use errors are not included in the success rate.</p> <p>Some examples include:</p> <ul style="list-style-type: none"> • System failure • Not enough time to complete all tasks • Use error by propagation (a user was unable to complete a task due to a prior use error). 	No	Success Close Call Use Error N/A
IFU=instructions for use; N/A=not applicable			

Table 6 – Outcome definitions

2.9 Study recording process

All sessions were conducted using the remote usability testing platform Go Zoom and session were recorded in Go Zoom. The video data was then transferred onto external encrypted hard drives in line with PA’s standard operating procedures for recording and storing participant video data.

2.10 Study deviations

Due to the tight time constraints and lack of clinical input, the acceptance criteria were generated purely on a common sense approach adopted by the PA Human Factors team in response to reviewing the IFU. Due to this a number of acceptance criteria needed updating during the study.

Affected Article	Deviation Description	Justification
Task acceptance criteria	It was deemed a Success if participants removed all the test kit items out of the clear plastic bag and opened the foil package before needing to use the test strip.	“Take the test kit out of the foil packaging” as detailed in the IFU is an incorrect statement. Should read take the test strip out of the foil package. Hence this task was adjusted to remove the test kit items from the clear bag and the success criteria aligned to this.
Task acceptance criteria	It was deemed a Success if a participant performing the test handed the extraction tube to the other person (dependent or child) to hold and this was done safely	Due to the small size of the extraction tube some participants were unable to find a small container to safely put the extraction tube to keep this upright.
Task acceptance criteria	It was deemed a Success if a participant safely squeezed all of the fluid from the sachet into the extraction tube, even if they touched the sachet against the extraction tube.	The risk associated with touching the sachet against the tube was deemed minimal as this was a single use sachet. The instruction to avoid touching against the tube referred to the extraction bottle that was originally to be used which is designed for multiple usage and could be contaminated from repeated use.

Task Acceptance Criteria	Use step 6: wash and dry your hands again (or use hand sanitizer if this was available). If a caregiver and dependent/child were involved this was deemed a Success if either both re-sanitized hands or the caregiver only, as long as the child/ dependent did not interact with any elements of the test kit after blowing their nose.	This acceptance criteria was written originally based on self administration. Resanitization was required to ensure no contamination of the kit occurred.
Number of participants	1 additional adult participant and 1 additional adult with child pair of participants were seen. However the data for these 2 participants was not counted	Due to this being a summative study 15 users per user group were required. Two human factors teams were conducting interviews simultaneously due to the tight time constraints. At the end of the 5 th day it was established these 2 participants were surplus when the numbers for each users group were totalled for that day.
Materials Available	Replacement participants were sent a mocked up box with an extraction tube holder set within the box to assist users with the task of putting the extraction tube in a secure place	To gather feedback on the extraction tube holder which was developed during the fieldwork phase of the study (as a result of participants having issues with finding suitable containers to use to keep the extraction tube upright

Table 7 – Study deviations

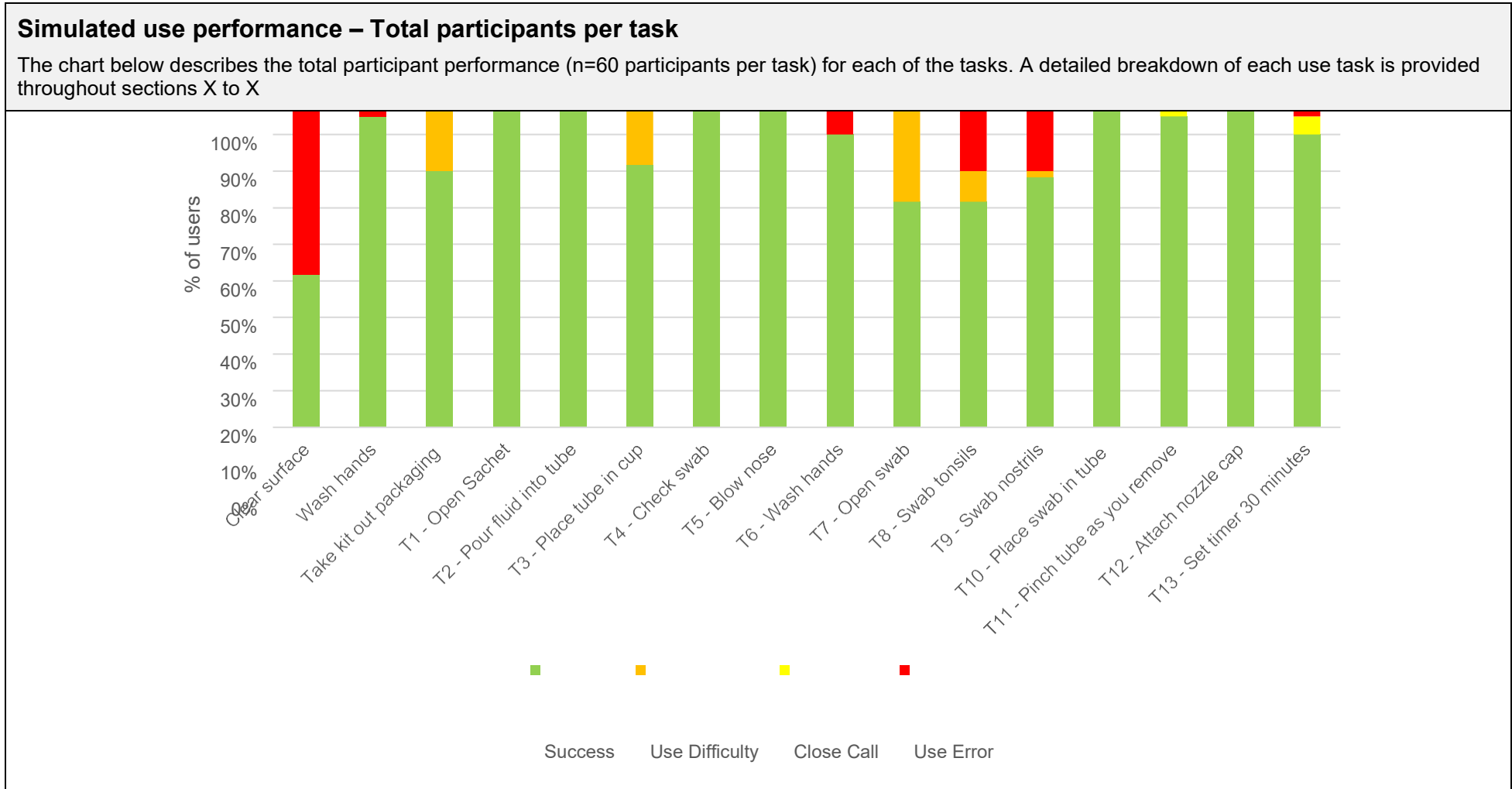
3 Results

The following sections present all use errors, close calls, and use difficulties that were observed during the simulated use and knowledge question tasks. Any subjective user feedback from participants has been analysed and presented thematically.

3.1 Overall task performance

Overall, there were a total of 960 data points analysed for the 16 tasks completed by the 60 participants. Total task performance is provided below in Figure 2. Section 3.2 provides a breakdown of performance on each task.

Figure 2 – Breakdown of simulated use task performance



3.2 Breakdown of task performance

Preparation: Clear, clean, and dry a flat surface to place the home test kit on

Summary

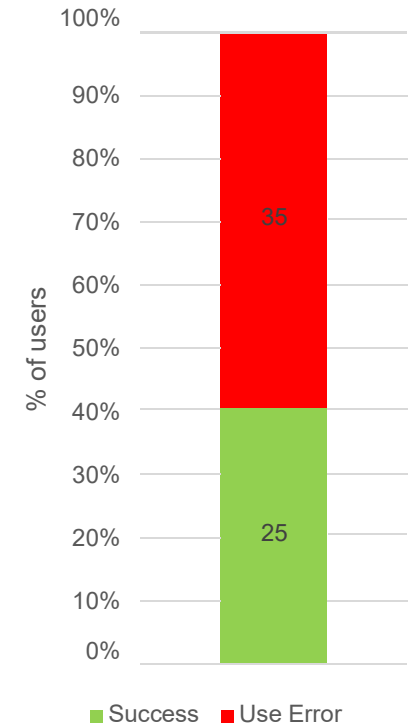
- 35 out of 60 (58%) users committed use errors on this step.

Use Errors:

- The most prevalent use errors were omitting the step completely.

Root Cause(s)

- **IFU Design:** Users stated that they did not see this step within the IFU due to the lack of colour in this step compared with the step below (wash hands) which does have colour, lack of boldening or highlighting of the information, and unclear imagery. Users recommended to include a spray bottle to convey the information better.
- **Study Artefact:** Users stated that they had already cleaned their surface before starting the study, or were conducting the study on a non-sanitisable surface (e.g. antique desk) due to the requirement to be in front of a laptop for the study.



Preparation: Wash your hands thoroughly for 20 seconds using soap and warm water, or hand sanitiser

Summary

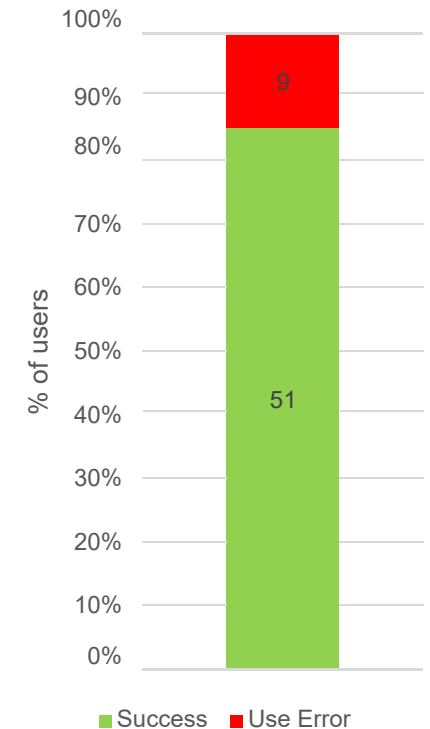
- 9 out of 60 (15%) users committed use errors on this step.

Use Errors:

- The most prevalent use errors were either omitting this step completely, or washing their hands in the wrong order (i.e. before they cleaned the surface, or after they had already handled the kit components).

Root Cause(s)

- **IFU Design:** The order of steps within the IFU led to some users removing the components from the kit before washing their hands. Users stated that this information should be at the very beginning of the instructions before you interact with anything else. Furthermore, the lack of step numbering during the preparation stages led some users to skip straight to the main use steps.



Preparation: Take the test kit out of the foil packaging and place it onto the cleaned flat surface

Summary

- 5 out of 60 (8%) users committed use errors on this step.
- 13 out of 60 (22%) of users had difficulty conducting this step

Use Errors:

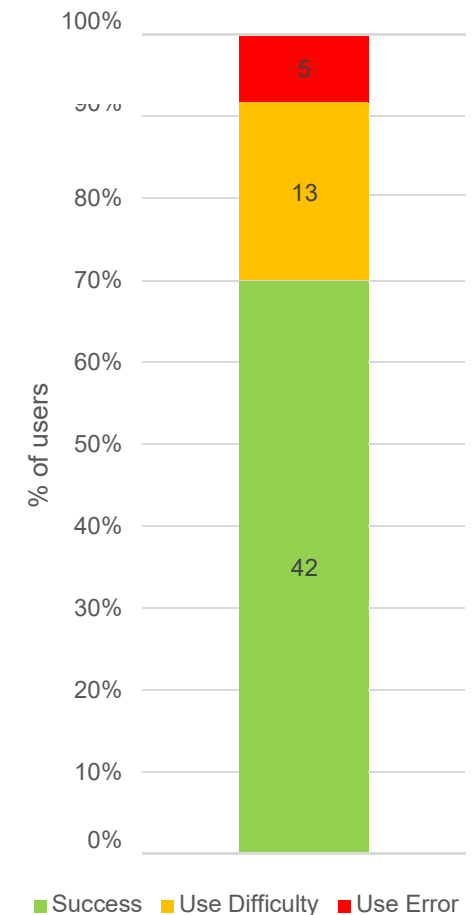
- The most prevalent use errors were users not being able to locate the test strip, and dropping components when removing from the packaging.

Use Difficulties:

- Similarly to use errors, those who experienced difficulties usually did so when trying to identify and locate the test strip.

Root Cause(s):

- **IFU Design:** The section of the instructions which shows the contents of the kit show the test strip out of its packaging which led to confusion. Users also stated that the wording 'foil' does not match their expectation with what the test strip packaging looks like. Participants were expecting a metallic package.
- **Packaging Design:** The wording on the test strip packaging is small, and inconsistent with the verbiage in the IFU. The IFU describes the test strip as a 'strip', whereas the packaging describes it as a test 'cartridge'. This led to confusion for some users.



Use step 1: Carefully twist or snap open the sachet

Summary

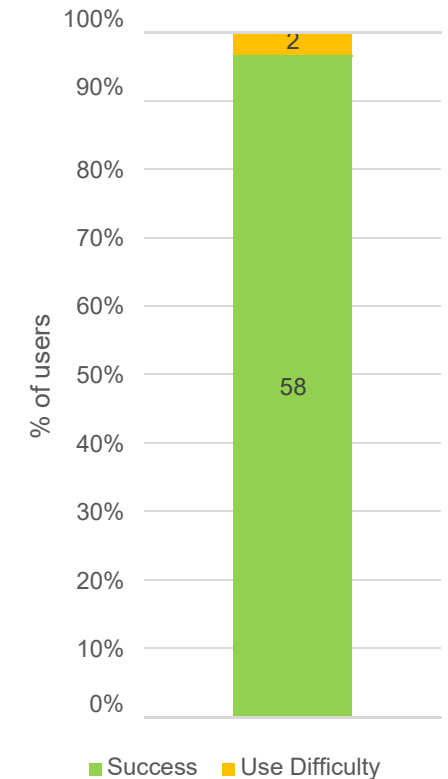
- 2 out of 60 (3%) users experienced difficulties on this step.

Use Difficulties:

- One user required scissors to open the sachet due to the force required.
- One user had difficulty in identifying the sachet, and initially thought that the foil packaging was the sachet.

Root Cause(s):

- **Sachet Design:** The force required to open the sachet was too high for one user. Note: This user has impaired manual dexterity due to arthritis, and stated that she uses scissors to open most packaging in her life.
- **Mental Model:** One user's mental model resulted in them not thinking that the foil packaging looked like a sachet to him, therefore he went to open that first.



Use step 2: Pour all of the fluid from the sachet into the extraction tube

Summary

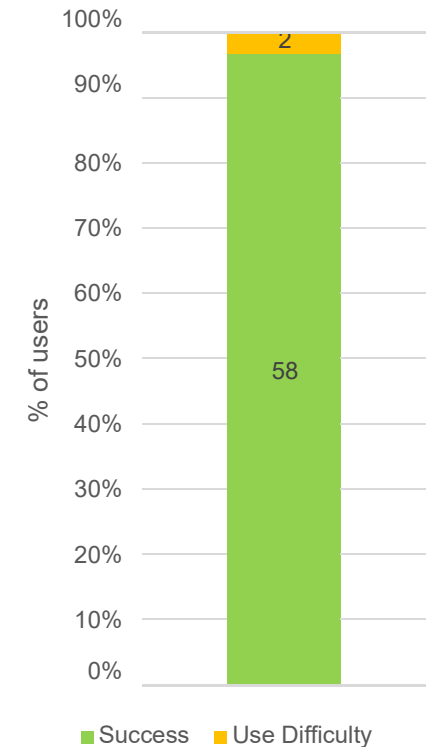
- No users committed use errors in this step.
- 2 out of 60 (3%) users had difficulty conducting this step.

Use Difficulties:

- One user stated that the force required to squeeze the liquid out was high
- One user spilled some liquid from the sachet when squeezing.

Root Cause(s):

- **Sachet Design:** The force required to push the liquid out of the sachet was high for one of the users.
- **Sachet Design:** One user was able to remove the cap from the sachet without difficulty, however due to the design of the sachet, a clean break in the seal was not achieved, therefore some of the liquid spilled when he tried to pour it into the extraction tube.



Use step 3: Place the filled tube in a cup or container to avoid spilling it while you use the swab

Summary

- 3 out of 60 (5%) users committed use errors in this step.
- 2 out of 60 (3%) users committed close calls in this step
- 12 out of 60 (20%) users experienced difficulty conducting this step.

Use Errors:

- The most prevalent use errors were users dropping the tube when trying to place it into a cup.

Close Calls:

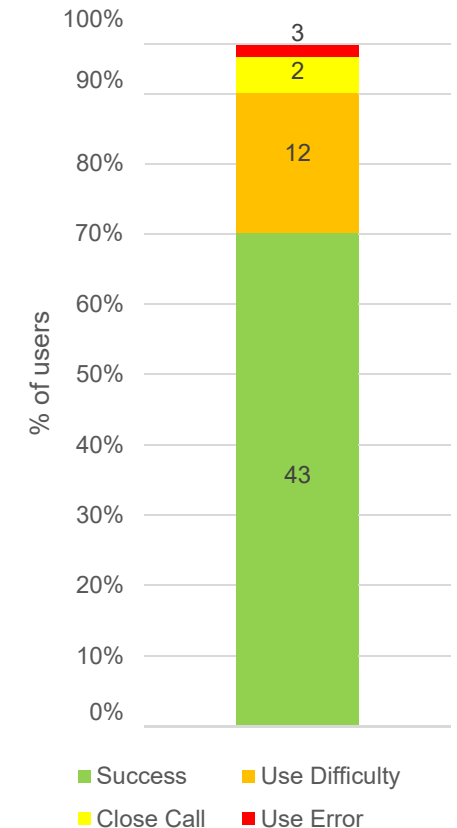
- The most prevalent close calls were users almost committing the use error of dropping it when trying to place it into a cup, but rescuing it before it dropped.

Use Difficulties:

- The most prevalent use difficulties were users not being able to find an appropriate cup size or shape to fit the tube, resulting in delays in the process and frustration from the users.
- Users also did not see the requirement to gather a cup at the beginning of the process, leaving them to find a cup whilst they had the filled extraction tube in their hand.

Root Cause(s):

- **Extraction tube design:** The size of the extraction tube is too small to fit in standard household cups/mugs. The base of the extraction tube is rounded, therefore is unable to support itself when placed into a cup or on a flat surface.
- **IFU Design:** The section stating to gather a small cup is not prominent enough in the instructions, and users stated that an illustration showing the cup within that section of the instructions would be beneficial. The wording within the IFU states to gather a 'small cup'. Users stated that this language is misleading because even a 'small' cup in their minds would not be suitable for the tube. They suggested that wording such as 'egg-cup or similar size' would help them in identifying a suitable vessel.



Use step 4: Check the swab in the sealed wrapper in front of you

Summary

- 4 out of 60 (6%) users committed use errors in this step.
- 2 out of 60 (3%) users committed a close call in this step.

Use Errors:

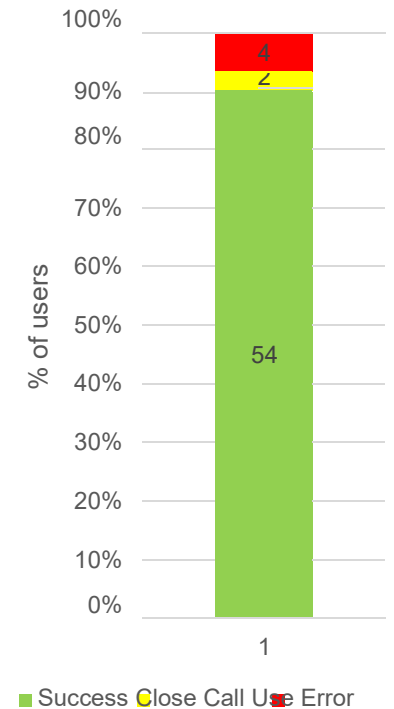
- The most prevalent use errors were users opening the swab at this stage.

Close Calls:

- Close calls on this step related to users almost opening the swab at this step then correcting themselves.

Root Cause(s):

- **IFU Design:** Users who opened or almost opened the swab packaging at this stage did so because the sequence of steps in the IFU led them to do so. The users assumed that because they were being asked to check the swab, this meant that they would then be asked to open the swab. It was not until later in the process that they saw the instruction to open the swab that they realised their mistake.



Use step 5: Gently blow your nose

Summary

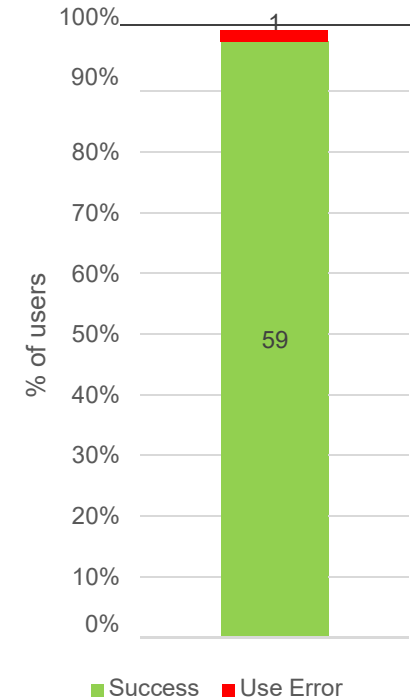
- 1 out of 60 (1%) users committed use errors in this step.

Use Errors:

- One user (caregiver) blew her nose instead of her dependent's.

Root Cause(s):

- **IFU Design:** The user stated that the instructions aren't clear as to who should blow their nose if a caregiver is administering the test to a dependent.



Use step 6: Wash and dry your hands again (or use sanitizer if this is available)

Summary

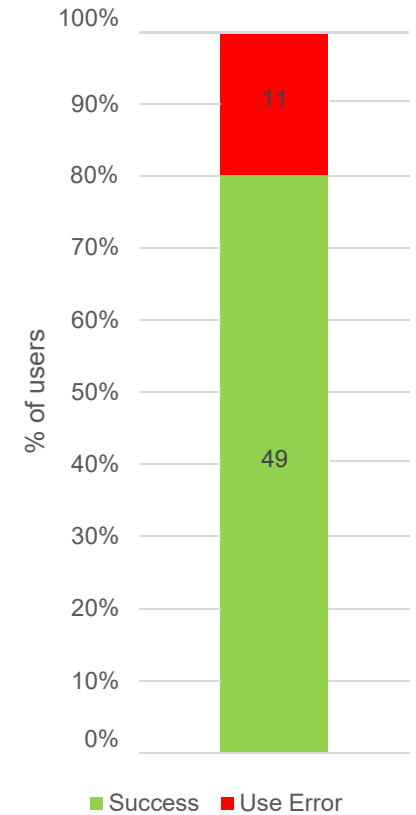
- 12 out of 60 (20%) users committed use errors in this step.

Use Errors:

- The most prevalent use errors occurred during caregiver/parent administration, where users either washed their dependent's hands again, or their own hands again, but not both of their hands again.

Root Cause(s):

- **IFU Design:** User stated that the instructions aren't clear as to who should wash their hands again if a caregiver is administering the test to a dependent.



Use step 7: Open the swab package and gently take out the swab

Summary

- 3 out of 60 (5%) users committed use errors in this step.
- 3 out of 60 (5%) users committed close calls in this step
- 18 out of 60 (30%) users experienced difficulties in this step.

Use Errors:

- Two of the three use errors related to opening the swab package at the wrong end, however the users did not touch the fabric tip when doing so. One of the use errors was attributed to a user not being able to open the swab package without the use of scissors. Note, this user suffers with arthritis in the hands and stated that she frequently uses scissors to open packages in real life.

Close Calls:

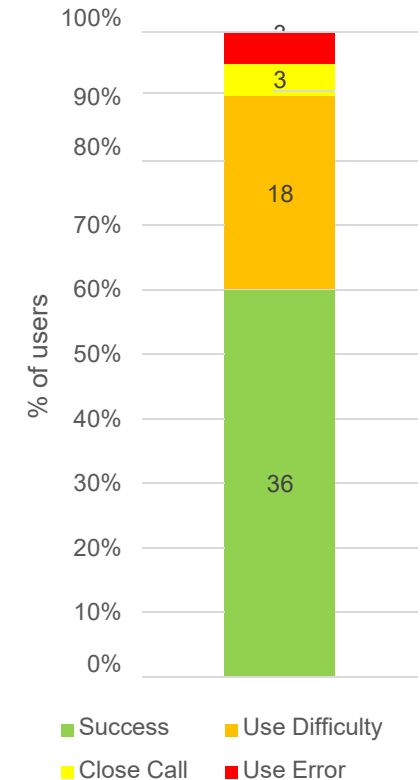
- Close calls on this step related to users almost opening the swab at the wrong end, then correcting themselves, and a user opening it at the incorrect end but realising her mistake immediately after she had opened it.

Use Difficulties:

- The most prevalent use difficulties occurred when participants took a long time to open the packaging, and often showed frustration in doing so.

Root Cause(s):

- **Swab packaging design:** The label 'peel here' on the swab packaging was said to be too small by numerous users, causing them to not see it at all. Furthermore, the peelable area on the packaging was also too small and difficult to separate, resulting in users tearing the package to remove the swab instead of using the intended peel method.



Use step 8: Swab the tonsils (self-administration and caregiver/parent administration)

Summary

- 4 out of 30 (13%) **self-administrating** users committed use errors in this step.
- 14 out of 30 (47%) **caregiver/parent** administrating users committed use errors in this step.
- 2 out of 30 (6%) **self-administrating** users experienced difficulties with this step.
- 3 out of 30 (10%) of **caregiver/parent** administrating users experienced difficulties with this step.

Use Errors:

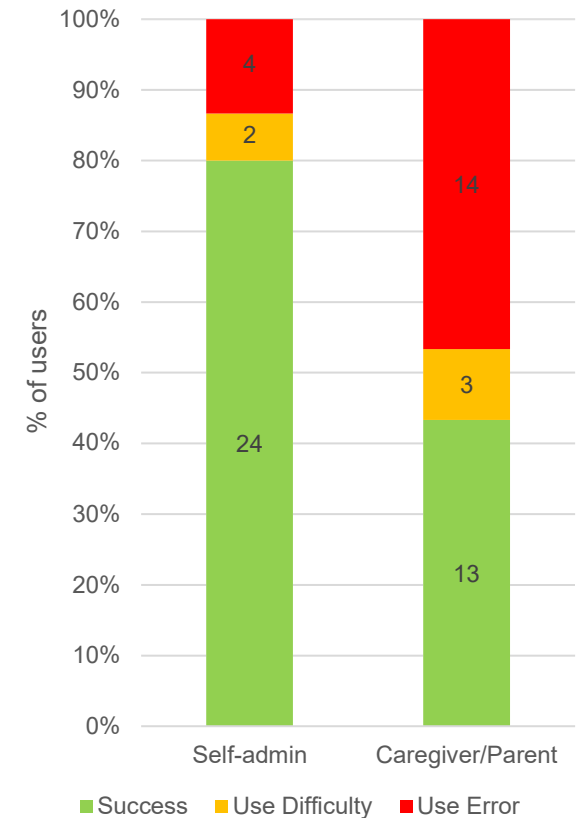
- The most prevalent use errors for all user groups were that users did not swab the required number of times; users touched tongue when swabbing. Touching the tongue was especially prominent for those administering it to a dependent. Some younger children showed great distress during the process, with the parent either giving up, or the moderator stepping in to stop the process.

Use Difficulties:

- From those who were administering to dependents, difficulty in keeping the tongue out of the way was expressed. For those who were self-administering, locating the tonsils proved difficult for two users.

Root Cause(s):

- **Kit design:** The requirement to not touch the tongue, without offering any way for the user to keep the tongue out of the way led many users to touch the tongue. Users who were administering the test kit to a dependent stated that offering a wooden tongue depressor would be very beneficial in reducing the risk of touching the tongue.
- **IFU Design:** The wording which directs parents to swab both nostrils if they cannot access the tonsils is located poorly, leading most parents to miss that advice.
- **IFU Design:** The wording in the swab section which states how many times to swab is currently lost within the bulk of the text, causing some users to miss the information. Furthermore, the image within this step shows 'x4'. This led users to think that they needed to swab 4 times total (2 on each), instead of 8 times total.



Use step 9: Swab the nostrils (self-administration and caregiver/parent administration)

Summary

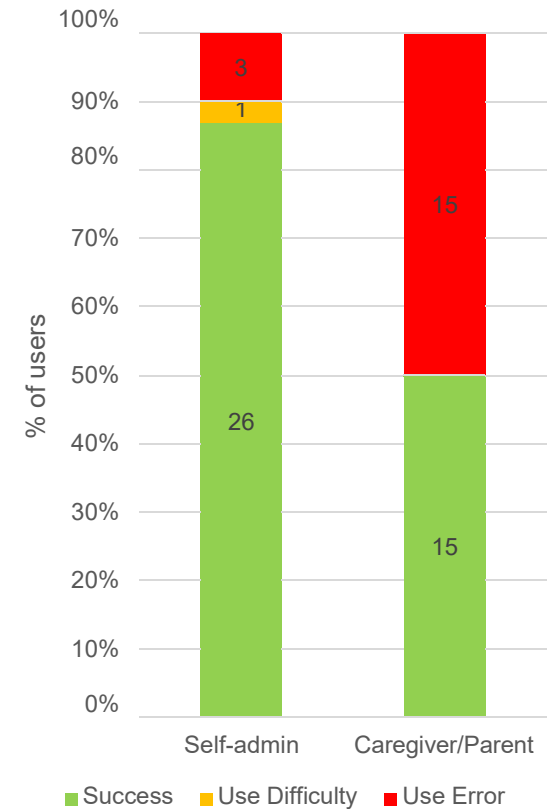
- 3 out of 30 (10%) self-administrating users committed use errors in this step.
- 15 out of 30 (50%) caregiver/parent administrating users committed use errors in this step.
- 1 out of 30 (3%) self-administrating users experienced difficulties with this step.

Use Errors:

- The most prevalent use errors occurred with parents administering to children. Many younger children tended to recoil and show distress when receiving the swab in the nostril, resulting in the parents giving up or not fully complying with the correct process. Some users also did not see instruction to swab both nostrils if they could not swab the tonsils. Other use errors included not doing 10 complete circles, or not going far enough up the nose.

Root Cause(s):

- **Device Design:** The process of swabbing the nostril in itself is discomforting to younger users who aren't able to self-administer.
- **IFU Design:** The wording which directs parents to swab both nostrils if they cannot access the tonsils is located poorly, leading most parents to miss that advice.



Use step 10: Place the fabric tip of the swab into the extraction tube and rotate for 15 seconds

Summary

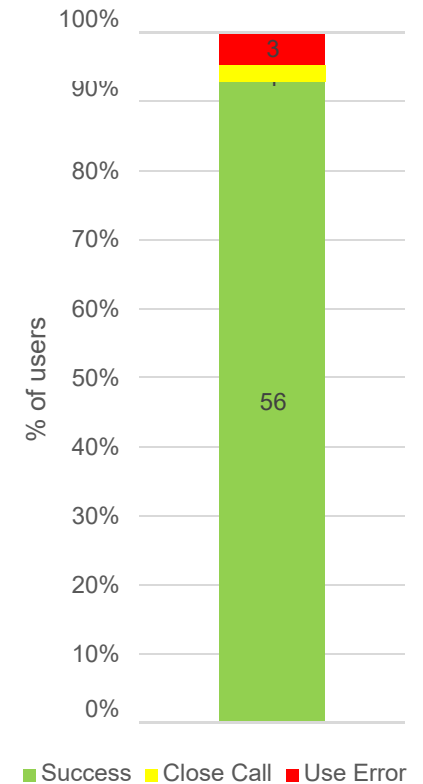
- 3 out of 60 (5%) users committed use errors in this step.
- 1 out of 60 (2%) users committed close calls in this step.

Use Errors:

- All user errors were attributed to users rotating for less than 15 seconds.

Root Cause(s):

- **IFU Design:** Two users stated that the IFU is not clear enough in conveying the 15 seconds, due to a lack of boldening of the step, and also the 15 second wording being missed as it is close to the Use Step numbering within the IFU.
- **Mental model:** One user stated that they knew to do 15 seconds and believed they did, however they counted too quickly in their head and therefore mistimed the 15 seconds.



Use step 11: Pinch the tube as you remove the swab to make sure that all the fluid is removed from the soft tip of the swab

Summary

- 7 out of 60 (12%) users committed use errors in this step.
- 2 out of 60 (3%) users committed close calls in this step.

Use Errors:

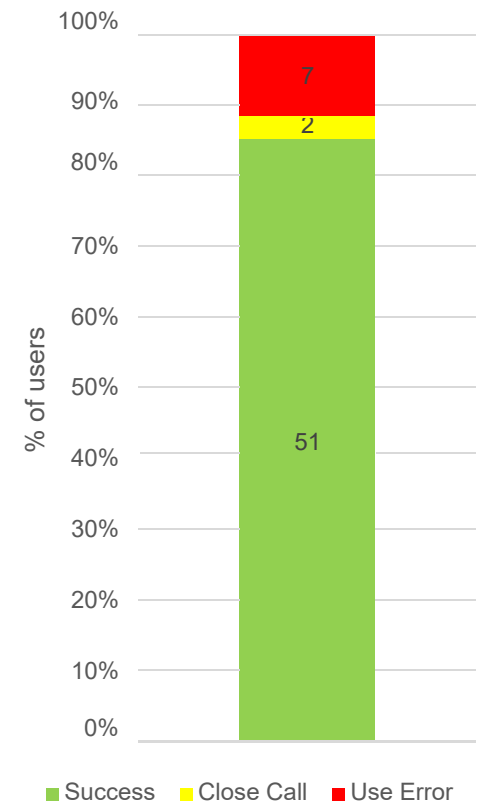
- The most prevalent use errors were users not pinching the tube when removing the swab, and some users disposing of the swab straight into the household waste without placing it into the disposal bag.

Close Calls:

- Close calls occurred twice when two participants removed the swab from the tube without pinching, then realised their mistake and put it back in to pinch.

Root Cause(s):

- **IFU Design:** Two users stated that the IFU is not clear enough in conveying the requirement or correct method to pinch.
- **IFU Design:** The direction to place the swab into the disposal bag is not boldened, which led to this step being omitted.



Use step 12: Press the nozzle cap tightly on to the extraction tube to avoid any leaks

Summary

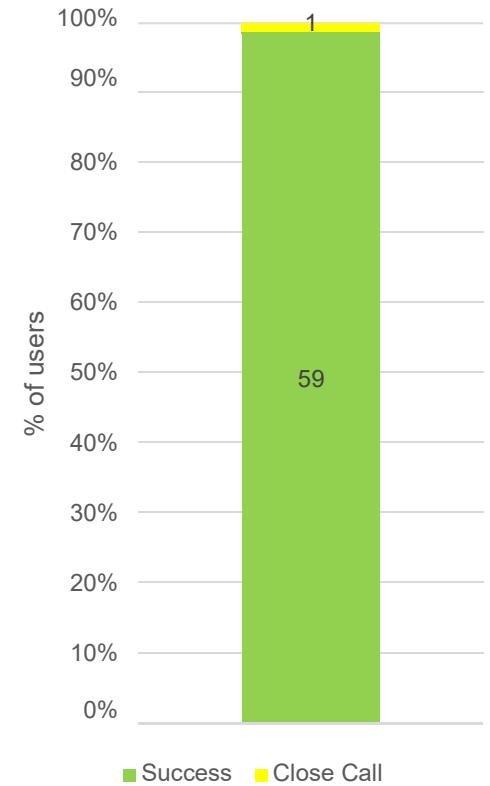
- No users committed use errors in this step.
- 1 out of 60 (2%) users committed close calls in this step.

Close call:

- One user attempted to place the cap on upside down but quickly realised their mistake and recovered.

Root Cause(s):

- **Slip:** User stated that it was a slip of the mind and that there was nothing related to the design of the component or the instructions which led her to make the mistake.



Use step 13: Gently squeeze the extraction tube to place 2 drops of liquid onto the specimen well on the test strip

Summary

- 9 out of 60 (15%) users committed use errors in this step
- 3 out of 60 (5%) users committed close calls in this step.

Use Errors:

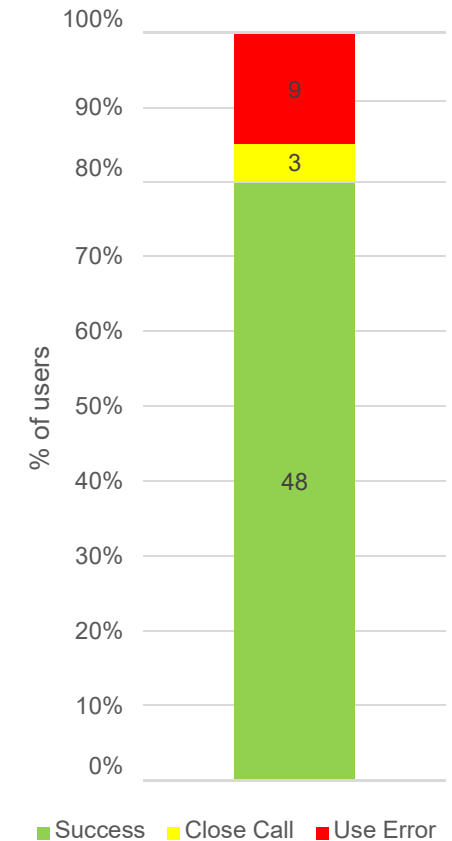
- The most prevalent use errors were users adding too many drops/the entire contents of the extraction tube, removing the nozzle cap to add the drops, or adding the drops to the incorrect location on the test strip (in the slot next to the barcode, and onto the centre square).

Close Calls:

- Close calls were attributed to users almost removing the nozzle cap then realising it needed to remain on the extraction tube.

Root Cause(s):

- **Nozzle cap design:** Some users did not think that liquid could come out of the nozzle cap. Due to the size and transparency of the nozzle cap, they could not see the hole in the top. These factors combined with the transparent liquid also led some users to add more drops as they could not see the correct amount of drops.
- **IFU Design:** Some users stated that this section of the IFU is not clear enough in conveying which part of the test strip the drops should be placed into, and that the image of the test strip should be larger. Furthermore, some participants stated that there was too much information being conveyed within this step, which led to information overload.



Use step 14: Place the test strip on a flat and level surface. Check the time or set a timer if you have one. Wait 30 minutes to read your result

Summary

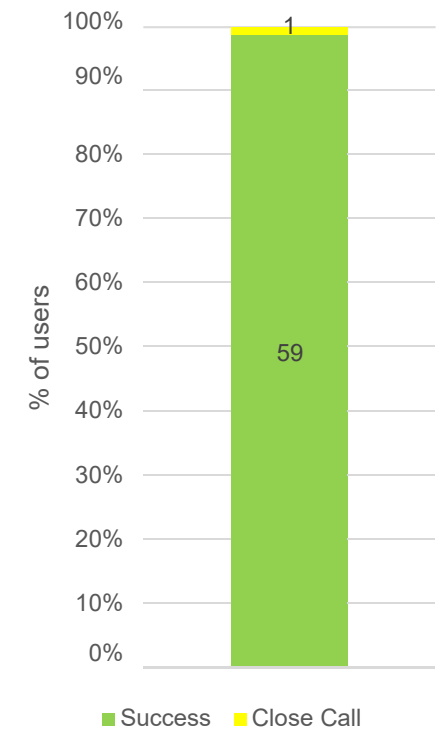
- No users committed use errors in this step.
- 1 out of 60 (2%) users committed close calls in this step.

Close Call:

- One user verbalised '30 seconds' instead of '30 minutes, but realised her mistake when asked by the moderator.

Root Cause(s):

- **Slip:** The user stated that she knew the correct time to wait, and wasn't sure why she said 30 seconds.



3.3 Knowledge based question

The use problems encountered during knowledge based questioning are detailed for each question asked to the participants.

3.3.1 How often is it recommended that you do this test?

- 11 out of 60 users encountered a use error in answering this question
 - Those who committed use errors in this task either stated they were unable to find the information, often stating they were looking for a specified frequency or provided an incorrect answer. Root causes included the information was not optimally positioned with users suggesting it needed to be either at the top or bottom of the page, rather than in the centre, the text itself was not prominent enough (text size, lack of headings) and information overload on the page.
 - out of 60 users encountered use difficulties due to initially not locating the information. Root causes for the use difficulties included users having a preconceived idea of the answer, information layout, information not prominent enough and user looking for an actual number frequency in the instructions.

3.3.2 Where can you find information on what to do if you have coronavirus symptoms or have a positive test for coronavirus?

- 3 out of 60 users encountered a use error in answering this question.
 - Those who committed use errors in this task did not find the information in the grey box due to information density causing information not to be clear enough or due to the heading in the grey box not matching with the information they were looking for i.e. looking for symptom checker in the heading.
- There were no close calls.
 - 2 out of 60 users encountered use difficulties in answering this question.
- The use difficulties in this task were associated with initially looking for a heading with symptoms detailed in it; expecting to find the information in the reporting section

3.3.3 What are you advised to do if you have coronavirus symptoms and are deteriorating, or your symptoms last longer than a week?

- 2 of 60 users encountered a use error in answering this question
 - Those who committed use errors in this task did not find the information in the grey box due to information density causing information not to be clear enough or due to the heading in the grey box not matching with the information they were looking for i.e. looking for symptom checker in the heading.
- 1 out of 60 users encountered a use difficulty in answering this question
- The use difficulty in this task was associated with initially looking for a heading with symptoms detailed in it.

3.3.4 What should you do if there is something missing or damaged in the kit?

- 7 of 60 users encountered a use error in answering this question

- Those who committed use errors either did not notice see the “do not use” as this got lost in the density of text, due to the information not being in bold or expecting to find this information before the checklist section. One user had noticed the information but did not mention this as they thought it was common sense not to use if something was missing or damaged.
- There were no close calls or use difficulties.

3.3.5 If while using the kit something breaks what in addition should you do?

- 1 of 60 users encountered a use error in answering this question due to negative transfer, drawing on her previous experience of COVID-19 telephone numbers.
- 3 of 60 users encountered a use difficulty in answering this question
 - The use difficulties in this task were associated with the ordering of information in the IFU (initially drawn to page 8), expecting to find the information in the steps of use pages. One user took a long time to find the information (expert opinion – user reading slowly).

3.3.6 How should you ensure your hands are clean before you start using the test?

There were no use problems associated with answering this question.

3.3.7 Once you have opened the test kit when should the test be started?

- 7 of 60 users encountered a use error in answering this question
 - Those who committed use errors expected to find the information on the first page of the IFU, due to the information layout (paragraph of text with no image next to it), due to the information not being prominent enough,
- There were no close calls
- 3 of 60 users encountered a use difficulty in answering this question
 - The use difficulties in this task were associated with *{insert use difficulties}* and description

3.3.8 What should you do if you touch the swab with your gum?

There were no use problems associated with answering this question.

3.3.9 How long should you wait before reading the test result?

- 1 of 60 users encountered a use error in answering this question
 - The user who committed a use error in answering this question reported the IFU was not clear as the text stated a positive result could occur 20 minutes.

3.3.10 What should you do if you leave the test to develop but get distracted and only come back to looking at the test after 1 hour?

- 2 of 60 users encountered a use error in answering this question
 - Those who committed use errors reported the information was not clear and got lost in the page. The other user felt the information that the test would be invalid if left longer than 30 minutes should be located on the previous page, where it states not to read the result after 30 minutes.

3.3.11 What does this test result indicate?



- 2 of 60 users encountered a use error in answering this question
 - One user who encountered a use error in answering the question was not able to see the faint line due to study artefact due to camera angle and shadow. User reported I think I am due an eye test. One user felt the information in the IFU was not clear and needed to explicitly state: if a line appears anywhere at all next to T this indicates a positive result.
- 2 out of 60 users had a close call answering this question.
 - One user encountered a close call answering this question due to their mental model and expecting a negative result to be displayed next to a positive result. The other user stated the IFU format was not clear as the information about the faint line was not in bold and did not initially register with him.

3.3.12 What does this test result indicate?



There were no use problems associated with answering this question.

3.3.13 What does this test result indicate?



There were no use problems associated with answering this question.

3.3.14 How should you report a positive result?

- 1 of 60 users encountered a use error in answering this question
 - The user who encountered a use error expected the information to be located at the front of the booklet due to the importance of this. There were no close calls.
- 1 of 60 users encountered a use difficulty in answering this question
 - The use difficulties was due to the information not being prominent enough as it was not bolded or in a grey box.

3.3.15 What should you do if a child's symptoms are worsening?

- 15 of 60 users encountered a use error in answering this question.
 - Those who committed use errors in this task did not find the information in the grey box due to information density causing information not to be clear enough, due to the heading in the grey box not matching with the information they were looking for, due to expecting to find the information in the section 'Testing a child' or expecting to find the information at the end of the instruction booklet.
- There were no close calls.
- 3 of 60 users encountered a use difficulty in answering this question.
 - The use difficulties encountered were due to the ordering of the information in the IFU (expected to find the information in the test a child section).

3.3.16 How should the test kit be disposed of after using?

- There were no use errors answering this question.
- 1 out of 60 users had a close call answering this question.
 - The user who encountered the close calls got confused between the waste bag and the household waste information. 1 of 60 users encountered a use difficulty in answering this question
- 1 out of 60 users encountered a use difficulty answering this question
 - The use difficulty was due to the ordering of information as the user expected the information on disposing of the kit to be before the report your results section.

3.4 Test results

There was 1 use difficulty interpreting the test results. The user had some difficulty reading the result as they were not sure which way up to hold the test strip.

For actual test results:

- There was 1 positive test.
- There were 54 negative tests
- There were 5 invalid tests.

The reason for the invalid results may include the users putting the extraction tube fluid into the wrong part of the test strip, the user just having had a cup of coffee and also unknown cause.

3.5 User subjective feedback

3.5.1 General feedback provided

Users had a mixture of positive and negative feedback on their experience of conducting the test.

Some users comments the instructions were fine :

- "I thought the instructions were clear"
- It was fine and straight forward.
- Instructions were clear and it was a quick test to do

Some users commented on their negative experience of performing the test:

- It's not a pleasant process but its tolerable"
- "Pretty uncomfortable"
- Didn't like putting swab down throat
- Found it quite stressful because the child did not like the swabbing process

3.5.2 IFU feedback

Users had various comments on the IFU layout.

Some users felt the IFU should state to read this in full before starting the process:

- The IFU should have at start "Read all instructions before start"

Some users would also have preferred the IFU to not have been in a booklet format:

- Would be better if it was all on one page. Would be easier than turning pages in a booklet.

A number of users had problems not realising they needed additional items such as cup, mirror, tissues due to the presentation of this information in the IFU:

- ■ didn't see the written paragraph underneath the picture checklist that says.....you will also need, tissue, cup etc "it's because they weren't pictures".
- PAGE 5 IFU: really annoyed that they have clean surface and washed hands, then see the additional items they will need such as a cup, tissue etc.. this should be repositioned before preparing the area. Should also say that she would need disinfectant.
- Page 5 of IFU: "there's some lovely picture, humans are good at visuals" "I don't know why it then went into written format for the tissue, mirror etc.. it was too much of an afterthought." Dependent thinks they should all be in pictures, "it makes it seem like these items are not important, the middle bit gets lost as it is underneath the pictures and above a grey important box." It may lead you to miss the items such as a tissue but then run around panicking mid test to get what you need.
- List at the start what you need e.g. bullet points.
- Page 5 IFU: she thinks the paragraph that lists the cup, tissues and clock should be above the picture checklist
- Underneath the picture the written description of the other equipment they would need, such as a cup. This was missed. "I would add it as a picture".

Some users found the IFU was too text dense:

- The introduction to the IFU is quite "wordy" - ■ would have liked it at the back.
- "I'm dyslexic so all of these words (in IFU) make me panic" and "There's too many words, generally" "I just panic, like page 5....I found an answer but not necessarily the complete answer. That was enough."
- "It's like reading a book"

Many users had problems with the instructions to use a cup:

Some users also found the IFU language not specific enough:

- Instructions need to specify a thin cup so the tube doesn't fall over. Also said need to specify if the cup needed to be cleaned.
- Give a diameter on the size of cup needed to hold extraction tube. Found it hard to find a small enough cup

A number of users commented the placement of this information to get additional items meant they were making multiple trips to get items:

- Needed to make a few trips to find a cup small enough
- PAGE 5 OF IFU: ■ thought everything they needed would have come with the test kit. Couldn't find a cup, had to leave to search for tissues/wipes
- Read IFU carefully. One thing that got caught out was the container needed . Its critical step so needs to be aware. There is less liquid than thought.
- Difficult to find a cup small enough but managed to balance the tube in the mug.
- Put it in a cup, he emptied out an ashtray to keep coins in

- Caregiver asked the child to hold extraction tube instead of finding a cup. Got to step 8 and then said (referring to the extraction tube), "I need to find somewhere to put that."
- I tried to find something I could use" - but [REDACTED] chose not to use a cup. [REDACTED] thought it was okay for the child to hold seeing as [REDACTED] was there next to [REDACTED].

One user (a mother of a child) commented:

- It was a 4 handed job.

3.5.3 Package and device labelling

Users also encountered problems with the package labelling for the test strip:

- Opening the foil pack - the test strip packaging wasn't obvious - he would have liked the foil packaging to be labelled 'test strip'.
- Confused whether the test strip was in the pack.
- Issue identifying test strip. He thought the foil packaging was the waste bag. "Looking at the pictures from the instructions, my presumption it looked like the waste bag."

Users also had some issues with the labelling on the test strip itself:

- Looked at the test strip, "first thought was that C meant Covid." This was before they had read through the 'reading the results' section of IFU. "The letter C has become massive in our lives this year"

3.5.4 Opening packages

Some users had difficulties with opening the packaging with comment including:

- Sachets are sometimes difficult to open.
- Getting into the swab itself was a bit fiddly

3.5.5 Additional support services

Users were asked what additional support services they would like to be available to assist in carrying out the test. Users mentioned the following support services: Face to face support, telephone support, online chat, video and app. The most popular suggested support services were telephone and app.

Users who mentioned telephone support wanted the reassurance of being able to speak to someone. Also they felt this was the most accessible service for everyone as not all users would have internet available to them:

- "If I got stuck I would like to talk things through with someone"

- "The value of talking through with someone is better than just an app."
- "I don't have a smart phone so that app would be no good."
- "Meets all eventualities, doesn't matter where you are."

Users who favoured having an app talked about the flexibility of options offered by an app:

- With a help section, with a live chat box and troubleshooting options (FAQ page).
- "I always have my phone on me, it's easy to download." ■ currently uses the government track and trace app, ■ would like the two to be integrated into the same app.
- Would like this to report the test results (on an app). Would also like it to order a test kit through the app.
- Previously had difficulties contacting NHS with telephone service so would prefer an app.
- Would like an app with a video call. Also like to follow videos.

Some users talked about wishing to be able to access an online video to see the process in more detail. Most of these users expressed a preference for an animated version:

- Live person or animation. Would be helpful to show things like swabbing.
- Would like child friendly video.
- If I was a panicking mum would be good to see. Would prefer animated version.
- Prefer animation. Like on the aeroplane because pay more attention. Less graphic for a child. INDICATE KEY TIMES WITHIN ANIMATION e.g. now wait 30mins.
- On line step by step tube and audio as well as pictures. I would have used a video. Probably better as an animation.

Of the users who wanted face to face support generally this was because they valued the human interaction:

- Would prefer real person.
- the errors I made, spillage, finding a cup, guidance through each step would have helped."
- "I'm just old fashioned, you can see their expressions in their face and can see them demonstrating something."
- Would like to ask a district nurse to administer the test. Ring 111 is preferred route. Because if problem when you start than need immediate response.

3.5.6 Additional comments

Results

One user commented that the line that should be against C was not level with C:

- Line came out near the C but not completely level.

Some users wanted additional information about what an invalid results means and what to do if this occurred:

- if you have trouble, say with a child and get an invalid result? Yes, I would expect to be told what to do if invalid?

Extraction tube holder

During the study in response to user feedback the PA Design team developed a carton containing an extraction tube holder. The carton was sent out to participants were recruited as replacements. Feedback regarding the carton with the extraction tube holder was positive:

- Thinks it's a good idea. "A lot better solution than the cup". Also thinks doing this with children the risk of the tube being swiped off the table is inevitable.
- "Oh so I could use this as my sterile area then?" (referring to the inside of the carton). She thinks it's a good idea.

Other comments

Users also made various other comments related to the inclusive design of the IFU:

- How do blind people read this? Does it come in braille?
- Colour blind people wouldn't be able to see blue

One user was confused about the test strip placeholder in the IFU:

- Unsure about the page with the "place your test strip here" - if that meant you needed to have the test strip resting on the page

One user commented they had seen the instruction to place the test kit on a flat surface (they had placed it on a wooden table with a beanbag base):

- "You have to make do."

Another user at the end of session commented the test was not really designed for 1 person:

- Thinks it would be difficult to do a self test. Thinks it takes two people to do.

4 Recommendations

For results please see attached spreadsheet – IFU recommendations ASJ-20-1317



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