# STUDY PROTOCOL FOR LFD IFU REMOTE BASED STUDY

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**Prepared for:** DHSC

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# Document control

## Revision History

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## DOCUMENT APPROVAL

| Responsibility | Name | Signature | Date |
|---|---|---|---|
| PA Consulting | [redacted] | | |
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| DHSC | Tom Fowler | | |

This document shall be considered valid from the final date of signature in the table above.

PRINCIPAL RESEARCHER AGREEMENT

I have read this protocol and agree that it contains all necessary details for carrying out this study. I will conduct the study as outlined herein and will complete the study within the time designated.

I will provide copies of the protocol and all pertinent information to all individuals responsible to me who assist in the conduct of this study. I will discuss this material with them to ensure that they are fully informed regarding the conduct of the study and the obligations of confidentiality.

Principal Researcher: [redacted]

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Signature: _____ Date: _____

(Day Month Year)

# 1 Definitions and acronyms

| Abbreviation | Definition |
|---|---|
| LFD | Lateral Flow Device |
| HCP | Healthcare professionals |
| HF | Human Factors |
| IFU | Instructions for use |

# 2 Introduction

## 2.1 Purpose

The purpose of this document is to define the study protocol for a remote based summative study to evaluate the IFU used with the LFD Covid-19 virus test kit.

## 2.2 Objective

The primary objective of this study is to validate that the LFD kit is safe and effective to use by the intended user population in the intended use environment.

## 2.3 Scope

The following components of the pack user interface will be tested.

1. The LFD test kit and IFU.

The outer packaging and general information presented on the packaging will not form part of this study

## 2.4 Background

The LFD 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 would therefore like to determine whether the IFU design enables safe and accurate test results to be achieved.

## 2.5 Intended use

The LFD in-home test kit is intended to be used as a self-test by adults and adolescents and performed by adults on children and other adults.

## 2.6 Intended users

The intended users of the LFD 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 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 |

## 2.7 Study sponsor

The sponsor for this study is the DHSC.

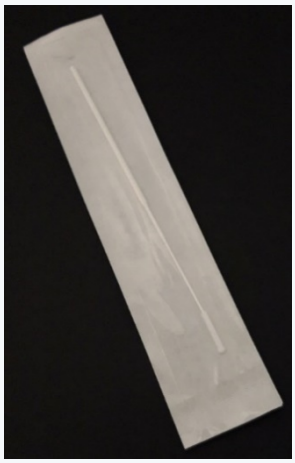
## 2.8 Intended use environment

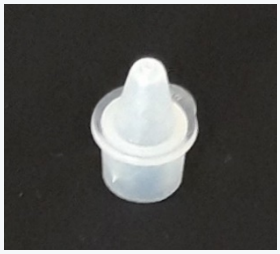
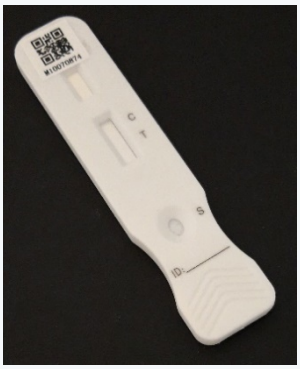
The LFD in-home test kit is intended to be used primarily in-home where standard lighting, room temperature, and noise levels are expected.

## 2.9 User interface

The user interfaces evaluated as part of this summative study will include the following components in Table 2.

*Table 2 - Intended user interface*

| Component | Image | Description | Quantity provided per participant |
|---|---|---|---|
| **IFU** |  | A paper booklet describing user step to undertake a Covid-19 test | 1 |
| **Swab inside sealed wrapper** |  | Swab used to take test sample | 1 |
| **Extraction buffer sachet** |  | *Test reagent container* | 1 |

| Component | Image | Description | Quantity provided per participant |
|---|---|---|---|
| **Nozzle cap** |  | *Cap placed on extraction tube to deliver reagent drops on test strip* | 1 |
| **Extraction tube** |  | *Tube to hold reagent to extract sample from swab* | 1 |
| **Test strip** |  | *Test strip to analyse and display test results* | 1 |
| **Bag** |  | *Plastic bag to transport and to place items before disposal* | 1 |

# 3 Study design

## 3.1 Approach

The study will involve 60 participants divided into 4 distinct user groups as described in section 3.6 and following the recruitment selection criteria Appendix 3.

The session will be run in participants homes, using a remote based usability testing platform due to the current COVID-19 pandemic and to be in keeping with the intended use environment.

Participants will be interviewed by an experienced Human Factors session moderator. The session will also be observed by a note taker. The participant and moderator will be linked visually and by audio. The notetaker will have visual or audio access with the participant and moderator. In addition, the note taker and observers will have contact with the moderator using the text chat function.

The participant will be guided in the sequence of locating and using the study material by the moderator.

## 3.2 Simulated use session

Each study session will be conducted as a 1:1 interview (moderator to participant). Each session will last approximately 60 minutes. The session will be conducted remotely using the remote user testing platform, Validately.

The simulated use evaluation will be conducted with an adolescent user group, adult participant user group, an adult plus child participant user group and a caregiver and adult user group.

The simulated-use test session will require participants to demonstrate the preparation, testing and recording of results using the LFD test kit and IFU. Their performance will be assessed through performance-based measures, knowledge-based questions, root cause analysis and subjective feedback.

## 3.3 Use environment

Due to the current social distancing measures in the UK, testing will be done remotely. Participants will participate from their own homes and will be advised of the required set up needed. This will include access to a table, chair, hand mirror, torch, cup, tissues and bin.

The use environment will be typical of the environment when patients access and take their LFD test at home.

## 3.4 Study personnel and general description of roles

Study personnel and description of their roles in Table 3

*Table 3 - Study personnel and roles*

| Role | Description |
|---|---|
| **Study Moderator** | • Introducing the participants to the session.<br>• Ensuring that participants understand the verbal task instruction.<br>• Observing the participants performance throughout the simulated use, identifying whether they have committed any use problems.<br>• Conducting the pre-task and post-test interview.<br>• Video recording of the study to capture participants' interactions with the study items<br>• Requesting participants to adjust the webcam as needed, ensuring all interactions with the study items<br>• Excluding participants from the study if needed, in accordance with the established exclusion criteria. |

| Role | Description |
|---|---|
| **Study Observer** | • Recording use errors, close calls, and use difficulties in addition to key findings and participant-reported root causes |

## 3.5 Study personnel

Human Factors experts at PA Consulting will act as the researchers during the study.

**Principle investigator**

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**Co-investigators**

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## 3.6 Participants

The total sample size for this study will be 60 participants administering the test. There will be 4 user groups. A breakdown of composition of each group is detailed Table 4.

*Table 4 - Study sample*

| User groups | Sample size |
|---|---|
| Adolescents between the age of 12 and 17 | 15 |
| Adults aged 18+ | 15 |
| Adults administering the test to an adult dependant | 15 caregivers plus 15 dependants |
| Adults administering the test to a child under the age of 12 | 15 parents plus 15 children |

## 3.7 Screening criteria

Participants will be screened during the recruitment process and will also be asked a set of screening questions at the beginning of the study session (Appendix 3). Any participants not meeting the screening criteria will be excluded from participating in the study session.

## 3.8 Participant identification

All participants will be assigned a unique identifying code to ensure their anonymity is protected. This identification code will be:

**Adolescents**: ADO1, ADO2 etc

**Adults**: ADU1, ADU2 etc

**Adult caregiver for children**: ADUC1, ADUC2 etc

**Adult caregiver for adult dependent**: ADUD1, ADUD2 etc

## 3.9 Study locations

This summative study will be conducted remotely with participants from within the UK, over a 5 day period, during the week of 16 November 2020.

## 3.10 Study materials/equipment

The primary study articles are listed below in table 5.

*Table 5 - Study materials*

| Study material | Image | Description of study material |
|---|---|---|
| IFU |  | A5 IFU booklet Version 0.9.2 |
| Test kit |  | LFD test kit |

## 3.11 Supporting equipment

- Webcam (one per participant)
- Bottle of hand sanitiser (one per participant)
- Moderator's discussion guide
- Observer workbook
- Participant information sheet and Informed Consent Form
- Each participant to provide a table, chair, hand mirror, torch , cup, tissues, timer and bin

## 3.12 Packaging of supplies sent to participants

For this remote study participants will be sent a package of supplies that they will need to participate in the study. The supplies will consist of:

- A sealed envelope marked A containing the LFD test kit components and IFU
- 1 webcam
- Bottle of sanitiser
- An addressed pre-paid return envelope to return the webcam

Personnel who pack the packages will wear gloves to mitigate any risk of contaminating packed items.

## 3.13 Study plan

*Table 6 - Study plan*

| Stage of session | Objective | Tasks | User Interface tested | Duration |
|---|---|---|---|---|
| Technical setup | To organise the technical setup before the study begins | • Setup camera and position<br>• Unpack materials | N/A | 5 mins |
| Introduction | Introduce participant to session and material to be used | • Check consent<br>• Welcome and introduce participants to session<br>• Familiarise participant with study material | N/A | 5 mins |
| Simulated use | To observe the participant's interaction with the test kit and approach to the test | • Open pack and perform test | Market ready sample | 30 min |
| Root cause investigation | Understand the root causes of use errors /difficulties/close calls | • Employ a line of questioning to investigate use errors /difficulties/close calls which occurred during the simulated use | N/A | 10 mins |
| Improvements | To gather user feedback on how the IFU could be improved | • Employ line of questioning to understand improvements | N/A | 5 min |
| Close session | To observe the participant, repack study materials and advise them to dispose of used test kit components | • Repacking of study material | N/A | 5 min |
| TOTAL TIME OF SESSION | | | | 60 mins |

# 4 Detail procedures description

## 4.1 Session introduction

Participants will be asked to review and electronically sign the Informed Consent Form (Appendix 4 and 5). The moderator will ask a number of questions about the participant's personal background, included in the discussion guide (Appendix 6). The interview will confirm each individual's eligibility for participation and provide context for the study data. Participants will be made aware of the test material and how they are expected to interact with the material.

## 4.2 Introduction to test

Participants will be introduced to the Covid-19 test, its purpose and regimen.

## 4.3 LFD introduction

The participant will be introduced to the test kit

## 4.4 Simulated use adult and adolescents

Participants will be asked to open the pack and to follow the steps of use presented to them.

The moderator will observe the participant complete the steps of use. To ensure the task is representative of a real-use scenario, the moderator will not interact with the participant during this task and will not offer help to the participant. The moderator will only verbally interject if the participant gives up on the task, or if the moderator foresees a dangerous scenario developing. A list of tasks and their success/use-error criteria are found in the discussion guide Appendix 6 and section 4.1.1

During the simulated use participants are expected to undertake all steps as described in the IFU to perform a self-test using the LFD test kit.

This task begins with all the study components in their unopened form on the table and ends with the participant indicating that they have done everything they would do at home to perform the test.

### 4.4.1 Adult/Adolescent self-test use: Use Steps

*Table 7 - Adult/adolescent use steps*

| 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.<br>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**<br>**Carefully twist or snap open the sachet** | The user opens the sachet without spilling any of the fluid. |

| | |
|---|---|
| **Use Step 2**<br>**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**<br>**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**<br>**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**<br>**Gently blow your nose into a tissue.** | Participant blows nose into a tissue. |
| **Use step 6**<br>**Wash and dry your hands again (or use sanitiser if this is available).** | Participant washes their hands. |
| **Use Step 7**<br>**Open the swab package and gently take out the swab.** | Participant opens the swab package without using any tools.<br>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)** | |
| **Use step 8**<br>**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. | 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<br>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.<br>Participant removes the swab from their throat without touching any part of their mouth at this stage (not touching tongue, teeth, cheeks, gums etc) |

| | |
|---|---|
| **Use step 9**<br>**Put the same swab gently into one nostril until you feel a slight resistance (about 2.5cm up your nose).**<br>Roll the swab firmly around the inside of the nostril, making 10 complete circles. | Participant puts the **same swab** fabric/soft tip into one nostril about 2.5 cm up nostril.<br>Participant rolls the swab around the circumference of their nostril in full circles at least 10 times.<br>Participant then places the **same swab** fabric/ soft tip into the other nostril about 2.5 cm up nostril.<br>Participant rolls the swab around the circumference of the other nostril in full circles at least 10 times. |
| **Process the swab sample** | |
| **Use step 10**<br>**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.**<br>Press the tip against the edge of the extraction tube with force, while rotating it around the tube for 15 seconds. | Participant places the fabric/soft tip of the swab into the extraction tube.<br>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. |
| **Use step 11**<br>**Pinch the tube as you remove the swab to make sure that all the fluid is removed from the soft tip of the swab.**<br>Place the swab in the plastic waste bag provided. | 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).<br>Participant puts the swab into a plastic bag and disposes of it into their household rubbish. |
| **Use step 12**<br>**Press the nozzle cap tightly on to the extraction tube to avoid any leaks** | Participant presses the nozzle cap tightly onto the extraction tube (to avoid leaks). |
| **Use step 13**<br>**Gently squeeze the extraction tube to place 2 drops of liquid onto the specimen well on the test strip.** | Participant tips the extraction tube to place 2 drops of liquid onto the test strip sample well. |
| **Use step 14**<br>**Place the test strip on a flat and level surface**<br>**Check the time or set a timer if you have one. Wait 30 minutes to read your result.** | Participant places test strip on a flat surface<br>Participant checks the time or sets timer for 30 minutes and leaves the test strip without touching it.<br>After 30 minutes the participant reads the result. |

## 4.5 Simulated use caregivers of paediatrics and dependents

Participants will be asked to open the pack and to follow the steps of use presented to them to perform the test on their child/ dependent.

The simulated use steps to be observed are as follows in table 8:

*Table 8 - Use Steps for adult testing a child or dependent*

| Use Step | Acceptance criteria |
|---|---|
| **Repeat Use Steps 1 through 7** as per Section 4.4.1 (table 7) of this protocol, then proceed with Use Steps 8 and 9 below. | As per section 4.4.1 (table 7) |
| **Use step 8 (child/dependant)**<br>**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.**<br>Carefully remove the swab.<br>If you cannot swab the tonsils, you can swab both nostrils. | 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).<br>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) |
| **Use Step 9 (child/dependent)**<br>**Put the fabric tip of the same swab gently into one of their nostrils until you feel some resistance.**<br>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.** | Participant puts the fabric tip of the same swab gently into one of their nostrils<br>Participant rolls the swab firmly around the inside of the nostril, making 10 complete circles and slowly removes it.<br>If the user could not swab the throat, they repeat in the other nostril. |
| **Repeat Use Steps 10 through 14**, as per Section 4.4.1 (table 7) of this protocol. | As per section 4.4.1 (table 7) |

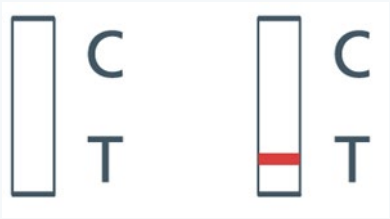
## 4.6 Knowledge-based questions

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

*Table 9 - Knowledge-based 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.<br>**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:<br>Go online to: NHS 111 online coronavirus service, **111.nhs.uk**.<br>If you do not have internet access, call NHS 111.<br>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:<br>Do not use it.<br>Call, using the numbers below, and ask for a new kit:<br>- England, Wales and Northern Ireland: **119** (free from mobiles and landlines)<br>- 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 | What does this test result indicate:<br>  | Two lines – even faint lines – indicate the test is positive. |

| | | |
|---|---|---|
| 12 | What does this test result indicate:<br>  | The test is invalid |
| 13 | What does this test result indicate:<br>  | This indicates the test is negative.<br><br>. |
| 14 | How should you report a positive result? | **Answers can include:**<br><br>Report online **www.gov.uk/covid19-self-test-help/**<br><br>Or scan this **QR code** with your smart phone to open the reporting website<br><br>**Report by telephone**<br><br>England, Wales and Northern Ireland: **119** (free from mobiles and landlines)<br><br>Scotland: **0300 303 2713** (charged at your standard network rate) |
| 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 |

## 4.7 Root cause investigation

Once participants have completed the simulated use, the moderator will conduct 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.

## 4.8 Suggested improvements

Following root cause investigation, the participant will be asked for their views on what could be improved with the IFU and testing process.

## 4.9 Debrief

After the interview the moderator will thank the respondent and conclude the interview. The respondent will be offered the chance to ask any questions and offer any further improvements to the packaging and IFU.

## 4.10 Data Collection

Study personnel will include the study moderator, who will facilitate the study and interview the participant, and a study observer, who will capture data. The study observer will capture notes in electronic form. A video recording will be taken of each session.

Specifically, the following data will be collected during each session:

- Participants' demographic background information
- 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
- Participants' comments (paraphrased)
- Participants' responses to subjective and open-ended questioning posed during the post-task and post-study interviews
- Moderator and observer observations.

The definitions used to categorise task performance are located in Table 4.

Any previously unanticipated use errors will be observed and recorded and included in the follow-up interviews with participants. In the unlikely event of system failures, these will be noted in the data collection and sequence of events leading up to the device failure will be described in the report.

## 4.11 Analyses

After all sessions are completed, the collected data will be analysed to determine if the task performance was a success, use error, close call, or use difficulty, as per the criteria defined in Table 10. Root cause analysis will be conducted on all tasks where use errors, close calls, and use difficulties were present. This analysis will draw upon study video data, participant responses from post-task interviews, and expert review of the use problem.

*Table 10 - Scoring definitions*

| **Outcome** | **Definition** | **Root Cause Investigation Required?** | **Method of Scoring Data** |
|---|---|---|---|
| Success | Participant performs the task correctly on the initial attempt without assistance | No | **Success**<br>Close Call<br>Use Error<br>N/A |

| Outcome | Definition | Root Cause Investigation Required? | Method of Scoring Data |
|---|---|---|---|
| Close Call | Any instance in which a participant makes a use error e.g. by attempting to undertake an action without accurate reference to the IFU, but then retries resulting in a successful completion of a user step.<br>This outcome also considers:<br>• The user verbally expresses frustration or facial expressions and body postures indicate frustration when using the device;<br>• The user re-reads the same section of the IFU during a task, in an attempt to comprehend a sequence of steps use<br>• The user is able to accomplish a task or step, but experiences frustration or discomfort in the process of doing so. | Yes | Success<br>**Close Call**<br>Use Error<br>N/A |
| Use Error | Any action or lack of action while using the packaging that leads to a different result than that intended by the manufacturer or expected by the user, including:<br>• A participant's inability to complete a task;<br>• A deviation from the IFU that leads to a device response that is different than intended or expected by the participant;<br>• An instance where the participant requires assistance from study personnel to advance through tasks.<br>The following will not be considered use errors:<br>• A malfunction of the packaging that causes an unexpected result. | Yes | Success<br>Close Call<br>**Use Error**<br>N/A |
| Use Difficulty | Any observed difficulty on the part of the user while performing the test, which does not result in a use error, but points to an underlying usability concern with the IFU or test kit, Examples include (but are not limited to):<br>• The user verbally expresses frustration or facial expressions and body postures indicate frustration when using the packaging;<br>• The user re-reads the same section of the IFU during a task, in an attempt to comprehend a sequence of steps<br>• The user is able to apply the required amount of force or dexterity to accomplish a task or step with the kit, but experiences frustration or discomfort in the process of doing so. | Yes | Yes/No<br>This metric is collected in addition to the observational score of Success/Close Call/Use Error |

| Outcome | Definition | Root Cause Investigation Required? | Method of Scoring Data |
|---|---|---|---|
| N/A | 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. Some examples include:<br>• Packaging failure | No | Success<br>Close Call<br>Use Error<br>**N/A** |

# 5 Study considerations

## 5.1 Study deviations

During the study, any deviations from the signed protocol will be noted and highlighted in the study report.

## 5.2 Ethical considerations

Each participant will be asked to read, sign and date an informed consent form, including information on confidentiality agreement, audio video release and adverse events reporting. Adolescents and children will be asked to sign the relevant informed assent form. A blank copy of the consent forms and assent forms can be found in the appendices. Participants will only be allowed to participate in their sessions following their informed consent/ assent to do so. The participants will be screened with the help of a recruitment questionnaire to make sure that they qualify for the study using a pre-defined list of screening criteria. The sessions will be moderated by a Senior Consultant at PA who has experience in conducting usability studies

Due to the nature of the study and material used ethical approval is not considered necessary for this study.

## 5.3 Confidentiality of participant information

Only PA employees who are involved with the project will have access to this data. Participants' data will not be linked to their personal details and only fully anonymized data will be reported to the DHSC All audio-visual recordings will be used for research purposes only by PA and DHSC and will not be passed to a third party.

Data will be controlled in accordance to current GDPR guidelines

## 5.4 Risks to participants

Participants will be exposed to minimal risks during the usability test session. The minimal risk could include discomfort when taking the sample in the throat or nose, participants might become fatigued by the study's endpoint or might experience negative emotions, such as frustration and annoyance when trying to use the test kit or are disappointed if they receive a positive result.

Participants will be advised that if they have any concerns or experience distress during the study, to tell the Study Staff immediately.

In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with participating in this study. Participants will be informed in a timely manner both verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence their willingness to continue with their participation in this study.

# 6 Study deliverables

The study deliverables will be:

- Study Protocol and supporting appendices
- Study report

# Appendix 1 – IFU

HM Government

NHS Test and Trace

## Your step-by-step guide for COVID-19 self-testing

This guide explains how to test yourself or another person for COVID-19, and self-report results to the NHS.

Get more help at www.gov.uk/covid19-self-test-help including demonstration videos and instructions in alternative languages.

## About this test

**Many people with COVID-19 have mild, or even no symptoms, but can still spread the virus. With regular self-testing we can slow the spread, and help protect the most vulnerable in our families and communities.**

The 'COVID-19 Self-Test Kit' is a test for the detection of antigens from the COVID-19 virus, using throat and nose swabs. Antigens are specific proteins found on the surface of the virus.

The test kit can be used to test individuals who are suspected of having COVID-19 and displaying symptoms, or to test asymptomatic individualsto detect infection at an early stage.

**How often you should test may vary depending on your circumstances and current national or local guidelines.**

### What your results mean

Positive results indicate the presence of viral antigens. Positive results do not rule out other bacterial or viral infections. Anyone testing positive should comply with current national and local guidance for reporting and self-isolation.

Negative results do not rule out COVID-19 infection, particularly in the early stages of infection when viral loads are lower. It is important to consider any possible recent exposure to potentially infected individuals plus the presence of any symptoms consistent with COVID-19. Anyone with a negative test but with symptoms of concern should seek medical advice.

### This test is suitable for the following people:

| | |
|---|---|
| **Adults aged 18+** | Self-test and report, with assistance if needed. |
| **Adolescents aged 12 – 17** | Self-test and report with adult supervision. |
| **Children under 12** | Children under 12 years of age should be tested by an adult. **Do not conduct this test if you do not feel confident testing a child.** Do not continue the test if the child feels any pain. |

**Please see page 9 for tips on how to test a child.**

### COVID-19 guidance and help

If you have COVID-19 symptoms or have contracted COVID-19, visit: www.nhs.uk/conditions/coronavirus-COVID-19.

You can also get more advice about COVID-19 in children at: www.nhs.uk/conditions/coronavirus-COVID-19/coronavirus-in-children.

If an adult or child has symptoms of COVID-19 and the condition gets worse, or does not get better after 7 days, visit NHS online (www.111.nhs.uk) or call 111.

If you have a medical emergency, or if a baby or child seems very unwell, is getting worse, or you think there is something seriously wrong, call 999.

**Do not delay getting help if you are worried. Trust your instincts.**



## What you need to do

It's very important you read the instructions and follow the steps in the correct order. **Each test will take about 15 minutes to set up and results will be ready after a further 30 minutes.**



**Store the test kit at room temperature or in a cool dry place (2°C to 30°C). Do not leave in direct sunlight and do not store in a fridge or freezer.**

The kit should be used at room temperature (15° to 30°C). If the kit has been stored in a cool area (less than 15°C), leave it at normal room temperature for 30 minutes before using.

**Keep the test kit away from children.**



### Guidance and contraindications

Use a separate test kit for each person. All items in the test kit can only be used once. Do not re-use them. You will need to report each person's result.

If you have problems with your hands or vision, you may need someone to assist you with the swabbing and testing process.

If you have a nose piercing swab the other nostril. If pierced on both sides remove the piercing on one side before swabbing.

If you have had a nosebleed within the last 24 hours, swab the other nostril or wait 24 hours.

Avoid eating or drinking for at least 30 minutes before doing the test to reduce the risk of spoiling the test.

These kits are only designed for human use.

**Failure to follow the instructions in this booklet may affect the performance of the test and invalidate the test results.**

**If you have a tracheostomy do not swab your throat, instead swab both nostrils.**



## 1. Prepare your test area and check your test kit contents

**Read this instruction guide carefully.**

You can also see a demonstration of how to take the test by watching the video at www.gov.uk/covid19-self-test-help

**Clear, clean and dry a flat surface to place the test kit on.**

**Wash your hands thoroughly for 20 seconds, using soap and warm water, or hand sanitiser.** This is so that you do not contaminate the test kit. Now dry your hands.

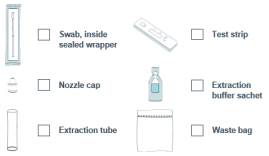
**Take the test kit out of the foil packaging and place it onto the cleaned flat surface. Once opened, start the test within 30 minutes.**

If doing more than one test, clean the surface and wash your hands again between each test.

**Do not use the test kit if the foil packaging is damaged.**



**Check your contents. Make sure that nothing is damaged or broken.**



- ☐ Swab, inside sealed wrapper
- ☐ Test strip
- ☐ Nozzle cap
- ☐ Extraction buffer sachet
- ☐ Extraction tube
- ☐ Waste bag

You will also need a **watch or a clock**. We also recommend that you have to hand: **tissues, a mirror, hand sanitiser** as well as **a small clean container or cup** to keep the extraction tube upright and prevent spillage.

**Any problems, or something damaged, broken or missing?** If you have any questions, problems or you are unable to use the test call the NHS for advice. Do not use the test kit if it is damaged, broken or something is missing. Call the customer contact centre and ask for a new one. Open every day, 7am to 11pm.

- England, Wales and Northern Ireland: **119** (free from mobiles and landlines)
- Scotland: **0300 303 2713** (charged at your standard network rate)

If something in the kit is difficult to use or breaks whilst using it, please also report the problem via the Coronavirus Yellow Card website: https://coronavirus-yellowcard.mhra.gov.uk



## 2. Set up your test

1.  **Carefully twist or snap open the sachet.** Being careful not to spill any of the fluid.
2.  **Pour all of the fluid from the sachet into the extraction tube.** Avoid touching the sachet against the tube.
3.  **Place the filled tube in a cup or container to avoid spilling it while you use the swab.**
4. 

**Check the swab in the sealed wrapper in front of you.** Identify the soft, fabric tip of the swab.



5.  **Gently blow your nose into a tissue and throw it away in your household rubbish. If you are testing a child help them to blow their nose.** This is so that you get rid of excess mucus.
6.  **Wash and dry your hands again (or use sanitiser if this is available).**
7.  **Open the swab package and gently take out the swab.** This will be used for both throat and nose.

**Never touch the soft, fabric tip of the swab with your hands.**

## 3. Take your swab sample

Do not touch the tongue, teeth, cheeks, gums, or any other surfaces with the fabric tip of the swab. If this happens, the swab is invalid and you will need to start again with a new test kit.

**Never touch the fabric tip with your hands.**

Swabbing may feel uncomfortable, do not insert swab any deeper if there is strong resistance or pain.

**If testing a child under 12, use the steps on the next page.**

8 x4

**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.

9 x10

**Put the same swab gently into one nostril until you feel a slight resistance (about 2.5cm up your nose).** Roll the swab firmly around the inside of the nostril, making 10 complete circles.



## Testing a child

**Children under 12 should be tested by an adult.** Follow the guidelines below on how to prepare and test a child. You can watch a demonstration video at **www.gov.uk/covid19-self-test-help**

Show the child the test kit and take them through the steps. Try practising taking the test without using any of the test kit materials. If possible, sit them on someone's lap or have someone hold their hand.

Tell the child that the swab may feel uncomfortable. For example you might say, "You may want to push the swab away but it is really important you let me tickle your throat and nose".

Ask the child to open their mouth as wide as they can and say 'Ahhhh' (this will make the tonsils easier to see) for as long as they can while you swab their tonsils (or where their tonsils would be if they have been removed).

8 x4

**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.

9 x10

**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.**



## 4. Process the swab sample

10 15 sec

**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.** Press the tip against the edge of the extraction tube with force, while rotating it around the tube for 15 seconds. This is to transfer your sample into the fluid.

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.** Place the swab in the plastic waste bag provided.

12

**Press the nozzle cap tightly on to the extraction tube to avoid any leaks.**

13 2 drops


**Gently squeeze the extraction tube to place 2 drops of the fluid onto the specimen well on the test strip.** Make sure that you are dropping fluid and not an air bubble.

Put the extraction tube in the waste bag along with the swab.



Make sure you place the test strip on a flat and level surface.

14

**Check the time and set a timer if you have one. Wait 30 minutes before you read your result.**

**Waiting the full 30-minute development time before you read your result is very important.** A positive result can appear at any time after 20 minutes, however you must wait for the full 30 minutes to record a negative result as the test line (T) may take this long to appear.

Find out how to read and report your result on the next page.

Do not read your result after 30 minutes.



## 5. Read your result

**You will see the control line (C) begin to appear after about 4 minutes. You must wait 30 minutes before your result is ready.**

Do not leave the test to develop for longer than 30 minutes as this will make the result invalid.


**Negative result**

One line next to C indicates the test is negative.


**Positive result**

Two lines, one next to C and one next to T. Even faint lines indicate the test is positive. You must report this test result to the NHS, please see **section 6** for guidance on how to do this.

If your test result is positive, you and your household must self-isolate following Government Guidelines.


**Invalid result**

No lines or one line next to T indicates the test is invalid.



## 6. Report your result

**You must report a positive result to the NHS.** You are also asked to report negative and invalid results.

Reporting your result will help the NHS monitor the spread of the virus and support affected communities across the UK. This will help the NHS combat the virus and save lives.


**You need the barcode on the test strip** or the ID number printed under it to report your positive result.

**Report online**

Visit: **www.gov.uk/report-covid19-result**

Or scan this **QR code** with your smartphone camera to open the reporting website

**Report by telephone**

Lines are open every day, 7am to 11pm.

England, Wales and Northern Ireland: **119** (free from mobiles and landlines)

Scotland: **0300 303 2713** (charged at your standard network rate)

## 7. Safely dispose of your test kit

Once your test is complete, put all of the used test kit contents in the waste bag provided and place in your household waste.



## Make a note of your test results

**This is for your own records. You must still report your result to the NHS** (see page 13 for information).

| Who took the test | Date | Time | Test result |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

**Manufactured for:** Department of Health and Social Care, 39 Victoria Street, Westminster, London, SW1 0EU.

**Manufactured by:** Xiamen Biotime Biotechnology Co., Ltd. 3FHF, No. 188, Pingcheng South Road, Haicang Street, Haicang District, Xiamen, Fujian, 361026, P. R. China.

**Index of symbols**

| | | | | | |
|---|---|---|---|---|---|
| 2°C 30°C | Store at 2 – 30°C | Sterilized using ethylene oxide | Manufacturer | Do | Don't use the product when the package is damaged |
| Batch | Lot number | Expiry date | In vitro diagnostic medical device | | |
| keep | Keep away from sunlight | Date of manufacture | Do not re-use | | Warning, please refer to the instruction |
| keep | Keep dry | Consult instructions for use | | | |

Version 0.9.2, 18 November 2020

# Appendix 2 – Test kit

# Appendix 3 – Participant screener

## - Participant Screener

This is a research study to gather user feedback on the use of coronavirus (COVID-19) test kit.

The research will be conducted in the UK remotely. We will do this by sending a link to join a remote viewing session, where the interviewer will run the session. We will also send materials that participants will need for the interview. This material we will fit into a large envelope. The envelope will contain webcam, test kit and prepaid envelope to be used to return the webcam. All test kit materials will be disposed of by the participant in their home.

- **For Tuesday – please recruit locally to enable hand delivery of supplies on the Monday 16th November 2020**

**Participants**:

General UK population

**Eligible for inclusion:**

- Participants are willing to participate in a 1:1 session lasting approximately 60 minutes at their home via a remote platform
- Be willing and provide written informed consent (including audio and video data capture).
- Be able to participate in the study on between: Tuesday 17th November – Saturday 21st November 2020 (remote UK)
- Have access to a computer or laptop
- Be able to be on their own in a room for the duration of the session without being interrupted
- Have good internet connection
- Be IT literate
- Have Google Chrome
- Have experience of using remote platforms such as Skype, Microsoft Teams, Zoom etc

**Exclusion criteria**

- Are unwilling to give written informed consent (including audio and video data capture).
- Do not have access to a computer or laptop with a camera
- Are not able to be on their own in a room for the duration of the session without being interrupted
- Are not IT literate
- Do not have google chrome
- Do not have experience of using remote platforms such as Skype, Microsoft Teams, Zoom etc.
- Do not have good internet connection

| **User group** | **Quota** | **Key comments** |
|---|---|---|
| Adolescents 12-17 | 15 + 2 over-recruits | Parent/ guardian present in background whilst session in progress |
| Adults 18 and over | 15 + 2 over-recruits | Broad range of ages to cover 18 through to older adults |
| Adults with a child aged 4-11 who they care for | 15 + 2 over-recruits | Adult and a child aged 4-11 count as 1 for the quota |
| Adults who provide caregiver role to another adult and provide assistance | 15 + 2 over-recruits | Adult and person they care for count as 1 for the quota |

**Participants**

Target: 60 participants in total consisting of 15 participants from each of the 4 user groups detailed in the table

**Device research.**

Target - Male and female adolescent respondents, male and female adult respondents, Male or female respondents and their child, male or female respondents and the person they care for

Respondent Name
_____

Address
_____

_____

City_____
_

Phone _____ Mobile _____

Email _____

Hello Mr./Ms. _____, I am calling on behalf of a company called PA Consulting Group, a design and development company in the UK. Today we are speaking to individuals with the aim for them to join an interview.

During the interview we will gather your views and feedback on the use of a test kit. We are interested in seeing how you would use the device and we will ask you to perform a test during the interview.

These discussions are being held strictly for research purposes and in confidence; no promotion or sales of any kind are involved. If you are chosen to participate, we will invite you to attend an interview lasting between 60 minutes. We will compensate you for your time and opinions. Are you happy for me to carry on?

1. Can I start by asking you your age.
( ) 12-17
( ) 18 to 35
( ) 36 to 65
( ) 65+

**ATTEMPT TO RECRUIT A RANGE OF RESPONDENTS FROM 18- 65+ FOR THE ADULTS 18 AND OVER USER GROUP.**

2. Are you male or female
( ) Male
( ) Female

**ATTEMPT TO RECRUIT 50% FEMALE AND 50% MALE RESPONDENTS**

3. Do you have any children below the age of 12 living with you?
( ) Yes
( ) No

4. **If yes to 3** - What is the age of your child?
( ) 4 – 12 Years old
( ) < 4years old **NOT REQUIRED**

**AT END OF A POSITIVE SCREENER CHECK IF WILLING TO DO A TEST ON YOUR CHILD**

**TARGET 15 TESTS WHERE TEST IS ADMINISTERED ON THE CHILD**

5. Do you provide a caregiving role to another adult and provide assistance to them?
( ) Yes
( ) No

6. If yes to 5 – Do you provide assistance in assisting them to take medication?
( ) Yes
( ) No

**TARGET 15 TESTS WHERE TEST IS ADMINISTERED ON THE ADULT DEPENDENT**

7. Can you speak and read the English language?
( ) Yes
( ) No **TERMINATE**

8. Which is your dominant hand?
( ) Right
( ) Left

9. How is your eyesight?
( ) Normal – no correction required
( ) Reading glasses
( ) Distance glasses
( ) Contact lenses
( ) Colour blind (record type)
( ) Impaired (record severity and impairment e.g. blurred vision, double vision etc)

---

10. Are you red-green color-blind?
( ) Yes; please describe: [For info only]
( ) No

**ATTEMPT TO RECRUIT SOME VISUALLY IMPAIRED AND COLOUR BLIND RESPONDENTS**

11. Do you have trouble remembering information, solving problems or concentrating?
( ) Yes (record type and severity)
( ) No

---

**ATTEMPT TO RECRUIT SOME RESPONDENTS WITH TROUBLE REMEMBERING INFORMATION IF POSSIBLE**

12. Do you have trouble performing day to day tasks with your hands?
( ) Yes ( record open ended response, ask if diagnosed with physical related illness e.g. Rheumatoid arthritis))

---

( ) Difficulty picking up small objects from a flat surface e.g. coins, pen?
( ) Difficulty fastening buttons?
( ) Difficulty writing?
( ) Tremors

**ATTEMPT TO RECRUIT SOME RESPONDENT WITH DEXTERITY ISSUES IF POSSIBLE**

13. Do you have access to a computer or laptop with a camera?
( ) Yes
( ) No **TERMINATE**

14. Do you have a good internet connection at home?
( ) Yes
( ) No **TERMINATE**

15. What is your IT experience?

Detail:……

16. Do you have Google Chrome installed on your computer/ laptop?
( ) Yes
( ) No **TERMINATE**

17. What remote platforms have you used, if any?

Detail: ……..

18. Do you, or does anyone in your immediate family, work in the following industry?

( ) Market research/ advertising [gather details and refer to PA for decision]

19. Ask as applicable - Are you willing to perform a test on child?
( ) Yes
( ) No

20. If no - are you willing to do a test on yourself?
( ) Yes
( ) No

21. Ask as applicable – Are you willing to perform a test on your dependent?
( ) Yes
( ) No

22. If no - are you willing to do a test on yourself?

( ) Yes
( ) No

The interview will take place remotely using your computer and will last between 60 minutes. We will ask you to keep confidential the details discussed and ask you to sign a confidentiality agreement. We will send you an informed consent form to sign ahead of your participation so that you can make an informed decision. Are you willing to agree to confidentiality?

Please be aware that the interview will be videotaped and pictures will be taken to document the research and produce a transcript of your comments. Only members of the research team and the research sponsor will have access to the video, photographs and transcripts. None of these materials will be released to the public. Are you OK with this?

In compensation for your time and views you will receive £50 as an honorarium.

Would you like to participate?

_____Yes - Schedule interview

_____No - Terminate

**SCHEDULE AND RECORD INFORMATION ON FRONT OF SCREENER**

# Appendix 4 – Informed Consent Adult

## Information Sheet and Informed Consent For Covid-19 home test

STUDY NAME LFD in-home test research 1:1 interview to gather human factors data

Before you agree to take part in this study, please read the following, and if you have any questions please ask.

**Invitation and Background:**

The sponsor of this study is the DHSC and they are evaluating the ease of use of a potential Covid-19 self-test test kit to be used in the home.

Under the General Data Protection Act (GDPR) we are required to gain your written consent to use your personal data. Personal data is any information relating to an identified or identifiable natural person such as video images or information about you.

Your consent given here will be the lawful basis required to process your personal data. This processing will include recording, storing, and when it is time, the deletion and destruction of your personal data.

You can withdraw your consent at any time without your legal rights being affected.

Under the General Data Protection Regulations (GDPR), you now have a number of rights,

- The right to be informed of how we will use your data
- The right of access to your data (called a Subject Access Request)
- The right to have incorrect data rectified
- The right to erasure, for instance, if you withdraw your consent
- The right to restrict processing, if you want more clarification on how we use your data
- The right to ask us to send your data to another data controller
- We will not be making any decisions about you in an automated way, or profiling you using the data you provide us

A detailed explanation of these rights is described in our privacy policy to be found on the PA website at, https://www.paconsulting.com/legal/privacy-policy/#request-access

**What would taking part in this study session involve?**

This study will involve you using an in-home test kit to test for Covid-19 and providing feedback on your experience.

This study will help the sponsor to inform the manufacturer of any improvements that might be needed to the test kit to improve ease of use.

The interview will require approximately 60 minutes of your time. You will be compensated £50 for your time.

The session will be conducted remotely using the remote user web-based platform, Validately.

During the session you will be interviewed by a researcher and there may also be people observing remotely.

During the study session you will be asked for your opinion on various aspects of the testing kit and other information which can be reasonably be considered to be confidential (the “Confidential Information”). We ask that you keep what you have heard or seen confidential, and do not disclose this Confidential Information to third parties.

This study is for research purposes and your data will only be processed for this research purpose; no sales of any kind are involved.

**What will happen if you agree to take part?**

If you qualify for the study you will be invited to join a remote research session via your home PC via a secure internet connection.

Before the scheduled interview the researchers will send you a pack containing the Covid-19 test kit, that will arrive at your home. All we would ask you to have access to or provide is a computer or Mac, a table, a chair, a cup or beaker, tissues, a hand mirror, a torch and a bin. There will be instructions inside the pack for you to follow. The researchers will also send you a link to connect your PC or Mac to a remote research testing platform called Validately which is specifically designed to conduct remote studies of this type. When you join the session, you will be greeted by a member(s) of the research team. The researcher will start by asking you some background questions such as your age, your work, whether you are right- or left-handed etc.

Next you will perform hands-on tasks to perform the Covid-19 test. This will require you to take a swab sample from your nose and mouth and then perform the test on the sample using the kit provided. You will then be asked a series of questions about the test you have completed.

It is important that you follow the researcher's instructions throughout the study. If you have questions or want further information, contact the researchers.

**What Are the Potential Risks If I Participate?**

There is minimal risk associated in taking part in the study. You might feel some mild discomfort when the swab is inside your nose or mouth. You might also become fatigued by the study's endpoint or might experience negative emotions, such as frustration and annoyance when trying to use the test kit or disappointment if you receive a positive Covid-19 test result.

If you have any concerns or experience distress during the study, please tell the researcher immediately.

**Who else will take part in the study?**

The study will involve other members of the general public

**What will happen if I don't want to carry on with the study?**

Your participating in this research is voluntary. If after giving consent you decide to stop your involvement you can do so at any time by contacting ([redacted], [redacted])
You do not need to provide an explanation for your decision.

**What are the benefits of taking part?**

Your input will provide valuable feedback to the sponsor on improvements that could be made to the test kit material.

As part of the test kit evaluation you will receive a test result during the study session and will be advised what you need to do if this result is positive for COVID-19.

**How will my information be kept confidential?**

Your name will not be used in any study reports or external publications.

We will be assigning a participant number to you. This way you will remain anonymous to the sponsor.

We do ask that we can audio tape or video record the session. This is so that we can check the recordings if we miss something during the session. All recordings, including those shared, will be held securely and in confidence, in accordance with data protection legislation.

If the sponsor resides outside of the EU your data will be leaving Europe and your data will be protected under that country's data protection laws and the EU's General Data Protection Regulations (GDPR).

Your data will be held according to PA's retention policy, a copy of which is available on request. Further details can be found in the Privacy policy on the PA website at, https://www.paconsulting.com/legal/privacy-policy/#request-access

**Contacts:**

If you have any further questions or concerns about the study you have taken part in, please contact

Your study researcher: [redacted]

PA Consulting
Cambridge Innovation and Technology Centre
Melbourn
Royston
SG8 7DB
UK

Telephone [redacted]

E-mail [redacted]

Data Protection Contact: [redacted]

You have the right at any time to make a complaint to the Information Commissioner's Office (ICO), the UK Supervisory Authority for data protection issue. We would however appreciate the chance to deal with your concerns before you approach the ICO, so please contact us in the first instance.

Information Commissioner's Office (ICO): www.ico.org.uk

## Participant Consent Form

Participant Study Identifications Number: _____

Please tick all the boxes that apply, then sign and date duplicate copies of this consent form:

| STATEMENT | SIGNATURE |
|---|---|
| I confirm that I have read the Participant Information Sheet (PIS). | |
| I confirm that I have had the opportunity to consider the information, and ask questions which have been answered to my satisfaction. | |
| I consent to audio (sound) and video (images) being recorded during the interview, and that information will only be used by the Sponsor for research purposes. | |
| I understand that the Sponsor may choose to either, watch the session remotely, or watch the video recording at a later date | |
| I understand that the identity of the Sponsor, the research topic discussed and materials examined during this study, and any other information which could reasonably be considered to be confidential (the “Confidential Information”) will be held by me in confidence. I agree not to disclose the Confidential Information to third parties. | |
| I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. | |
| I understand that I will receive a counter-signed copy of this consent form once both parties have signed it. | |
| **I consent to my participation in this research study conducted by PA Consulting for their sponsor.** | |

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent,

I have provided the study information sheet to the potential participant.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent and the consent has been given freely and voluntarily.

A copy of this consent form has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year

# Appendix 5 – Informed Assent - Adolescent

## Informed assent form: Adolescent

## Participant Information Sheet (PIS)

Please read this, or ask your parent or guardian read it to you, as it explains what this study is about before we ask you if you would like to take part.

If this does not answer all your questions, please ask. We are happy to explain anything you are not sure of.

### Why do you want me to be in this study?

We are testing a new product that will show if people have Covid-19 and we would like to see how you perform the test on yourself.

### Do I have to take part?

You do not have to do this if you do not want to.

### How long will it last?

The session will last about an hour.

### What do I have to do if I take part?

If you do want to take part, we will ask you to perform the test on yourself. This will involve you following the instructions on how to use the test. This will involve you blowing your nose and then using a swab to take a sample from your nose and near your tonsils.

Once this is done, we may ask you a few questions about what you thought about the test.

You will not have to do anything more.

### Will I get anything for taking part?

If you do want to take part, you will be paid some money. You and your guardian will be given £50 at the end of the session.

### What if I change my mind about doing this?

That is fine. If you start but change your mind and you don't want to take part any longer, you can just ask to stop the session. We will still pay you for taking part.

### Could I be hurt if I do this?

We will not be asking you to do anything dangerous. You might feel some mild discomfort when you insert the swab into your nose or mouth.

### Confidentiality:

If you do take part your information and what you have done will stay secret. The only people who will know about this are you, your guardian, me, and the people trying to make their new device better.

I think I know about this study and what it means, and

☐ NO, I do not want to take part

☐ YES, I will do the study, but I know I can stop at any time if I change my mind

| Your name (printing is ok) | Today's date |
|---|---|

I certify that this study has been explained in terms that he/she can understand and that he/she has freely assented to take part in this study

| Signature of person obtaining assent | Date |
|---|---|

Print name

# Appendix 6 – Informed consent for adult performing test on child

## Information Sheet and Informed Consent For Covid-19 home test

STUDY NAME LFD in-home test research 1:1 interview to gather human factors data

Before you agree to take part in this study, please read the following, and if you have any questions please ask.

**Invitation and Background:**

The sponsor of this study is the DHSC and they are evaluating the ease of use of a potential Covid-19 self-test test kit to be used in the home.

Under the General Data Protection Act (GDPR) we are required to gain your written consent to use your personal data. Personal data is any information relating to an identified or identifiable natural person such as video images or information about you.

Your consent given here will be the lawful basis required to process your personal data. This processing will include recording, storing, and when it is time, the deletion and destruction of your personal data.

You can withdraw your consent at any time without your legal rights being affected.

Under the General Data Protection Regulations (GDPR), you now have a number of rights,

- The right to be informed of how we will use your data
- The right of access to your data (called a Subject Access Request)
- The right to have incorrect data rectified
- The right to erasure, for instance, if you withdraw your consent
- The right to restrict processing, if you want more clarification on how we use your data
- The right to ask us to send your data to another data controller
- We will not be making any decisions about you in an automated way, or profiling you using the data you provide us

A detailed explanation of these rights is described in our privacy policy to be found on the PA website at, https://www.paconsulting.com/legal/privacy-policy/#request-access

**What would taking part in this study session involve?**

This study will involve you using an in-home test kit to test for Covid-19 and providing feedback on your experience.

This study will help the sponsor to inform the manufacturer of any improvements that might be needed to the test kit to improve ease of use.

The interview will require approximately 60 minutes of your time. You will be compensated £50 for your time.

The session will be conducted remotely using the remote user web-based platform,Validately.

During the session you will be interviewed by a researcher and there may also be people observing remotely.

During the study session you will be asked for your opinion on various aspects of the testing kit and other information which can be reasonably be considered to be confidential (the “Confidential Information”). We ask that you keep what you have heard or seen confidential, and do not disclose this Confidential Information to third parties.

This study is for research purposes and your data will only be processed for this research purpose; no sales of any kind are involved.

**What will happen if you agree to take part?**

If you qualify for the study you will be invited to join a remote research session via your home PC via a secure internet connection.

Before the scheduled interview the researchers will send you a pack containing the Covid-19 test kit, that will arrive at your home. All we would ask you to have access to or provide is a computer or Mac, a table, a chair for you and your child, a cup or beaker, tissues, a hand mirror, a torch and a bin. There will be instructions inside the pack for you to follow. The researchers will also send you a link to connect your PC or Mac to a remote research testing platform called Validately which is specifically designed to conduct remote studies of this type. When you join the session, you will be greeted by a member(s) of the research team. The researcher will start by asking you some background questions such as your age, your work, whether you are right- or left-handed etc.

Next you will perform hands-on tasks to perform the Covid-19 test. This will require you to take a swab sample from the nose and mouth of your child and then perform the test on the sample using the kit provided. You will then be asked a series of questions about the test you have completed.

It is important that you follow the researcher's instructions throughout the study. If you have questions or want further information, contact the researchers.

**What Are the Potential Risks If I Participate?**

There is minimal risk associated in taking part in the study, but you might become fatigued by the study's endpoint or might experience negative emotions, such as frustration and annoyance when trying to use the test kit or disappointment if the person you are testing receives a positive Covid-19 test result.

If you have any concerns or experience distress during the study, please tell the researcher immediately.

**Who else will take part in the study?**

The study will involve other members of the general public

**What will happen if I don't want to carry on with the study?**

Your participating in this research is voluntary. If after giving consent you decide to stop your involvement you can do so at any time by contacting ([redacted], [redacted])
You do not need to provide an explanation for your decision.

**What are the benefits of taking part?**

Your input will provide valuable feedback to the sponsor on improvements that could be made to the test kit material.

As part of the test kit evaluation you will receive a test result during the study session and will be advised what you need to do if this result is positive for COVID-19.

**How will my information be kept confidential?**

Your name will not be used in any study reports or external publications.

We will be assigning a participant number to you. This way you will remain anonymous to the sponsor.

We do ask that we can audio tape or video record the session. This is so that we can check the recordings if we miss something during the session. All recordings, including those shared, will be held securely and in confidence, in accordance with data protection legislation.

If the sponsor resides outside of the EU your data will be leaving Europe and your data will be protected under that country's data protection laws and the EU's General Data Protection Regulations (GDPR).

Your data will be held according to PA's retention policy, a copy of which is available on request. Further details can be found in the Privacy policy on the PA website at,
https://www.paconsulting.com/legal/privacy-policy/#request-access

**Contacts:**

If you have any further questions or concerns about the study you have taken part in, please contact

Your study researcher: [redacted]

PA Consulting
Cambridge Innovation and Technology Centre
Melbourn
Royston
SG8 7DB
UK

Telephone [redacted]

E-mail [redacted]

Data Protection Contact: [redacted]

You have the right at any time to make a complaint to the Information Commissioner's Office (ICO), the UK Supervisory Authority for data protection issue. We would however appreciate the chance to deal with your concerns before you approach the ICO, so please contact us in the first instance.

Information Commissioner's Office (ICO): www.ico.org.uk

## Participant Consent Form

Participant Study Identifications Number: _____

Please tick all the boxes that apply, then sign and date duplicate copies of this consent form:

| STATEMENT | SIGNATURE |
|---|---|
| I confirm that I have read the Participant Information Sheet (PIS). | |
| I confirm that I have had the opportunity to consider the information, and ask questions which have been answered to my satisfaction. | |
| I consent to audio (sound) and video (images) being recorded during the interview, and that information will only be used by the Sponsor for research purposes. | |
| I understand that the Sponsor may choose to either, watch the session remotely, or watch the video recording at a later date | |
| I understand that the identity of the Sponsor, the research topic discussed and materials examined during this study, and any other information which could reasonably be considered to be confidential (the “Confidential Information”) will be held by me in confidence. I agree not to disclose the Confidential Information to third parties. | |
| I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. | |
| I understand that I will receive a counter-signed copy of this consent form once both parties have signed it. | |
| **I consent to my participation in this research study conducted by PA Consulting for their sponsor.** | |

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent,

I have provided the study information sheet to the potential participant.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent and the consent has been given freely and voluntarily.

A copy of this consent form has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year

# Appendix 7 – Informed consent for adult performing test on dependent

## Information Sheet and Informed Consent For Covid-19 home test

STUDY NAME LFD in-home test research 1:1 interview to gather human factors data

Before you agree to take part in this study, please read the following, and if you have any questions please ask.

**Invitation and Background:**

The sponsor of this study is the DHSC and they are evaluating the ease of use of a potential Covid-19 self-test test kit to be used in the home.

Under the General Data Protection Act (GDPR) we are required to gain your written consent to use your personal data. Personal data is any information relating to an identified or identifiable natural person such as video images or information about you.

Your consent given here will be the lawful basis required to process your personal data. This processing will include recording, storing, and when it is time, the deletion and destruction of your personal data.

You can withdraw your consent at any time without your legal rights being affected.

Under the General Data Protection Regulations (GDPR), you now have a number of rights,

- The right to be informed of how we will use your data
- The right of access to your data (called a Subject Access Request)
- The right to have incorrect data rectified
- The right to erasure, for instance, if you withdraw your consent
- The right to restrict processing, if you want more clarification on how we use your data
- The right to ask us to send your data to another data controller
- We will not be making any decisions about you in an automated way, or profiling you using the data you provide us

A detailed explanation of these rights is described in our privacy policy to be found on the PA website at, https://www.paconsulting.com/legal/privacy-policy/#request-access

**What would taking part in this study session involve?**

This study will involve you using an in-home test kit to test for Covid-19 and providing feedback on your experience.

This study will help the sponsor to inform the manufacturer of any improvements that might be needed to the test kit to improve ease of use.

The interview will require approximately 60 minutes of your time. You will be compensated £50 for your time.

The session will be conducted remotely using the remote user web-based platform, Validately.

During the session you will be interviewed by a researcher and there may also be people observing remotely.

During the study session you will be asked for your opinion on various aspects of the testing kit and other information which can be reasonably be considered to be confidential (the “Confidential Information”). We ask that you keep what you have heard or seen confidential, and do not disclose this Confidential Information to third parties.

This study is for research purposes and your data will only be processed for this research purpose; no sales of any kind are involved.

**What will happen if you agree to take part?**

If you qualify for the study you will be invited to join a remote research session via your home PC via a secure internet connection.

Before the scheduled interview the researchers will send you a pack containing the Covid-19 test kit, that will arrive at your home. All we would ask you to have access to or provide is a computer or Mac, a table, a chair for you and the person you will be performing the test on, a cup or beaker, tissues, a hand mirror, a torch and a bin. There will be instructions inside the pack for you to follow. The researchers will also send you a link to connect your PC or Mac to a remote research testing platform called Validately which is specifically designed to conduct remote studies of this type. When you join the session, you will be greeted by a member(s) of the research team. The researcher will start by asking you some background questions such as your age, your work, whether you are right- or left-handed etc.

Next you will perform hands-on tasks to perform the Covid-19 test. This will require you to take a swab sample from the nose and mouth of the person you provide care for and then perform the test on the sample using the kit provided. You will then be asked a series of questions about the test you have completed.

It is important that you follow the researcher's instructions throughout the study. If you have questions or want further information, contact the researchers.

**What Are the Potential Risks If I Participate?**

There is minimal risk associated in taking part in the study, but you might become fatigued by the study's endpoint or might experience negative emotions, such as frustration and annoyance when trying to use the test kit or disappointment if the person you are testing receives a positive Covid-19 test result.

If you have any concerns or experience distress during the study, please tell the researcher immediately.

**Who else will take part in the study?**

The study will involve other members of the general public

**What will happen if I don't want to carry on with the study?**

Your participating in this research is voluntary. If after giving consent you decide to stop your involvement you can do so at any time by contacting ([redacted], [redacted])
You do not need to provide an explanation for your decision.

**What are the benefits of taking part?**

Your input will provide valuable feedback to the sponsor on improvements that could be made to the test kit material.

As part of the test kit evaluation you will receive a test result during the study session and will be advised what you need to do if this result is positive for COVID-19.

**How will my information be kept confidential?**

Your name will not be used in any study reports or external publications.

We will be assigning a participant number to you. This way you will remain anonymous to the sponsor.

We do ask that we can audio tape or video record the session. This is so that we can check the recordings if we miss something during the session. All recordings, including those shared, will be held securely and in confidence, in accordance with data protection legislation.

If the sponsor resides outside of the EU your data will be leaving Europe and your data will be protected under that country's data protection laws and the EU's General Data Protection Regulations (GDPR).

Your data will be held according to PA's retention policy, a copy of which is available on request. Further details can be found in the Privacy policy on the PA website at, https://www.paconsulting.com/legal/privacy-policy/#request-access

**Contacts:**

If you have any further questions or concerns about the study you have taken part in, please contact

Your study researcher: [redacted]

PA Consulting
Cambridge Innovation and Technology Centre
Melbourn
Royston
SG8 7DB
UK

Telephone [redacted]

E-mail [redacted]

Data Protection Contact: [redacted]

You have the right at any time to make a complaint to the Information Commissioner's Office (ICO), the UK Supervisory Authority for data protection issue. We would however appreciate the chance to deal with your concerns before you approach the ICO, so please contact us in the first instance.

Information Commissioner's Office (ICO): www.ico.org.uk

## Participant Consent Form

Participant Study Identifications Number: _____

Please tick all the boxes that apply, then sign and date duplicate copies of this consent form:

| STATEMENT | SIGNATURE |
|---|---|
| I confirm that I have read the Participant Information Sheet (PIS). | |
| I confirm that I have had the opportunity to consider the information, and ask questions which have been answered to my satisfaction. | |
| I consent to audio (sound) and video (images) being recorded during the interview, and that information will only be used by the Sponsor for research purposes. | |
| I understand that the Sponsor may choose to either, watch the session remotely, or watch the video recording at a later date | |
| I understand that the identity of the Sponsor, the research topic discussed and materials examined during this study, and any other information which could reasonably be considered to be confidential (the “Confidential Information”) will be held by me in confidence. I agree not to disclose the Confidential Information to third parties. | |
| I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. | |
| I understand that I will receive a counter-signed copy of this consent form once both parties have signed it. | |
| **I consent to my participation in this research study conducted by PA Consulting for their sponsor.** | |

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

# Appendix 8 – Informed consent for adult dependent having test performed on them

## Information Sheet and Informed Consent For Covid-19 home test

STUDY NAME LFD in-home test research 1:1 interview to gather human factors data

Before you agree to take part in this study, please read the following, and if you have any questions please ask.

**Invitation and Background:**

The sponsor of this study is the DHSC and they are evaluating the ease of use of a potential Covid-19 self-test test kit to be used in the home.

Under the General Data Protection Act (GDPR) we are required to gain your written consent to use your personal data. Personal data is any information relating to an identified or identifiable natural person such as video images or information about you.

Your consent given here will be the lawful basis required to process your personal data. This processing will include recording, storing, and when it is time, the deletion and destruction of your personal data.

You can withdraw your consent at any time without your legal rights being affected.

Under the General Data Protection Regulations (GDPR), you now have a number of rights,

- The right to be informed of how we will use your data
- The right of access to your data (called a Subject Access Request)
- The right to have incorrect data rectified
- The right to erasure, for instance, if you withdraw your consent
- The right to restrict processing, if you want more clarification on how we use your data
- The right to ask us to send your data to another data controller
- We will not be making any decisions about you in an automated way, or profiling you using the data you provide us

A detailed explanation of these rights is described in our privacy policy to be found on the PA website at, https://www.paconsulting.com/legal/privacy-policy/#request-access

**What would taking part in this study session involve?**

This study will involve the person who provides care for you using an in-home test kit to perform a test for Covid-19 on you.

This study will help the sponsor to inform the manufacturer of any improvements that might be needed to the test kit to improve ease of use.

The interview will require approximately 60 minutes of your time. You will be compensated £50 for your time.

The session will be conducted remotely using the remote user web-based platform, Validately.

During the session the person who provides care for you will be interviewed by a researcher and there may also be people observing remotely.

During the study session they will be asked for their opinion on various aspects of the testing kit and other information which can be reasonably be considered to be confidential (the “Confidential Information”). We ask that you keep what you have heard or seen confidential, and do not disclose this Confidential Information to third parties.

This study is for research purposes and your data will only be processed for this research purpose; no sales of any kind are involved.

**What will happen if you agree to take part?**

If you qualify for the study the person who provides care to you will be invited to join a remote research session via your home PC via a secure internet connection.

Before the scheduled interview the researchers will send you a pack containing the Covid-19 test kit, that will arrive at your home.

The person who provides care for you will set up the supplies required: a computer or Mac, a table, a chair for person performing the test and a chair for you, a cup or beaker, tissues, a hand mirror, a torch and a bin. There will be instructions inside the pack for them to follow. The researchers will also send you a link to connect your PC or Mac to a remote research testing platform called Validately which is specifically designed to conduct remote studies of this type. When they join the session, they will be greeted by a member(s) of the research team. The researcher will start by asking them some background questions such as their age, their work, whether you are right- or left-handed etc.

Next they will perform hands-on tasks to perform the Covid-19 test. This will require they take a swab sample from your nose and mouth and then perform the test on the sample using the kit provided. They will then be asked a series of questions about the test they have completed.

**What Are the Potential Risks If I Participate?**

There is minimal risk associated in taking part in the study. You might feel some mild discomfort when the swab is inside your nose or mouth. You might become fatigued by the study's endpoint or might experience negative emotions, such as frustration and annoyance or disappointment if you receive a positive Covid-19 test result.

If you have any concerns or experience distress during the study, please tell the researcher immediately.

**Who else will take part in the study?**

The study will involve other members of the general public

**What will happen if I don't want to carry on with the study?**

Your participating in this research is voluntary. If after giving consent you decide to stop your involvement you can do so at any time by contacting ([redacted], [redacted])
You do not need to provide an explanation for your decision.

**What are the benefits of taking part?**

Your input will provide valuable feedback to the sponsor on improvements that could be made to the test kit material.

As part of the test kit evaluation you will receive a test result during the study session and will be advised what you need to do if this result is positive for COVID-19.

**How will my information be kept confidential?**

Your name will not be used in any study reports or external publications.

We will be assigning a participant number to you. This way you will remain anonymous to the sponsor.

We do ask that we can audio tape or video record the session. This is so that we can check the recordings if we miss something during the session. All recordings, including those shared, will be held securely and in confidence, in accordance with data protection legislation.

If the sponsor resides outside of the EU your data will be leaving Europe and your data will be protected under that country's data protection laws and the EU's General Data Protection Regulations (GDPR).

Your data will be held according to PA's retention policy, a copy of which is available on request. Further details can be found in the Privacy policy on the PA website at,
https://www.paconsulting.com/legal/privacy-policy/#request-access

**Contacts:**

If you have any further questions or concerns about the study you have taken part in, please contact

Your study researcher: [redacted]

PA Consulting
Cambridge Innovation and Technology Centre
Melbourn
Royston
SG8 7DB
UK

Telephone [redacted]

E-mail [redacted]

Data Protection Contact: [redacted]

You have the right at any time to make a complaint to the Information Commissioner's Office (ICO), the UK Supervisory Authority for data protection issue. We would however appreciate the chance to deal with your concerns before you approach the ICO, so please contact us in the first instance.

Information Commissioner's Office (ICO): www.ico.org.uk

## Participant Consent Form

Participant Study Identifications Number: _____

Please tick all the boxes that apply, then sign and date duplicate copies of this consent form:

| STATEMENT | SIGNATURE |
|---|---|
| I confirm that I have read the Participant Information Sheet (PIS). | |
| I confirm that I have had the opportunity to consider the information, and ask questions which have been answered to my satisfaction. | |
| I consent to audio (sound) and video (images) being recorded during the interview, and that information will only be used by the Sponsor for research purposes. | |
| I understand that the Sponsor may choose to either, watch the session remotely, or watch the video recording at a later date | |
| I understand that the identity of the Sponsor, the research topic discussed and materials examined during this study, and any other information which could reasonably be considered to be confidential (the “Confidential Information”) will be held by me in confidence. I agree not to disclose the Confidential Information to third parties. | |
| I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. | |
| I understand that I will receive a counter-signed copy of this consent form once both parties have signed it. | |
| **I consent to my participation in this research study conducted by PA Consulting for their sponsor.** | |

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent,

I have provided the study information sheet to the potential participant.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent and the consent has been given freely and voluntarily.

A copy of this consent form has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year

# Appendix 9 – Informed Assent – Child

## Informed assent form: Child

## Participant Information Sheet (PIS)

Please read this, or ask your parent or guardian read it to you, as it explains what this study is about before we ask you if you would like to take part.

If this does not answer all your questions, please ask. We are happy to explain anything you are not sure of.

### Why do you want me to be in this study?

We are testing a new product that will show if people have Covid-19 and we would like to see how your parent or guardian performs the test on you.

### Do I have to take part?

You do not have to do this if you do not want to.

### How long will it last?

The session will last about an hour.

### What do I have to do if I take part?

If you do want to take part, we will ask your parent to perform the test on you. This will involve them asking you to blow your nose and then using a swab to take a sample from your nose and near your tonsils.

Once this is done, we may ask you a few questions about what you thought about the test.

You will not have to do anything more.

### Will I get anything for taking part?

If you do want to take part, you will be paid some money. You and your guardian will be given £50 at the end of the session.

### What if I change my mind about doing this?

That is fine. If you start but change your mind and you don't want to take part any longer, you can just leave. We will still pay you for taking part.

### Could I be hurt if I do this?

We will not be asking you to do anything dangerous. You might feel some mild discomfort when you have the swab inserted into your nose or mouth.

### Confidentiality:

If you do take part your information and what you have done will stay secret. The only people who will know about this are you, your guardian, me, and the people trying to make their new device better.

I think I know about this study and what it means, and

☐ NO, I do not want to take part

☐ YES, I will do the study, but I know I can stop at any time if I change my mind

| | |
|---|---|
| Your name (printing is ok) | Today's date |

I certify that this study has been explained in terms that he/she can understand and that he/she has freely assented to take part in this study

| | |
|---|---|
| Signature of person obtaining assent | Date |
| Print name | |

# Appendix 10 – Discussion guide

## Introduction

**Name:** Introduce PA representative

**Duration of review meeting:** 60 minutes

**Note to moderator: Warn participants that the computer will say "This session is now being recorded" when press record [allow pause for this]**

***PRESS RECORD IN VALIDATELY***

**Moderator:** *Welcome and thank you for agreeing to take part in this study. My name is _____ and I am an independent researcher.*

*I would just like to check that you have read the Informed Consent/assent you agree to what it says, and have signed the form.* **[pause for answer].** *Do you have any questions about the form?*

*I will be asking a you to undertake a Covid-19 virus test and I will be asking a few questions about your experience doing this.*

*I do have a colleague and representatives from our client observing the session remotely.*

*The study that we are running today is a regulatory study which we are conducting on behalf of the government before this test kit is allowed to be released to the public. We therefore ask that you take this session very seriously as your contribution today has a direct impact on the release of this test kit to the wider public.*

**Remind:**

- *If you have a mobile phone, please would you mind turning it on silent for the session?*
- *The session will last about between 60 minutes.*
    - *The session is being video recorded by the cameras in Validately*
    - *The session will be viewed remotely by members of the research team.*
- *The material you will be using today is Confidential, and the document you have signed is a Confidentiality Agreement, so please don't talk to anyone else about what* you see today.
- *We will be keeping any sensitive information you provide to us confidential, as outlined in the consent form.*
- *You can withdraw from the session at any time and without penalty; you do not have to give a reason.*

*I am now going to get you to unpack the supply of items you will need for today.*

*Please can you open the envelope labelled 'Do not open until instructed' and take out the contents.*

***…BUT PLEASE DON'T OPEN THE TEST KIT (which is contained within the clear bag).***

***INSIDE UNTIL I TELL YOU TO***

**In your envelope there should also be:**

- Hand gel
- Participant ID label
- Stamp addressed envelope for return of the webcam
- IFU
- Spare swab

**Note to moderator: Check you can see whole of the assessment area with the participant positioned as if they were about to start doing the simulated use.**

## 6.1 Introductory questions / screener confirmation (5 mins)

Today we are going to ask you to administer a Covid-19 test using the materials provided to you, and then ask you some follow up questions on your experience.

First, I would like to ask you some background questions about yourself and any experience you may have using an in-home test kit

| | | |
|---|---|---|
| 1. | Are you right or left-handed? | |
| 2. | How old are you? | |
| 3. | Do you wear glasses/contacts to read? [Ensure they have brought their glasses with them] | |
| 4. | Are you colour blind or colour deficient? | |
| 5. | Do you have trouble gripping and holding objects? | |

## 6.2 Baseline patient experiences (2 mins)

1. Have you taken a home test before for anything?
   Probe: What was the test for?
   Probe: What was your experience when taking the test?
   Probe: How easy was the test to perform?
   Probe: Did you have any difficulty following the instructions?

| |
|---|
| |

## 6.3 **ADULT/ADOLESCENT** Simulated use and Root Cause (40 mins)

**NOTE TO MODERATOR – GO TO NEXT SECTION IF CAREGIVER**

The test-kit that you are going to use today is detects the presence of COVID-19. You would use this test-kit on yourself or someone you care for, and it would be posted to your home as part of the UK Government's Test and Trace scheme.

I now want you to imagine that you have been sent the test kit and it's time to perform the test on yourself. Remember this is a real test which is going to give you a real result, so please do everything you would do if I weren't here today. Once you have finished let me know and I will ask you some questions.

**When giving yourself the test, please refer to the instructions provided to you in the kit.**

Do you have any questions before we start?

You may now proceed to do the test.

**REFERRED TO IFU? YES / NO**

### 6.3.1 LFD TEST ADULT OR ADOLESCENT SELF TEST

| Use Step/Acceptance criteria | Use Error | Use Difficulty | Close Call | Pass | Comments |
|---|---|---|---|---|---|
| Clear, clean and dry a flat surface to place the home test kit on. | | | | | |
| Wash your hands thoroughly for 20 seconds, using soap and warm water, or hand sanitiser. | | | | | |
| Take the test kit out of the foil packaging and place it onto the cleaned flat surface. | | | | | |
| **Setup your test** | | | | | |
| **Use Step 1**<br>**Carefully twist or snap open the sachet** | | | | | |

| Use Step/Acceptance criteria | Use Error | Use Difficulty | Close Call | Pass | Comments |
|---|---|---|---|---|---|
| **Use Step 2**<br>**Pour all of the fluid from the sachet into the extraction tube.** | | | | | |
| **Use Step 3**<br>**Place the filled tube in a cup or container to avoid spilling it while you use the swab** | | | | | |
| **Use Step 4**<br>**Check the swab in the sealed wrapper in front of you** | | | | | |
| **Use step 5**<br>**Gently blow your nose into a tissue.** | | | | | |
| **Use step 6**<br>**Wash and dry your hands again (or use sanitiser if this is available).** | | | | | |
| **Use Step 7**<br>**Open the swab package and gently take out the swab.** | | | | | |
| **Take your swab sample** | | | | | |
| **Use step 8**<br>**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. | | | | | |

| Use Step/Acceptance criteria | Use Error | Use Difficulty | Close Call | Pass | Comments |
|---|---|---|---|---|---|
| **Use step 9**<br>**Put the same swab gently into one nostril until you feel a slight resistance (about 2.5cm up your nose).**<br>Roll the swab firmly around the inside of the nostril, making 10 complete circles. | | | | | |
| **Process the swab sample** | | | | | |
| **Use step 10**<br>**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.**<br>Press the tip against the edge of the extraction tube with force, while rotating it around the tube for 15 seconds. | | | | | |
| **Use step 11**<br>**Pinch the tube as you remove the swab to make sure that all the fluid is removed from the soft tip of the swab.**<br>Place the swab in the plastic waste bag provided. | | | | | |
| **Use step 12**<br>**Press the nozzle cap tightly on to the extraction tube to avoid any leaks** | | | | | |
| **Use step 13**<br>**Gently squeeze the extraction tube to place 2 drops of liquid onto the specimen well on the test strip.** | | | | | |

| Use Step/Acceptance criteria | Use Error | Use Difficulty | Close Call | Pass | Comments |
|---|---|---|---|---|---|
| **Use step 14**<br>**Place the test strip on a flat and level surface**<br>**Check the time or set a timer if you have one. Wait 30 minutes to read your result.** | | | | | |

**START TIMER (30 minutes)**

**NOTE TO MODERATOR: AFTER STEP 14 ASK THE PARTICIPANT HOW LONG THEY SHOULD WAIT TO READ THE RESULTS**

Wait full 30 minutes before reading results. A positive result can appear at any time after 20 minutes, however you must wait for a full 30 minutes to record a negative result as the test line may take longer to appear.

**WHILE WAITING FOR THE TEST RESULTS PROCEED WITH 6.5**

**NOTE TO MODERATOR: RECORD CURRENT TIME AND SET A TIMER FOR 30 MINUTES.**

## 6.4 **CAREGIVER** Simulated use and Root Cause (40 mins)

The test-kit that you are going to use today is detects the presence of COVID-19. You would use this test-kit on yourself or someone you care for, and it would be posted to your home as part of the UK Government's Test and Trace scheme.

I now want you to imagine that you have been sent the test kit and it's time to perform the test on your child/family member. Remember this is a real test which is going to give you a real result, so please do everything you would do if I weren't here today. Once you have finished let me know and I will ask you some questions.

**When giving yourself the test, please refer to the instructions provided to you in the kit.**

Do you have any questions before we start?

You may now proceed to do the test.

**REFERRED TO IFU? YES / NO**

| Use Step/Acceptance criteria | Use Error | Use Difficulty | Close Call | Pass | Comments |
|---|---|---|---|---|---|
| Clear, clean and dry a flat surface to place the home test kit on. | | | | | |
| Wash your hands thoroughly for 20 seconds, using soap and warm water, or hand sanitiser. | | | | | |
| Take the test kit out of the foil packaging and place it onto the cleaned flat surface. | | | | | |
| **Setup your test** | | | | | |
| **Use Step 1**<br>**Carefully twist or snap open the sachet** | | | | | |
| **Use Step 2**<br>**Pour all of the fluid from the sachet into the extraction tube.** | | | | | |

| Use Step/Acceptance criteria | Use Error | Use Difficulty | Close Call | Pass | Comments |
|---|---|---|---|---|---|
| **Use Step 3**<br>**Place the filled tube in a cup or container to avoid spilling it while you use the swab** | | | | | |
| **Use Step 4**<br>**Check the swab in the sealed wrapper in front of you** | | | | | |
| **Use step 5 (Not required for non self test)**<br>**Gently blow your nose into a tissue.** | | | | | |
| **Use step 6**<br>**Wash and dry your hands again (or use sanitiser if this is available).** | | | | | |
| **Use Step 7**<br>**Open the swab package and gently take out the swab.** | | | | | |
| **Take your swab sample** | | | | | |
| **Use step 8 (child/dependant)**<br>**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.**<br>Carefully remove the swab.<br>If you cannot swab the tonsils, you can swab both nostrils. | | | | | |

| Use Step/Acceptance criteria | Use Error | Use Difficulty | Close Call | Pass | Comments |
|---|---|---|---|---|---|
| **Use Step 9 (child/dependent)**<br>**Put the fabric tip of the same swab gently into one of their nostrils until you feel some resistance.**<br>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.** | | | | | |
| **Process the swab sample** | | | | | |
| **Use step 10**<br>**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.**<br>Press the tip against the edge of the extraction tube with force, while rotating it around the tube for 15 seconds. | | | | | |
| **Use step 11**<br>**Pinch the tube as you remove the swab to make sure that all the fluid is removed from the soft tip of the swab.**<br>Place the swab in the plastic waste bag provided. | | | | | |
| **Use step 12**<br>**Press the nozzle cap tightly on to the extraction tube to avoid any leaks** | | | | | |

| Use Step/Acceptance criteria | Use Error | Use Difficulty | Close Call | Pass | Comments |
|---|---|---|---|---|---|
| **Use step 13**<br>**Gently squeeze the extraction tube to place 2 drops of liquid onto the specimen well on the test strip.** | | | | | |
| **Use step 14**<br>**Place the test strip here (Optional).**<br>**Check the time or set a timer if you have one. Wait 30 minutes to read your result.** | | | | | |

**START TIMER (30 minutes)**

**NOTE TO MODERATOR: AFTER STEP 14 ASK THE PARTICIPANT HOW LONG THEY SHOULD WAIT TO READ THE RESULTS**

Wait full 30 minutes before reading results. A positive result can appear at any time after 20 minutes, however you must wait for a full 30 minutes to record a negative result as the test line may take longer to appear.

## 6.5 Overall experience / Route cause investigation (10 mins)

Now that you have performed the test I want to ask you about your experience of doing this.

2. Did you have any difficulties?
   Probe: Root cause and areas of difficulties observed

## 6.6 Knowledge based questions

I am now going to ask you some questions about using the COVID-19 testing kit.

**This is not a memory test, and I would like you to refer to the instructions when answering these 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.<br>**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:<br>Go online to: NHS 111 online coronavirus service, **111.nhs.uk**.<br>If you do not have internet access, call NHS 111.<br>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:<br>Do not use it.<br>Call, using the numbers below, and ask for a new kit:<br>- England, Wales and Northern Ireland: **119** (free from mobiles and landlines)<br>- 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 | What does this test result indicate:<br>  | Two lines – even faint lines – indicate the test is positive. |
| 12 | What does this test result indicate:<br>  | The test is invalid |
| 13 | What does this test result indicate:<br>  | This indicates the test is negative.<br><br>. |
| 14 | How should you report a positive result? | **Answers can include:**<br><br>Report online **www.gov.uk/covid19-self-test-help/**<br><br>Or scan this **QR code** with your smart phone to open the reporting website<br><br>**Report by telephone**<br><br>England, Wales and Northern Ireland: **119** (free from mobiles and landlines)<br><br>Scotland: **0300 303 2713** (charged at your standard network rate) |

| | | |
|---|---|---|
| 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 |

**AFTER 30 MINUTES HAVE PASSED AND TIMER RINGS, PROCEED TO READ RESULTS**

## 6.7 Reading the test results (5 mins)

We have now reached the time to read your test results. Can you now tell me what the result is?

Ask to describe what they see.

| |
|---|
| |

Participant answer:……

Circle applicable Correct interpretation: Success Incorrect interpretation: Use error

## 6.8 Closing session (5 mins)

3. Considering the test that you have performed today what kind of support service do you prefer to use?
   1. Direct face to face HCP/pharmacy support
   2. Telephone support
   3. Connected solutions e.g Apps

| |
|---|
| |

That is all I would like to discuss today.

Is there anything that you would like to ask me about what you have seen today or to mention something that is important to you that I haven't asked about?

**THANK PARTICIPANT.**

**REMIND PARTICIPANT TO PLACE THE WEBCAM IN THE PRE PAID ENVELOP AND RING THE NUMBER FOR COLLECTION**

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