**Covid Lateral Flow Testing Clinical Standard Operation Policy**

**Document Control**

**Version Control**

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| **Version** | **Version Date** | **Author** | **Reason for Change** |
| 1 | 25/11/2020 | Shelagh Cleary | Initial Draft |
| 2 | 26/11/2020 | Karen Jackson | Confirmatory PCR added into positive results section following SLT sign-off |
| 3 | 29/11/2020 | Barry Jones | Cleaning and waste added |
| 4 | 9/12/2020 | Shelagh Cleary | Incorporating changes from the DHSC Master SOP v2.6 |
| 5 | 4/1/2021 | Shelagh Cleary | Incorporating changes from the DHSC Master SOP v2.8 and PH Pharmacy Team |
| 6 | 7/1/2021 | Shelagh Cleary | Changes from DHSC regarding eligibility and testing for those under 18 |
| 7 | 21/01/2021 | Shelagh Cleary | Changes made to confirmatory PCR test |
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**Authorship**

|  |  |  |
| --- | --- | --- |
| **Name** | **Department** | **Contact Details** |
| Shelagh Cleary | Healthcare Public Health | 01384 816032 |
| Barry Jones |  |  |
| Karen Jackson |  |  |
| Louise Grainger |  |  |

**Review**

This Standard Operating Procedure will be reviewed monthly, or more frequently if new guidance became available, or upon request by a stakeholder involved in the effective operation of this SOP.

**Use of this Operational Policy**

This Standard Operation Policy (SOP) is intended for all those employed by Dudley MBC and contractors and sub-contractors thereof.

**Contractors include:**

West Midlands Fire service

Central Health

The Pensnett Covid Assessment Centre (Dudley CCG)

Solutions for Health

**Introduction**

Lateral Flow Testing (LFT) is a new kind of technology that could enable us to identify and isolate more asymptomatic people who are at high likelihood of spreading coronavirus, whilst simultaneously minimising disruption for those who test negative.

The device detects a protein (antigen) produced by the virus at its most infectious stage, i.e. those with a high viral load.

The test is complete in 30 minutes and so gives real time results with no time lag between testing and receiving results to aid more prompt measures to reduce the risk of transmission in positive cases and to reassure those who test negative.

The test is for the asymptomatic population, i.e. those without symptoms of Covid 19, but who may carry the virus and be able to infect others without their knowledge. Therefore, the aim of this test is to identify background cases in the population that otherwise would remain a potential risk of transmission.

If the result of the LFD is positive, the person will be asked to self-isolate for 10 days in line with normal NHS T&T procedures.

It should be noted that a negative result does not rule out Covid 19 infection and there can be false negative results. If negative and it is clinically indicated, a repeat test should be undertaken using PCR to detect presence of the virus.

**CQC Registration**

COVID-19 an activity that falls outside the scope of registration with CQC. It is therefore not a requirement for pilot studies of Use Cases to register with the CQC to provide COVID-19 diagnostic and screening services

**Consent to Testing**

The test is available to all those 18 and over consenting to testing, as well those aged 16-17 who can consent to their own medical treatment without parent or guardian present. Those under 16 must have the consent of a parent or guardian.

**Training for Staff**

The link below is to the training video recommended by PHE for this test with accreditation questions provided.

All those to be involved in the test process must first undertake the training and pass the accreditation process. Clinical support is available through this process and thereafter for all trained testers.

Link: <https://go.tessello.co.uk/TestDeviceTraining/Login.aspx>

Access token: 3wkcVi4UTX

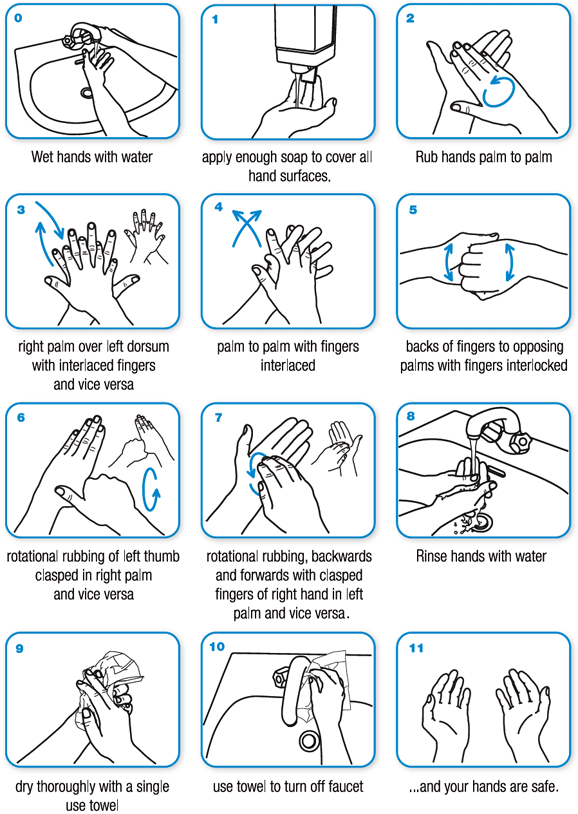
**The Quality Assurance** of the process will be maintained by periodic assessment of the testing staff and confirmatory random PCR testing of a selection of LFD results (see page 13).

**Hand Washing**

[Hand washing video NHS](https://www.youtube.com/watch?v=bQCP7waTRWU)

Hand washing guidance will be displayed in all donning and doffing areas. Staff will also have this information included in any Covid 19 testing training.

**Hand Washing Technique**



**Personal Protective Equipment (PPE)**

**All those who are involved in carrying out LFT must wear full PPE. It is of vital importance that this is donned and doffed correctly in a clean covid safe area.**

**Donning and Doffing of PPE**

**Instruction pre-donning PPE**

1. Worker is hydrated
2. Hair is tied back, and long beards are tied up or a beard net is used
3. Jewellery is removed
4. PPE is correct size for worker
5. Hands must be cleaned - soap and water for at least 20 seconds. This should be the last step before donning PPE

**Instructions for donning PPE**

1. Apron

Apron is pulled over the head and fastened at the back of the waist

1. Surgical mask
   1. Mask is secured over face, ensuring it is well fitted and covers both mouth and nose
   2. Mask must not be allowed to dangle around the neck of wearer
2. Eye protection
   1. Eye protection is applied, ensuring eyes are well covered
   2. Eye protection must not be touched once put on
3. Gloves
   1. Gloves are applied, covering both hand and wrist

**Instructions wearing PPE**

1. Always keep hands away from face
2. Limit surfaces touched in the testing environment
3. Change any PPE if torn or contaminated

**When to doff PPE**

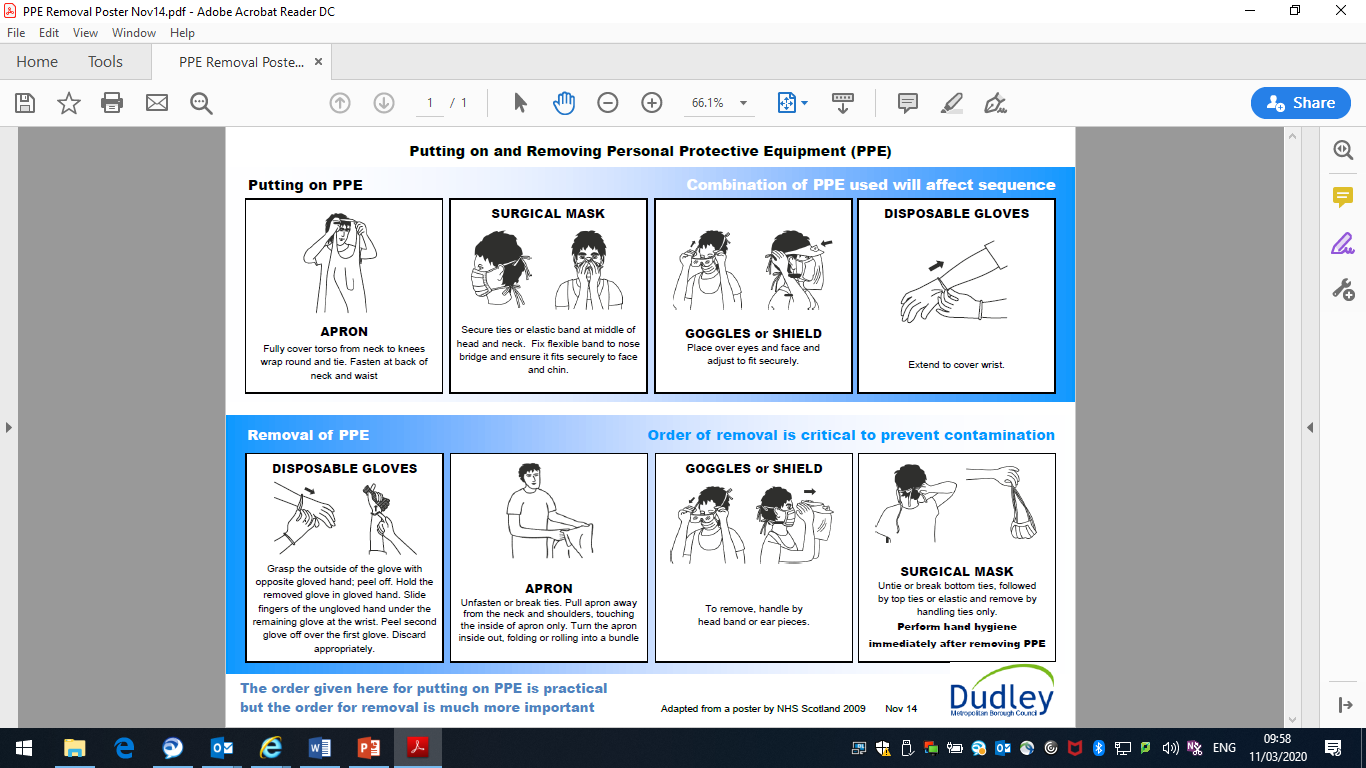
1. PPE should only be removed once the member of staff leaves the testing station and are at no further risk from any subject
2. PPE to be removed *if contaminated*, once the member of staff leaves the testing station and are no further risk from any subject
3. All used PPE must be discarded as category B clinical waste in the clinical waste bins provided

**Instructions for doffing PPE**

1. Gloves
   1. The outside of the gloves is contaminated. Grasp the outside of the cuff of the glove with the opposite gloved hand; peel off
   2. Hold the removed glove in the gloved hand. Slide the fingers of the un-gloved hand under the remained gloved at the wrist. Peel the second glove off over the first glove
   3. Discard gloves into the clinical waste bins provided
2. Hand hygiene via application of alcohol hand sanitiser after removal of gloves and before removal of apron
   1. Front of apron is contaminated. Apron is pulled away from neck and shoulders, by breaking or unfasten apron ties from the neck - touching only the inside of the apron allow it to fall forward
   2. Break or unfasten apron ties at the back, fold and roll into a bundle and discarded into the clinical waste bins provided
3. Eye protection
   1. Outside of goggles/visor are contaminated. Handle only the headband or the sides
   2. Eye protection is discarded into the clinical waste bins provided.
   3. Hands are cleaned with alcohol rub
4. Surgical mask
   1. Front of mask is contaminated. Without touching the mask, the strap is unfastened, first at the bottom, then at the top. The mask is pulled away from the face without touching front of the mask. If ear loop mask is used, slip fingers into the loops and pull the loops outwards over the ears then pull the mask away from the face
   2. Mask is discarded into the clinical waste bins provided

Full hand hygiene procedure, using soap and water must always be performed after removal and disposal of PPE.

**Video** [COVID-19: Donning and doffing of Personal Protective Equipment in Health and Social Care Settings](https://www.youtube.com/watch?v=-GncQ_ed-9w&feature=youtu.be)



## Eligibility

Subject eligibility criteria

* The subject will be asymptomatic
* The subject will consent to sharing their data with the National T&T programme (registration process completed).

Exclusions (those non-consenting to test, parental refusal, unable to self-swab)

For those under 18, the approach will be the same as that currently employed in PCR testing.

* That the child will be accompanied by a consenting parent/guardian.
* That 12-17-year olds may self-swab with supervision of a parent or guardian.
* Children aged 16-17 may attend a Test Site unaccompanied for either self-test or assisted, provided the site staff are satisfied that they are ‘Gillick Competent’ (able to consent to their own medical treatment without parent or guardian present)
* For children 11 or under, the accompanying adult is to administer the swab for the child. The accompanying adult should only administer the swab if they are comfortable to do so and appropriately trained individuals are not available to undertake swabbing.
* Specific instructions have been prepared and made available for swabbing young children see appendix 3

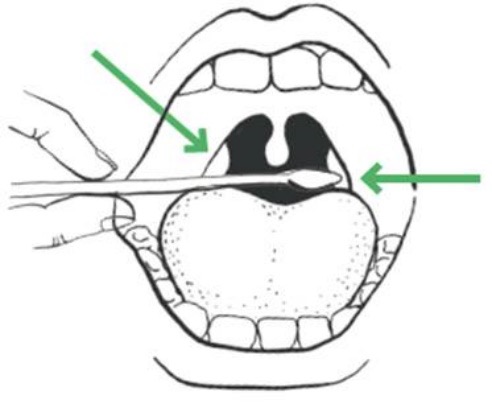
More information can be found at <https://www.gov.uk/government/publications/testing-for-coronavirus-at-home/covid-19-home-test-step-by-step-guide-adults-and-children#test-a-child>

### Self-swabbing sample collection procedure:

directed to a sample collection booth from the check-in zone. A crowd control system should be in place to ensure the subject is only sent into a booth when the Processing Operative (tester) is ready to process the swab.

Before commencing swabbing, the Test Assistant will explain the process to the subject. The subject will also be informed that the swab may sometimes make them gag and they should use a sick bowl for any expectoration or vomit and guidance will be given regarding what to do with this if used.

1. Once in the booth, the barcode should be handed immediately to the Processing Operative. The subject will then be required to remove their mask, blow their nose and complete hand hygiene using hand gel.
2. The subject will be required to open their mouth and visually identify the left and right tonsils (or tonsillar pits for subjects with the previous tonsillectomy). A mirror is provided in each booth for this.



*Figure 1 Swab rubbing the tonsil*

1. The subject should complete hand hygiene using the sanitiser in the booth
2. The swab should be removed from sterile packaging by the subject.
   1. The swab must be kept dry before taking a sample from the back of the throat and therefore it must not touch any surfaces including the teeth, gums, and tongue or cheek surfaces when conducting the test.

**Please note:** **The swab will be invalid if it touches these parts during or after sampling and it must be put in clinical waste and a fresh swab selected**.

1. Holding the swab in their hand, the subject should open their mouth wide and rub the fabric tip of the swab over both tonsils (or where they would have been) at the back of the throat with good contact at least 3 times. Carefully remove the swab stick from the back of the throat taking care to ensure that it does not come into contact with any other structure or surface.
2. The subject should then insert the same swab into one nostril. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa of the inside of the nostril to ensure that both mucus and cells are collected.
3. **Note:** In children, adults and the very elderly where throat swabbing is more difficult, double anterior nares swabbing can be used. The subject will be required to place their swab directly into the prepared extraction tube on the bench at the window with the cotton bud end facing down.
   1. The subject should not grasp the cotton bud end, which has been in contact with the tonsils and nostril.
4. The subject then completes hand hygiene using the sanitiser in the booth. If the operational model includes the subject handling any equipment (e.g. hand mirror) they should disinfect the surfaces with anti-viral wipes
5. The subject will put back on their face covering and leave the booth.

If a subject vomits, operations at the testing bay shall be ceased and the site personnel should follow the spillage guidelines until the area has been cleaned adequately to allow resumption.

**Sample processing and analysis procedure**

The manufacturer’s instructions for use can be found here: [Innova SARS-Cov-2 Antigen Test IFU](https://cdn.website-editor.net/6f54caea7c6f4adfba8399428f3c0b0c/files/uploaded/Innova-SARS-Cov-2-Antigen-test-IFU.pdf)

The test cartridge and extraction solution should be stored at ambient temperature (2-30 degrees Centigrade). The reagents and devices must be at room temperature (15-30 degrees centigrade) when used for testing.

Testing should be conducted on a flat surface with adequate light.

Reagents and devices must be at room temperature (15–30 °C) when used for testing.

The Processing Operative should prepare the area in advance of receiving the sample and barcode from the subject.

The Processing Operative should only process one sample at a time.

The following steps should be followed in line with the manufacturer’s instructions for use and with equipment available:

1. The Processing Operative receives the barcode directly from the subject (as described in self-swab section above)
2. The Processing Operative then removes the LFD device from the pouch and applies a barcode to the underside of the LFD cartridge. LFD cartridges should be used without a long delay after opening the pouches in which they are supplied.
3. The Processing Operative sets up the extraction tube by following these steps:
4. Place the extraction tube in the tube rack with the opening facing up
5. Press the extraction solution bottle to drip 6 drops of extract solution into the extractor tube without touching the edge of the tube. **Do not let the buffer bottle touch the edge of the tube**.
6. The buffer bottle should be decontaminated with anti-viral using wipes between samples to prevent cross-contamination.

The extraction tube is placed in the tube rack on the processing bench next to the window for the subject to place the swab

1. The Subject places the swab sample into the prepared extraction tube (as described in self-swab section above) located on the table at the window (to potentially prevent the swab from drying out)
2. The Processing Operative then takes the swab and commences the following steps:
3. Extract: Hold and press the swab head against the wall of the tube with force while rotating the swab for about 10 seconds to release the antigen into the extraction solution from the swab head.
4. Remove swab: Squeeze the swab head by squeezing the lower end of the tube while removing the swab in order to remove as much liquid as possible from the swab as shown in Figure 2.
5. On withdrawal, immediately dispose of the swab into the non-hazardous waste bin.
6. Install a nozzle cap onto the extraction tube
7. Load: drip 2 drops of extraction solution into the sample well (marked ‘S’) of the LFD cartridge
8. Record the time of test drop (XX:XX) in marker on the LFD and make sure you have set a timer to read the results at 30 minutes.
9. Re-check that the liquid can be seen seeping along the cartridge (to ensure the drop was not an air bubble) If the cartridge appears dry, the subject will need to be recalled for a repeat sample to be taken.
10. Move the cartridge to a defined processing space for reading and leave for between 20-30 minutes as below, *N.B. the LFD movement should be kept to a minimum and where it is required to be moved, keep horizontal using a tray.*
11. Clean the sample preparation area thoroughly with disinfectant spray provided (70% alcohol).

Diagram

Description automatically generated

Figure 2 Extraction buffer preparation

The Processing Operative is responsible for preparing and loading (‘dropping’) the sample onto the cartridge after receiving the subject’s swab.

The subject will then leave the test centre to await the results communication. The subject is entitled to request to wait for the results, but this will be away from the testing area.

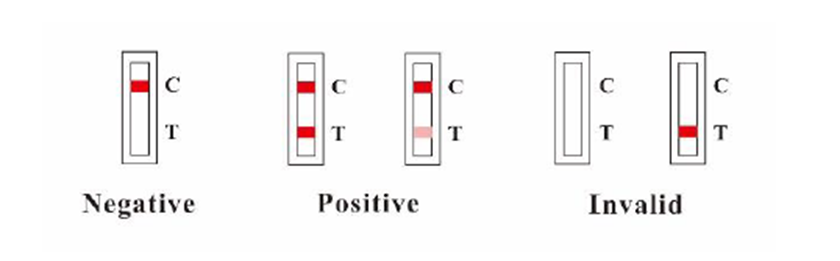
The Processing Operative may move the LFD to a different area to read results with a tray grouped by time cohort.

### Reading and interpreting the LFD result

1. Reading: The result is read according to the manufacturer’s instructions for use between 20 and 30 minutes
2. Results Interpretation:

Strong positive results can be reported at 20 minutes however, negative results must be reported at 30 minutes.

If a positive signal appears *after* 30 minutes, it should not be reported as positive. Line C must be coloured to have a valid test result (see Figure 7).

Figure 3. Result interpretation taken from IFU

**Valid results:**

Negative result: There is coloration on line C only, suggesting that there is no SARS-CoV-2 antigen in the specimen.

Positive result: There is coloration, even if faint, on both line C and line T indicating that there is SARS-CoV-2 antigen in the specimen.

**Invalid results:**

There is no coloration on line C, as shown in Figure 3. The test is invalid or an error in operation occurred.

1. Tests are marked with a black **permanent** pen and removed from the desk. A symbol system should be used to avoid confusion:
   * + **‘+’** mark for positives – removed any time before 30min
     + **‘V’** mark for invalid – removed 30min after “drop”
     + **’-‘mark** for negatives – removed 30min after "drop"
2. The LFD is then moved to next station for data logging/result recording
3. The area where the device was situated is then cleaned.

### Recording of results

Results can be uploaded using a web portal so any device such as a smart phone or tablet can be used. If managed devices have been supplied by DHSC they can also continue to be used.

1. Scan the LFD barcode as per digital results recording process (Figure 4) with the mobile application supplied, and digitally record the result.
2. The area where the device was situated and equipment (i.e. pen, tray, etc) are then cleaned after each batch with anti-viral wipes

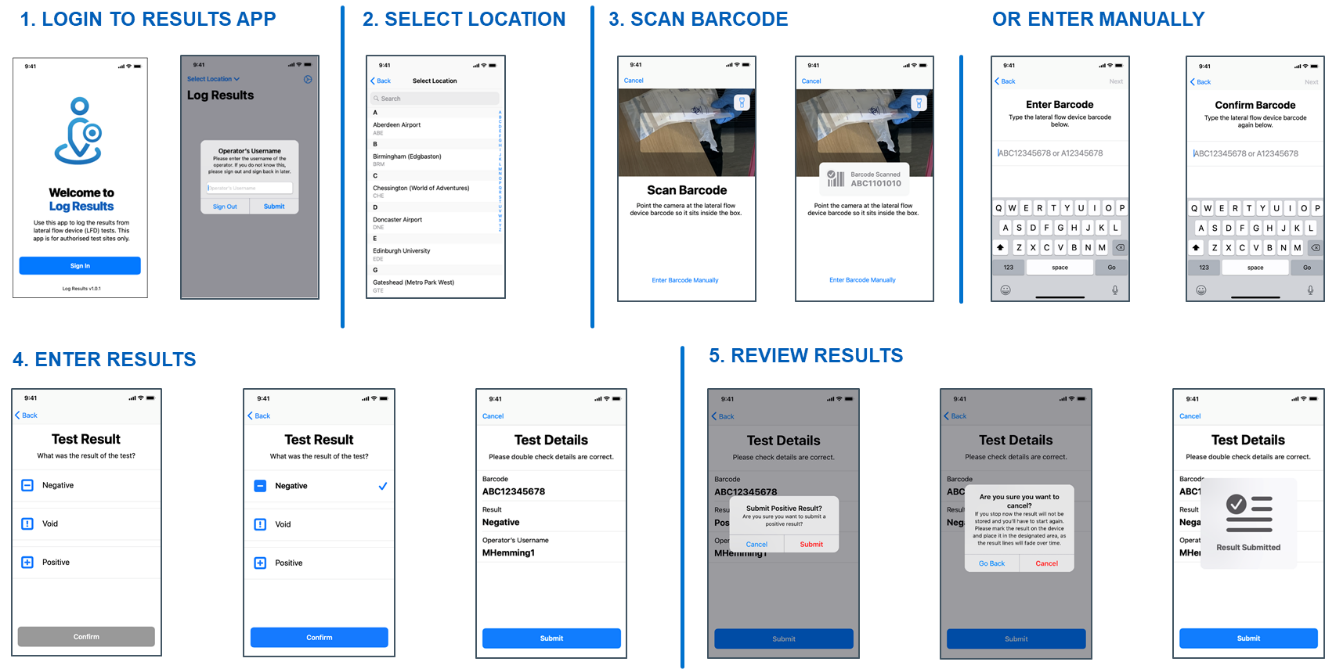


Figure 4. Digital solution that records and captures results.

**Graphical user interface, application

Description automatically generated**

**Graphical user interface, application

Description automatically generated**

Fig 5: Results logging using iOS app *(for DHSC provided managed devices)*

1. Login to the results application
2. Select the test site location
3. Scan the LFD barcode as per digital results recording process (Figure 5) with the iOS mobile application and digitally record the applicable result
4. The area where the device was situated and equipment (i.e. pen, tray, etc.) are then cleaned after each batch anti-viral wipes

Once the result has been logged, the LFDs are disposed of as non-hazardous waste.

**Data Management:**

The results are uploaded as linked to the barcode. Hence, there is no visibility or access to linking the results with the subject’s identity.

### Communication of results

If giving the result in person (in the context of a pilot), this needs to be given using a prepared script, and people will be advised to contact one of the NHS T&T nurses for further advice if necessary.

The test results linked to the barcode are received by the NHS Test & Trace digital system. The testing centre is unable to link any results to individuals, but the Test & Trace system will link the registration record details with the test result.

Results will be sent to the subjects via text message and/or an e-mail using contact details given at the registration or check-in process. The results will be communicated within a day of the test. The wording of the result text will reflect the national guidance published by the NHS.

Only positive results will be updated into GP records (not negative or void).

**Confirmatory test**

After seeking advice from PHE and NHS Test and Trace, the government has decided to suspend the requirement for routine confirmatory PCR for positive LFD results while prevalence is very high nationally. Under the new system, an LFD result will trigger the legal duty to self-isolate, eligibility for support payments and contact tracing for those who do not report their own LFD results. Routine confirmatory PCR will be retained for those who self report including NHS or adult social care staff. This takes effect from 25 January 2021.

**Those who test positive will receive this message:**

*Dear (Full name)*

*Birth date (Date of birth)*

*Test date (Date of test)*

*Your coronavirus test result is positive. This means it’s likely you were infectious when the test was done.*

*You must take a different follow-up test today, or as soon as possible, to confirm the result. Please follow the instructions you were given to take your follow-up test. If you were not given instructions, go to* [www.gov.uk/get-coronavirus-test](http://www.gov.uk/get-coronavirus-test) *to book your test. Choose a test site if you can, it’s faster than a home test.*

*Until you get further advice you must self-isolate immediately for 10 days and everyone you live with must self-isolate for 14 days. Only leave home for your follow-up test.*

*Use 111 online or call 111 if you need medical help. In an emergency dial 999.*

*See* [www.gov.uk/coronavirus](https://www.gov.uk/coronavirus) *for more advice.*

### Travelling home advice for positive results

If a person tests positive they should be advised to:

* Travel home immediately, wearing a face covering
* Wherever possible they should travel home in their own vehicle or by walking or cycling
* If it is not possible to do so, they should arrange for a member of their household to pick them up
* They should avoid public transit or a taxi service
* If they have no other option, they should arrange a taxi to get home preferably equipped with a protective screen between themselves and the driver
* Asymptomatic contacts of positives cases should go home as they would normally do. If the contact becomes symptomatic, they should follow same travel advice as positive cases.
* It is especially important that people follow Government guidance on hygiene, including hand washing before leaving, throughout the process of attending a testing site.

### Reporting and Notification

NHS Test & Trace will also send results to NHS Digital, so they can collate data to the subject’s registered GP and Public Health England or relevant national and local public health authorities.

### Negative results

Subjects who return a negative test result do not need to self-isolate (unless otherwise indicated).

### Invalid results

Subjects who return an invalid LFD result should be retested once by LFD.

If the LFD result is invalid a second time, they should be retested with an RNA test.

If operationally more feasible it is acceptable to retest with an RNA test after the first invalid result.

### Positive results

Subjects who return a positive LFD result are advised to self-isolate immediately after receiving a positive result communication and follow the guidance from NHS Test and Trace. Until the subject gets further advice they and everyone in their household must self-isolate immediately for 10 days. The 10 days begin the day after the test date. They should only leave home for their follow-up test.

A confirmatory PCR test is required for a person who received a positive result.

Confirmatory testing is available *where requested*, regardless of result. Where a confirmatory test is requested by the subject who received a positive result, this can be done using a home testing kit, or by visiting the local testing site to provide a nasopharyngeal swab sample for PCR analysis. If the subject requests a confirmatory PCR, they still have to self-isolate from when they receive LFD result.

**Coronavirus Yellow Card Reporting Site**

Report suspected side effects to medicines or medical device and diagnostic adverse incidents used in coronavirus treatment to the Medicines and Healthcare products Regulatory Agency to ensure safe and effective use.

<https://coronavirus-yellowcard.mhra.gov.uk/>

**MHRA Adverse Incidents**

**Adverse incidents – unresolved locally:** Where there are incidents that cannot be resolved locally and require escalation i.e. the device is damaged or breaks during use, if the user of the test has any concerns about the performance of the test, if a user injury occurs (clinical incidents), or if there are multiple missing test results (individual test subjects should continue to contact 119 if they do not receive their results),  please escalate this to [Karen.jackson@dudley.gov.uk](mailto:Karen.jackson@dudley.gov.uk) or [Shelagh.cleary@dudley.gov.uk](mailto:Shelagh.cleary@dudley.gov.uk)

**Adverse incidents – resolved local:**Should pilot sites deal with any adverse incidents related to the lateral flow product which are then resolved locally i.e. the packaging is damaged or a component is missing, these should also be reported as above.

**Quality Management**

Training:

* Knowledge assessment at the end of on-line training
* Face-to-face training by trained supervisor during mobilisation or first day
* Staff competence and training checks

Observing the testing process:

* Daily/weekly clinical governance audits by site supervisor checking:
  + Subjects understand self-swab procedures and are performing correctly
  + All testing staff have appropriate training
  + Onsite testing supervision: Observing the end-to-end testing process of a sample of tests to ensure that knowledge and skills are appropriate
  + Taking off and putting on PPE and hand washing is within guidelines
  + Supplies and equipment are being stored and handled correctly
  + Waste is segregated and managed correctly
* A clinical governance record should be used to document that the checks have been undertaken and that if any actions are necessary that they are documented and followed up in a timely manner
* Where interventions do not improve with further training/guidance, the staff should be removed from performing clinical tasks

Monitoring results/KPIs:

* Void rates and invalid tests
* Rates of discordant results where confirmatory testing is in place

**Cleaning**

Maintaining high standards of cleanliness at the LFT site is essential to prevent cross infection amongst those using at working at the site. The following key principle must be followed by all staff.

* Staff handling disinfectants must wear appropriate personal protective clothing e.g. plastic aprons, gloves and face/eye protection as appropriate.
* All surfaces that the subject has come into contact with must be cleaned and disinfected after each use, including all potentially contaminated and frequently touched areas such as handles, light switches, and the surfaces that the subject may have had contact in between each individual that is tested.
* Use disposable cloths or paper roll and disposable mop heads, to clean all hard surfaces, floors, chairs, door handles and sanitary fittings – think one site, one wipe, in one direction.
* Any mop heads used for cleaning must be disposed of and should be placed into the orange waste stream at the end of each day.
* Surfaces will require to be cleaned at the end of the session before the next session starts i.e. in between test group batches of subjects
* Avoid mixing cleaning products together as this can create toxic fumes. Avoid creating splashes and spray when cleaning.
* The minimum specifications stipulated by the government for surface disinfectant wipes, is that the disinfectant is effective against envelop viruses. It is recommended were possible that combined detergent and disinfectant wipes is used, as they will both clean and sanitise the surface at the same time. The standards staff should check for are below:

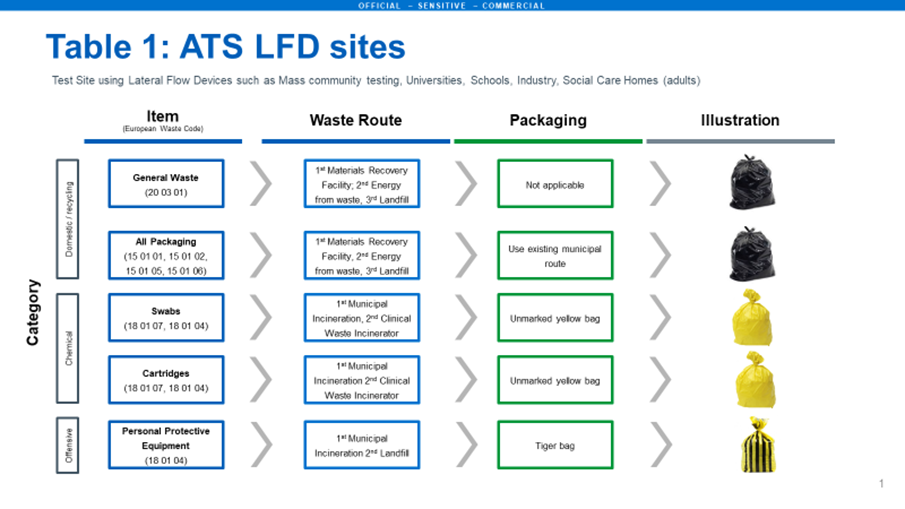
|  |  |
| --- | --- |
| Bactericidal activity (antimicrobial) | EN 1276, EN14348, EN 13727, EN1040, EN1499 |
| Fungicidal / yeasticidal activity | EN 1650, EN 13624 |
| **Virucidal activity** | EN 14476 |

* For all wipes it is important that the manufactures instructions are following in relation to the contact time required. It is advisable where possible to purchase packets that have a reliable closure mechanism to ensure wipes do not dry out between uses, as this will affect their ability to be effective against the virus.
* Hard surface antimicrobial wipes effective against COVID-19. These are wet wipes disinfectant, which is effective against viruses, fungi, bacteria and most spores. This is a one-stage process, eliminating the need to clean before disinfection. The wipes are single use and must be discarded in between each activity/surface/item. Where wipes are used the cleaning process must be as thorough as with neutral detergent and water.
* Cleaning staff should follow the following principles when decontaminating <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/877533/Routine_decontamination_of_reusable_noninvasive_equipment.pdf>
* The cleaning schedule in Appendix III provides guidance on frequencies for cleaning.
* **Information on Body fluid spillages can be found below a body fluid spill kit should be used at all times (follow manufacturer’s instructions).**



**Waste**

**It is important that the correct waste is always segregated into the appropriate waste stream.** The following table indicates the appropriate waste stream



N.B. for all pharmacies, Dudley MBC Refuse have agreed that all waste from LFD testing should go into black, clear or yellow bags and be placed in municipal waste.

All bags should be tied with the appropriate bag tie provided and stored in the refuse area provided outside the building in the garage opposite the main exit of the hall.

The refuse area should be kept locked at all times. Open only to place waste in the bins provided and lock again on exit.

The waste bags need to be placed in the corresponding bin in the refuse area depending on the classification.

Waste from Saltwells will be collected 2.30 p.m. each day.

**Appendix I**

**Donning and doffing of PPE** including ’aide memoir’. This information will be displayed in all donning and doffing areas of the testing centre.

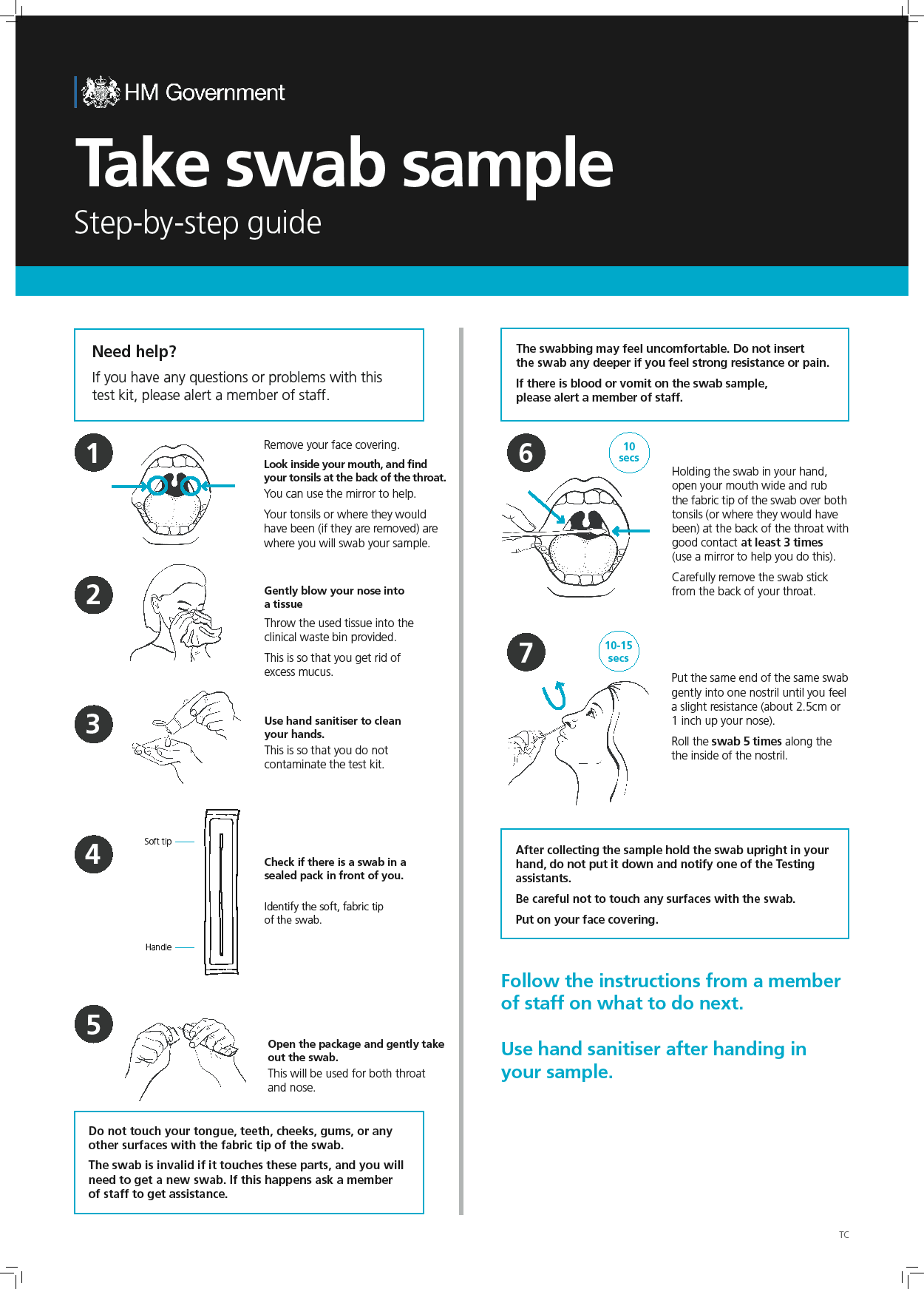


|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Role** | **Disposable gloves** | **Disposable plastic apron** | **Fluid-resistant (Type IIR) surgical mask (FRSM)** | **Eye protection**  **(Googles or visor as per individual preference)** |
| **Processing Operative2** | ✓ | ✓ | ✓ | ✓ |
| **Indicates single or sessional use** | Replace after each **test (single)** | Replace after each **session** | Replace after each **session** | Replace after each **session** |
| **Cleaning Staff3** | ✓ | ✓ | ✓ | ✓ |
| **Test Assistant4** | **×** | **×** | ✓ | **×** |
| **Site Coordinator / Team Leader** | **×** | **×** | ✓ | **×** |
| **Registration Assistant** | **×** | **×** | ✓ | **×** |
| **Results Recorder** | **×** | **×** | ✓ | **×** |
| **Supplies Coordinator** | **×** | **×** | ✓ | **×** |
| **Queue Coordinator** | **×** | **×** | ✓ | **×** |
| **Indicates single or sessional use** | Replace after each **session** | Replace after each **session** | Replace after each **session** | Replace after each **session** |

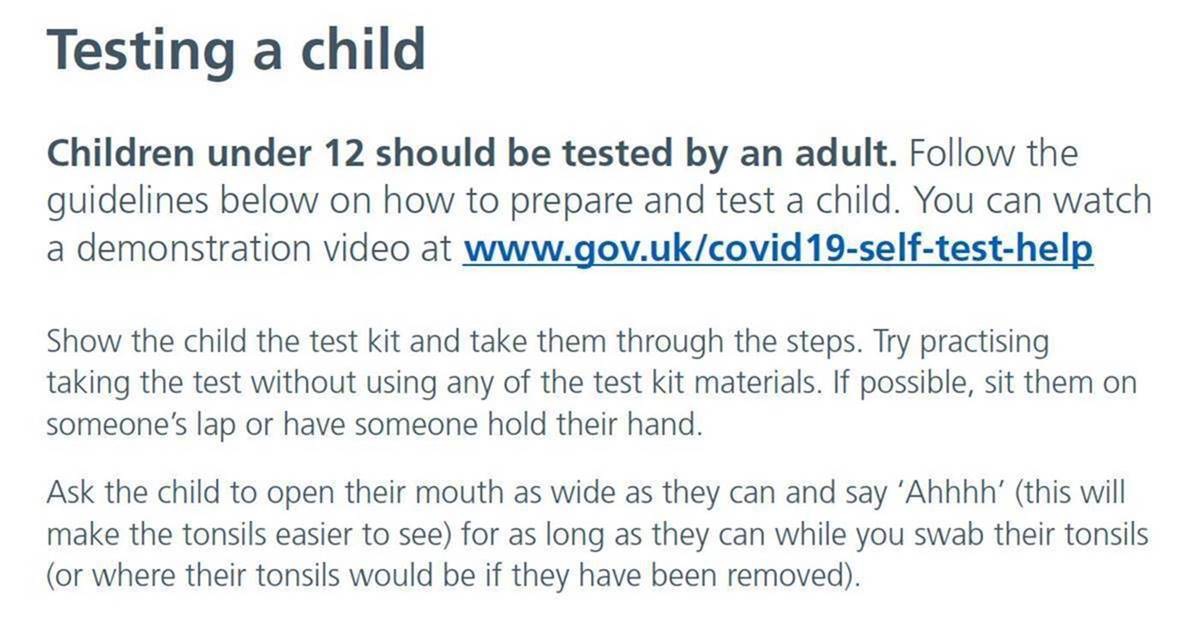
**Appendix II: Instructions on Self-Swabbing**. This information should be displayed in all testing booths.

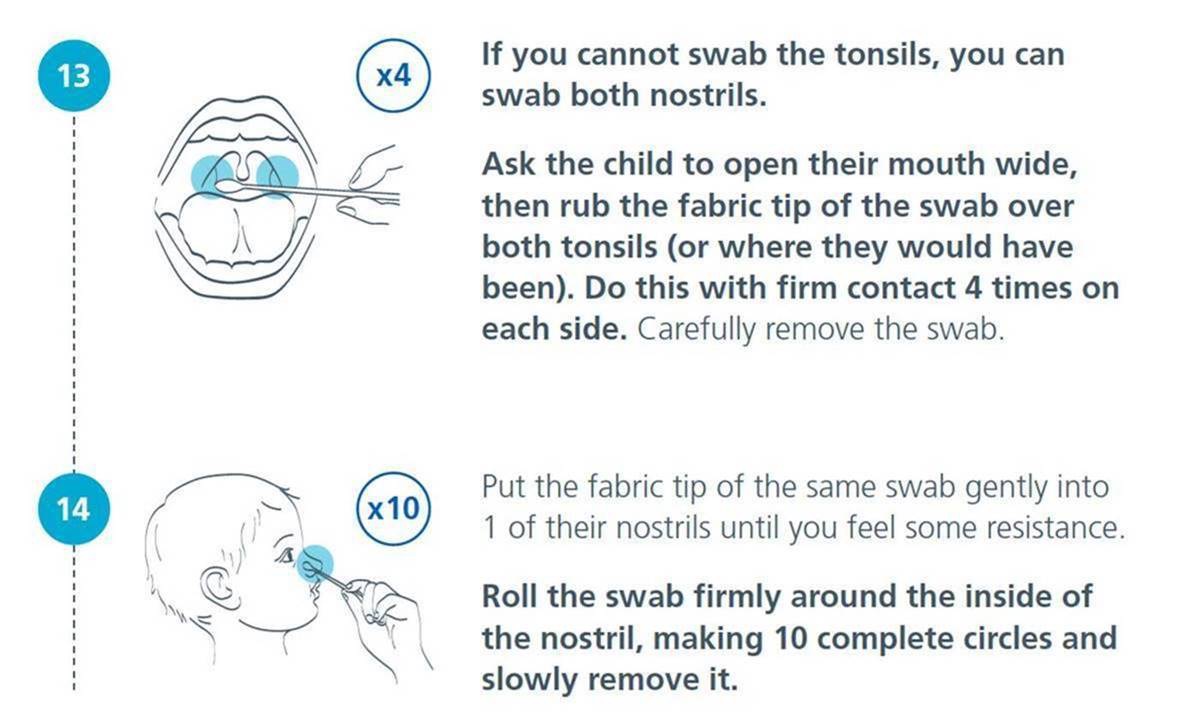


Taking a swab sample



**Appendix 111 Testing a Child**







**Appendix IV: Recommended Cleaning Schedule**

**CLEANING SCHEDULE**

**Saltwells EDC Lateral Testing Centre**

|  |  |  |  |
| --- | --- | --- | --- |
| Day and Date: | |  | |
| Cleaning Undertaken by: | |  | |
| **Area/Object to be cleaned:** | **Products to be Used** | | **Frequency**  **How often** |
| **Hall (Testing Area)** |  | |  |
| Doors handles and touch points entrance and exit | Using Chlorine releasing agents/70% alcohol/Antiviral wipes meeting appropriate EN standard | | Every hour |
| Booths: Desk, Plastic Screens | Using Chlorine releasing agents/70% alcohol/Antiviral wipes meeting appropriate EN standard | | After each person has been tested |
| Reception Desk | Using Chlorine releasing agents/70% alcohol/Antiviral wipes meeting appropriate EN standard | | Every hour |
| Laminate instructions | Using Chlorine releasing agents/70% alcohol/Antiviral wipes meeting appropriate EN standard | | Every hour |
| Signage | Using Chlorine releasing agents/70% alcohol/Antiviral wipes meeting appropriate EN standard | | 2 x day |
| Floors to be mopped | Chlorine releasing agent/appropriate cleaning product for enveloped viruses | | Start and end of each day |
| Empty bins from booths when 2/3rd full. Empty into main outside waste skip |  | | Check when cleaning between clients |
| Replace bin Liner when 2/3rds full |  | | As part of spot checks |
| Portable hand wash sink:  Wipe taps  Wipe soap dispenser  Wipe out sink bowl | Follow manufacturers instructions | | 3x daily. |
| Portable hand wash sink:  Change water | Follow Manufacturers instructions | | As required Empty at end of day. |
| Check Liquid soap, hand sanitiser, wipes and replenish |  | | 3x daily |
| Testing station work surfaces | Using Chlorine releasing agents/70% alcohol/Antiviral wipes meeting appropriate EN standard | | Twice daily (Morning and end of day |
| **Other rooms used by testing team:** |  | |  |
| Office accommodation (room number X)  Door Handles, Doors  Desks, Computer equipment,  Chairs | Using Chlorine releasing agents/70% alcohol/Antiviral wipes meeting appropriate EN standard | | Twice daily |
| Rest Room: wipe down:  Tables, Chairs, Door Handles  Doors, other Equipment?? | Using Chlorine releasing agents/70% alcohol/Antiviral wipes meeting appropriate EN standard | | Twice daily |
| Toilet: to be cleaned paying particular attention to touch points | Chlorine releasing agents | | Twice daily |

## Appendix IV: Consent from the data subject

The organisation is responsible for communicating the purpose of the testing to develop an understanding of the service. Participation by the subject is voluntary.

If an employer or host institution is classified as a data processor or controller, they must issue a data privacy notice that informs the subject of how their data will be used. If the subject wishes to participate, having now received this information, the subject will issue their consent. The organisation is responsible for capturing consent. The organisation must store a copy of the subject’s consent for the duration of the pilot.

#### **How subject data is captured and shared with DHSC**

The following data elements are captured by the Registration process, a service that is operated by DHSC and NHS Digital:

1. Whether the test is being taken at a test site or at home
2. [If at a test site] The postcode of where the test is being taken
3. [If at a test site] The test site the test will be taken at
4. Test kit URN (barcode of test kit)
5. The date and time that test will be taken
6. Subject date of birth
7. Subject name
8. Subject gender
9. Subject ethnic group
10. Subject ethnic background
11. Whether the subject is displaying any coronavirus symptoms
12. The country the subject lives in (Member of the UK)
13. Subject home postcode
14. Subject address line 1
15. Work OR Study Status – plus Industry, Occupation, Employer OR Study Grade, Institution, Institution Town
16. Whether the subject has an email address and, if so, what that address is
17. Whether the subject has a mobile phone number and, if so, what that number is
18. Whether the subject has a landline phone number and, if so, what that number is
19. Whether the subject knows their NHS number and, if so, what it is