Name of Policy, Procedure or Guidance			**SARS-CoV-2 (COVID-19) patient PCR testing pathways (including rapid DnaNudge)**	
Who should read the objectives of this policy/procedure			This policy is for use by healthcare professionals assessing patients in an emergency setting, that require an overnight admission and for those managing elective patients on the day of admission.	
Executive Summary			Currently all patients admitted to hospital should be tested for SARS-CoV-2 irrespective of their symptoms if they require an overnight admission or elective procedure. This policy directs SARS-CoV-2 testing pathways including how to use the rapid DnaNudge platform and where the patient should be placed pending a test result.	
Committee & date approved			**Date:**	**Chair's signature**
			Endorsed by:	
Review Date				
Director(s) responsible for ensuring this document is implemented			Corporate	
For further information contact			e.g. Clinical Infection Department e.g. Point of Care (POC) Committee	
The formal/legal documents forming the basis of this document are			Public Health England coronavirus resources DnaNudge MHRA derogation/CE mark	
Cross reference to			PHE COVID Infection Prevention & Control policy. SARS-CoV-2 (COVID-19) near-patient/point-of-care molecular PCR diagnostics risk assessment. SARS-CoV-2 (COVID-19) DnaNudge point of care PCR verification.	
Communication/ implementation/ training plan			This policy will be promoted to all staff via divisional cascade, and training will be overseen by the POC Committee	
	No	**Date & Author**	**Description of changes**	
Version				

1. Background

This SOP provides information on SARS-CoV-2 (COVID19) testing pathways for all patients who require admission to hospital irrespective of presence/absence of compatible symptoms. It provides guidance on where to place patients who are in receipt of a PCR result or who are pending a result.

It also provides guidance on which patients' should utilise the rapid near-patient PCR testing pathway for SARS-CoV-2 (using the DnaNudge, Cepheid, and bioFire platforms), and who should have a standard laboratory based PCR.

This policy is for use by healthcare professionals assessing patients in an emergency setting who require an overnight admission, and for those admitting elective patients.

2. Abbreviations used within this policy

COVID-19	Clinical syndrome caused by infection with Severe Acute Respiratory Syndrome coronavirus-2 (aka SARS-CoV-2)
HCW	Healthcare worker
ICU	Intensive care unit (aka Intensive therapy unit; ITU)
IPC	Infection prevention and control
PCR	Polymerase chain reaction
PHE	Public Health England
PPE	Personal protective equipment
AGP	Aerosol generating procedure
SOP	Standard operating procedure
POC	Point of care

3. Responsibilities

Chief Executive is responsible for ensuring the Trust has an appropriate policy in place.
Point of Care Committee responsible for implementing policy
All clinical staff are responsible for complying with all aspects of this policy.
Clinical Infection Department are responsible for providing support and advice both in and out of hours and will contact the DnaNudge team for technical support as needed.
Responsible persons:

Hospital Site A	**Hospital Site B**
Microbiology Consultants:	**Microbiology Consultants:**
Cross site Infection Prevention and Control Team	
Director of Infection Prevention & Control: **Lead nurse for Infection Prevention & Control:**	

4. Definitions

PHE COVID19 (PRE-TEST) CASE DEFINITION: (18 MAY 2020)
Patients who require admission to hospital
And
clinical or radiological evidence of pneumonia
Or
acute respiratory distress syndrome
Or
influenza like illness (fever ≥37.8°C and at least one of the following respiratory symptoms, which must be of acute onset: persistent cough (with or without sputum), hoarseness, nasal discharge or congestion, shortness of breath, sore throat, wheezing, sneezing.
Or
loss of/change in sense of taste or smell (anosmia) in isolation or in combination with any other symptoms

COVID19 (POST-TEST) CASE DEFINITION:
- **CONFIRMED COVID19:** Patients with a confirmed positive SARS-CoV-2 PCR result
- **POSSIBLE COVID19:** Patients with either (i) a pending SARS-CoV-2 PCR result, or (ii) a Detected at the lower limits of detection (i.e. 'indeterminate' SARS-CoV-2 result, or (iii) a negative SARS-CoV-2 result but a strong clinical suspicion (clinical symptoms/signs/radiology) of COVID19
- **UNLIKELY COVID19:** Patients with a negative SARS-CoV-2 PCR result and no clinical suspicion of COVID19.

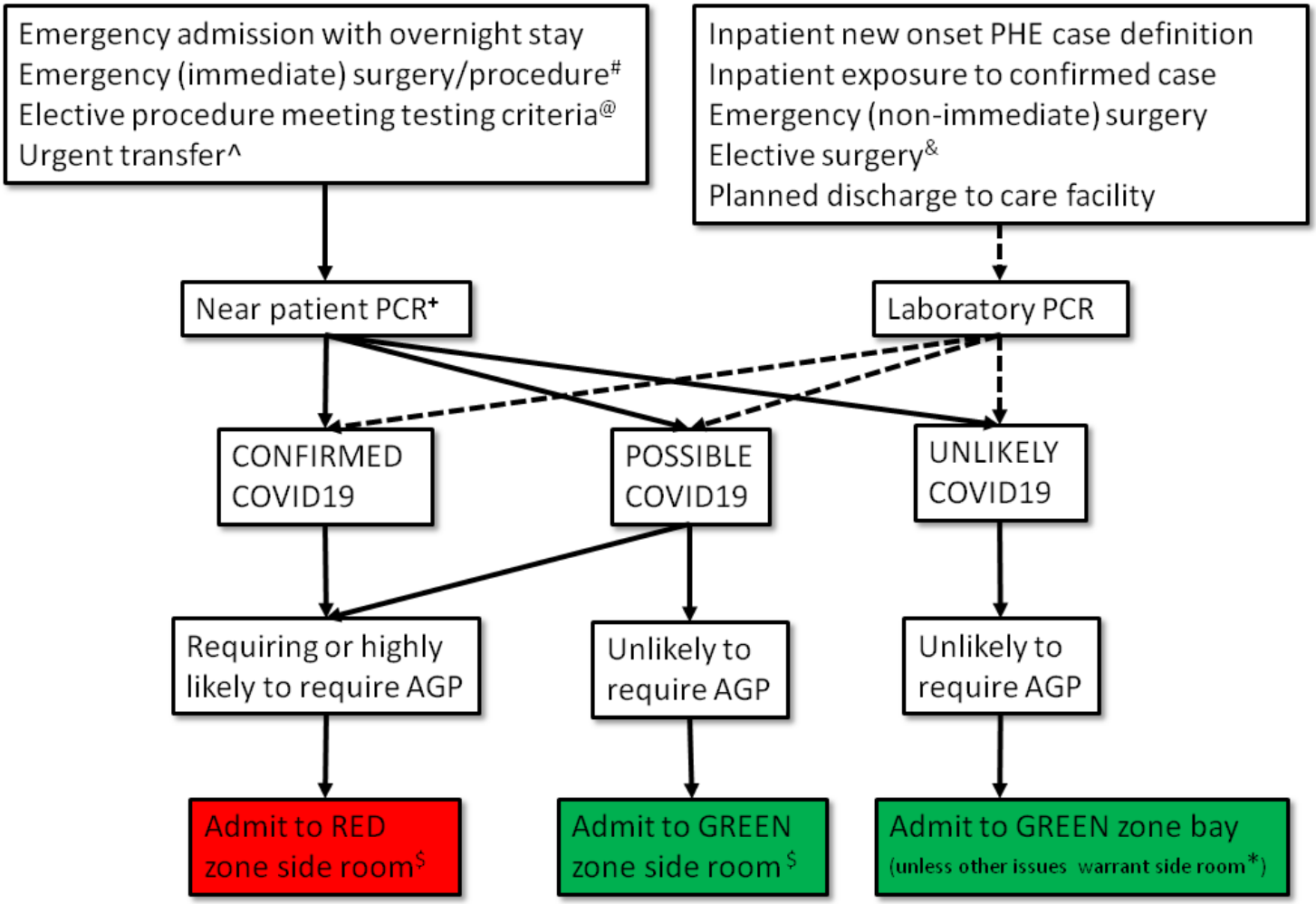
HOSPITAL ZONE DEFINITION: (30 JULY 2020)
- **RED Zone:** Acute care area with possible or confirmed case(s) undergoing regular or anticipatable AGP.
- **GREEN Zone:** Inpatient or outpatient areas with possible or confirmed case(s) but no regular or anticipatable AGP.

PHE AEROSOL GENERATING PROCEDURES DEFINITION: (17 MAY 2020)
- respiratory tract suctioning
- bronchoscopy
- manual ventilation
- tracheal intubation and extubation
- tracheotomy or tracheostomy procedures (insertion or removal)
- upper ENT airway procedures that involve suctioning
- upper gastro-intestinal endoscopy where there is open suctioning of the upper respiratory tract
- high speed cutting in surgery/post mortem procedures if this involves the respiratory tract or paranasal sinuses
- dental procedures using high speed devices such as ultrasonic scalers and high speed drills
- non-invasive ventilation (NIV); Bi-level Positive Airway Pressure Ventilation (BiPAP) and Continuous Positive Airway Pressure Ventilation (CPAP)
- High Frequency Oscillatory Ventilation (HFOV)
- induction of sputum using nebulised saline
- high flow nasal oxygen (HFNO)

MOLECULAR TESTING SUITE:
These rooms are not currently part of pathology laboratory infrastructure and are staffed by dedicated operators trained to use the molecular testing platforms contained therein. They are open 24 hours a day 7 days a week.
- At hospital site A this is located for **DnaNudge**: e.g. Treatment Centre, Ground Floor, Main Building.

- **5. SARS-CoV-2 testing algorithm for all admissions/elective patients**

The following flow chart provides advice on (i) which type of SARS-CoV-2 PCR to request and (ii) where patients should be placed with positive/ negative/pending results, according to need for AGPs.



In addition to emergency (immediate) surgery, all procedures being undertaken in the day-case surgery Treatment Centre, and other emergency (immediate) procedures include: ERCP/upper and lower GI endoscopy/ bronchoscopy

@ Depending on evolving supply chains, there is consideration being given to near patient rapid testing for elective bronchoscopy/endoscopy/lung function patients on day of their procedure or Gazzard day unit immunosuppressed patients attending for chemotherapy. Until this process is established, patients undergoing these procedures should continue to have a formal laboratory PCR prior to presenting for the procedure.

^ Either admission to ICU or urgent inter-hospital transfer where there is no COVID-19 result, e.g. for ECMO/PICU

+ Near Patient PCR platforms: DnaNudge, Cepheid, bioFire (this varies by site and by availability of cartridges)

* Other issues that might warrant a side room include: diarrhea, confirmed or suspected Carbapenemase resistant organism (CRO), confirmed or suspected MRSA, confirmed or suspected influenza, confirmed or suspected neutropaenia, confirmed or suspected pulmonary tuberculosis, other confirmed or suspected communicable diseases, end of life care

$ If there are significant numbers of patients with COVID-19 (either requiring AGPs or not) there may need be a need to cohort these groups in cohorted wards. These decisions will be made in conjunction with the IPC team and the Trust Executive team.

& NICE guidance (27 July 2020) moves away from the blanket requirement for patients and their families to self-isolate for seven or 14 days before coming in to hospital for planned care or diagnostics to allow a risk-based clinical assessment for individual patients. Most patients will have a COVID test 72 hours before their planned procedure and will then take sensible measures to limit exposure and to isolate themselves until the day of their procedure.

6. Requesting a SARS-CoV-2 PCR test

For both non-immediate Laboratory PCR and Rapid near patient (using the DnaNudge, Cepheid, and bioFire platforms) PCR request a **SARS-CoV-2 specimen (nasopharyngeal/throat)** on Cerner:

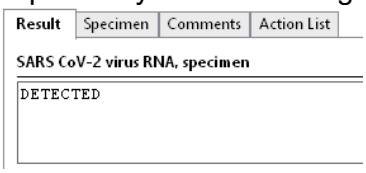
Laboratory PCR testing kits are available from pathology specimen reception (viral transport medium vial and swab).
Laboratory PCR test provides a result usually within 24 hours from time of receipt of the sample at the pathology specimen reception.

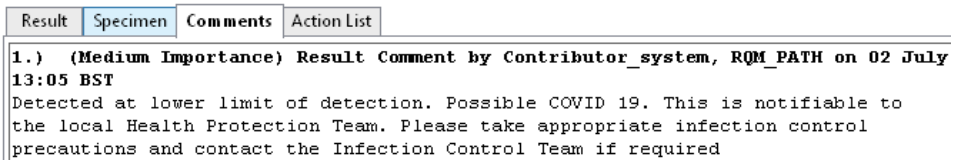
DnaNudge PCR testing kits are available from the Molecular Testing Suite (DnaNudge: cartridge and swab).
DnaNudge PCR testing provides a result within 2 hours from time of receipt of the sample in the Molecular Testing Suite

Cepheid PCR testing kits are available from pathology (viral transport medium vial and swab i.e. the same as for laboratory PCR).
Cepheid PCR testing provides a result within 2 hours from time of receipt of the sample in the pathology laboratory.

7. De-isolation of patients based upon SARS-CoV-2 results

When a Detected result appears on Cerner, double click on the Comments tab to look for any explanatory comments. E.g..





SARS-CoV-2 Detected

Patients' can continue to be managed in either the GREEN or RED zone if they are **SARS-CoV-2 Detected** depending on their clinical needs for AGPs (**RED** zone for those requiring or highly likely to require AGP, GREEN zone is for those not requiring AGP).

For suspect or confirmed COVID-19 patients who require hospitalisation, IPC measures should continue until 14 days have elapsed since their first positive SARS-CoV-2 PCR test (in line with guidance 30 July 2014), provided the clinical improvement criteria below have been met. This is due to uncertainties about the duration of infectiousness for patients with more severe illness or underlying immune problems that may delay them clearing the virus.

Clinical improvement criteria:

- clinical improvement with at least some respiratory recovery
- absence of fever (> 37.8°C) for 48 hours without the use of medication
- no underlying severe immunosuppression

Before control measures are stepped down for COVID-19, clinical teams must first consider the patient's ongoing need for transmission based precautions necessary for any other alert organisms (for example, MRSA carriage or *C. difficile* infection), or patients with ongoing diarrhoea.

For severely immunocompromised individuals, repeat testing at the end of 14 days should be undertaken. One negative test is acceptable for de-isolation. If repeat testing remains positive after 14 days, and only if local testing capacity allows, patient samples should be tested after a further 7 days if the patient remains in hospital, or at intervals of 2 weeks in the community (for example, at repeat hospital appointments if attending for another pressing indication).

If the patient is producing sputum or is intubated, a lower respiratory tract sample should be preferentially tested as the priority sample, as SARS-CoV-2 can be present in the lower respiratory tract despite being undetectable in the upper respiratory tract.

SARS-CoV-2 Detected at lower limit of detection

Patients' can continue to be managed in either the GREEN or RED zone if they are **SARS-CoV-2 Detected at lower limit of detection (Indeterminate result from the DnaNudge platform only)** depending on their clinical needs for AGPs (**RED** zone for those requiring or highly likely to require AGP, GREEN zone is for those not requiring AGP). These patients should have a repeat sample taken for Laboratory PCR 24 hours after the first swab. This second result is taken as definitive – if "Detected", manage as positive, if "NOT detected", manage as negative.

SARS-CoV-2 NOT detected

Once negative COVID-19 results are available, if there is no clinical suspicion of COVID-19 then patients should be de-isolated to a GREEN ward where they can be managed in a bay unless there is other need for transmission based precautions. In those cases such patients should remain in a side room with appropriate infection prevention and control precautions. However the need for a side room and appropriate IPC precautions should continue to be risk assessed.

8. DnaNudge device malfunction

In the case of a device malfunction, please contact covid@dnanudge.com who will reply within a 4 hour timeframe. Whilst awaiting device repair or replacement, use alternate devices for Rapid PCR testing. If there are concerns of capacity for rapid PCR testing in the context of high patient throughput, liaise with (i) duty manager to consider requisitioning a device from another area, and/or (ii) the microbiology/infectious diseases consultant on call to risk assess any infection prevention and control implications from delayed results.

9. DnaNudge stock control

Cartridges are delivered weekly according to allocation pre-agreed with DHSC. If too many or too few cartridges are available please raise this with the POC committee.

9. DnaNudge quality assurance

Internal quality assurance: all DnaNudge users will be required to submit dual samples on two occasions per month (i.e. for each of two patients run one sample on the DnaNudge and one sample through the Laboratory PCR pathway). Patients should be consented for having two swabs taken at the time of swabbing and a note entered on their electronic healthcare record. These results should be logged by the manager in the Molecular Testing Suite (Appendix 3) and will be audited and fed back to the POC committee.

External quality assurance: there is currently no national external quality assurance scheme for POC SARS-CoV-2 PCR platforms, but a NEQAS scheme is being developed.

Compliance with these guidelines will be monitored by the site team in conjunction with the Microbiology & Infectious and Infection Prevention and Control Team. This data will be reported to the Trust POCT Committee.

10. References

PHE COVID-19: infection prevention and control guidance, Updated 18 June 2020. Accessed 01/08 /2020. Available from:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/886668/COVID-19_Infection_prevention_and_control_guidance_complete.pdf

PHE COVID-19: investigation and initial clinical management of possible cases. Updated 22 May 2020. Accessed 01/08 /2020. Available from:
https://www.gov.uk/government/publications/wuhan-novel-coronavirus-initial-investigation-of-possible-cases/investigation-and-initial-clinical-management-of-possible-cases-of-wuhan-novel-coronavirus-wn-cov-infection

PHE Guidance for step down of infection control precautions and discharging COVID-19 patients. Updated 30 July 2020. Accessed 01/08 /2020. Available from:
https://www.gov.uk/government/publications/covid-19-guidance-for-stepdown-of-infection-control-precautions-within-hospitals-and-discharging-covid-19-patients-from-hospital-to-home-settings/guidance-for-stepdown-of-infection-control-precautions-and-discharging-covid-19-patients

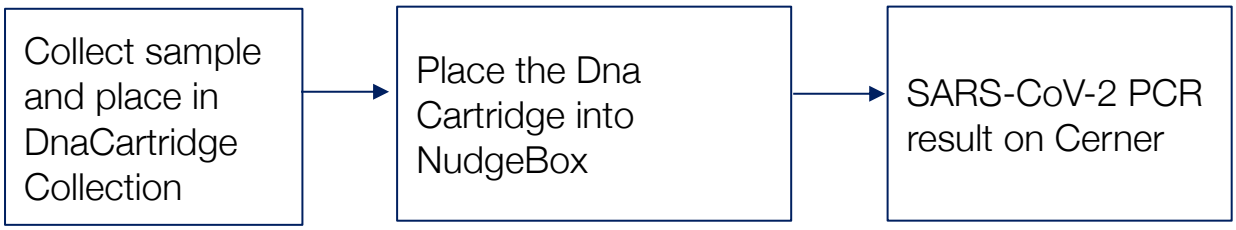
PHE. Coronavirus (COVID-19): scientific evidence supporting the UK government response. Accessed 20/05 /2020. Available from:
https://www.gov.uk/government/news/coronavirus-covid-19-scientific-evidence-supporting-the-uk-government-response

NICE. COVID-19 rapid guideline: arranging planned care in hospitals and diagnostic services. Published 27/07/2020. Accessed 03/08/2020. Available from:
https://www.nice.org.uk/guidance/NG179

Appendix 1
DnaNudge SARS-CoV-2 testing and results guide

For full instructions see http://www.dnanudge.com/covid-test-access

dnaNudge overview:



DnaNudge equipment:

Swabbing kit contains:
1x Nasopharyngeal FLOQ Swab (Paediatric molecular Swab)
1x Scissors (to cut the end of the swab)
1x DnaCartridge with bung
1x Specimen Bag

DnaNudge instructions:

1. HCW must perform hand hygiene and wear appropriate PPE and must have undergone competency training and be registered in the DnaNudge training log. The HCW must be participating in the monthly quality assurance programme (see section 9)
2. Prepare the patient for nasopharyngeal swab- sitting upright, advise them to blow their nose prior to procedure and enquire about any known nasal obstruction.
3. Using the paediatric nasopharyngeal swab provided in the kit pack, take swab from nasopharynx for 15 seconds.
4. Remove bung from DnaCartridge and insert nasopharyngeal swab into cartridge, use disposable scissors to cut swab tail off, leaving bud/swab tip in DnaCartridge
5. Discard tail and scissors in sharps bin.
6. Close DnaCartridge with bung, ensuring it is tightly closed when pushed down.
7. Label DnaCartridge with MRN sticker.
8. HCW must wipe down DnaCartridge with GREEN CLINELL wipes
9. Take the DnaCartridge to the Molecular Testing Suite where the NudgeBox operator will ensure the bung is adequately placed and insert the DnaCartridge into the NudgeBox
10. The NudgeBox drives the DnaCartridge and the process is fully automated and contained. In the first step, the sample is lysed with 6M guanidine salt which deactivates the virus.
11. Once the test is completed, the cartridges are considered a biohazard and all cartridges should be discarded into clinical waste.
12. The Nudge box should be wiped down using GREEN CLINELL wipes following each patient test
13. The NudgeBox operator should perform hand hygiene in-between and following each step
13. Results are uploaded onto a cloud server and then directly networked to Cerner.
14. Each result is linked to a unique cartridge ID, a unique NudgeBox ID, and the unique operator ID, providing traceability for a machine fault or a cartridge fault. These identifiers are also reported with the test results.

DnaNudge result interpretation:

Nudge Output	Reported
Positive	SARS-CoV-2 DETECTED Consistent with COVID-19. This is notifiable to the local Health Protection Team. Please use appropriate infection prevention and control precautions.
Indeterminate	Detected at lower limit of detection. Possible COVID 19. Repeat the PCR test using the Laboratory PCR pathway after 24 hours. This is notifiable to the local Health Protection Team. Take appropriate infection control precautions and contact the Infection Control Team if required.
Negative	SARS-CoV-2 NOT detected
Invalid	Invalid test. Please retest immediately using the Rapid PCR pathway. This may be because an inadequate sample (users with repeat inadequate samples may have to be retrained), or because the bung was not replaced properly, or other technical failure.

Appendix 2
DnaNudge SARS-COV-2 training log

All staff must complete training and be deemed competent, prior to undertaking a DnaNudge test. When registering each sample/cartridge with the DnaNudge Operator App, the user must scan their personalized barcode on their staff ID card, providing traceability.

Trainers must ensure that the NudgeBox operator is trained in and competent in each of the below steps and understands the clinical context in which a rapid test should be utilised, how to interpret and action results and how to escalate any concerns with the platform.

The training log (appendix 2) must be signed and dated by both the trainer and trainee. Training records should be stored by the CWFT POC committee and available for review if required.

DnaNudge training log	Competent (yes/no)	Date	Assessor Signature
1. HCW has read the "SARS-CoV-2 (COVID-19) patient PCR testing pathways (including rapid DnaNudge)" Policy, including any updates and understands the clinical context in which a DnaNudge test can be utilised			
2. HCW understands how to perform hand hygiene and wear appropriate PPE			
3. HCW confirms name and DoB with patient and can prepare the patient for nasopharyngeal swab- sitting upright, advising them to blow their nose prior to procedure and enquires about any known nasal obstruction.			
4. Using the molecular (FLOQ) paediatric nasopharyngeal swab provided in the kit pack, can take swab from nostril for 15 seconds.			
5. Removes bung from DnaCartridge and inserts nasopharyngeal swab into cartridge, use disposable scissors to cut swab tail off, leaving bud/swab tip in DnaCartridge			
6. Discards tail and scissors safely in sharps bin.			
7. Closes DnaCartridge with bung, ensuring it is tightly closed when pushed down.			
8. Labels DnaCartridge with MRN sticker, having checked name/DoB with patient.			
9. HCW wipes down DnaCartridge with GREEN CLINELL wipes prior to inserting in machine			
10. Places DnaCartridge into the NudgeBox and understands the test will be run immediately.			
11. HCW understands the NudgeBox drives the DnaCartridge and the process is fully automated and contained. In the first step, the sample is lysed with 6M guanidine salt which deactivates the virus.			
12. Once the test is completed, the cartridges are considered a biohazard and HCW understands all cartridges should be discarded into clinical waste.			

13. DnaNudge box is wiped down using GREEN CLINELL wipes following each patient test			
14. HCW should perform hand hygiene following procedure			
15. HCW understands that results will be received on iPad and then need to be entered manually on a CERNER structured note as an interim step until IT connectivity is achieved and it will then be directly visible under pathology results on CERNER.			
16.HCW understands how to interpret results as outlined in the DnaNudge SOP and understands how to mitigate the risk of an incorrect patient sample: by affix Cerner barcode to DnaNudge cassette at time of inoculating swab into cassette and checking patient details.			
17. HCW understands that they need to check for any transcription error when entering the result.			
18. Healthcare worker understands need to perform 2 swabs a month in tandem with standard laboratory SARS-CoV-2 swab and the internal quality assurance training log completed.			
18. HCW understands that the on-call microbiology consultant via switchboard can be contacted for any trouble shooting queries and support			

Trainer signature……

Date……

Role……

Trainee signature……

Date……

Role……

Appendix 3
DnaNudge SARS-COV-2 monthly internal quality assurance

Monthly internal quality assurance will be undertaken by each NudgeBox operator. Two swabs per month must be performed in tandem with laboratory SARS-CoV-2 swab and the log completed.

NAME…………………………………………………Role……………………….Department…………………………………

SARS-COV-2 PCR Swab	Date	Result	Trainer signature
DnaNudge swab			
DnaNudge swab			
NWLP PCR swab			
NWLP PCR swab			
DnaNudge swab			
DnaNudge swab			
NWLP PCR swab			
NWLP PCR swab			
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