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LABORATORY PROCEDURE

Detection of Respiratory Pathogens by Seegene Allplex™ RV Master Assay and NIMBUS extraction

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	2. Laboratory Procedure File, WGH

Stage	Risk Assessment	Manual Handling
Preparation	<5	<5
Instrumentation	<5	<5
Chemical	<5	<5
Sample	<5	<5
Disposal	<5	<5

Key	Risk Assessment/Manual Handling Score
<5	<5 No Action
6-10	6-10 Action within 12 months
10+	10+ Urgent Action Required

CONTENTS

0 Introduction

0.1 Scope and purpose

This SOP describes the procedure for using the Seegene Allplex™ RV Master Assay and NIMBUS extraction test kits for the detection of nucleic acid from of SARS-CoV-2, Influenza A virus, Influenza B virus, Human respiratory syncytial virus A/B, Human metapneumovirus, Human adenovirus A/B/C/D/E/F, Human rhinovirus A/B/C and Human parainfluenza virus 1/2/3/4 in throat swabs.

0.2 Responsibility

The laboratory manager is responsible for the implementation and maintenance of this procedure in conjunction with senior staff in the department.

BMS, laboratory technicians and MLA staff may carry out the procedures in which they have been trained and assessed as competent.

0.3 References

- EXPAT685 ISO 15189:2012

0.4 Definitions

- IQC – Internal quality control
- LIMS – Laboratory information management system
- WGH – Withybush General Hospital

0.5 Related document

- MPPAT628 External quality assurance in the pathology department
- MPPAT606 Procedure for assuring the quality of examinations
- LPMIC007 Specimen Collection and Handling
- LPPAT601 Waste management
- MPPAT625 Procedure for the Control of Clinical Material
- LPMIC071 Procedure for the IQC of all examinations
- LIPAT630 Pathology Services Handbook
- LFMIC074 Molecular IQC Record Sheet
- LFMIC075 Nimbus Maintenance Log
- COMIC001 COSHH assessment review – Microbiology
- UMMIC020 Nimbus troubleshooting guide
- LIMIC027 Acceptance Testing in Microbiology
- LFMIC075 Nimbus Maintenance Log
- LPMIC044 Class 1 Exhaust Protective Cabinet
- LIMIC042 Instructions for the preparation of stock reagent from patient samples for the IQC and acceptance testing of respiratory PCR assays

1 Clinical relevance/Purpose of the examination

Respiratory viruses cause significant morbidity and mortality in both healthy and vulnerable individuals. Clinically it can be difficult to diagnose the specific cause of any given respiratory infection due to similarities in presenting features, especially in the immunocompromised. Due to the availability in antiviral treatment for influenza it is important to rapidly diagnose the cause of an infection to instigate proper patient management, infection control measures and where possible antiviral treatment. Molecular techniques have been shown in numerous studies to be both sensitive and specific for detecting respiratory viruses when compared to traditional laboratory techniques, and they are now becoming more routinely used in diagnostic laboratories

SARS-CoV-2 is a newly identified strain of betacoronavirus which emerged in China in 2019. Rapid spread of the infection quickly resulted in a pandemic and consequent global health emergency. Infection with the SARS-CoV2 virus has been shown to cause the COVID-19 syndrome. COVID-19 disease may consist of a relatively mild flu-like illness, which can progress to severe pneumonia, respiratory distress, renal failure and death in vulnerable populations.

This document outlines the process for the extraction of nucleic acid using the Seegene NIMBUS system and the detection of SARS-CoV-2/FluA/FluB/Human metapneumovirus/Human Adenovirus A/B/C/D/E/F, Human Rhinovirus A/B/C, Human parainfluenza virus 1/2/3/4 & RSV in throat swabs.

2 Principle and method of the procedure used for examinations

The Allplex™ RV Master Assay is a qualitative test for the detection of SARS-CoV-2, Influenza A virus, Influenza B virus, Human respiratory syncytial virus A/B, Human metapneumovirus, Human adenovirus A/B/C/D/E/F, Human rhinovirus A/B/C and Human parainfluenza virus 1/2/3/4 in throat swabs.
Extraction of respiratory specimens is performed on the Seegene NIMBUS™ platform followed by real time PCR using the BioRad CFX ™. Amplified product is detected using fluorescent dyes that are linked to oligonucleotide probes, which bind to specific target sequences. The accumulation of the target is monitored in real time during the PCR run. Seegene's proprietary MuDT™ technology enables the provision of multi Ct values in a single fluorescence channel.
The AllPlex™ assay uses MS2 as an internal control (IC) to monitor for PCR inhibition, which is added at the point of extraction.
The use of Uracil-DNA glycosylase system is employed for Allplex™ assays to prevent amplified material acting a potential contaminant.

Negative results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information

3 Performance characteristics

See operating manual for performance specifications.

4 Specimen requirements and means of identification

4.1 Type of specimen

Dry throat swabs. After collection the dry swab sample can be held for up to 14 days at 15-28ºC. The swab can be stored in lysis buffer at 2-8ºC for up to a year or frozen at -20ºC or -80ºC. All samples must be opened and processed within the Microbiology Safety Cabinet in one of the enhanced Category II laboratories.

4.2 Patient preparation

No specific patient preparation is required.

4.3 Type of container and additives

Specimens should be taken using a dry swab. Swabs received in any medium are not suitable for testing.

4.4 Means of identification

All samples and request forms must be labelled with unequivocal identification criteria. Please refer to MPPAT613 Patient sample and request form identification criteria for further details.

5 Equipment and reagents

5.1 Equipment

Microlab NIMBUS™ extractor
CFX™ Real time PCR System (Biorad)
Screw capped containers for lysis buffer sample preparation
Filtered tips (200µl - 1000µl)
Calibrated pipette (00µl - 1000µl)

5.2 Reagents, standards or calibrants and internal control materials

5.2.1 Reagents

0.9ml BioMérieux Nuclisens easymag lysis buffer or equivalent
96-99% Ethanol
One of the following extraction reagents;
STARMag™ 96x4 Universal Cartridge System
STARMag™ 96x4 Viral DNA/RNA 200 C

5.2.1.1 Components of Extraction Kits

Item	Volume Supplied	Preparation
Extraction reagents are in cartridges that are clipped together. These can be separated if required but ensure they are linked in the following order before testing commences.		
Lysis Buffer (LB)	23 ml	If crystals present, incubate at 40°C until salts dissolve
Binding Buffer (BB)	68 ml	

Wash Buffer 1 (WB1)	55 ml	
Wash Buffer 2 (WB2)	10 ml	Add 48ml absolute ethanol at first use
Wash Buffer 3 (WB3)	55 ml	
Elution Buffer (EB)	18 ml	
Extraction reagents are sealed with film when shipped. They must be sealed with plastic tub covers after first use, which can be re-used for the life of the reagents. Extraction reagents can be used a maximum of 10 times.		
Magnetic Beads	1.8 ml	Flick tube to dislodge beads from the base of the tube and vortex for one minute before use. Must use the same tube of beads for each extraction cartridge – label the cartridge and beads with the same number. Beads may need to be aliquotted into supplied tubes depending upon which extraction kit is used. Ensure beads are vortexed thoroughly before aliquotting.

5.2.1.2 Allplex™ RV Master Assay PCR Reagents

Label	Volume Supplied (µl)	Description
SC2FabR/MOM	500 µl	MuDT Oligo Mix (MOM) - Amplification and detection reagent
EM8	500 µl	- DNA polymerase - Uracil-DNA glycosylase - Buffer containing dNTPs
PC SC2FabRPC	50 µl	Positive control (PC) SC2FABRPC - Mixture of pathogen and IC clones
RP-V IC 2	1000 µl	Exogenous internal control (IC) [MS2]
RNAse free water	1000 µl	Ultrapure quality, PCR grade water

5.2.2 Consumables

All stored at room temperature (20º - 25ºC)
Reagent tub covers
96 well PCR plate (Biorad)
Sealing strips (Biorad)
Supercon 96 Deep well plate
Hamilton 1000µl tips
Hamilton 300µl tips
Hamilton Waste bag
1.5ml Eppendorf tubes
Calibrated Pipette (100ul-1000ul) x2
Filtered tips (100ul-1000ul)
PPE
10% bleach
70% ethanol or denatured ethanol
Absorbent material/blue roll

5.3 Acceptance testing

Acceptance testing is performed on opening of each new batch and recorded on LFMIC056. Please refer to LIMIC027 Acceptance Testing in Microbiology and RAMIC016 Risk assessment – Acceptance testing of reagents.

Acceptance testing is performed using confirmed previously positive patient samples. These may also be used to test the analyser post intervention from an engineer, mechanical failure, continuous invalid results, or any other intervention which may give rise to suspect results. The results must be recorded to ensure that there are no errors.

6 Environmental and safety controls

Samples, reagents, and quality control materials must be stored so as to ensure their integrity. In particular, samples must be stored in such a way that cross contamination is not possible. All areas where consumables are stored are monitored for temperature. All equipment undergoes portable appliance testing (electrical safety) which is undertaken by the Health Boards estates department at pre-defined intervals depending on the equipment concerned.

Material safety data sheets (MSDS) are obtained for all reagents, quality controls, chemicals etc as applicable and from these COSHH assessments are completed. Manual handling and risk assessments are also completed. All MSDS, manual handling assessments, risk assessments and COSHH assessments can be found in the documents module of Q-Pulse. All documents are controlled.

6.1 Electrical

Potential electrical hazards exist behind covers and panels. Keep doors, covers, and panels closed during normal operation.

Do not operate the system if any of the assemblies have been removed. Removing assemblies from their normal positions may create electrical hazards.

6.2 Biological

Positive results are indicative of presence of SARS-CoV-2-RNA.

- The opening of packages and pre preparation of swabs from will be carried out in a MSC safety cabinet within CL2.
- Only fully trained and competent staff must undertake the work; in addition to this the level of training provided should be appropriate to the level of risk and the complexity of the procedures being undertaken.
- Lysis buffer contains Guanidinium thiocyanate and is disposed of in sealed containers, stored in the Histology flammable store and collected periodically by specialist waste collectors (arranged through Estates and in accordance with national regulations).
- Caution when dealing with accidental release/spillage of lysis buffer. Wear protective equipment (gloves and safety glasses). Isolate spill area. Collect with absorbent material and place in a container for disposal. Wash spill area with 70% ethanol then disinfect the surface with a 10% bleach or an equivalent disinfectant. If staff come into contact with lysis buffer please seek first aid immediately.

DO NOT add bleach to spilled lysis buffer – a dangerous reaction may occur.

7 Calibration Procedure

7.1 Calibration

N/A

7.2 Metrological traceability

N/A

8 Instructions for Performance of the Examination

8.1 Booking Samples into LIMS

Test Set: RESPS
Common Sample Types:

37	Bronchoalveolar lavage (BAL)
38	Endotracheal secretions
41	Throat swab
42	Non directed bronchoalveolar lavage (NBL)

Scan all forms once result has been transcribed on to the form.

8.2 Sample processing

8.2.1 Sample handling

All specimens received should be opened in a MSC safety cabinet in the enhanced CL2 laboratory.

8.2.2 Swab preparation

The swabs and their corresponding request forms are allocated episode/accession numbers. The forms will be used to book the specimens onto LIMS. For each sample, label 1x 0.9ml lysis tube with the episode number (barcode). If the samples are being referred ensure lysis tubes are labelled with the patients name as well.

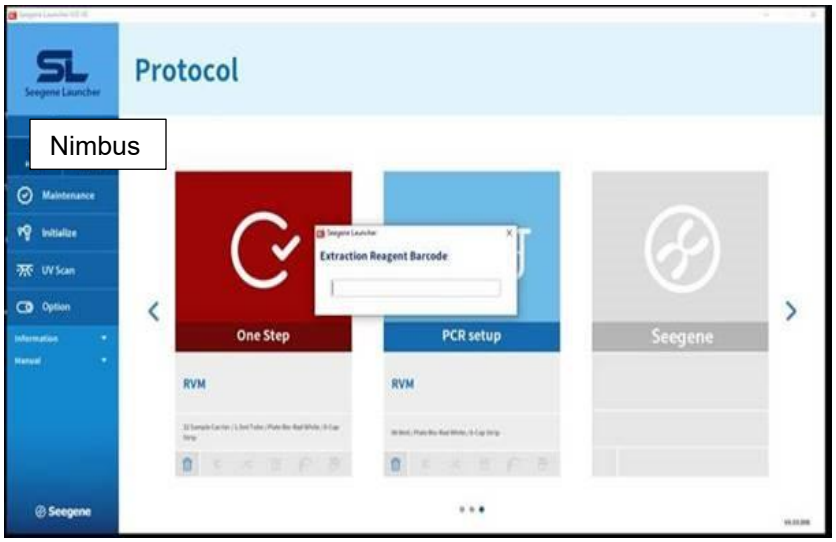
- Remove the lid from the lysis tube.
- Remove swab from tube. Refrain from touching the end of the flocked swab with your gloves. If this occurs change gloves immediately.
- Place swab into lysis buffer and snap/cut swab into 0.9ml lysis buffer, recap & vortex well (ensure swab is snapped/cut off as short as possible to allow space for pipette tip to reach liquid).
- Scissors are recommended to cut swab, ensure the scissors are cleaned thoroughly with bleach cloth between each patient sample.
- Place the snapped swab into the COVID19 sweetie jar within the cabinet. Repeat steps 5 until all swabs are snapped.

All 0.9ml lysis buffers containing samples should be left at room temperature(20º - 25ºC) for 10 minutes.
After the 10-minute incubation period, vortex all 0.9ml lysis tubes for a second time and pulse centrifuge to remove liquid from the cap.
Note: When testing is complete, store all 0.9ml lysis tubes in freezer FR2 for 1 week.

8.2.3 Specimen Extraction Set Up

Switch on the NIMBUS extractor using the power switch on the bottom right hand side. Switch on the laptop and charger. Open to the SARS-CoV-2 Launcher program (purple icon) on the desktop. Perform the required maintenance procedure (see section 9 Maintenance Procedures for details). Select “Launcher Run” to begin the extraction set up. Select the “**One Step** 2019-nCoV” program

You may need to scan the barcode of the extraction reagent in at this point.



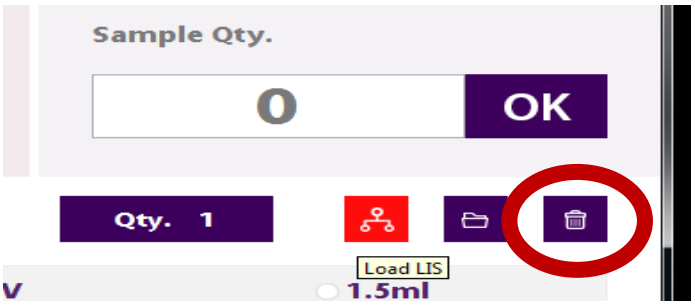
To open the NIMBUS door, pull the handle towards you and pull up.
Begin loading the analyser, starting with the waste bag. You will need to move the gantry by clicking the “Move Gantry” option on the right hand side of the screen (the door must be closed for this step).

Prepare the waste bin by securing the plastic bag in the box with the silver metal ring and return the gantry to the home position by pressing “OK” (note this window may be behind the others).
Load the 1000µl tips in the correct position as indicated on the screen. You will confirm the number of tips that are present in a later step. **DO NOT REFILL PARTIALLY USED TRAYS**.
Load the 300µl tips in the correct position. There is an opportunity to replace the 300µl tips during the extraction if insufficient tips are loaded. **DO NOT REFILL PARTIALLY USED TRAYS.**
Load the deep well plate in the correct orientation, as directed on screen.

Load the Biorad PCR plate in the correct orientation, as directed on screen.
When prompted, load the internal control in the designated space (place the lids of the controls on paper in front of the waste bin)
Proceed through the menu until you reach the worklist screen.
In the worklist screen, type the number of samples you are testing in the box in the top right hand side of the screen. This will allocate the number of spaces required for scanning your samples.
Ensure the extraction reagents are completely thawed. Vortex all components **EXCEPT EM8.** Gently invert the enzyme several times to ensure it is well mixed. Pulse spin all reagents. Mastermix components can be used a maximum of 5 times within 30 days of opening and before the expiry date.
Ensure the magnetic beads are thoroughly mixed by flicking the base of the tube multiple times to suspend them and then vortexing thoroughly for one minute**. IMPORTANT – Number the lid of the beads. Ensure that the same aliquot is reused with each extraction cartridge.** The analyser does not measure the volume of micro-particles remaining in the tube, but calculates the remaining volume when the extraction cartridge are scanned. An additional aliquot of magnetic particles can be added in the second space if an additional extraction cartridge is required.

Loading Specimens without Using the LIS

In the PCR Plate tab, create your worklist and load the samples to be tested.
Scan the barcodes of the samples to be tested.
Note the zigzag pattern of sample loading as indicated on the screen. Click worklist see the list of samples to be tested. The adapters are required for 1.5ml tubes. Load the samples in correct order. **NOTE** that the kit positive and negative controls are not allocated a space by the user.
Empty spaces without samples present should be removed from the worklist. Untick the 2019-CoV boxes of any missing samples and select delete to remove the positions from the worklist.



Before proceeding to the next step, verify that ticks are present for the following boxes for all samples to be tested:

- 2019-CoV testing for all samples

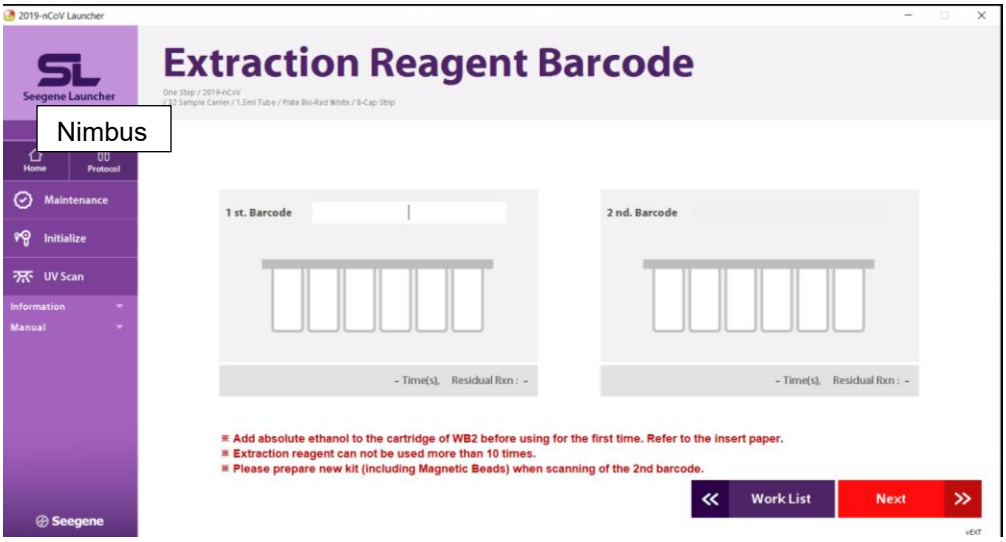
- 1.5ml tube box is ticked for all samples.

Note that the boxes may be extremely faint and hard to see.

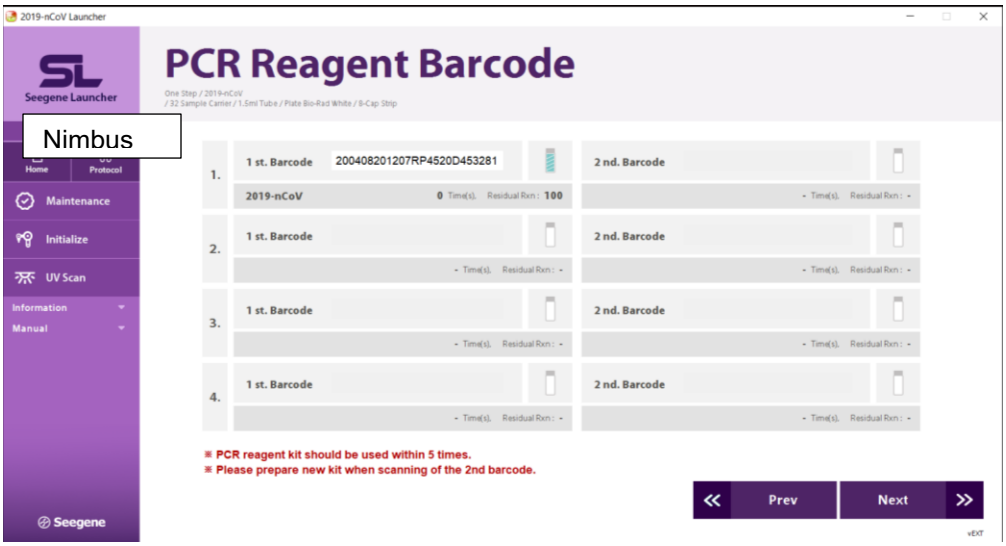
Loading the Remaining Reagents

Ensure the extraction reagents are completely thawed. Vortex all components **except the enzyme mix**. Gently invert the enzyme several times to ensure it is well mixed. Pulse centrifuge all reagents.
Mastermix components can be used a maximum of 5 times within 30 days of opening and before the expiry date.
Note the number of uses on the worksheet and the box
This screen provides a summary of the sample volumes required for testing. Click next.
Load the samples in correct order.
Click **NEXT.**
For the first use of the extraction reagent cartridge, remove the sealing film and add 48ml of ethanol to wash buffer 2. Ethanol is stored in the flammables cabinet. Ensure the ethanol use log on the front of the cabinet is completed.
Load the cartridge onto the extractor and scan the barcode of the extraction reagents. The number of uses and the remaining tests will be shown on screen. Extraction reagents can be used a maximum of 10 times.

- An additional cartridge can be added if the current reagents are not sufficient for the number of tests required.
- Cartridges that have been used more than once will be sealed with plastic lids. These must be labelled with the reagent abbreviation and retained for resealing the reagents upon completion of the extraction.

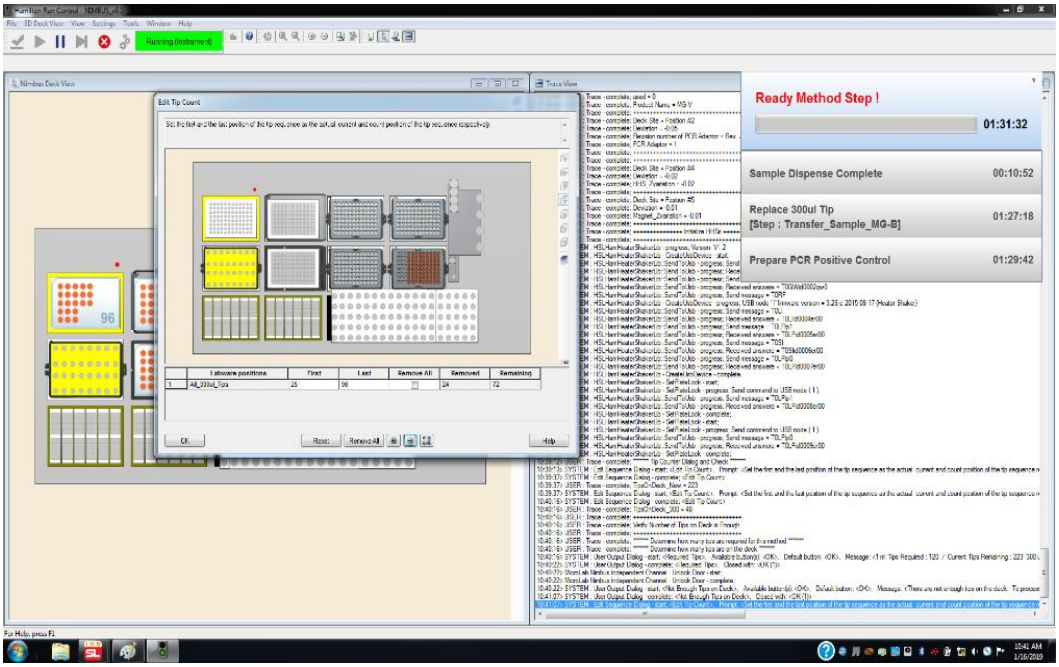


Scan the PCR reagent barcode for kit. The number of uses and the remaining tests will be shown on screen. Record the number of uses on the box. PCR reagents can be used a maximum of 5 times.



Load the PCR reagents in the order shown on screen. Ensure the lids are kept to replace at the end of the extraction. Lay them out on clean blue roll, face down, inside the analyser during the run.
NOTE The positive control is not added until after the extraction is completed to reduce the risk of contamination.

If there are insufficient reagents remaining in the kit, repeat and add another set of master mix reagents in the next row.
The PCR plate layout is shown for information purpose. All these details will be stored in the PLRN file upon completion.
Before starting the run, the program will ask you to finally confirm the tube position for samples and reagents. Check the placement and tick the boxes to confirm the order is correct.
Click RUN and wait for tip position confirmation screen to appear (approximately 30 seconds).
In the tip count screen, confirm the position of the 1000µl and 300µl tips. Individual tips can be selected or drag to highlight a larger selection. Zoom in using the mouse wheel if required.



The analyser will indicate the number of tips required and loaded. The machine will prompt to load more 1000µl tips if there are not enough loaded. 300µl tips can be replaced during the run when the alarm sounds towards the end of the run. Click OK. The analyser will perform a self-test and will then begin the extraction. A countdown will appear in the top right hand side of the screen indicating how long is left in the run and when the positive control will need to be added (approximately 2 minutes before the end of the run). The extraction and PCR setup time varies depending on the number of samples.

Count	One Step Extraction & PCR Setup Time
8	57 min
24	1hr 24 min
40	1hr 52 min
56	2hr 25 min
72	2hr 52 min

For larger sample numbers you will need to change the bin and 1ml tips during the run. Ensure the volume on the laptop is turned up as the alarm will sound if there are any errors, when the positive control needs to be added and on completion of the run. When the positive control is being added, keep hold of the lid and replace it immediately upon completion. **Change gloves before handling the PCR plate or any reagents.**

8.3 Completion of Extraction

Upon completion of the extraction, remove the PCR plate from the extractor and seal with the Biorad lids.
Remove the PCR reagents and return them to the freezer if they are to be re-used or discard in triple orange bag. Replace the lids on the extraction reagents if they are to be re-used.
Remove the magnetic beads and store them in the box with the extraction reagents.
DO NOT DISCARD THE DEEP WELL PLATE.

8.4 PCR Setup

Switch on the CFX-1000 (at the back of the machine) and load the PCR plate.

IMPORTANT – USE THE BUTTON TO OPEN AND CLOSE THE LID.

Switch on the laptop next to the CFX96
Open todays run in the PLRN file.
The Biorad CFX Manager IVD will open and will communicate with the CFX-1000 for a short time.
Click “Start Run” when it becomes available.
Save the results.
The CFX-1000 will initialise briefly before starting the run. The time to completion will be displayed on the front of the machine (1 hr 45 min).

8.5 Waste Disposal, Cleaning and Shutdown Procedure

Replace caps on extraction reagents. Discard into triple orange bags for chemical waste disposal if they are not to be used again. Clean the tip eject plate thoroughly with 70% ethanol followed by distilled water.

Used sample containers are placed into sweetie jars for specialist waste disposal, plastics and tip waste bags are disposed in triple orange bags for infectious waste disposal.
Clean the waste box and all internal surfaces with 10% bleach, followed by distilled water and ethanol. Pay particular attention to the master mix, sample and extraction reagent racks.
Check the condition of the carriers and alert a senior member of staff if any damage is apparent.
Check the liquid waste bottle. When the waste bottle is half full, carefully transfer the liquid into a jerry can. Due to the presence of guanidinium thiocyanate in the lysis buffer, all liquid waste needs to be disposed of via a licensed disposal company. Eye protection must be worn and the waste must not come into contact with bleach.
Close the NIMBUS door and click OK to return the gantry to the home position.
Click “UV Scan” on the right hand side of the Seegene Launcher menu and set the timer to 60 minutes. This must be done before a new run is performed.

9 Maintenance Procedures

There are daily and weekly maintenance processes required by the analyser. Record results on LFMIC075. The NIMBUS will not allow you to start an extraction without the necessary maintenance being performed. It is not necessary to run the daily maintenance if the weekly

maintenance is being run on a particular day. All cleaning associated with the daily maintenance is performed at the end of a sample extraction procedure.

The semi-annual maintenance is performed by the field service engineer.

9.1 Daily Maintenance

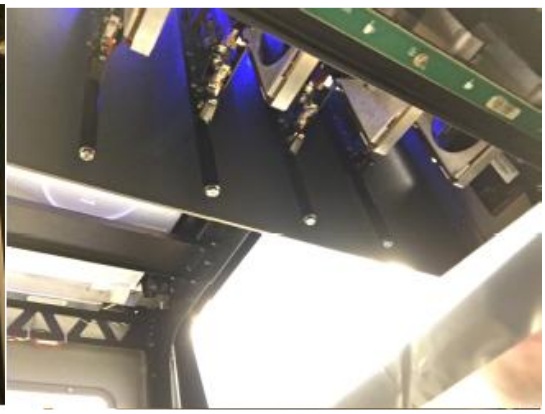
Open the Seegene Launcher IVD program and select “Maintenance”
Choose the daily maintenance procedure.
The tip eject plate does not need to be removed, as it has the hole to enable checks to be performed.
A list of tasks will appear on screen.

Inspect the deck and carriers for cleanliness.
Check there is no tip waste and the liquid waste is not too full. These should have been done at the end of the run.
The analyser will check the tightness of the pipetting channels. Tick the box and select continue. This procedure will take approximately 5 minutes.
The analyser will check the cLLD. Tick the box and select continue. This procedure will take approximately 1 minutes.
(The tip eject plate was not removed).

9.2 Weekly Maintenance

Open the Seegene Launcher IVD program and select “Maintenance”
Choose the weekly maintenance procedure.
A list of tasks will appear on screen

Inspect the condition of the carriers and other devices. Alert a senior member of staff if anything appears damaged in any way.
Inspect the deck and carriers for cleanliness.
Check there is no tip waste and the liquid waste is not too full. These should have been done at the end of the run.
The O-ring and tip eject sleeve is shown below. **It is NOT recommended that these are cleaned** due to the risk of unscrewing and dislodging the tips.



The analyser will check the tightness of the pipetting channels. Tick the box and select continue. This procedure will take approximately 5 minutes.
The analyser will check the cLLD. Tick the box and select continue. This procedure will take approximately 1 minutes.
(The tip eject plate was not removed).

9.3 Troubleshooting

See embedded guidance from SeeGene below

NIMBUS troubleshooting.pd

10 Quality assurance procedures

10.1 Internal quality control

Each run includes a positive and negative control. Ensure these have passed. Results are recorded on the analyser. Any failures should be recorded on LFMIC074. The internal positive control must be **POSITIVE** for the result to be valid. Unless a sample is strong positive, in which case the results can also be authorised as positive. If a sample is inhibitory, the result is reported as inhibitory and a new sample is requested. Each run should also include 2-3 'negative snaps' ie an unused swab in lysis buffer. These are included to highlight any contamination issues and should be 'invalid'. If positive inform a senior member of staff.

Also, process one previous patient positive control (see LIMIC042) and one negative control on starting a new batch. Record results on LFMIC074 Molecular IQC Record Sheet. Any IQC failures should be brought to the attention of senior staff.

10.2 External quality assurance

The laboratory participates in the NEQAS SARS-CoV-2 and Respiratory EQA schemes. Process EQA samples as normal and give results to a senior member of staff. For further information please refer to MPPAT628 External Quality Assurance in the Pathology department.

10.3 Environmental Testing

Environmental monitoring is performed monthly. Record results on LFMIC070.

11 Interferences and cross reactions

The manufacturer (Seegene) advises that the Allplex™ RV Master Assay is validated for throat swabs, nasopharyngeal swabs, sputum, BAL and nasal wash/aspirates. A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if inadequate numbers of organisms are present in the specimen. The test cannot rule out diseases caused by other bacterial or viral pathogens.

12 Principle of procedure for recording and calculating results

12.1 Exporting Results

On completion of the run, click Export>Seegene export. Export file to QUANTSTEP4 (this should be the default file). Minimise all of the screens and open SARS-CoV-2 Viewer (the purple icon). Click the open file icon and open todays run. Select all results by ticking the box next to the Sample No column. Click File, HL7, Send.
Remove the PCR plate and switch off the Biorad.

12.2 Negative results

Negative results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

12.3 Positive results

All SARS-CoV-2 positive results (CTU<27) are referred to the Pathogen Genomics Unit, Cardiff for sequencing. Positive Flu A results are referred to UHW.

13 Measurement Uncertainty of measured quantity values

N/A

14 Reporting results

14.1 Biological reference intervals or clinical decision values

N/A

14.2 Reportable interval of examination results

N/A.

14.3 Determination of quantitative results outside the measurement interval

N/A

14.4 Alert/critical values

Inform Infection Control of any Positive results from Ward patients

14.5 Responsibilities of personnel in authorising, reporting and monitoring of reports

Results are sent from the Biorad to LIMS via interface and are automatically authorised.

14.5.1 Authorisation

All results are authorised automatically at the bench

14.5.2 Report Issue (Interim/Final/Additional)

All reports will have the following comment added as an auto comment:
COVCOM3

SARS-CoV-2 is the causative virus of COVID 19 infection.

If the internal quality control gives a CT value of >30 it suggests that extraction has not been optimal and a repeat sample requested.

14.5.3 Reporting to other departments

Positive SARS-CoV-2 results are reported to health protection via automated methods via TrakCare lab data via Labexpert and Tarian.

15 Referral

15.1 SARS-CoV-2 positive

All extracts from positive samples must be sent to the Pathogen Genomics Unit in Cardiff as soon as possible.

15.2 Flu A positive

Send sample to UHW

16 Laboratory clinical interpretation

Clinical interpretation of results is available via Consultant Microbiologists 24/7 who can advise clinicians on the evaluation and interpretation of the results of laboratory examinations including precision and accuracy of methods, significance of results in relation to the laboratory's reference values, clinical significance of the requested procedure and its fitness for purpose and any further procedures that may be helpful.

17 Potential sources of variation

Sources of variation may include biological, rhythmical/cyclical or random e.g., pre-analytical sources of variation, analytical variation etc. Please refer to MPPAT606 Procedure for assuring the quality of examinations" for further details.