# Guidance and Standard Operating Procedure
# COVID-19 Virus Testing in NHS Laboratories

NHS England and NHS Improvement

# 1. 0 Background

- In December 2019, a novel coronavirus (COVID -19) caused an outbreak in Wuhan, China, and soon spread to other parts of the world. It is believed that COVID-19 is transmitted through the respiratory tract and can induce pneumonia.
- The ongoing outbreak poses a challenge for public health laboratories as the outbreak is widespread and international spread through travellers is now evident as is spread from affected individuals.
- The priority to facilitate public health testing was undertaken by Public Health England (PHE) at the Colindale facility and their regional laboratories.
- The preferred screening/testing is by Molecular diagnosis of COVID-19 by real-time RT-PCR (RdRp gene assay) based on oral swabs, which has been used for confirmation of this disease by PHE laboratories.
- PHE has been working closely with NHS England and Improvement (NHS E and I) Pathology Network Laboratories to increase capacity of testing, which is now needed to continue to identify and maintain the required containment of affected individuals and delay and mitigation of spread.
- As part of the escalation and management of this viral infectious outbreak, a Phased approach to onboarding NHS E and I Pathology Network Laboratories, across England, is being undertaken, working closely with PHE, so that patients and NHS E and I Staff can receive timely testing, intervention and treatment.

# 2.0 Aims and Objectives

- This document provides guidance and the standard operating procedure (SOP) for COVID-19 testing for NHS E and I Pathology Network Laboratories. This document will also provide information on the communication routes and information flows that support the management of return of patient results.
- This guidance and SOP has been developed with PHE and NHSE and I working in partnership.
- The aim is to deploy robust diagnostic methodology for use in all laboratory settings using accepted validation and verification protocols with positive control virus material available from Colindale PHE laboratory as part of the capability and assurance framework.

# 3.0 Scope

- This SOP covers COVID-19 testing to be deployed by NHS E and I Pathology Networks

- This SOP does not cover the investigation and testing of other respiratory infections not caused by COVID -19.

# 4.0 Overview

Public Health England (PHE) have been undertaking all formal testing for COVID-19 and now have an established service in all regional PHE and some NHS E designated testing laboratories (mainly in London).

This initial capacity now needs to be supported and increased using NHS laboratories with appropriate facilities, and with some initial support from PHE.

This guidance outlines the requirements for a designated NHS Laboratory to deliver a COVID-19 testing service using their preferred testing protocols and processes. This guidance also specifies the type of specimens that will be tested and other regulatory requirements.

Due to the nature and need to establish greater testing capability we are asking each pathology network to identify a hub laboratory to lead on this work, with the stated aim to provide a **minimum capacity of 500 tests per day for COVID-19 testing in the NHS**. This activity is **in addition** to existing capacity that may be available in the network via existing PHE testing laboratories.

Laboratories must consider how these services can be provided 7 days per week and clearly identify any potential bottle necks in the testing pathway that may restrict processing capacity. This may include, availability of staff, other assays that use the equipment that may restrict capacity, containment facilities – taking note of the HSE requirements (Appendix 9) and any logistics and supply chain issues.

It is expected that the nominated NHS Laboratories will be mobilised rapidly to undertake local testing of individuals for COVID-19, in whichever locality they may arise in England. All the participating microbiology/virology labs will be UKAS 15189 accredited and have an accredited quality management system. Although they may have similar tests/technologies within the scope of their accreditation, it is likely that the introduction of testing for COVID-19 will not be included in this accreditation. However, there are stringent requirements to demonstrate assay performance using accepted validation and acceptance criteria, which will mitigate in part this requirement, and NHS Laboratories will need to assure that they have undertaken this using internal and external Quality Assurance (QA), before offering this testing service to patients. In the meantime, NHSE and I is working with UKAS to explore how urgent extensions to scope could be introduced.

In addition, PHE have been working with the Health and Safety Executive (HSE) to establish the appropriate level of containment for sample handling and processing (see PHE guidance in Appendix 9). All Laboratories undertaking testing will need to complete their own Risk Assessments, guidance can be found at Appendix 9.

This document is not designed to replicate, duplicate, or supersede any relevant PHE guidance or other guidance (see Appendix 1) or legislative provisions which may apply. In the event of new guidance emerging, this guidance will be reviewed and amended with as much rapidity as possible.

# 5.0 Testing Standard Operating Procedure

## 5.1 Background

Due to the need to establish greater testing capability NHS E and I are asking identified pathology network laboratories to commence working up validation of commercially available kits that can be automated to further increase the available testing capacity across England. Due to the public health requirement for this action to be taken at pace we do not expect these assays to be provided in scope, initially, in terms of UKAS ISO 15189 accreditation, however, it is expected that an in-house validation to demonstrate the acceptance of these assays has been performed. Commercial kits should be CE marked and any in-house assay must meet locally agreed acceptance criteria prior to patient use.

Once the test is validated, and Risk Assessments have been completed, (see Appendix 9) a 24/7 offering should be considered, and testing should be prioritised above other Pathology Tests as Urgent and High Priority including the return of results.

Samples that are positive on testing by the NHS Pathology Network Laboratories can be considered as presumptive positives, initially, if confirmation is required to be carried out by a local Public Health England (PHE) Laboratory (See list – Appendix 2). Although this is not required if Network Laboratories are confident in the test they have adopted and assured of an accurate result. If in any doubt, samples can be referred to a Public Health England (PHE) Regional Laboratory local to the NHS Testing Laboratory, for confirmatory testing, for an initial period, until the NHS Network Laboratory is assured their testing is robust, accurate and safe, after which time confirmation by Local PHE Laboratories will no longer be required. Any Positive results that are sent for confirmation to a PHE Laboratory, will be considered Presumptive Positives until confirmed. Presumptive Positive/Positive results will be notified to the coordination center for contact tracing, which will commence immediately.

Please note that patients who are admitted to hospital will need additional respiratory samples taken for testing for other respiratory pathogens, such as influenza, in addition to those detailed below for COVID-19. These additional tests must be carried out by the local referring laboratory – other samples must not be forwarded to the designated PHE regional or NHS E and I laboratory that will be carrying out the

COVID -19 screening test, unless this is the same laboratory, i.e. routine practice must be followed for other tests.

If testing for avian influenza is also indicated (based on assessment of travel and exposure histories), specific and separate samples will need to be collected and sent to the appropriate laboratory as per routine practice.

If testing for MERS-CoV is also indicated (based on assessment of travel and exposure histories), specific and separate samples will need to be collected and sent to the relevant laboratory as per routine practice.

Where Ct values are below an agreed value (based on analysis of Proficiency Testing performance and other local testing data) with satisfactory quality control parameters including internal control performance, the result is considered valid and should be telephoned and a report issued as a final result. Any such positive result will be recorded as “confirmed” for Public Health reporting purposes and will be **notifiable** under recent legislation.

Results where:

- the Ct value is => 40, AND/OR
- there is an abnormal assay curve, AND/OR
- the clinical context makes the positive result highly unexpected

should be considered interim or held until reviewed by a laboratory clinician. Laboratories will undertake the following actions:

- defer telephoning of the uncertain result to the clinician looking after the patient (or telephoning it with clear caveat regarding the uncertainty)
- re-extract the original sample and repeat the PCR in the original and new ex-tract in duplicate
- perform testing on a further respiratory sample (or samples) from the same patient
- confirm with an alternative, equivalent sensitivity assay locally or where none is available, they should forward the sample to Colindale
- Regular review of expected performance of reagents, particularly control materials

The actions taken should be expedited in order to minimise the delay in obtaining a definitive result for the patient. Only confirmed results are expected to be notified to public health and other stakeholders.

A fully validated protocol for N gene detection, which is of equivalent sensitivity to RDRP assay, is available for immediate implementation as an additional assay

**Ambiguous samples for referral to Colindale for further characterisation (genomics/virus isolation/phenotypic work):**

- Deaths, and/or other very severe clinical cases
- Unusual samples which cannot be resolved locally
- Unexpected findings eg cases associated with neurological features
- As required for surveillance purposes, as schemes are developed.

Further instructions will be provided as these are developed.

## 5.2. Explanation of sample sets

### 5.2.1 Samples required for initial diagnostic testing (possible case)

1. Upper respiratory tract sample(s): combined viral nose and throat swab, or a viral nose swab and a viral throat swab combined into one pot of viral transport medium, or a single swab used for throat then nose, or a nasopharyngeal aspirate in a universal transport pot.
2. Lower respiratory tract sample (sputum) if obtainable, in a universal container

Additionally, if the patient is admitted to hospital, take a sample for acute serology.

- 5mL serum tube or plain (no additive) tube; for children <12 years, 1mL is acceptable.

Important points about sample-labelling and request forms include:

- label each sample with ID, date of birth and type of sample
- use the specific form for requesting COVID-19 acute respiratory disease testing (E28), one form for each sample
- do not place paperwork (request forms) in the primary container for Category B transport
- request form must include a contact phone number for sharing of results and a contact number for the patient
- samples without appropriate paperwork will not be tested or testing will be delayed

See Appendix 6 for Sampling and Packaging Poster.

### 5.2.2. Samples required for monitoring confirmed COVID-19 acute respiratory disease

Sequential sampling may be required to monitor the progress of confirmed COVID-19 acute respiratory disease, decided on a case-by-case basis.

### 5.2.3. Sending samples to the testing laboratory

The referring laboratory must send the sample to the designated pathology network laboratory listed in how to arrange laboratory testing. There is no need to call the local testing laboratory or HPT or PHE regional laboratory to request testing.

All samples for COVID-19 testing should be packaged and transported in accordance with Category B transportation regulations and labelled ‘Priority 10’. UN 3373 packaging must be used for sample transport.

Further guidance is given on packaging and transport of samples in safe handling and processing for laboratories. PHE follows the World Health Organization (WHO) guidance on regulations for the transport of infectious substances 2019-2020, NHS E and I Laboratories are advised to do the same.

If the referring laboratory needs to know whether the samples have arrived at the designated laboratory, they should contact the courier for tracking information.

### 5.3 Testing protocols for COVID -19

The PHE testing protocol, if NHS Laboratories are **NOT** adopting CE Marked commercial assays, can be found at Appendix 5. This protocol describes a uniplex real-time RT-PCR assay for the detection of the 2019 novel coronavirus (2019-nCoV).

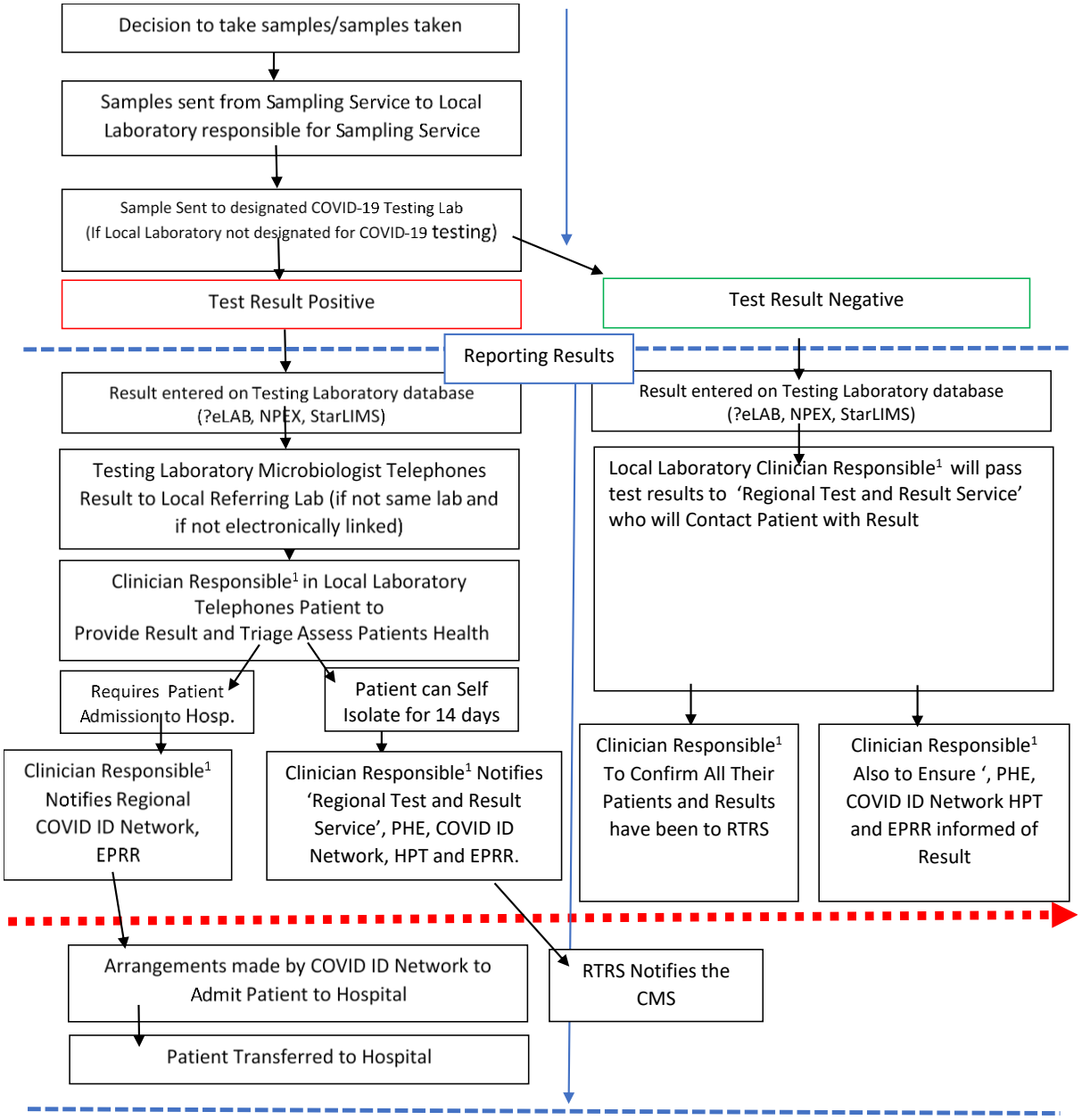
NHS E Laboratories can choose to process samples on the laboratory’s chosen platform and protocol, please see recommended list that appears in section 5.4 below. (This will be updated as other systems, devices and protocols become available). NHS E Laboratories will need to show **local validation and verification** of testing, before providing these services, which must include internal and external QA.

**In addition, local Risk Assessment will need to be carried out by every Laboratory as part of the HSE requirement for testing, see Appendix 9.**

### 5.4 Systems under evaluation for COVID testing

The current Systems (as of 06/03/2020) under evaluation can be found at Appendix 8.

## 5.5 Notification of Presumptive Positive/ Positive Results and Negative Results




1. The clinician responsible may devolve the work to another clinician but must maintain accountability for patient being done.
2. To note: Regional Test and Result Service is provided by ambulance services as part of the Regional Incident Coordination Centre

# 6.0 Information Flows

## 6.1 Information Flows

Electronic requesting and reporting should be the accepted standard. All laboratories referring and receiving requests should seek to automate this process. Many laboratories are linked via the NPEx or similar. These links should be used if available. Laboratories should seek to ensure transmission of results via Text is possible.

Positive results can be confirmed by PHE Regional Laboratories until the NHS E Testing Laboratory is confident of their testing, the Testing Laboratory will need to liaise with their local PHE Laboratory and send sample(s) for confirmatory testing, if confirmation of results is needed, this also applies for ambiguous results. See link below for further guidance.

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/laboratory-investigations-and-sample-requirements-for-diagnosing-and-monitoring-wn-cov-infection

Presumptive Positive/Positive results **will** be reported back to patients by Testing Laboratory or Clinician Responsible at Referring Laboratory, according to flow diagram above, within 48 hours, and confirmed if local PHE lab has undertaken confirmatory testing. Confirmed results will be reported back to patients within 72 hours of presumptive positive test results, if PHE Lab confirmation has been requested.

All negative results will be reported back to the clinician responsible* for patient sampling, who will have responsibility for ensuring patients are informed. This is currently envisaged to be via the route that results are normally communicated to the requesting clinician for onward communication to the patient. We are currently reviewing this with DHSC and NHS Digital. The diagram in section 5.5 above, outlines the current expected practice. Some centres are using SMS messaging via their electronic patient record to pass on negative results directly to patients. Where possible these options should be explored.

# 7.0 Additional Support

## 7.1 From PHE

PHE will provided expert support through dedicated experts who can be contacted to address any technical or clinical issues, Laboratories seeking such support will need to make all requests via nhsi.pathemergencyresponse@nhs.net.

## 7.2 From NHS E and I

NHS E and I has a dedicated Laboratories and Specialised Services Shortage Response Group (LSS SRG) for Pathology that can be contacted at this email (nhsi.pathemergencyresponse@nhs.net ), who will be able to provide support in the

event of supplies shortages, advice on resilience and business continuity (See Appendix 4).

## 8.0 Further Information

8.1 Further information can be found in the annexes in the following sections:

- Appendix 1: Other relevant guidance
- Appendix 2: List of PHE Laboratories
- Appendix 3: List of NHS E and I Pathology Network Laboratories in Phase 1 roll out.
- Appendix 4: LSS SRG – Pathology Central Contact Email
- Appendix 5: PHE COVID-19 Testing Protocol
- Appendix 6: Sampling and Packaging Poster – PHE Guidance
- Appendix 7: PHE Presumptive Positive Testing Request Form
- Appendix 8:Testing Systems Under Evaluation by PHE (As of 06/03/2020)
- Appendix 9: Health and Safety Guidance

## For any queries please contact:

nhsi.pathemergencyresponse@nhs.net

# Appendices

Appendix 1: Public Health England and other Guidance

- Public Health England (PHE) 2020 ‘Guidance - Wuhan novel coronavirus: epidemiology, virology and clinical features’ (Updated 27 January 2020) https://www.gov.uk/government/publications/wuhan-novel-coronavirus-background-information/wuhan-novel-coronavirus-epidemiology-virology-and-clinical-features
- Public Health England (PHE) 2020 ‘Guidance - Wuhan novel coronavirus: infection prevention and control’ (updated 15 January 2020) https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control
- Public Health England (PHE) 2020 ‘Laboratory investigations and sample requirements for diagnosing and monitoring WN-CoV infection - Guidance (Updated 27 January 2020) https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/laboratory-investigations-and-sample-requirements-for-diagnosing-and-monitoring-wn-cov-infection
- Public Health England (PHE) 2020 ‘Guidance - Wuhan novel coronavirus: guidance for clinical diagnostic laboratories’ (Updated 27 January 2020) https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories
- Public Health England (PHE) 2020 ‘Public Health England (PHE) 2020 ‘WN-CoV: Laboratory Investigations and Sample Requirements (Version 1.0, 17 January 2020)’ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/859086/Laboratory_investigations_algorithm_WN-CoV_v1_17_Jan.pdf
- World Health Organization’s (WHO) (2019) ‘Guidance on regulations for the transport of infectious substances 2019–2020’ https://www.who.int/ihr/publications/WHO-WHE-CPI-2019.20/en/ (1 January 2019)

- World Health Organization's (WHO) (2020) '*Global Surveillance for human infection with novel coronavirus (2019-nCoV) - Interim guidance' (20 January 2020)*

  https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov)
- World Health Organization's (WHO) (2020) 'Surveillance case definitions for human infection with novel coronavirus (nCoV)' (10 January 2020) https://www.who.int/publications-detail/surveillance-case-definitions-for-human-infection-with-novel-coronavirus-(ncov)
- World Health Organization's (WHO) (2020) 'Household transmission investigation protocol for 2019-novel coronavirus (2019-nCoV) infection - Interim guidance' (25 January 2020) https://www.who.int/publications-detail/household-transmission-investigation-protocol-for-2019-novel-coronavirus-(2019-ncov)-infection
- World Health Organization's (WHO) (2020) 'Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected - Interim guidance' (25 January 2020)

  https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125
- World Health Organization's (WHO) (2020) 'Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases - Interim guidance' (17 January 2020) https://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117

**Note:** This list is not exhaustive and is rapidly evolving. The Provider will be expected to respond to new and emerging guidance.

## Appendix 2: PHE Laboratories

| NHS Region | Designated laboratory | Address for sample dispatch | Contact telephone numbers | |
|---|---|---|---|---|
| | | | Normal hours | Out of hours |
| East of England | Cambridge PHL | Public Health England, Public Health Laboratory, Box 236, Cambridge University Hospitals NHS Foundation Trust, Cambridge Biomedical Campus Hills Road, Cambridge, CB2 0QQ | 01223 257037 | 01223 245151 (Ask for on call Virologist) |
| London | Respiratory virus unit, Colindale | Respiratory virus unit (RVU), Public Health England, 61 Colindale Avenue, London, NW9 5EQ | 0208 327 7887 | 020 8200 4400 (Ask for Duty Doctor) |
| Midlands | Birmingham PHL | Public Health Laboratory Birmingham, Birmingham Heartlands Hospital, Bordesley Green East, Birmingham, B9 5SS | 0121 424 3111 | 0121 4242000 (ask for duty virologist) |
| North East | Newcastle lab | Molecular Diagnostics Laboratory, Microbiology and Virology Department, Freeman Hospital, Newcastle upon Tyne, NE7 7DN | 0191 233 6161 (Newcastle upon Tyne Hospitals NHS Foundation Trust, switchboard) Ask for Consultant Virologist | 0191 233 6161 (Newcastle upon Tyne Hospitals NHS Foundation Trust, switchboard) Ask for on-call Consultant Virologist |
| North West | Manchester PHL | Virology Reception, Third Floor, Clinical Science Building 1, Oxford Road, Manchester, M13 9WL | 0161 276 8853 | 0161 276 1234 (Ask for on-call Microbiologist) |
| South East | Southampton lab | Microbiology, Level B, South Laboratory block, Southampton General Hospital, Tremona road, Southampton SO16 6YD | 023 8120 6408 | 023 8077 7222 (ask for out of hours Microbiology biomedical scientist) |

| NHS Region | Designated laboratory | Address for sample dispatch | Contact telephone numbers | |
|---|---|---|---|---|
| South West | Bristol PHL | PHE Microbiology, Public Health England, Pathology Sciences Building, Westbury, Bristol, BS10 5NB | 0117 414 6222 | 0117 950 5050 (Ask for on-call Virologist or Microbiologist) |
| Yorkshire and Humber | Leeds lab | Virology Department, Old Medical School, Leeds General Infirmary, Thoresby Place, Leeds LS1 3EX | 0113 392 8750 (option 2) (Leeds Teaching Hospitals Trust, switchboard) Ask for on-call Consultant Virologist | 0113 243 2799 or 0113 243 3144(Leeds Teaching Hospitals Trust, switchboard) Ask for on-call Consultant Virologist |

Appendix 3: List of Phase 1 NHS E and I Laboratories already undertaking COVID-19 testing -

**Guys and St Thomas's Hospitals**

**Health Services Laboratories (HSL - UCLH, RFH, The Doctors Laboratory)**

**Kings College Hospital**

**St Bart's Hospital**

Appendix 4: LSS SRG – Pathology Central Contact

Email: nhsi.pathemergencyresponse@nhs.net

Appendix 5: PHE COVID -19 Testing Protocol – <u>If not using Commercial Assay</u>

Public Health England

## 2019-nCoV real-time RT-PCR RdRp gene assay

### A. Background

This protocol describes a uniplex real-time RT-PCR assay for the detection of the 2019 novel coronavirus (2019-nCoV). A 100 bp long fragment from a conserved region of the RNA-dependent RNA polymerase (RdRP) gene is detected with FAM labelled hydrolysis probes. The assay will detect 2019-nCoV and SARS virus, as well as other bat-associated SARS-related viruses (Sarbecovirus). In the validated and published format, the assay employs the use of two probes; one will detect 2019-nCoV, SARS-CoV and bat-SARS-related CoVs, and the other 2019-nCoV only.[1]
The RdRp gene assay has been evaluated in the Respiratory Virus Unit, PHE, on the ABI 7500 Fast real-time PCR system.

### B. Reagents

1. Primers and probes – order from TIB Molbiol, Germany.

| Assay | Oligonucleotide ID | Sequence (5' - 3') | Concentration* |
|---|---|---|---|
| RdRp gene | RdRp_SARSr-F2 | GTGARATGGTCATGTGTGGCGG | use 600 nM per reaction |
| | RdRp_SARSr-R1 | CARATGTTAAASACACTATTAGCATA | use 800 nM per reaction |
| | RdRp_SARSr-P2 | FAM-CAGGTGGAACCTCATCAGGAGATGC-BBQ | Specific for 2019-nCoV, will not detect SARS-CoV<br>use 100 nM per reaction and mix with P1 |
| | RdRp_SARSr-P1 | FAM-CCAGGTGGWACRTCATCMGGTGATGC-BBQ | Pan Sarbeco-Probe, will detect 2019-nCoV virus, SARS-CoV and bat-SARS-related CoVs<br>use 100 nM per reaction and mix with P2 |

FAM, 6-carboxyfluorescein; BBQ, blackberry quencher

*Optimized concentrations are mol per liter of final reaction mix.
*(e.g., 1.5 microliters of a 10 micromolar (uM) primer stock solution per 25 microliter (ul) total reaction volume yields a final concentration of 600 nanomol per liter (nM) as indicated in the table)*

[1]Drosten et al. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Eurosurveillance 2020; 25 (3).

Version 1.0 28.01.2020

2. Invitrogen SuperScript III Platinum one-step qRT-PCR kit. Cat nos. 11732-020 and 11732-088. Order from ThermoFisher Scientific, UK.

### C. Preparation of RT-PCR mix and cycling conditions

**RdRp-assay**

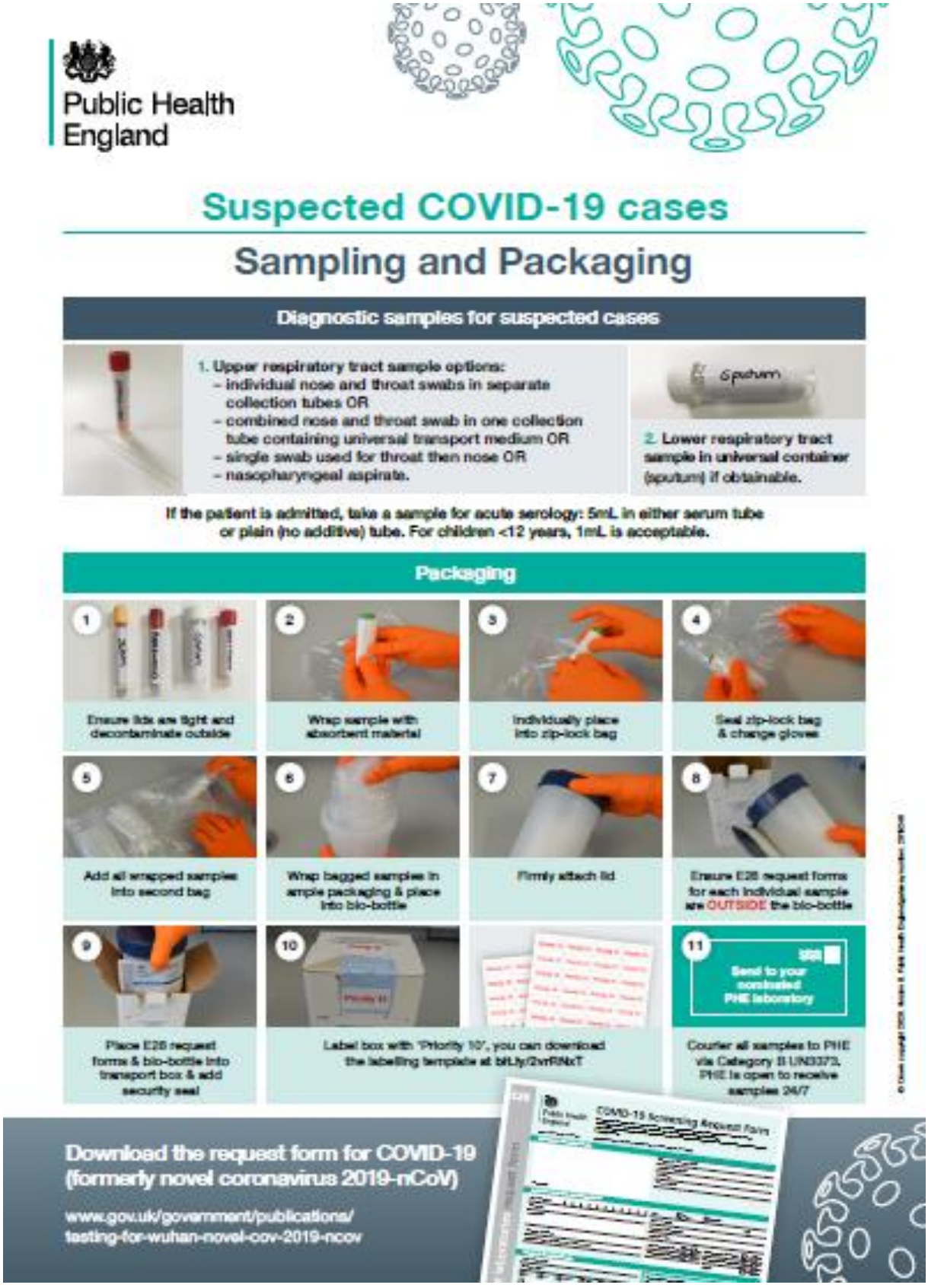
| **MasterMix:** | **Single rxn (µl)** |
|---|---|
| $H_2O$ (RNAse free) | 2.1 |
| 2x Reaction mix | 12.5 |
| $MgSO_4$(50mM) | 0.4 |
| RdRp_SARSr-F2 primer (10 µM) | 1.5 |
| RdRp_SARSr-R1 primer (10 µM) | 2 |
| RdRp_SARSr-P1 probe (10 µM) | 0.25 |
| RdRp_SARSr-P2 probe (10 µM) | 0.25 |
| SSIII/Taq Enzyme Mix | 1 |
| MasterMix per well / total | 20 |
| | |
| Template RNA | 5 |
| | **25µl** |

**Cycler:**

| | | |
|---|---|---|
| 55°C | 10 min | |
| 94°C | 3 min | 45x cycles |
| 94°C | 15 sec | |
| 58°C | 30 sec | |

Passive reference: none
Standard mode

Appendix 6


Public Health England
Suspected COVID-19 cases
Sampling and Packaging
Diagnostic samples for suspected cases
1. Upper respiratory tract sample options:
– individual nose and throat swabs in separate collection tubes OR
– combined nose and throat swab in one collection tube containing universal transport medium OR
– single swab used for throat then nose OR
– nasopharyngeal aspirate.
Sputum
2. Lower respiratory tract sample in universal container (sputum) if obtainable.
If the patient is admitted, take a sample for acute serology: 5mL in either serum tube or plain (no additive) tube. For children <12 years, 1mL is acceptable.
Packaging
1 Ensure lids are tight and decontaminate outside
2 Wrap sample with absorbent material
3 Individually place into zip-lock bag
4 Seal zip-lock bag & change gloves
5 Add all wrapped samples into second bag
6 Wrap bagged samples in ample packaging & place into bio-bottle
7 Firmly attach lid
8 Ensure E28 request forms for each individual sample are OUTSIDE the bio-bottle
9 Place E28 request forms & bio-bottle into transport box & add security seal
10 Label box with 'Priority 10', you can download the labelling template at bit.ly/2vrRNxT
11 Send to your nominated PHE laboratory
Courier all samples to PHE via Category B UN3373. PHE is open to receive samples 24/7
Download the request form for COVID-19 (formerly novel coronavirus 2019-nCoV)
www.gov.uk/government/publications/testing-for-wuhan-novel-cov-2019-ncov
COVID-19 Screening Request Form

Appendix 7: Presumptive Testing Request Form

V28

PHE National Infection service laboratories request form

Public Health England

# COVID-19 Presumptive Positive Virus Reference Division Referral Form

**Virus Reference Division**
61 Colindale Avenue
London, NW9 5HT

**Phone** +44 (0)20 8327 6017/6266
VRDqueries@phe.gov.uk
www.gov.uk/phe

Please write clearly in dark ink

**IMPORTANT: please complete all fields below to avoid delays in processing.**

## SENDER'S INFORMATION

**Postcode**

**Report to be sent FAO**

Contact Phone

In Hours

Out of Hours

## PATIENT/SOURCE INFORMATION

NHS number

Surname

Forename

Hospital number

Hospital name *(if different from sender's name)*

Sex ☐ Male ☐ Female

Date of birth Age

**Patient's postcode**

Patient's HPT

## SAMPLE INFORMATION

Your reference

Sample type

☐ TS ☐ NS ☐ NS/TS ☐ BAL ☐ Sputum

Other

Date of collection Time

Date sent to PHE

**All samples submitted should be treated as though the patient is infected with a Hazard Group 3 pathogen and YOU MUST contact the reference Lab BEFORE sending samples.**

**All samples must be sent in accordance with Cat B transport guidance.**

☐ Please tick the box if your clinical sample is post mortem

## SENDER'S LABORATORY RESULTS

Flu A ☐ Yes ☐ No ☐ H3 ☐ H1 (pdm09)

Flu B ☐ Yes ☐ No

☐ Other respiratory viruses *(please specify)*

☐ Other pathogens *(please specify)*

**COVID-19 PCR Testing details**

RdRP – assay ☐ Yes ☐ No CT

E-gene assay ☐ Yes ☐ No CT

Any other COVID-19 testing (please give details)

## OTHER COMMENTS



Version 4 effective from Feb -2020 VW-2127-01

## Appendix 8: Testing Systems under evaluation as of 06/03/2020

| Supplier | PCR platform required | Other equip required? | DNA extraction | |
|---|---|---|---|---|
| AusDiagnostics | Proprietary workstation / platform | PCR set-up on board platform | off board | |
| Seegene-Mast | BioRad CFX | No, but their 'NIMBUS' unit can do extraction and PCR set-up | off board or on NIMBUS | |
| Roche - TiB molbio - Manchester evaluation | Roche LightCycler 480, 480 II or cobas z480 (open channel) | no | Roche MagNa Pure or other product manufacturers | |
| Altona | Mx3005P (Stratagene), VERSANT (Siemens), ABI7500 SDS (AppliedBiosystems), Rotorgene 6000 or Q5/6 (Qiagen), CFX96 (BioRad), LightCycler480 II (Roche) | No | Extracted RNA! | |
| PrimerDesign-Novacyt | RT-PCR instrument (not defined) 5 channels required | No | Extracted RNA! | |
| Genetic Signatures | BioRad CFX, QuantStudio 5 or 7 | Extraction & PCR set-up GS1-HT or GSmini | GS-1 or GSmini | |
| Randox | Standard block PCR (not RT-assay) | Randox Investigator, X2 theremoshaker, carrier-holders | off board | |
| Genefirst | SLAN 96P, BioRad CFX96 | No | off board | |
| BGI | ABI7500 | No | off board | |
| Elitech Group | RT-PCR instrument (not defined) 5 channels | No | Commecrially available extractions systems - long list of inclusions | |
| Qiagen | QIAstat-Dx Analyser | | on-board QIAstat | |
| Pro-Lab-Certest | ABI7500-FAST, ABIStep-One, BioRad CFX96, AgilentAriaMx,DNA-Technology DT-Prime,Dtlite, Rotor-Gene-Q, Cepheid SmartCycler, Roche Cobasz480, VIASURE 48 or 96 RTPCR system. | No | off-board | |
| Shanghai ZJ Bio-tech_ Liferiver | ABI 7500/7900, BioRadCFX98, RotorGene 6000, SLAN-96, MIC POC Dx48 | No | off-board | |
| Genetic PCR Solns_Bioconnections | StepOne, StepOne-plus, BI 7500 Fast, LightCycler Nano, BioRad CFX96, PikoReal 24well, MiniOpticon 48-12, OptiCon 2. | No | off board | |
| Diagnostics for the Real World | N/A | SAMBA II platform, Tablet, Printer | N/A | |
| GenMark e-plex | e-Plex | | | |
| Cepheid GeneXpert | GeneXpert | | | Not yet to market |
| bioMerieux Biofire | Biofire, PCR RUO | | | Not yet to market |
| Hologic | Panther Fusion | No | | |

## Appendix 9: Health and Safety Guidance

HS002G Guidance for samples suspected of

RA07238_Template Assessment HG3 SARS

Appendix 2_Checklist to support risk assess