Publications approval reference: 001559

Guidance and standard operating procedure

COVID-19 virus testing in NHS laboratories

This guidance is correct at the time of publishing.

However, as it is subject to updates, please use the hyperlinks to confirm the information you are disseminating to the public is accurate.

NHS England and NHS Improvement

Contents

1. 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 infection is widespread and its international spread through travellers is now evident, as is spread from affected individuals.
- The priority is to scale up public health testing, which has to date been undertaken by Public Health England (PHE) at the Colindale facility and their regional laboratories.
- The preferred screening/testing is molecular diagnosis of COVID-19 using real-time RT-PCR (RdRp gene) assay based on oral swabs, which PHE laboratories have been using to confirm this disease.
- PHE has been working closely with NHS England and NHS Improvement pathology network laboratories to increase testing capacity, which is now needed to continue to identify and maintain the required containment of affected individuals, and delay and mitigate spread.
- As part of the escalation and management of this viral infectious outbreak, a phased approach to onboarding NHS England and NHS Improvement pathology network laboratories across England is being undertaken, working closely with PHE, so that patients and NHS England and NHS Improvement staff can receive timely testing, intervention and treatment.

This guidance is correct at the time of publishing. However, as it is subject to updates, please use the hyperlinks to confirm the information you are disseminating to the public is accurate.

2. Aims and objectives

- This document provides guidance and the standard operating procedure (SOP) for COVID-19 testing for NHS England and NHS Improvement pathology network laboratories. It also provides information on the communication routes and information flows that support the management of the return of patient results.
- This guidance and SOP have been developed with PHE and NHS England and NHS Improvement working in partnership.
- The aim is to deploy robust diagnostic methodology that follows accepted validation and verification protocols for use in all laboratory settings. Positive control virus material available from Colindale PHE laboratory as part of the capability and assurance framework.

3. Scope

- This SOP covers COVID-19 testing to be deployed by NHS England and NHS Improvement pathology networks.
- This SOP does not cover the investigation and testing of respiratory infections other than COVID-19.

4. Overview

PHE has been undertaking all formal testing for COVID-19 and now has an established service in all regional PHE and some NHS England and NHS Improvement 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 its 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 of the outbreak 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 of providing a **minimum capacity of 500 tests per day for COVID-19 in the NHS**. This activity is **in addition** to existing capacity that may be available in the network via PHE testing laboratories.

Laboratories must consider how these services can be provided seven days per week and clearly identify any potential bottlenecks in the testing pathway that may restrict processing capacity. These may include availability of staff, other assays that use the same equipment and may restrict capacity, containment facilities – taking note of the Health and Safety Executive (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 laboratories will be UKAS 15189 accredited and have an accredited quality management system. Although similar tests/technologies may be 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, the stringent requirements to demonstrate assay performance using accepted validation and acceptance criteria 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, NHS England and NHS Improvement are working with UKAS to explore how urgent extensions to scope could be introduced.

In addition, PHE has been working with 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 in 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 quickly as possible.

5. Testing the standard operating procedure

5.1 Background

Due to the need to establish greater testing capability, NHS England and NHS Improvement are asking identified pathology network laboratories to start 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 before 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.

Positive results that are sent by NHS England and NHS Improvement pathology network laboratories for confirmation to a PHE laboratory will be considered presumptive positives until confirmed. (see list – Appendix 2). Confirmation 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 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 this time confirmation by local PHE laboratories will no longer be required. Presumptive positive/positive results will be notified to the co-ordination center for contact tracing, which will start immediately.

Please note that patients who are admitted to hospital will need 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 and the other samples not forwarded to the designated PHE regional or NHS England and NHS Improvement laboratory carrying out the COVID-19 screening test, unless this is the same laboratory – that is, routine practice must be followed for other tests.

If testing for **avian influenza** or **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 appropriate 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 the uncertain result to the clinician looking after the patient (or telephoning it with the clear caveat of uncertainty)
- re-extract the original sample and repeat the PCR in the original and new extract 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, forward the sample to Colindale
- regularly review the performance of reagents, particularly control materials.

The actions taken should be expedited 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, a test equivalent in 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

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 the patient's 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 forms must include a clinical contact phone number for sharing of results and one for the patient
- samples without appropriate paperwork will not be tested or testing will be delayed.

See Appendix 6 for a sampling and packaging poster.

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.

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 health protection team, 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 guidance on regulations for the transport of infectious substances 2019-2020; NHS England and NHS Improvement 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 in Appendix 5. This protocol describes a uniplex real-time RT-PCR assay for the detection of the 2019 novel coronavirus (2019-nCoV).

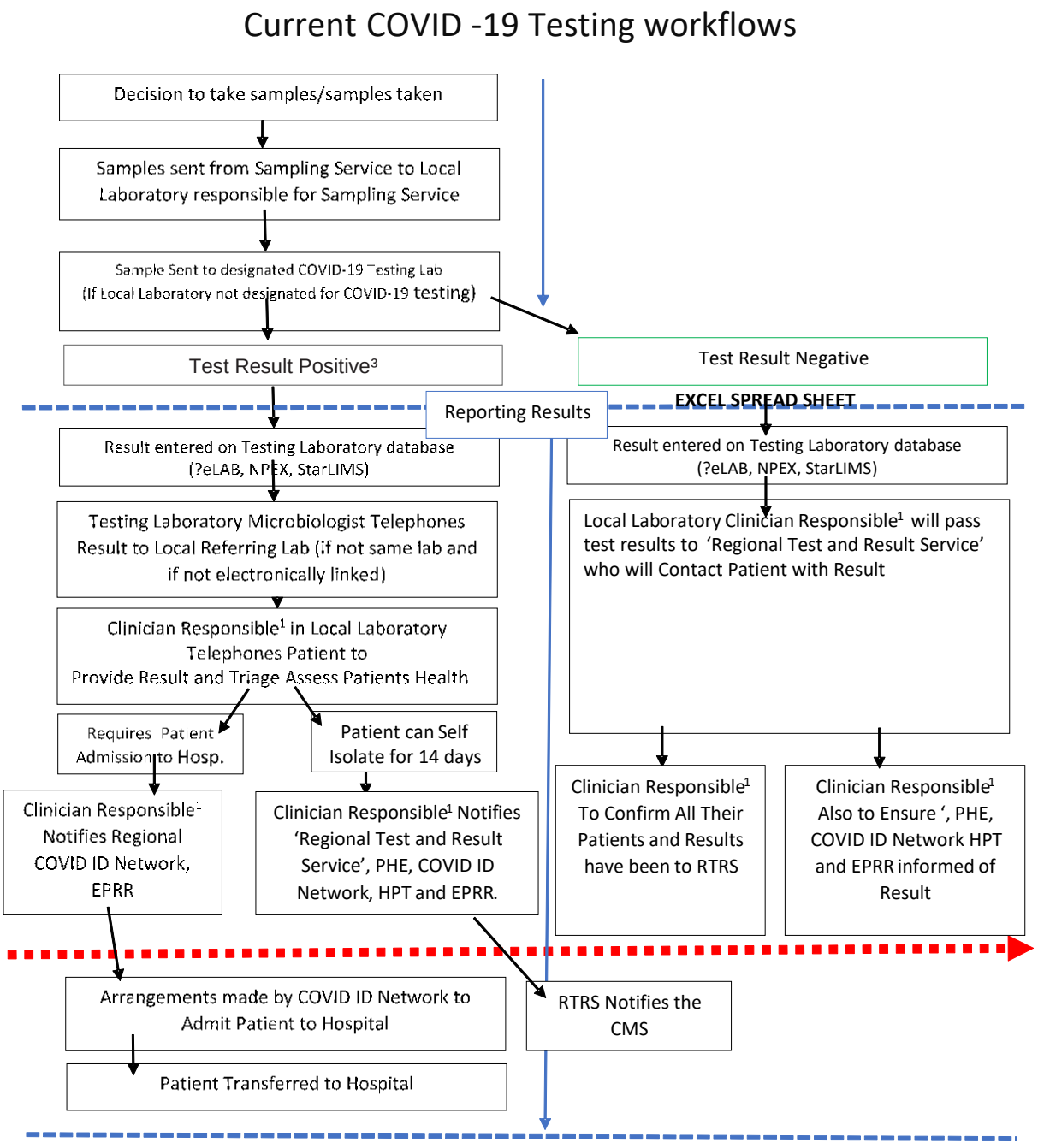
NHS England and NHS Improvement pathology network laboratories can choose to process samples on the laboratory's chosen platform and protocol; please see the recommended list in Section 5.4 below. (This will be updated as other systems, devices and protocols become available.) NHS England and NHS Improvement pathology network 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 6 March 2020) under evaluation can be found in Appendix 8.

5.5 Notification of presumptive positive/positive and negative results



1. The clinician responsible[1] for patient sampling may devolve the work to another clinician but must retain accountability for it being done.
2. To note: the regional test and result service is provided by ambulance services as part of the regional incident co-ordination centre.

3. Includes presumptive positives that have been confirmed positive by a PHE laboratory.

6. 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 results can be transmitted via text.

Positive results can be confirmed by PHE regional laboratories until the NHS England and NHS Improvement pathology network laboratory is confident of its testing. The testing laboratory will need to liaise with its local PHE laboratory and send sample(s) for confirmatory testing, if confirmation of results is needed, this also applies for ambiguous results. Further guidance is available here.

Presumptive positive/positive results **will** be reported back to patients by the testing laboratory or clinician responsible for patient sampling at the referring laboratory, according to the flow diagram in Section 5.5, within 48 hours, and confirmed if the local PHE laboratory has undertaken confirmatory testing. Confirmed results will be reported back to patients within 72 hours of presumptive positive test results, if PHE laboratory confirmation has been requested.

All negative results will be reported back to the clinician responsible[1] for patient sampling; they will be responsible for ensuring patients are informed via the Regional Test and Results Service (RTRS) as part of the Regional Incident Coordination Centre. This is currently envisaged to be via the same route as results are normally communicated to the requesting clinician for onward communication to the patient. We are currently reviewing this with the Department of Health and Social Care and NHS Digital. The flow diagram in Section 5.5 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. Additional support

7.1 From PHE

PHE will provide 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 England and NHS Improvement

NHS England and NHS Improvement have 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. Further information

Further information can be found in the appendices:

- Appendix 1: Other guidance
- Appendix 2: PHE laboratories
- Appendix 3: Phase 1 NHS England and NHS Improvement pathology network laboratories already undertaking COVID-19 testing
- Appendix 4: LSS SRG – pathology central contact
- Appendix 5: PHE COVID-19 testing protocol (if not using commercial assay)
- 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 6 March 2020)
- Appendix 9: Health and safety guidance

For any queries please contact:

nhsi.pathemergencyresponse@nhs.net

Appendix 1: Other guidance

- Public Health England 2020 *Guidance – Wuhan novel coronavirus: epidemiology, virology and clinical features* (updated 27 January 2020)
- Public Health England 2020 Guidance – *Wuhan novel coronavirus: infection prevention and control* (updated 15 January 2020)
- Public Health England 2020 *Laboratory investigations and sample requirements for diagnosing and monitoring WN-CoV infection – Guidance* (updated 27 January 2020)
- Public Health England 2020 *Guidance – Wuhan novel coronavirus: guidance for clinical diagnostic laboratories* (updated 27 January 2020)
- Public Health England 2020 *Public Health England (PHE) 2020 'WN-CoV: laboratory investigations and sample requirements (version 1.0)* (17 January 2020)
- World Health Organization (2019) *Guidance on regulations for the transport of infectious substances 2019–2020* (1 January 2019)
- World Health Organization (2020) *Global surveillance for human infection with novel coronavirus (2019-nCoV) – interim guidance* (20 January 2020)
- World Health Organization (2020) *Surveillance case definitions for human infection with novel coronavirus (nCoV)* (10 January 2020)
- World Health Organization (2020) *Household transmission investigation protocol for 2019-novel coronavirus (2019-nCoV) infection – interim guidance* (25 January 2020)
- World Health Organization (2020) *Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected - Interim guidance* (25 January 2020)
- World Health Organization (2020) *Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases – interim guidance* (17 January 2020)

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	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 laboratory	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	Southampton	Microbiology, Level B, South Laboratory Block,	023 8120 6408	023 8077 7222 (ask for out-of-

NHS region	Designated laboratory	Address for sample dispatch	Contact telephone numbers	Out of hours
East	laboratory	Southampton General Hospital, Tremona Road, Southampton SO16 6YD		hours microbiology biomedical scientist)
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 laboratory	Virology Department, Old Medical School, Leeds General Infirmary, Thoresby Place, Leeds LS1 3EX	0113 392 8750 (Leeds Teaching Hospitals Trust, switchboard; ask for on-call consultant virologist)	0113 392 8750 (Leeds Teaching Hospitals Trust, switchboard; ask for on-call consultant virologist)

Appendix 3: Phase 1 NHS England and NHS Improvement pathology network laboratories already undertaking COVID-19 testing

- **Guy's and St Thomas' Hospitals**
- **Health services laboratories: University College London Hospital, Royal Free Hospital, The Doctors Laboratory**
- **King's College Hospital**
- **St Bartholomew's Hospital**

Appendix 4: LSS SRG – pathology central contact

Email: nhsi.pathemergencyresponse@nhs.net

Appendix 5: PHE COVID-19 testing protocol (if not using commercial assay)

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 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 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:

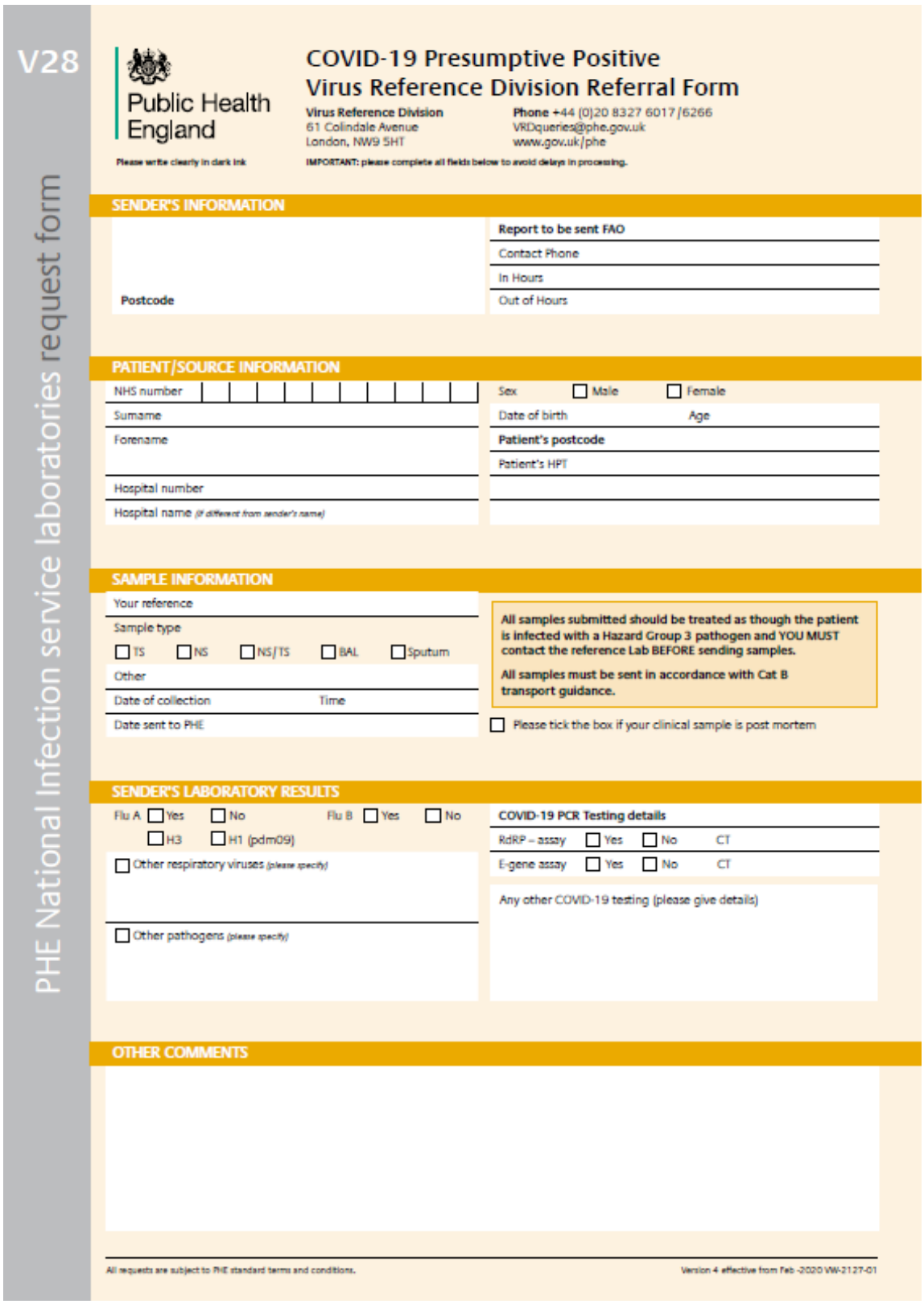
55°C	10 min	
94°C	3 min	45x cycles
94°C	15 sec	
58°C	30 sec	

Passive reference: none
Standard mode

Appendix 6: Sampling and packaging poster – PHE guidance

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/866632/COVID-19_Sample_Packaging_Instructions_PHE_A3_poster_12.pdf

Appendix 7: PHE presumptive positive 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 Flu B ☐ Yes ☐ No
☐ H3 ☐ H1 (pdm09)

☐ 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

All requests are subject to PHE standard terms and conditions.

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

Appendix 8: Testing systems under evaluation by PHE (as of 6 March 2020)

Supplier	PCR platform required	Other equipment 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

Supplier	PCR platform required	Other equipment required	DNA extraction
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), five 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

Supplier	PCR platform required	Other equipment required	DNA extraction
GenMark e-plex	e-Plex		
Cepheid GeneXpert	GeneXpert		
bioMerieux Biofire	Biofire, PCR RUO		
Hologic	Panther Fusion	No	

Appendix 9: Health and safety guidance

9.1: Laboratory advice for handling specimens

Public Health England (March 2020) COVID-19: safe handling and processing for samples in laboratories

9.2 PHE checklist

These are the questions laboratories need to ask themselves as part of the risk assessment and part of the requirement for the Health and Safety Executive derogation to Containment Level 3 to Containment level 3 minus. It is part of the laboratory health and safety process and there to support laboratories to go live more quickly.

Section 1 – The nature of the work and whether it meets the criteria for dispensing with some containment measures

1. Laboratory title and location

2. Description of work carried out in laboratory

Is the work defined as (tick all that apply):

Deliberate ☐ **Diagnostic** ☐ **Reference** ☐

If deliberate work with the HG3 pathogens is intended, this MUST be under full CL3 containment.

3. Which HG3 pathogens are present or suspected to be present in the biological material to be processed?

4. Are these agents included on the ACDP list of agents which may be processed at less than full CL3 conditions, because their normal route of transmission is not respiratory

Yes ☐ **No** ☐

*Tick as applicable. If the answer is 'No', full CL3 containment control measures MUST be met.

5. For the diagnostic/reference clinical samples under consideration in this assessment, is a screening procedure in place to review any hazard information provided, pertaining to individual diagnostic samples, which may indicate that respiratory-borne (or HG4) pathogens coincident to those under investigation are or may be present (e.g. *M. tuberculosis* in a patient being tested for bloodborne viruses)? Such samples require full containment conditions.

Yes ☐ **No** ☐

*Tick as applicable. If the answer is 'No', this control measure MUST be introduced before the removal of any CL3 containment control measures.

Section 2 – identifying CL3 containment measures which are not required for this work

For each CL3 containment control measure, state whether this will be implemented or dispensed with, with justification including what conditions or alternative measures will be implemented for safe working:

1. Room at negative air pressure

2. Room air extracted by HEPA filtration

3. The workplace / Laboratory is sealable for disinfection/fumigation

4. Treatment of all waste prior to removal from laboratory (e.g. integral autoclave)[1]

[1] COSHH does not require explicitly that cultures of biological agents are inactivated on-site, but the regulations place a duty on employers to assess risk and apply control measures to reduce the risk of exposure to harmful substances to a minimum and it is recommended that infectious or potentially infectious wastes are inactivated on-site before final disposal because they may contain high concentrations of biological agents and pose an increased risk of exposure.

5. The workplace is separated from any other activities in the same building

6. The laboratory is to contain its own equipment so far as is reasonably practicable

7. There is a means of viewing occupants from outside such as an observation window or alternative

Section 3 – CL3 control measures which are required for manipulating High-Hazard agents or samples containing them in a facility with less than the full COSHH containment measures and how these control measures will be achieved

1. There MUST be a Laboratory manual or code of practice

2. Access MUST be restricted to trained or supervised workers with appropriate competency documentation in place for all procedures

3. Arrangements MUST be in place for the effective monitoring of compliance by audit, including observational audits

4. Work with HG3-containing material should be separated[2] from other activities by location in the laboratory or scheduling of work activities.

5. Spillage and emergency procedures, including exposures management MUST be in place including spill practices and drills

6. Any work that could give rise to an aerosol of infectious material (or splash) MUST be carried out within a Microbiological Safety Cabinet (or equivalent containment).

[2] Requires consideration of what 'the workplace is to be separated from any other activities in the same building' means in each circumstance

7. Centrifugation MUST be conducted with a bio-safe[3] type centrifuge with rotor/buckets loaded and unloaded within an MSC.

8. ALL sharps MUST be avoided so far as possible including items potentially capable of causing a sharps injury under foreseeable circumstances e.g. plastic tips, pointed scissors, scalpels, blades, serrated tape cutters. Where sharps are unavoidable, risk assessment MUST identify any additional control measures that could be introduced, e.g. the use of cut-resistant gloves, e.g. guarding to protect from contact with probes or tips on robotic analysers

9. Lone working MUST be avoided as far as possible, with suitable arrangements for supervision where unavoidable

10. Handwashing within the laboratory wherever possible

11. Work surfaces MUST be impervious to water; easy to clean and resistant to acids, alkalis, solvents and disinfectants.

12. Arrangements for safe storage of biological agents MUST be in place.

Checklist completed by:

Name	Job Title/Role	Signature

Persons consulted:

Name	Job Title / Role	Signature

Date: ……Date of review……

[3] Bio-safe type centrifuges are designed with sealed buckets and rotors for work with infectious agents. More information is available in HS005A, PHE Laboratory Precautions Handbook.