Department of Health & Social Care

Guidance for organisations seeking to support the COVID 19 Testing Programme

Department of Health and Social Care

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Contents

1. Who is this guidance aimed at?

1.1 This guidance is for laboratories (usually without ISO 17025 or ISO 15189 accreditation) or organisations across the UK with available equipment based in:

- Universities;
- Research institutions; or
- other relevant industries/sectors

who are interested in supporting the NHS deliver the SARS-CoV-2 testing programme.

1.2 These laboratories or organisations with available equipment may not specifically be working on health-related applications.

1.3 In the first instance this will be focussed on harnessing the support that laboratories can provide to the testing effort for NHS trusts and associated pathology services, however we are urgently looking to expand this into other key public sector fields such as Social Care, Prisons Service and Police Service.

1.4 This is UK-wide guidance. However, the Scottish Government, Welsh Assembly and Northern Ireland Assembly may decide to take a different approach to engaging with laboratories within their region.

1.5 Further details on the COVID-19 Testing Programme can be found at: https://www.gov.uk/government/publications/coronavirus-covid-19-scaling-up-testing-programmes

2. How can organisations help the NHS?

The help that these organisations can provide to the NHS includes:

2.1 Direct help, by partnering with local NHS trusts to enhance their extraction, test capacity and results generation or any element of this pathway; and/or

2.2 Indirect help, by supporting the NHS through:

(a) Providing specialist workers, such as PhD students, postdoctoral research staff, laboratory technicians and assistants; and/or

(b) Sourcing, and providing critical items, such as RNA extraction and PCR Capital Equipment, Machine Ancillaries, Laboratory Consumables, Laboratory Reagents and Personal Protective Equipment (PPE); and/or

(c) Providing research capability to develop new assays or verification of test results, alternatives to the currently available reagents and/or to the overall testing pathway.

3. What criteria does a laboratory need to be able to meet in order to partner with a local NHS trust to provide part or all of the testing pathway?

3.1 Laboratories will need to meet the following criteria:

- Sample reception area for accepting and logging samples adhering to national infection control procedures
- Sample tracking capability (e.g. barcoding) for the end-to-end pathway
- Access to Category 3 compliant facilities or Category 2+ facilities that have been risk assessed and confirmed by HSE, if handling clinical samples prior to viral inactivation. Further information can be found here: https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens
- Automated RNA extraction equipment and access to a Real Time PCR assay machine
- Automated result analysis systems in line with national policy and working in conjunction with the Standard Operating Procedures (SOP) in place within the partnering NHS pathology network
- Utilising equipment and test kits that are validated by PHE/NHSE
- To avoid supply chain issues ideally you should have access to test kits and reagents for RNA extraction and PCR that are not closed platform and from different manufacturers to those used by the NHS
- Quality processes in place including validation and verification methodologies
- Specialist workforce available e.g. PhD students or Postdocs with relevant experience that can work in rotas according to the needs of the NHS

4. My laboratory fully meets these criteria to provide testing within the NHS – what form can partnering with a local NHS take?

4.1 The most appropriate partnership model for local NHS trusts and interested laboratories/organisations will depend on a range of contextual factors and local NHS needs. An agile approach centred around early engagement with the local NHS trust/pathology network will be essential to success and help can be provided to organisations from NHS England and the NHS Improvement testing programme to ensure the appropriate laboratories within a network are connected.

4.2 The following organisations have already set up partnerships with local NHS trusts to support the Testing Programme. Please review details of these exemplars and work closely with your partner NHS trust to determine:

- Which model (if any) is most appropriate in your local context;
- How sustainable the work will be with regards to resources of reagents and setup; and
- How it could be adapted to suit local needs, facilities and staffing.

4.3 Workforce upskilling to NHS requirements can be provided following an initial competence assessment and with links to relevant e-based learning and other modules.

Exemplar	Description	Further information
The Francis Crick Institute	This is carrying out tests on behalf of an NHS trust, supported by locally agreed data and sample sharing processes and working to agreed Standard Operating Procedures	Annex A
The Pirbright Institute	This is providing a local NHS trust with equipment and staff to enhance their testing capacity	Annex B

5. My laboratory partially meets these criteria, or we have equipment and staff that could be used in NHS laboratories – can we still help?

5.1 Yes – there are examples of organisations who partially meet these criteria who are able to directly or indirectly support local NHS trusts in elements of the testing pathway for example;

- by providing access to Category 3 facilities;
- by providing RNA extraction equipment or capability;
- by providing Real Time PCR platforms or performing this part of the pathway;
- by assisting the ongoing delivery of the NHS service by performing validation of new assays; and/or
- by developing sustainable sources of reagents.

5.2 The following are indicative of the type of partnerships currently in place:

Exemplar	Description	Further information
Fera Science Ltd	Fera Science Ltd meet the criteria above but there are difficulties surrounding Fera joining up with the NHS reporting system. For now, they are focussing on validating a LAMP assay as an alternative testing method to help overcome global reagent shortages but may move to carrying out testing in the future.	Further information can be found in Annex C
Exeter University	Exeter University is providing equipment and expertise to support the Royal Devon and Exeter NHS Trust with its testing capability.	Further information can be found via the online link here

6. My laboratory or organisation partially or fully meets these criteria – what are my next steps?

6.1 If your laboratory has existing relationships with a local NHS trust, you should approach them to discuss what type of support you might be able to offer and whether they would be interested in partnering with you.

6.2 If you do not have an existing relationship with a local NHS Trust, you should use our online portal to:

- Register your interest in supporting a local NHS Trust; and
- Make clear what support you might be able to offer.
- Our online portal is here: https://www.gov.uk/guidance/help-the-government-increase-coronavirus-covid-19-testing-capacity

6.3 We will review this and:

- Identify which (if any) local NHS Trusts may be in need of the type of support that you can provide; and
- Put you in contact with them.

6.4 You will then be able to work directly with the local NHS trust about the best way you can support them.

6.5 If you are not matched with a local NHS trust (for example, if they do not require assistance), and are still interested in supporting the COVID-19 testing programme, we recommend that you follow the steps under question 7.

7. My laboratory doesn't meet the criteria for fully or partially partnering with a local NHS trust – can we still help?

7.1 The NHS also needs help to supply materials and equipment; and supply complete testing methods. Further information can be found here: https://www.gov.uk/guidance/help-the-government-increase-coronavirus-covid-19-testing-capacity

7.2 From time to time, the government may issue a call out for specialist workers, such as PhD students, postdoctoral research staff, laboratory technicians and assistants through relevant channels, for example, via Universities UK.

7.3 Workforce upskilling to NHS requirements for these specialist workers can be provided following an initial competence assessment and with links to relevant e-based learning and other modules.

7.4 Should the government approach your organisation about recruiting these types of specialist workers, please make your staff aware and release them to support in enhancing COVID-19 testing capacity in this way.

8. How will we communicate with laboratories and organisations going forwards?

8.1 We will share comms and updates to the following networks:

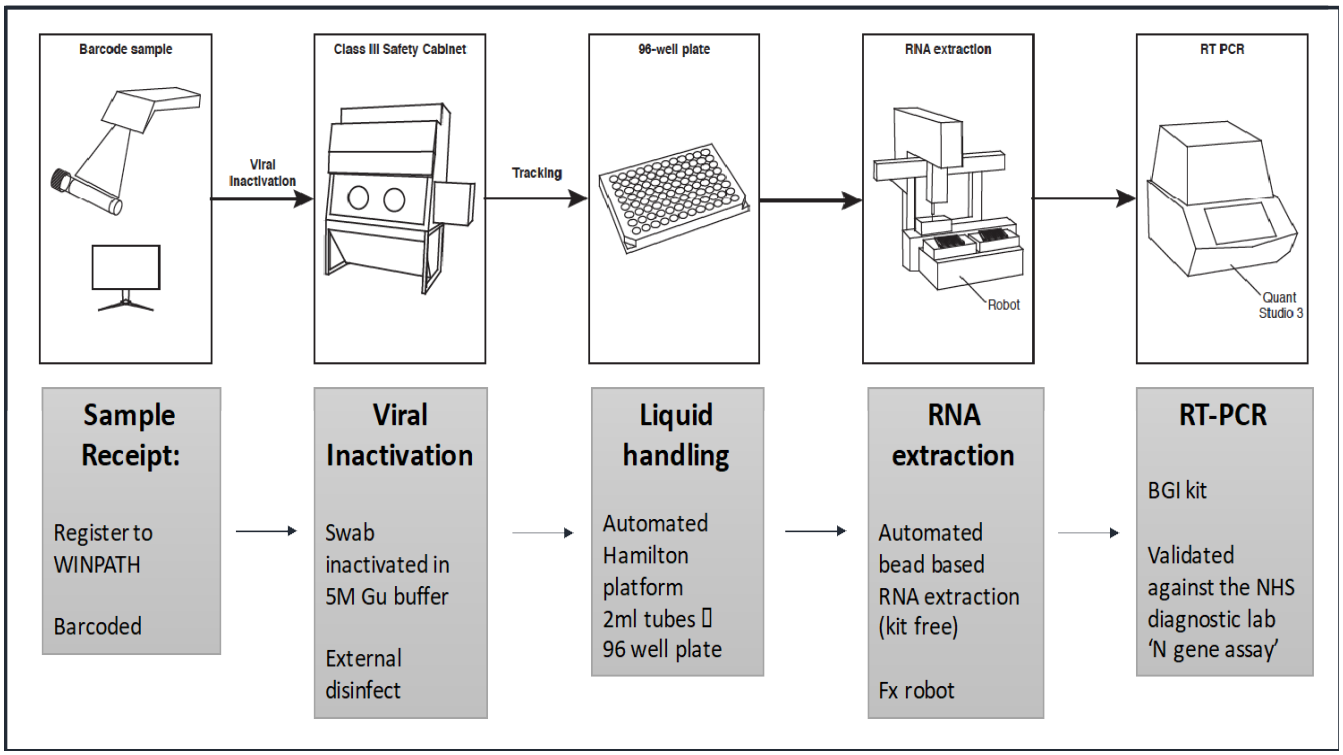
- NHS Pathology network
- Pathology Alliance
- Universities UK
- NHS Genomic Laboratory Hubs and British Society of Genomic Medicine
- Health related Industry partners including pharmaceutical companies
- PHE
- Other government departments i.e. DEFRA, OLS
- Broader industry partners

Annex A – the Francis Crick Institute

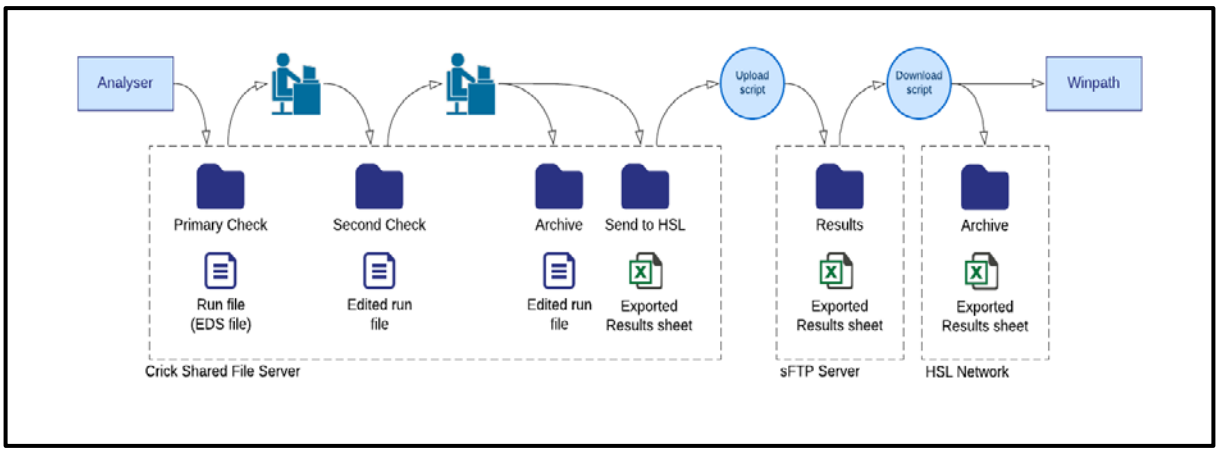
The Francis Crick Institute is a biomedical discovery institute dedicated to understanding the fundamental biology underlying health and disease.

At the core of the Crick model is an Operations Team, consisting of the NHS trust virologists (University College London Hospitals), the NHS trust diagnostic laboratory (HSL), clinical scientists working at the both the NHS trust and the Crick, and Crick scientists and leaders. The approach was developed from the outset as a partnership with the Crick considered as an extension of the accredited diagnostic partner laboratory (HSL). All processes have been established at the Crick with close coordination with the NHS trust diagnostic laboratory HSL. The SOPs, and the verification data sets for the pipeline were approved by NHS trust staff and HSL laboratory staff before proceeding. The pipeline was tested in parallel with the NHS diagnostic laboratory for validation. NHS trust staff and HSL staff are part of the clinical diagnostic working group within the operations team and oversee the quality and governance of the pipeline.

The Crick approach is based on five main work-streams, that were developed and tested independently, and are therefore largely standalone. The approach relies on a highly trained research staff to support a semi-automated, but not highly integrated, pathway. The advantage is that the approach is agile and can make use of different lab-space distributed across the building but, particularly with respect to sample reception/handling, requires substantial teams working in shifts. The five steps in the Crick-COVID testing pipeline are shown in the box below:



The end-end data pathway has been established by the NHS trust diagnostic lab (HSL) in collaboration with the Crick scientific computing platforms, to enable sample registration from WINPATH, and tracking throughout the process. Analysis of the RT-PCR data is performed with a 1st pass (technical report of the run), followed by a 2nd level reporting with accredited clinical scientists using a web portal (in conjunction with HSL), before being exported to WINPATH, and verified and completed by the UCLH virology team. The Crick COVID reporting pipeline is shown below:



With an adequate supply chain, numerous institutes/labs could carry out the PCR step, and many could do the robotic non kit-dependent RNA extraction, but only a few could process a significant number of samples/reception/curation/inactivation/exports using CL3 trained staff with suitable containment facilities.

For further information, please contact testing-response@crick.ac.uk

Annex B – The Pirbright Institute

The Pirbright Institute is a world leading centre of excellence in research and surveillance of virus diseases of farm animals and viruses that spread from animals to humans.

The Institute is the world reference laboratory for many high consequence livestock diseases, for example foot-and-mouth disease and has considerable experience of large-scale testing of samples from disease epidemics, ISO/IEC17025 accredited. The institute currently has no links with the NHS or PHE sample reception or reporting systems

- Despite the availability of high throughput diagnostic platforms at Pirbright, it was clear linking to the NHS IT networks would not be straightforward. The quickest way to increase capacity of the local NHS laboratory was to deploy equipment and reagents.

- Pirbright Kingfisher flex nucleic acid extraction system (Thermofisher) and ABI7500 Fast PCR machine (Thermofisher) were fumigated out of high containment, and moved into the local NHS laboratory of the Berkshire and Surrey Pathology Service at the Royal Surrey County Hospital

- Thermofisher technical support commissioned the equipment

- The Managing Director of Berkshire and Surrey Pathology Services expects to increase the network's testing capacity from 2000 tests per day to 3000 tests per day

- Pirbright will set up the COVID-19 PCR with alternative reagents, superscript express Taq polymerase using their remaining Kingfisher flex nucleic acid extraction system and ABI7500 Fast PCR machine and transfer the protocol to Royal Surrey County Hospital

- Additional testing of other reagents can be carried out at Pirbright and transferred to Berkshire and Surrey Pathology Services as required. These protocols can be shared more widely with NHS laboratories

- Pirbright to provide available consumables, extraction kits and reagents (for the above) required to perform 15,000 tests

- This should help solve some of the reagent supply problems and keep the front-line instruments running for diagnostic tests

- Pirbright will provide Berkshire and Surrey Pathology Services with training and technical assistance and/or staff if required on rotation

For further information, please contact Carrie Batten at carrie.batten@pirbright.ac.uk and/or Valerie Mioulet at valerie.mioulet@pirbright.ac.uk

Annex C – Fera Science Ltd

RNA based detection of COVID-19

COVID-19 detection from virus RNA is conducted in three methodological steps: RNA extraction, amplification, and detection of amplification (which confirms the presence of SARS-CoV-2 RNA in the sample).

Real time PCR

Within the current real time PCR protocols, the extraction step has to produce good quality RNA which is relatively free of inhibitors (generally kit-based extraction with multiple steps).

The amplification step is via PCR using PCR reagents, primers and fluorescent labelled probes, with the reactions taking place on a thermocycling instrument over around 1 -1.5 hours.

Detection of the fluorescence emitted by the fluorescent probe during amplification is performed within the real time PCR instrument, which confirms the positive/ negative/ inconclusive result.

LAMP (Loop-mediated isothermal amplification)

LAMP is an alternative chemistry / reaction to PCR. Within a typical protocol, the extraction step is basic and fast (e.g. shaking, heat the sample within a buffer) as the LAMP assay is more robust to inhibitors. The amplification uses LAMP reagents and primers, takes place at 60ºC without the need for temperature cycling and is fast (typical reaction times 8-20 minutes).

Detection is by measurement of fluorescence emitted by a fluorescent dye during amplification. The amplification/ detection steps can either be performed on real time PCR instruments which are high throughput but lab based, or on instruments such as the Optigene Genie II that are portable and low throughput; see http://www.optigene.co.uk/instruments/instrument-genie-ii/.

LAMP assays exist which can be run on a hot block, and amplification is determined by a visible dye colour change (transparent to blue). Sensitivity and robustness are theoretically lower.

LAMP versus real time PCR:

- Similar technology to real time PCR with the same outputs
- Slightly lower sensitivity (likely not an issue)

- Simpler, quicker workflow as LAMP does not require a complex DNA extraction step. This saves extraction reagents and kit.
  The detection step is quicker (15-20 min versus 1- 1.5 hours)

- LAMP uses different reagent needs to existing real time method so eases supply chain (although some key ingredients are the same)

Key points

- Fera uses LAMP in the lab as accredited and/ or validated tests for the detection of plant pest and pathogens and has used LAMP on portable devices for in-field detection in plant disease outbreaks.

- With the loan of high throughput KingFisher Flex extraction robots to support COVID-19 swab testing, Fera no longer has any meaningful capacity to offer high throughput COVID-19 testing using existing PHE real time PCR protocols.

- Using LAMP, Fera or other labs may be able to offer COVID-19 testing but the methods and protocols are still under development and validation for this application.

- Access to appropriate samples is key to being able to validate the methods

- Two possible use cases for LAMP are;

  (i) In-field: Low throughput but tried and tested by Fera in plant health contingency scenarios. Limitations will be around validation, deployment of the devices and training.

  (ii) Within laboratories: High throughput. Benefits as described above (faster protocol, possible better availability of reagents).
  Can be carried out on existing real-time PCR machines for high throughput of samples (verification testing would be required). Could be carried out at Fera

- Validation: Progress is being made by the Basingstoke NHS lab on protocols and validation data for the assays and the crude extraction steps. An assumption is that the samples can be heat inactivated, which allows them to be processed at CL2. We understand that this was the case at the Basingstoke lab but, separately from PHE, that heat inactivation is not proven.
  For the method to be usable, it needs to be possible to work with it in CL2.

For further information, please contact Andrew Swift at Andrew.Swift@capita.com and/or Paul.Robb@fera.co.uk

Published to GOV.UK in pdf format only.

COVID-19 Testing Programme

www.gov.uk/dhsc