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Public Health England provision of SARS-CoV-2 genotyping and sequencing services for the NHS: frequently asked questions

25 May 2021

Introductory questions

Question 1 – what changes are proposed?

In response to the urgent national public health imperative, NHS Test and Trace has commissioned Public Health England (PHE) to provide a standardised and consistent England-wide service to NHS laboratories[1] for the provision of SARS-CoV-2 sequencing, and for the interim provision of reflex assay/genotyping testing for variants of concern until such time as NHS lead laboratories can include testing for the B1.617.2 variant in their repertoire on behalf of their networks.

For sequencing, this will deliver:

- a 7-day service with simplicity of arrangements for NHS sample provision
- standardised sample quality requirements and agreed arrangements specific for platforms as required
- end-to-end sample tracking using a LIMS system or similar
- early Variant of Concern (VoC) detection and genotyping within 36 hours laboratory turnaround time against standardised reflex assay protocols
- maximum of 96 hours laboratory turnaround time for sequencing with plans to reduce this to 48 hours
- e-reporting of genotyping and sequencing results to NHS laboratories/clinicians
- ability to retain any local research arrangements with COG UK laboratories
- regular review and audit of arrangements.

[1] In this document, guidance for 'NHS laboratories' is taken to include all laboratories commissioned by the NHS in England to undertake COVID-19 testing for NHS use cases.

Question 2 – when will these changes be put in place?

The services will be operational from Wednesday 26 May and all NHS laboratories that process COVID-19 samples are required to use them from that date.

Reflex assays/genotyping

Question 3 – what is the proposal for reflex assays/genotyping?

From Wednesday 26 May, PHE will provide a service to NHS laboratories providing SARs COV2 testing using Thermofisher platforms and validated reflex assays which are able to detect the agreed list of variants of concern.

NHS laboratories should use this service until such time as NHS lead laboratories can include 7-day testing and reporting for the B1.617.2 variant in their repertoire for their networks. NHS England and NHS Improvement will agree a schedule of transition with these laboratories; in the meantime, the PHE service must be used.

Question 4 – how will reflex assay samples be transported?

NHS laboratories will be required to submit extracted RNA (on dry ice) or primary samples using PHE's existing transport/courier solutions. Detailed instructions about this transport service (contact details, account number, address for samples to be sent to, etc) are included in referral instructions from PHE [to be published on gov.uk].

This courier service will be funded by PHE.

Laboratories should ensure they make arrangements to have sufficient stock of dry ice available to facilitate a 7-day service. Samples must not be batched over more than one day.

Question 5 – what happens if a nearby or co-located laboratory can do reflex assays/genotyping?

All NHS laboratories must use the PHE service as described in this document. This is required as a response to the current public health imperative to ensure that we immediately move to a standardised and uniform system that operates on a 7-day basis with a single reporting and surveillance structure.

For additional information please see also question 9 below.

Question 6 – what are PHE's sample requirements for reflex assays/genotyping?

These are identified in separate referral instructions provided by PHE which will be available to all NHS laboratories that process COVID-19 samples [to be published on gov.uk].

Question 7 – what will be the turnaround times for reflex assays/genotyping?

The target laboratory turnaround time is 36 hours for return of results to the NHS (via the e-Lab system) from receipt at Colindale.

NHS laboratories are required to provide samples to PHE without delay to minimise the whole pathway turnaround time. Trusts are already required to provide a daily SitRep which

includes information to clarify turnaround time across the whole pathway. NHSE/I will as part of this monitor the time taken from sample being reported as positive to sample being dispatched to PHE.

Question 8 – what are the reporting arrangements for reflex assays/genotyping?

Sequencing and genotyping results will be sent to the requesting laboratory via Colindale's e-Lab system. All laboratories should ensure they have access to eLAB; further guidance on this is available from eLAB.Helpdesk@phe.gov.uk

NHS Laboratories should ensure they have put a local system in place to frequently and routinely check eLab to ensure they receive results in a timely manner including out of hours, and input these as required into the appropriate laboratory and other information systems (eg LIMS, Patients Administration/Electronic Patient Record systems, etc). Trusts should use this information to complete the existing nationally required daily (7-day) SitRep.

Question 9 – how does this affect reflex testing by NHS hub laboratories?

Work on the planned delivery of variant of concern reflex testing by the NHS's 29 pathology network lead laboratories will continue. Full delivery of this service by the NHS is linked to commercial availability of assays with the B.1.617.2 variant and subsequent validation and verification (V&V).

Subject to this V&V and commercial availability of assays, a full NHS laboratory variants of concern reflex testing service is expected to begin to go live in NHS lead laboratories in mid-June. The list of lead laboratories is attached in Appendix A. PHE reflex testing services will begin to transfer back to the NHS at that point, with a timeline to be agreed by NHS Test and Trace, PHE and NHS England and NHS Improvement. Separate communications will be issued to the agreed lead laboratories for the NHS reflex testing service.

This proposal sets out our planned response to an urgent national public health imperative. Plans for a sustainable national genotyping and sequencing service outside this specific and immediate response are out of scope for this document.

Sequencing

Question 10 – what is the proposal for sequencing?

From Wednesday 26 May, PHE will be the primary provider of sequencing for the purpose stated above through its Colindale site. All NHS laboratories that have detected a positive COVID-19 sample will be required to submit extracted RNA or Primary samples using PHE's existing transport/courier solution. In line with the information above, these samples will be used both for Variant of Concern reflex assay testing and for sequencing.

NHS laboratories are required to provide samples without delay in order to minimise the pathway turnaround time. Samples must not be batched over more than one day.

Question 11 – how will samples for sequencing be transported?

NHS laboratories will be required to submit extracted RNA using PHE's existing transport/courier solution. Detailed instructions about this transport service (contact details,

account number, address for samples to be sent to, etc) are included in referral instructions from PHE [to be published on gov.uk].

This courier service will be funded by PHE.

Laboratories should ensure they make arrangements to have sufficient stock of dry ice available to facilitate a 7-day service.

Question 12 – what happens if a nearby or co-located laboratory can do sequencing?

All NHS laboratories must use the PHE service as described in this document. This is required to ensure that we immediately move to a standardised and uniform system that operates on a 7-day basis with a single reporting and surveillance structure.

Question 13 – what are PHE's sample requirements for sequencing?

These are identified in separate referral instructions provided by PHE [to be published on gov.uk] which will be available to all NHS laboratories that process COVID-19 samples.

Question 14 – what are the arrangements if platforms cannot provide a sample extract for successful sequencing?

Sample and data requirements will be set out by PHE and arrangements will be agreed between NHS E/I and PHE for samples from specific platforms including Point of Care Testing devices as required.

Question 15 – what will be the turnaround times for sequencing?

The maximum laboratory turnaround time will be 96 hours, with a plan to reduce the target turnaround time to 48 hours.

Question 16 – what are the reporting arrangements for sequencing?

Sequencing and genotyping results will be sent to the requesting laboratory via Colindale's eLab system. All laboratories should ensure they have access to eLAB; further guidance on this is available from eLAB.Helpdesk@phe.gov.uk

NHS Laboratories should ensure they have put a local system in place to frequently and routinely check eLab to ensure they receive results in a timely manner including out of hours, and input these as required into the appropriate laboratory and other information systems (eg LIMS, Patients Administration/Electronic Patient Record systems, etc).

Question 17- how does this affect sequencing in NHS laboratories?

The information in this document pertains only to sequencing related to COVID-19. Non-COVID sequencing services should continue to use existing arrangements.

This proposal sets out our planned response to an urgent national public health imperative. Plans for a sustainable national genotyping and sequencing service outside this specific and immediate response are out of scope for this document.

Questions from clinicians

Question 18 – why are samples being sent for both genotyping and sequencing?

All positive COVID-19 samples are now being sent for urgent genotyping and sequencing in response to the current national public health imperative. This is being done to understand variants that may arise in the virus, and to monitor how many variants, particularly variants of concern, may be in circulation.

As full genome sequencing takes time, earlier detection of key variants through reflex testing/genotyping will give clinicians and public health colleagues information on known variants more quickly.

Question 19 - how do I know if my patient has been identified as having a variant of concern?

PHE will be reporting results within the turnaround times described above. These reports will be provided to NHS trusts via the eLab system which is already accessible by all but a small number of NHS laboratories. PHE is working with the remaining individual laboratories in order to ensure they can also access timely results.

NHS laboratories have been asked to ensure they have a system to frequently and routinely check eLab so they receive results in a timely manner including out of hours, and input these as required into the appropriate laboratory and other information systems (eg LIMS, Patients Administration/Electronic Patient Record systems, etc).

You may begin to see reports with comments about the indicative presence or absence of specific variants. These results are to help monitor the prevalence of virus variants and to assist in control.

Question 20 - what is the difference between the genotyping and sequencing report on my patient?

Genotyping will give an indication of whether a single variant of concern exists in a sample. Sequencing will provide a definitive answer as to the presence of any known variant of concern or variant under investigation – and allow us to track how the virus might change.

Question 21 - what implication might this have for the clinical management of my patient?

You should continue to follow the relevant guidance on the appropriate clinical management of patients from bodies including Royal Colleges, NICE, PHE and NHS England and NHS Improvement. At this time there are no known implications that change clinical management from any of the variants currently identified but should these arise, they will be communicated through the existing channels.

Question 22 - what implication might this have for IPC issues in relation to my patient?

You should continue to follow national guidance on COVID-19 Infection Prevention and Control, found at: COVID-19: infection prevention and control (IPC) - GOV.UK (www.gov.uk)

If a particular variant requires a change in these measures, this will be communicated to trusts via formal routes.

Other questions

Question 23 – how will logistical costs be covered?

Transport costs for reflex/genotyping assays and for sequencing will be covered by PHE as their existing courier service will be used.

Question 24 – where can I go for further information?

The separate instructions from PHE provide contact details covering a range of issues, including:

> Sequencing request form: COVID-19 (SARS-CoV-2): E53 sequencing request form - GOV.UK (www.gov.uk)
>
> Details on packaging samples: Packaging and transport requirements for patient samples – UN3373 - GOV.UK (www.gov.uk)
>
> Queries related to eLaB reporting system (Monday to Friday): eLAB.Helpdesk@phe.gov.uk
>
> Other enquiries about the sequencing and genotyping service: phe.genomics@phe.gov.uk

Further resources on variants of concern:

> Information on variants of the SARS-CoV-2 virus: COVID-19 (SARS-CoV-2) variants - GOV.UK (www.gov.uk)
>
> Technical briefings: Investigation of SARS-CoV-2 variants of concern: technical briefings - GOV.UK (www.gov.uk)

Within NHS England and NHS Improvement, queries should be directed to the Testing Cell via england.covid-testing@nhs.net

Appendix A

Lead labs by region and network for the Variants of Concern (VOC) Programme		
Region	**Network**	**Lead Lab**
London	London 1	North West London Pathology (NWLP)
London	London 2	Health Services Laboratories, University College London Hospitals NHS FT
London	London 3	Royal London Hospital, Barts Health NHS Trust
London	London 4	Viapath, Guy's and St Thomas' NHS FT
London	London 5	South West London Pathology Services, St George's Hospital
Midlands	Midlands & East 1	Black Country Pathology Services
Midlands	Midlands & East 2	University Hospitals of Derby and Burton NHSFT (Royal Derby Hospital)
Midlands	Midlands & East 3	PHE Birmingham
Midlands	Midlands & East 4	University Hospitals Coventry and Warwickshire
East	Midlands & East 5 & 6	PHE Cambridge
East	Midlands & East 7	Eastern Pathology Alliance, Norfolk & Norwich University Hospitals NHS FT
East	Midlands & East 8	Broomfield Laboratory
North East & Yorkshire	North 1	Newcastle upon Tyne Microbiology and Virology Laboratory Services
North East & Yorkshire	North 2	Leeds Teaching Hospitals NHS Trust
North East & Yorkshire	North 6 & 7	Sheffield Virology Service, South Yorkshire and Bassetlaw
North West	North 3	Lancashire and South Cumbria Pathology Network
North West	North 4	Liverpool Clinical Laboratories (LCL)
North West	North 5	PHE Manchester
North West	North 8	Royal Stoke University Hospital
South West	South 1	Royal Devon and Exeter Hospital

Appendix A

Lead labs by region and network for the Variants of Concern (VOC) Programme		
Region	**Network**	**Lead Lab**
South West	South 2	Southwest Pathology Services
South West	South 3	Severn Pathology, North Bristol NHS
South East	South 4	Microbiology, Oxford University Hospital
South East	South 5 & 8	Berkshire and Surrey Pathology Services
South East	South 6	Southampton Hospital
South East	South 7	Microbiology and Infection Department, Royal Sussex County Hospital