

COVID-19 Testing Strategy Update

20 May 2020

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Ministerial Foreword

On 7 April 2020, I agreed the COVID-19 Testing Strategy for Northern Ireland. At that time, I highlighted that this Testing Strategy would be reviewed on an ongoing basis and that it would be adjusted over time as further capacity became available and as our priorities for testing changed as the pandemic evolved.

Since publication of our strategy we have increased our testing capacity significantly. At the beginning of this pandemic, HSC laboratories were processing 40 tests per day. This figure has now increased to 1,700 tests per day in our HSC laboratories, with an additional 800 tests per day under the National Initiative, and I am confident that we will continue to increase our testing capability and capacity to ensure we continue to deliver a robust response to this unprecedented pandemic and protect the health of our population.

Health and Social Care (HSC) Trusts are continuing to provide testing for patients and health and social care staff as part of their in-house testing provision. In the next few weeks further expansion in testing capacity is expected through the Scientific Advisory Consortium established to increase access to testing as part of the pandemic response.

As part of the UK wide National Initiative, we have three drive-through test centres at the SSE Arena car park, City of Derry Rugby Club, and Craigavon MOT centre to enable testing of all key workers. This has included access to home testing kits for key workers who are unable to get to a test centre. During May, mobile test units will be introduced and satellite testing for facilities.

The increase in testing capacity has facilitated the commencement of a number of surveillance programmes in primary care, Emergency Departments and care home settings. These programmes help us to monitor trends in COVID-19 infections and put in place appropriate control measures where needed in hospital and community settings.

We are now at the stage in the pandemic where contact tracing is being introduced in May 2020. This approach will help us to identify where the virus is spreading and take action to limit further spread. This will bring additional demands on our testing capacity in the coming weeks that we will have to respond to.

There has been considerable progress in the last few weeks in antibody testing which require further validation and research before they can be used more widely. Initially their use will be limited to specific scenarios and complement existing tests before their more widespread use in testing.

The last few weeks have involved a tremendous amount of work on the part of a large group of people, and I am extremely grateful for this. I am pleased to present this updated Testing Strategy to you, and I would like to put on record, again, my sincere thanks to all those involved in developing this significant and vital work

ROBIN SWANN

Minister for Health, Northern Ireland

1. Strategic Context

- 1.1 The world is facing a global pandemic of the COVID-19 disease which has been caused by the rapid spread of the SARS-CoV-2 virus. The first case of COVID-19 in Northern Ireland was notified on the 27 February 2020. Since then there have been 4,439 laboratory confirmed cases in Northern Ireland, 41,470 individuals have been tested for COVID-19 and 14,792 samples have been taken at our National Testing Centres sites (as of 19 May 2020).
- 1.2 Testing for COVID-19 is a critical part of our pandemic response. In the earlier phase of our response, described as the 'containment phase', our priorities for testing were cases (people who became unwell - many of whom had travelled abroad) and contacts of cases, this was to establish if the virus had been transmitted between cases and their contacts.
- 1.3 Moving into the current 'delay phase' of our pandemic response (12 March 2020) involved a change in our approach to management of COVID-19 infection. Everybody is advised to stay at home, to observe social distancing and to ensure good hand hygiene and good respiratory hygiene. Each person developing symptoms (new persistent cough and/or fever and/or anosmia¹) is potentially a case and is advised to self-isolate for 7 days, members of their immediate household and other close contacts are advised to self-isolate for 14 days.
- 1.4 As part of our current response particular groups are deemed to be 'clinically vulnerable', meaning that they are at a higher risk of severe illness from coronavirus. These groups include those aged 70 years and over (regardless of underlying medical condition), those with specific pre-existing medical conditions and pregnant women. These groups are advised to ensure they adhere strictly to

¹ The UK case definition has now been expanded to include Anosmia, the loss or change in your normal sense of smell. Further details are set out at <https://www.health-ni.gov.uk/news/statement-four-uk-chief-medical-officers>

social distancing requirements, to practice good hand and respiratory hygiene and to minimise contact with others outside their household.

- 1.5 A further subset of the population are identified as 'clinically extremely vulnerable', and are advised to 'shield' by staying at home and avoiding all contact with others, except for essential medical treatment or support. The groups advised to shield are comprised of people with specific cancers, with severe respiratory conditions, with rare diseases, those who have had solid organ transplants, those who are on immunosuppression therapies, and those who are pregnant and who have significant heart disease.² The position on shielding is regularly monitored at both local and national level, the current advice will remain in place until the end of June 2020.
- 1.6 In the current 'delay phase' our priorities for testing were initially identified as i) people who become unwell and require hospital admission, including patients who require critical care, ii) health and care workers who treat and care for those who become unwell and/or are vulnerable, iii) circumstances where testing is used to inform the risk assessment and management of outbreaks or clusters in closed settings (such as care homes or prisons and more recently supported living settings), and iv) essential or key workers in sectors other than Health and Social Care (HSC).
- 1.7 Our Testing Strategy for Northern Ireland is supported by an Interim Protocol for Testing for COVID-19, this protocol is an operational tool which provides information on eligibility for testing, advice on how to access testing and guidance relating to interpretation of results of testing. As the position on testing is fast moving, this Interim Protocol is kept under constant review, with priority groups for testing extended regularly in line with emerging scientific evidence and expansions being delivered in our testing capacity.

² Public Health England: Guidance on shielding and protecting people who are clinically extremely vulnerable from COVID-19 (<https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19>)

- 1.8 Our Testing Strategy aligns with the UK's strategic approach to scale-up of testing for COVID-19³ (the Five Pillar Approach) and also with work being progressed in the other Devolved Administrations. Senior staff from Northern Ireland continue to liaise closely with colleagues working on testing programmes in the other UK countries, this is to ensure that resources, new knowledge and where appropriate procurement exercises are shared. A summary of the Five-Pillar Approach which is adopted by the Department of Health and Social Care (DHSC), London is included in **Annex 3**.
- 1.9 The Testing Strategy has also taken account of testing plans in the Republic of Ireland (ROI).
- 1.10 As we seek to increase testing across all our laboratory services and networks, we are working with laboratories outside of the traditional Health and Care sector. We have forged new partnerships and we have developed new services to increase our testing capacity, to validate new tests locally (in association with the national centre), and to investigate the scope for manufacturing reagents and other chemical products required for testing in Northern Ireland.
- 1.11 In the coming weeks, we expect the demand on our testing programme to increase significantly, it is important therefore that we continue to extend our testing programme and our testing capacity to take account of the following:
- Care Homes: we have extended testing available to care home staff and residents on a number of occasions during the current phase of our response. Most recently we have advised that testing will be made available to all residents and staff in care homes during June 2020 (announced on 18 May 2020). This extension is in addition to testing currently available for care homes who have single cases and possible outbreaks or clusters of infection. We will also continue to ensure that all patients and residents transferred to a

3

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878121/coronavirus-covid-19-testing-strategy.pdf

care home from any setting (e.g. hospital, community or their own home) are tested 48 hours prior to admission to the care home. Further information on care homes is available at paragraphs 3.37 to 3.44.

- **Contact Tracing Programme:** this programme will involve identifying people who have been in close contact with cases of COVID-19, informing them of this and providing them information on what they need to do as a result of this contact. Our testing capacity will need to grow as our contract tracing programme expands to cover the whole population of Northern Ireland. Further information on the Contract Tracing Programme is available at paragraphs 3.45 to 3.50.
- **Health and Care Workers:** it is expected that a programme of regular testing of health and care workers (HCWs) will be required in the coming weeks and months, to include those working in acute settings and those working in the community and in care homes. It is important that such a programme or programmes are underpinned by the emerging science and a robust evidence base. The purpose and format of a regular testing programme for health and care workers continues to be discussed at a national level, it is anticipated that introduction of this programme (or programmes) locally will require considerable additional testing capacity.
- **Hospital Admissions:** since the introduction of our Interim Protocol on Testing (in mid-March) testing has been extended to several groups of patients including - all patients admitted to acute hospitals, all patients admitted to mental health and learning disability in-patient wards, and more recently all obstetric admissions to hospital. As we move forward into the next phase of our pandemic response testing will also be required for patients admitted to hospital for planned care. This requirement for testing will become particularly important as we move into the 'new normal' for our health services and we begin to recommence elective care, such as planned surgery.

1.12 In addition to the above, the demand for testing of people in community settings is expected to increase for a number of reasons:

- Introduction of regular testing in residential and care settings such care homes, supporting living, and prisons – while testing has commenced and is available to all of these settings, consideration will need to be given to a requirement for regular testing;
- Commencement of seroprevalence studies which will include sequential laboratory blood tests – required to inform our understanding and monitor acquired immunity to COVID-19 infection among the population;
- Further expansion of the priority sector list of key and essential workers eligible for testing; and
- Extension of testing to symptomatic people in the community - Citizen's Portal which enables symptomatic members of the public to book tests, either through the drive-through test centre or a home postal service (as part of the National Testing Programme) is now operational in Northern Ireland.

1.13 As we move into planning for the second phase of our pandemic response, laboratory services in Health and Social Care Trusts (HSCTs) that were “paused” for the pandemic will be restarted in the coming weeks. This will be overseen by the pathology network and is out-with the remit of the EAGT.

1.14 Many planned services e.g. elective surgery and outpatients were downturned at the beginning of the pandemic to free capacity for the pandemic “Surge”. These services will need to be gradually restarted and testing of patients and staff will be central to this. This will bring an increase in testing requirements in the next 3 months. Many services developed new models of care to support patients during pandemic, these have worked well and should be retained and developed further.

2. Background

- 2.1 The Northern Ireland Testing Strategy aims to reduce harm to individuals from COVID-19 and to support measures needed to protect the general population.

Expert Advisory Group on Testing

- 2.2 To oversee the coordination and implementation of the Testing Strategy in Northern Ireland, the Minister for Health has established an Expert Advisory Group on Testing (EAGT). Details of membership of EAGT are set out at **Annex 1**. Delivering this strategic plan at pace will require cooperative working and engagement with a range of trusted partners and external stakeholders. Key stakeholders are listed in **Annex 2**. This strategic plan has drawn on advice and guidance provided by EAGT members, it has benefitted from local expertise within our HSCTs, our Pathology Network and the newly established Northern Ireland COVID-19 Testing Scientific Advisory Consortium. It has also included a desktop review of the testing strategies developed elsewhere in the United Kingdom (UK), and consideration of the COVID-19 testing plan in the ROI.
- 2.3 Central to the remit of the EAGT is the development and oversight of the rapid expansion of testing capability and capacity in Northern Ireland, as we move through the phases of our pandemic response. Significant progress has been made in a very short number of weeks.
- 2.4 The rapidly evolving nature of this pandemic brings new challenges in relation to existing laboratory information and intelligence systems and their reporting arrangements. In mid-April a subgroup of the EAGT was established to bring additional emphasis and expertise to the information and intelligence aspects of our COVID-19 testing programme. The subgroup (the testing programme data cell) considers and makes recommendations about how to improve the co-ordination and streamlining of data collation and reporting processes relating to this complex testing programme.

Achievements to Date

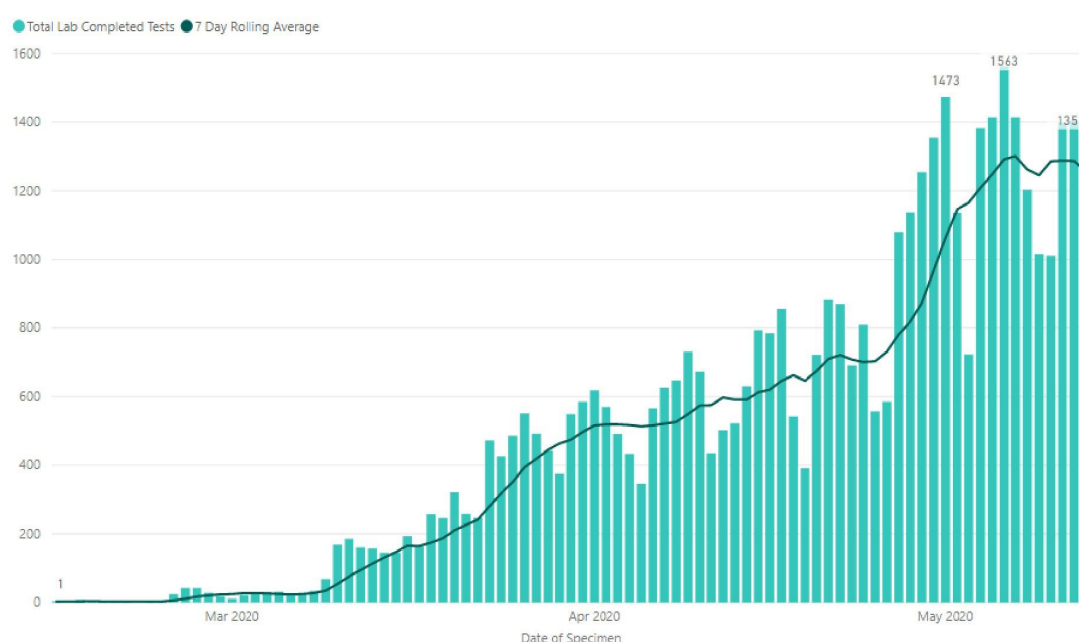
- 2.5 At the beginning of this pandemic, HSC laboratories in Northern Ireland were processing 30-40 tests per day for COVID-19. This testing capability has been

scaled up significantly and rapidly, with the currently available test capacity now reaching 1,700 tests per day in HSC laboratories. It is expected that this growth in capacity will continue over the coming weeks through the use of academic and commercial partners outside of the HSC sector.

2.6 At the request of the Minister for Health and the Chief Medical Officer, a Scientific Advisory Consortium on Testing (SACT) was established in March. The SACT includes several partners - Queens University, Belfast (QUB), Ulster University (UU) the Western Health and Social Care Trust/ Clinical Translational Research and Innovation Centre (WHSCT/C-TRIC), the Agri-Food and Biosciences Institute (AFBI) and local company Almac. The SACT has been established to support the Department of Health (DoH) and the health and care system to rapidly scale up diagnostic testing for COVID-19.

2.7. Information presented below (Figure 1) shows the increase in test capacity and tests completed delivered through HSC laboratories since the beginning of this pandemic. It presents the number of laboratory completed tests by the date on which the specimen (sample / swab) were taken.

Figure 1: Total Number of Laboratory Completed Tests by Date of Specimen

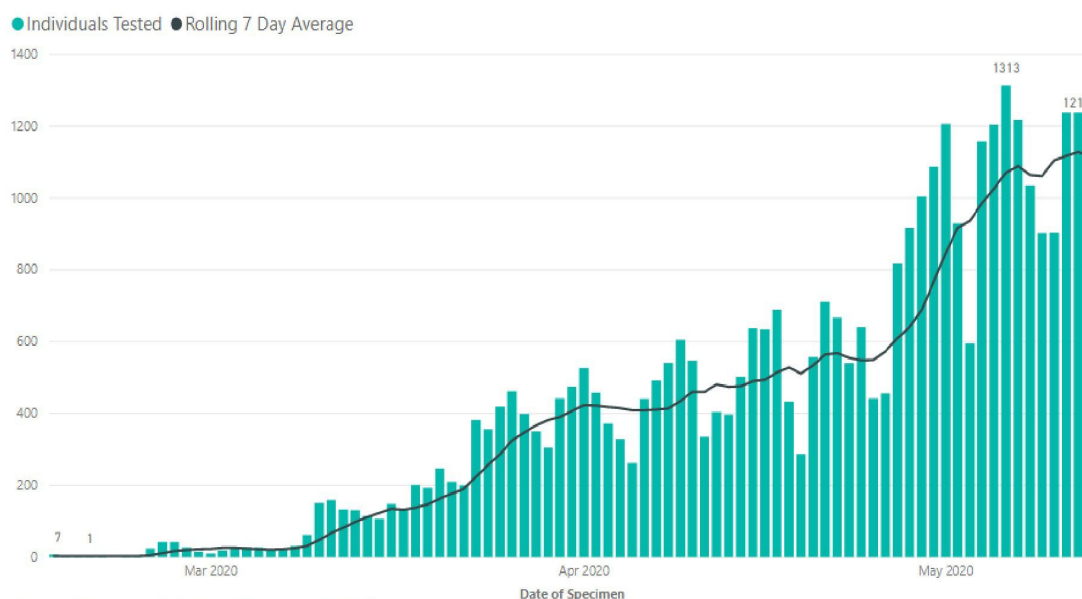


Source: Information & Analysis Directorate, DoH, NI

2.8 Figure 1 indicates that the total number of laboratory completed tests for COVID-19 increased steadily from a daily average of 30 completed tests at the beginning of March 2020 to on average 1,250 daily laboratory completed tests in May 2020. Of particular note is the marked increase in the number of laboratory completed tests since 22 April 2020. It is also worth noting that the information is presented by the date each sample was taken and is therefore a more accurate analysis of how cases have progressed over time.

2.9 Figure 2 below shows the number of individuals with a completed laboratory test by the date a specimen (swab) was taken.

Figure 2: Individuals with a Laboratory Completed Test by Date of Specimen



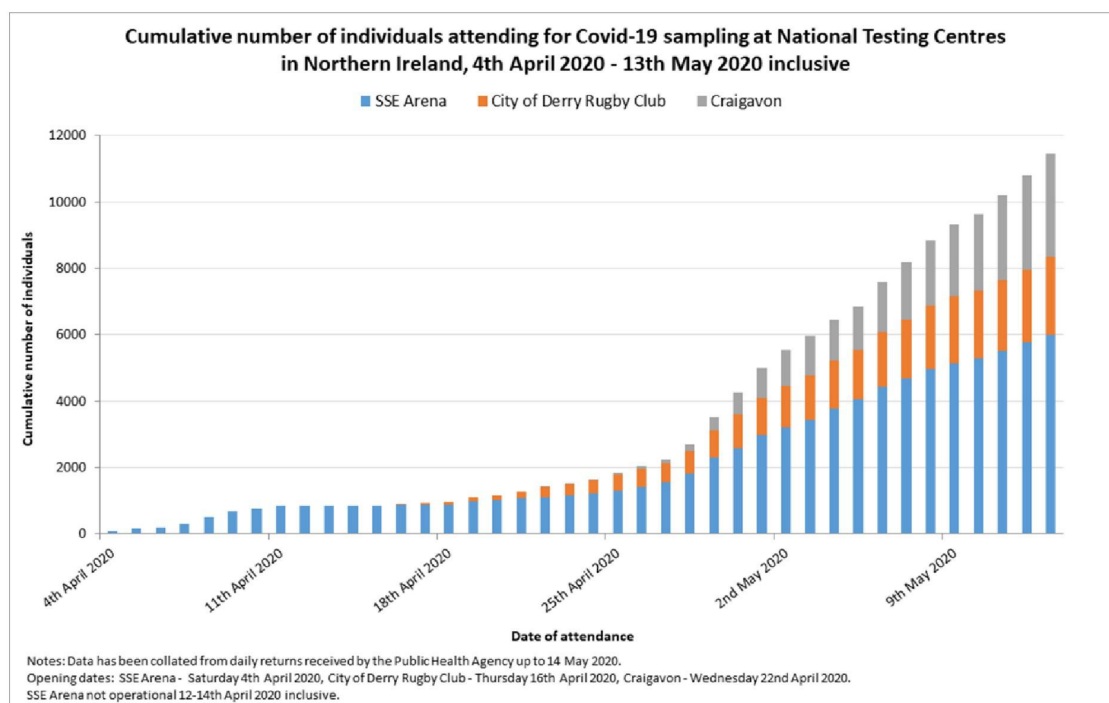
2.10 The number of individuals with a laboratory completed test has increased steadily from around 30 individuals at the start of March 2020 to around 800 individuals on 22 April 2020. From 22 April 2020, the number of individuals with a completed laboratory test increased to around 1,100 per day.

2.11 In addition to the increased test capacity delivered by HSC laboratories, a further growth in capacity has been delivered through the establishment of a network of drive-through test centres in Northern Ireland under the UK wide National Testing

Programme. This programme currently facilitates up to 800 tests per day. It is expected that testing capacity through this programme will increase over the coming weeks, with the development of a fourth test centre to be located in Enniskillen, the introduction of mobile testing units, at home test kits, and through the use of satellite test arrangements.

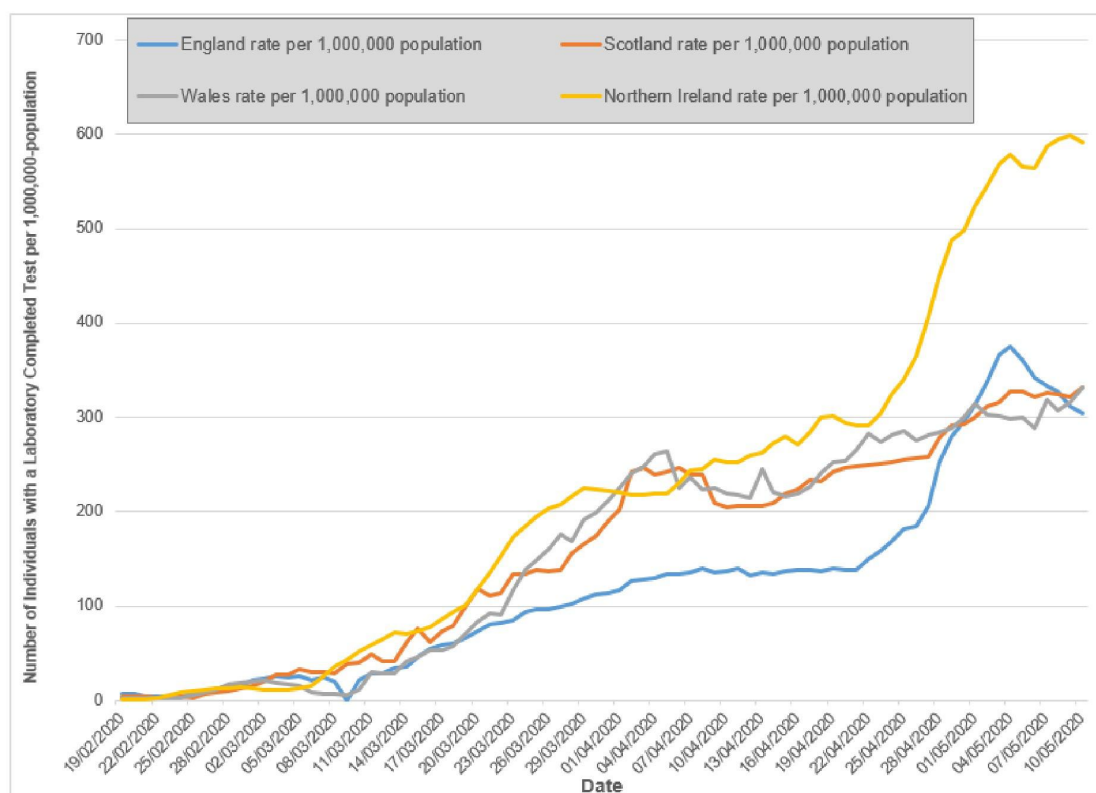
- 2.12 Figure 3 below displays the number of individuals attending for tests at the National Testing Programme test centres in Northern Ireland. It shows a steady increase in attendance at the test centres from early April to mid-May 2020.

Figure 3: Number of Individuals Attending National Testing Centres



- 2.13 Figure 4 sets out information on the number of individuals with a laboratory completed test per million population, for each of the four UK Jurisdictions. This data relates to testing completed through HSC laboratories in Northern Ireland and National Health Service (NHS) laboratories in the other UK countries. From early March onwards Northern Ireland has tested a higher number of the individuals per 1 million population.

Figure 4: Individuals with a Laboratory Completed Test in each UK Jurisdiction



- 2.14 Laboratory testing is, however, very much dependent on global supply chains working, on scalable and resilient laboratory services and on the use of multiple platforms for testing. This approach is important to lessen our reliance on single types of testing kits and reagents used as part of the testing process with a view to reducing reliance of our HSC testing capability on a single product or product supplier.
- 2.15 In this context, the SACT includes a workstream to examine the feasibility of local production of reagents required within the testing process. The SACT has also commenced a programme of work to undertake validation of antibody tests when they become available, in association with the national centre in Oxford. The SACT will also drive scientific innovation in COVID-19 testing.
- 2.16 The Procurement and Logistics Service in our Business Services Organisation (BSO PaLS) is represented on the EAGT and it has responsibility for leading on

the regional procurement of test kits and other consumables required for the testing process.

Reporting

- 2.17 Detailed information on testing is reported on a daily basis to the Minister for Health and DoH. The Department (DoH) reports information relating to testing, to the public via a public facing digital dashboard, to the Northern Ireland Executive, and to the DHSC and the Cabinet Office (CO) in London, also on a daily basis.
- 2.18 DoH and the Northern Ireland Statistics & Research Agency (NISRA) have introduced a dashboard to support regular reporting of information relating to COVID-19. This dashboard includes data on a range of issues of public interest as part of the pandemic response, it facilitates regular reporting of data relating to laboratory tests completed at HSC laboratories and samples taken at the National test centres.

3 Key Actions of the Strategy

- 3.1 The DHSC published its testing strategy for England, *Coronavirus (Covid-19): scaling up our testing programmes* on 4 April, setting out what it intended to do across ‘five pillars’.
- 3.2 The five pillar approach outlined for England is focussed on the following key actions: scale up of swab testing in Public Health England (PHE) laboratories and NHS hospitals for patients and HCWs (this is called Pillar 1), deliver increased commercial swab testing through use of the private sector (this is called Pillar 2), roll out of antibody tests for immunity (this is Pillar 3), population surveillance (this is Pillar 4) and a call to manufacturers and commercial developers to assist the UK’s diagnostic capability (this is Pillar 5). Further details on this approach are included at **Annex 3**.
- 3.3 The Testing Strategy for Northern Ireland follows a similar approach to that set out above, and therefore each of the actions within this document is described and categorised by its contribution to the relevant ‘Pillars’ of our overall COVID-19 Testing.

Expansion of Nucleic Acid Testing - Pillar 1

- 3.4 We will scale up testing for COVID-19 infection across our health and social care system through the use of swab tests which detect the presence of viral nucleic acid. These swabs test for the presence of the genetic signature of SARS-CoV-2, the virus which causes COVID-19 and can tell an individual if they currently have COVID-19. A swab is used to collect a sample from inside the nose or back of the throat of an individual who has symptoms.
- 3.5 The majority of Pillar 1 testing is being undertaken by the Regional Virology Laboratory (RVL) in the Belfast Health and Social Care Trust (BHSCT), with local testing taking place in Northern Health and Social Care Trust (NHSCT) and Southern Health and Social Care Trust (SHSCT) laboratories. Currently, all tests in Western Health and Social Care Trust (WHSCT) facilities are being transferred

to the RVL for processing. In general, results of these tests are available within 24 hours of receipt of samples in the laboratory. A turn-around time (TAT) of 24 hours is important in this context as this testing capability is used to test patients who are unwell and require clinical care (either in hospital or in a community setting such as a care home).

- 3.6 HSCTs have developed local operational arrangements for testing of HCWs and key workers in some other sectors, for example two HSCTs currently have their testing 'pods' located in MOT centres in Newtownards (SEHSCT) and Boucher (BHSCT) in Belfast. Pods are also in place at the Royal Victoria Hospital, Antrim Area Hospital, Crumlin Road Belfast and Antrim Road, Belfast. Samples (swabs) are collected from symptomatic key workers at these pods and then tested through HSCT laboratories.
- 3.7 The role of the Northern Ireland COVID-19 SACT has been described earlier in paragraph 2.2. The SACT brings important additional testing capacity to the HSC Trust laboratory system. The SACT should have the potential to add up to 2,000 tests PER day during June to local HSC testing capacity subject to adequate supply chains of reagents and testing kits being secured.
- 3.8 Point of care (POC) testing platforms would increase the scope for a diagnosis of COVID-19 to be made in the community and / or outside of laboratory settings. Many POC tests are Polymerase Chain Reaction (or PCR) tests which are used to directly detect the presence of a viral antigen, rather than the presence of the body's immune response to the virus (antibodies). By detecting the viral antigen, which will be present in the body before antibodies form or symptoms of the virus are present, PCR tests can tell whether or not an individual has the virus very early in the course of their illness. These systems will allow rapid detection of viral nucleic acid in clinical samples (20-45 minutes) on appropriate hospital wards and will be key to inform decisions relating to patient flow and use of mechanical ventilation. POC testing capability will be particularly important in the winter months when co-circulation of influenza and other respiratory viruses is expected. It is currently anticipated that POC tests will be available in June / July,

they will be evaluated by the RVL, BHSCT prior to their use to support and inform clinical care.

- 3.9 Multiple testing platforms are currently used in Northern Ireland to build resilience into the service and to utilise different supply chains. Capacity is carefully planned on a weekly basis. Whilst testing capacity has increased significantly since the beginning of this pandemic, plans are in place to increase this further. Through the SACT, AFBI and Almac have committed the use of their laboratories to increase capacity in Northern Ireland. This additional capability is expected to increase local testing capacity by up to 1,000 -1,500 tests per day.
- 3.10 The four key areas where there will be increased demand for testing over the coming months include care homes (for staff and residents), our contact tracing programme, regular/repeat testing of HCWs (currently in discussion) and patients admitted to hospital. Continued expansion of testing undertaken under this part of our testing programme (Pillar 1) will be essential to meet the anticipated increase in demand across these areas.
- 3.11 Figure 5 overleaf summarises the planned increase in testing capacity from the middle of May to the end of June 2020, by which time it is expected that the HSC/SACT laboratories will deliver up to 2,500 tests per day. Figure 6 summarises the cumulative increase in tests to be delivered over the same period. Anticipated capacity is wholly reliant on available supply of extraction agents, test kits & consumables; no analyser down-time associated with technical failure; and ability to maintain staffing levels

Figure 5: Estimated Daily Testing Capacity by Testing Platform, 15 May to 23 June 2020

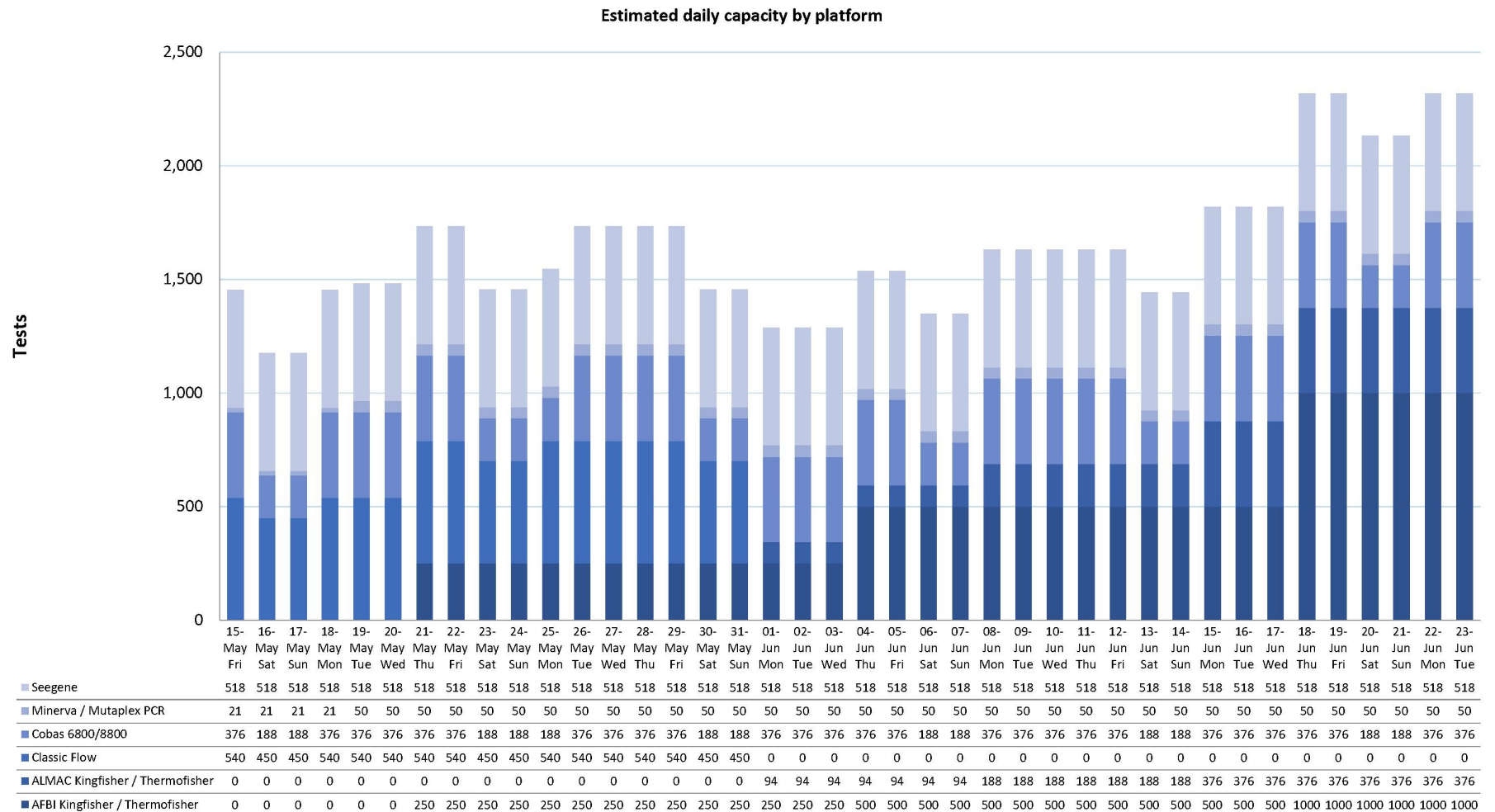
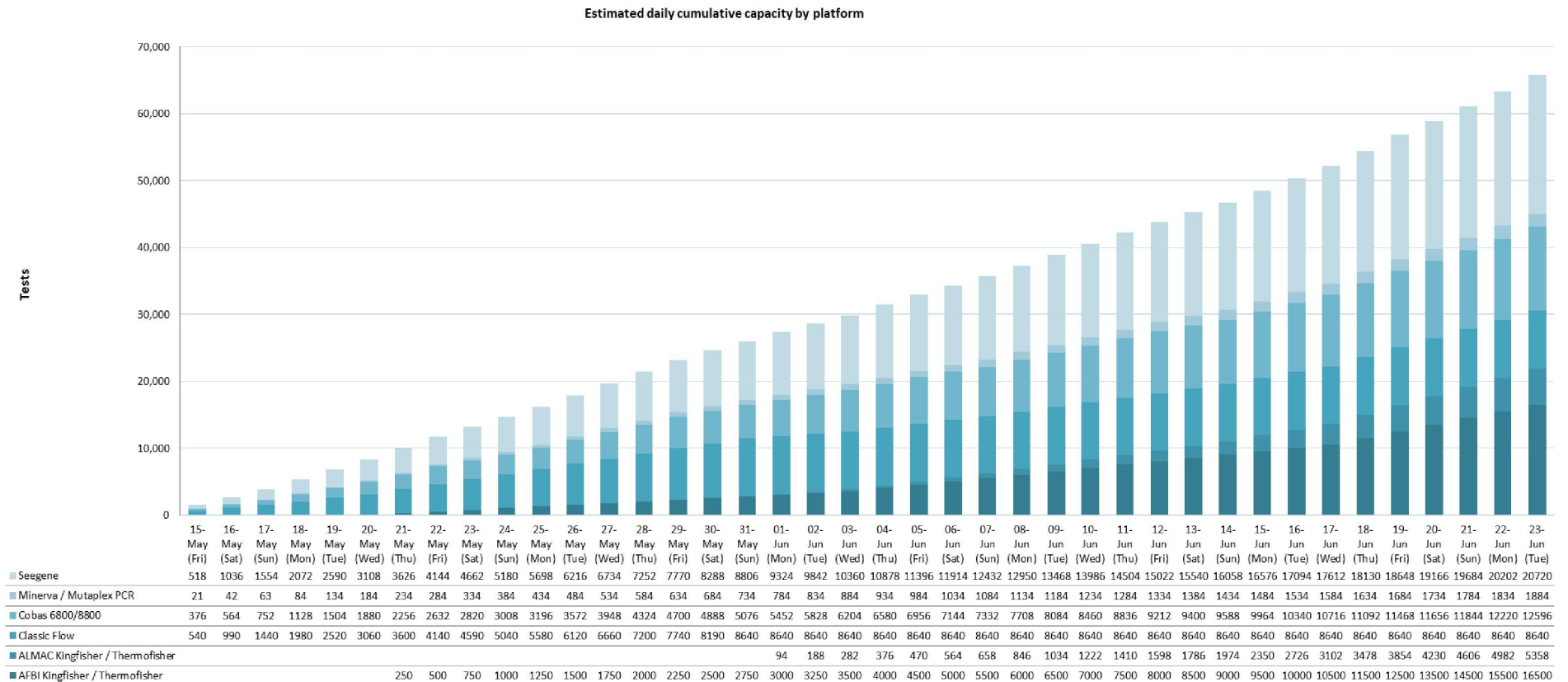


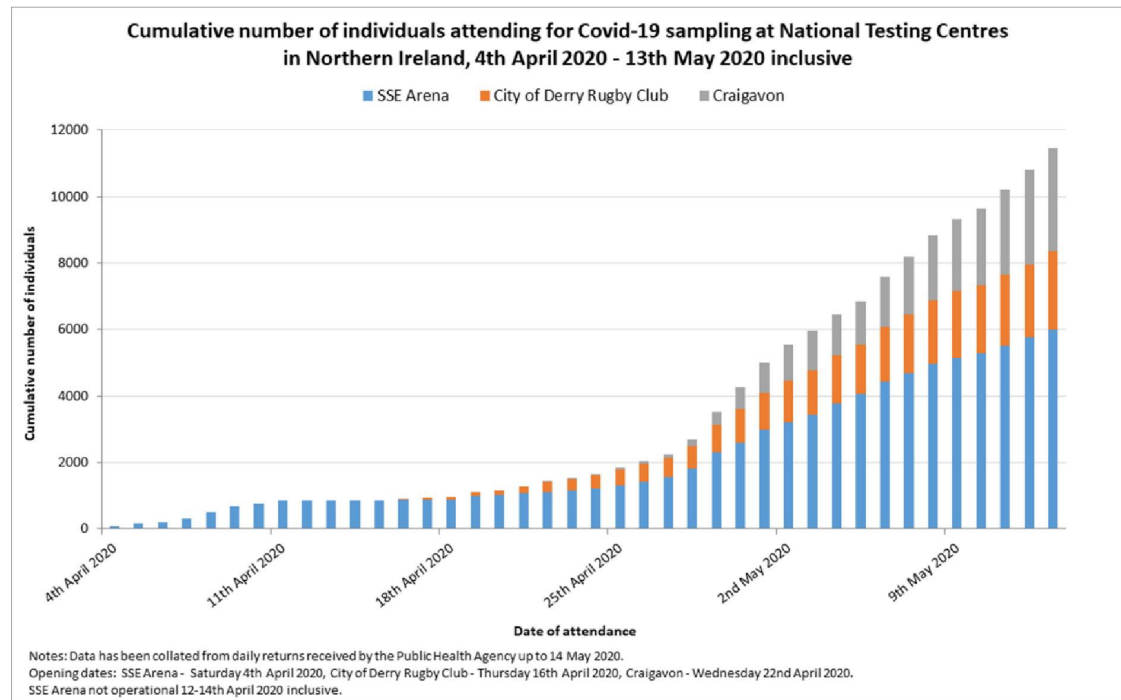
Figure 6: Estimated Cumulative Testing Capacity by Testing Platform, 15 May to 23 June 2020



National Testing Programme (Pillar 2)

- 3.12 There are four key approaches to testing within the UK-wide National Testing Programme:
- I. Fixed drive-through sites;
 - II. Mobile testing units;
 - III. Postal option for people to have tests delivered to their homes; and
 - IV. Satellite testing where tests are couriered to and from sites, for example care homes.
- 3.13 The National Testing Programme to enable testing of health and care workers and other key workers was introduced in Northern Ireland in April 2020. This programme was established by the DHSC on behalf of all UK countries. Testing under this programme is similar to that described under Pillar 1, however the key differences are that Pillar 2 is focused on the expansion of swab (antigen) testing as part of the UK-wide National Testing Programme, and unlike Pillar 1 testing is not mediated by General Practitioners or Secondary Care Physicians – all test results processed under Pillar 2 go directly back to the key worker/person who has been tested rather than to their clinician.
- 3.14 Under the National Testing Programme current testing capacity in Northern Ireland is up to 800 tests per day which is delivered through three drive-through testing centres, operating in: Belfast (SSE), Derry/Londonderry (City of Derry Rugby Club), and Craigavon (Craigavon MOT centre). These centres are used to test key workers in health and non-health agencies who are self-isolating because they are symptomatic and /or they are self-isolating as a member of their household is symptomatic. In general, test results are available to the person tested within 72 hours. A fourth drive-through test centre to be located in Enniskillen is scheduled to come into operation towards the end of May 2020.
- 3.15 Figure 7 below details the increasing number of individuals attending the National Initiative drive-through test centres since the first centre opened on 4 April 2020.

Figure 7: Number of Individuals Attending National Test Centres in NI



- 3.16 A digital platform is available to enable self-referral for testing through the National Testing Programme for key workers who are self-isolating⁴. The digital platform allows an individual who requires a test the choice between a postal service (where they self-administer the swab at home and send to laboratory under special arrangement with a courier), or an option to attend one of the three drive through centres across Northern Ireland (as above). A secure employer referral portal is also available to support this service, allowing an employer to refer essential workers who are self-isolating, for testing.
- 3.17 Arrangements for electronic transfer of test results from NHS-Digital on behalf of the DHSC to the Public Health Agency (PHA)/BSO are currently being finalised, arrangements will also be made for results to be recorded in the Northern Ireland Electronic Care Record (NICR) of the individual tested through the National Testing Programme.

⁴ <https://self-referral.test-for-coronavirus.service.gov.uk/>

- 3.18 Capacity for the home test kits which are available through the National Testing Programme is managed centrally by DHSC on behalf of the four UK nations, and allocated on a 'first come first served' basis as booked through the digital portal.
- 3.19 Local team members (in the PHA) are working with colleagues in DHSC to deliver a number of further developments for the National Testing Programme during May, they are as follows:
- A fourth testing centre will be established in the South West (Enniskillen) before the end of May, each fixed test centre has a capacity of 250 to 300 tests per day;
 - Four mobile testing units are being made available to allow rapid deployment of testing in the event of clusters of cases or outbreaks, each unit will have capacity to deliver 200-300 test per day, the first mobile unit will deploy week commencing 19 May 2020;
 - Satellite testing will be introduced to support testing in care settings whereby swabs will be delivered via a courier and returned to a private laboratory for testing. It is anticipated that this will increase testing capacity by approximately 700 tests per day;
 - A new digital portal will implemented in Northern Ireland will two key elements i) access to the citizen's portal which enables symptomatic members of the public to book tests (through test centre or home postal service) and ii) access to a new nursing home portal which will be used to support the programme of testing in clean (non-outbreak) care homes; and
 - Resilience for Laboratory Element of Programme – in order to avoid overreliance on one laboratory provider, the National Testing Programme will be expanded in Northern Ireland with the addition of a second laboratory provider.

Serology-antibody testing (Pillar 3)

- 3.20 Considerable advances have been made in serology (antibody testing) since our first Testing Strategy was issued on the 5 April 2020. Work is ongoing to determine if the presence of antibodies to the SARs-CoV-2 virus provides immunity, and if so, to what extent and for how long.
- 3.21 Assays that can reliably detect antibody responses specific to SARs-CoV2 can contribute to diagnosis of acute infection (via rises in IgM and IgG levels) and can identify those infected with or without symptoms and those recovered (via persisting IgG).
- 3.22 There are two main tests being developed for diagnosis:
1. **IgM** – used to diagnose early infection. These tests are not currently optimised for use and require further evaluation. IgM tests may never have sufficient sensitivity and specificity to replace swab PCR testing; and
 2. **IgG** – used to guide whether there has been an infection at any time.
- 3.23 Research is ongoing to determine if the presence of antibodies will lead to protection from the COVID-19 disease. Potential future uses of antibody testing in the next few months may include:
- Testing of key workers to determine if they have had COVID-19;
 - Triaging patients for elective appointments. Antibody testing will highlight if a patient has had exposure to the COVID-19 prior to surgery or other elective appointments. This will then guide clinical decision making;
 - Helping to determine if those in vulnerable groups have had COVID-19; and
 - Augment COVID-19 diagnosis of patients who have clinical COVID-19 but, owing to when symptoms first appear, relative to time of arrival in the healthcare setting, respiratory swabs are PCR negative. The time from which the antibody develops and becomes detectable in a patient is usually greater than or equal to 14 days therefore antibody testing could achieve a diagnosis of COVID-19 when the virus is no longer detectable in the body through a PCR test. As the seroprevalence increases in subsequent waves

of infection, the benefit of the antibody test in this setting will reduce (information on seroprevalence can be found in paragraphs 3.25 to 3.30).

- 3.24 There are five promising antibody tests currently being validated in regional virology laboratories in NHS/HSC. If successful, antibody testing may support the introduction of tailored social distancing measures, however there are likely to be logistical challenges around scaling up production and procurement of antibody kits which will require careful management.

Seroprevalence (Pillar 4)

- 3.25 Seroprevalence is the number of persons in a population who test positive for a specific disease based on serology (blood serum). Seroprevalence studies allow measurement of the occurrence of a disease and associated risk factors, providing important data on susceptible groups and the potential for future outbreaks.
- 3.26 An initial antibody seroprevalence study is proceeding in Northern Ireland through collection of 1000 anonymous residual blood samples from all HSC Trusts, these blood samples were originally collected for biochemistry testing. The only data available with these blood samples will be age and gender, COVID-19 test status and HSCT area; testing will initially be undertaken using the ELISA test from EuroImmune. These samples will be stored in the NI Biobank for analysis and future re-testing when improved antibody test kits become available. It is anticipated that results of initial antibody testing on these residual blood samples will be available in approximately six weeks (end of June) depending on advised delivery of testing kits.
- 3.27 A Laboratory-Based Community Antibody Seroprevalence Group has been established, the group and reports into the PHA COVID-19 operational response. This Seroprevalence Group is currently scoping options for a prospective population-based antibody seroprevalence study in Northern Ireland and an options paper for the Northern Ireland study will be submitted to the EAGT for consideration.

- 3.28 The Office for National Statistics (ONS) in England has been piloting a study (initially in London), involving 10,000 households which equates to approximately 25,000 people. The aim of the ONS study is to help improve understanding around the current rate of infection and the number of people likely to have developed antibodies to COVID-19. In the study, sampled household members complete an initial questionnaire on symptoms, a swab test is taken for all household members aged two years and over and a blood test is obtained for one household member over 16 years of age. The blood sample is taken by a trained nurse, phlebotomist or healthcare assistant. Participants are asked to take further swab tests every week for five weeks, then every month for 12 months.
- 3.29 As of 14 May 2020, ONS had received results of swab tests collected from 10,705 people in 5,276 households. Following completion of the pilot study, ONS intend to expand the size of the sample for the survey over the next 12 months to approximately 300,000 people from across the UK. The Seroprevalence Group is awaiting further information from the ONS on the details around costings, proposed sample size and a timeline for implementation of the study in Northern Ireland.
- 3.30 ROI is carrying out a prospective survey with blood samples in two regions (one high and one low incidence), drawing a random prospective sample from the primary care record and inviting one household member aged between 12 and 69 years old to provide a blood sample. A full comparison of the survey protocols being used by ONS, and that being used in ROI, has been completed. While there is sufficient similarity for the results to be comparable, the option of a local seroprevalence study in Northern Ireland (which may be more cost effective), using the existing NI Clinical Research Network resource⁵, is also being actively considered. Discussions are ongoing with colleagues in ROI who are represented on the Seroprevalence Group in NI with senior health care staff from

⁵ The NI Clinical Research Network provides infrastructure that allows high quality clinical research to take place across all HSC structures, so that patients can benefit from new and better treatments. The Network provides skilled health professionals who can help researchers to set up and run clinical studies quickly and effectively to work with patients and the public to ensure their needs are at the centre of research activity

Northern Ireland providing reciprocal representation on the oversight group for the ROI seroprevalence survey.

Engage with Industry (Pillar 5)

- 3.31 An engagement framework has been established to support discussions with industry partners, with a view to capitalising on Northern Ireland's strong diagnostics and clinical innovation base. This framework will ensure support the creation of effective relationships with industry, locally and internationally, in order to mount an appropriate and effective response to challenges encountered in a very dynamic environment. This includes challenges such as those relating to changes in the virus and disease, changing testing strategies and pressure on supply chains. The framework will also ensure that emerging innovative diagnostics tests can be more rapidly identified, assessed and adopted, as appropriate in Northern Ireland. The framework is attached at **Annex 4**.

Testing to Support Population Surveillance

- 3.32 Robust and timely surveillance information is essential to understand the epidemiology of disease by time, person and place, to track the spread of the infection in the community, care homes, and hospitals, and to assess the impact on the population. Population surveillance helps to quantify the number of people who may have been infected, including people who were asymptomatic, infections that were asymptomatic and allows us to plan for future healthcare needs. It also allows us to look at risk factors for disease such as age, gender, location and underlying conditions. Repeating surveillance can provide information about the duration of immunity following COVID 19 infections.
- 3.33 The PHA Health Protection surveillance team, in collaboration with other partner organisations, has established a number of surveillance systems to monitor COVID-19 activity in Northern Ireland. These systems provide information on the intensity, geographic spread, impact on healthcare system and severity of COVID-19 disease. Testing is an integral part of each of these surveillance systems, tests undertaken as part of these programmes are processed through our HSC / SACT laboratories.

- 3.34 These surveillance systems also allow us to monitor trends, to design and target public health measures to reduce COVID-19 transmission, and to measure the impact of public health measures designed to interrupt and stop COVID-19 transmission in both hospital and community settings.
- 3.35 Three surveillance programmes are underway for COVID-19 in Northern Ireland:
- Sentinel Spotter practices in general practice and primary care COVID centres – people who have respiratory symptoms and are triaged to attend for clinical assessment are tested;
 - Emergency Department surveillance currently being piloted in the Royal Victoria Hospital (RVH) Emergency Department with a view to repeating this in other ED Departments in Northern Ireland – people who have respiratory symptoms, attend for clinical assessment and deemed not to require hospital admission are tested; and
 - Outbreaks in Care Homes – when two or more people (either staff or residents) in a care home have symptoms, all staff and residents in the care home are tested.
- 3.36 The focus for population surveillance will change in the coming weeks to take account of the changing pattern of COVID-19 disease as the pandemic unfolds with more emphasis on Care Home testing, Contact Tracing, Health and Care worker testing and responding to clusters of diseases.

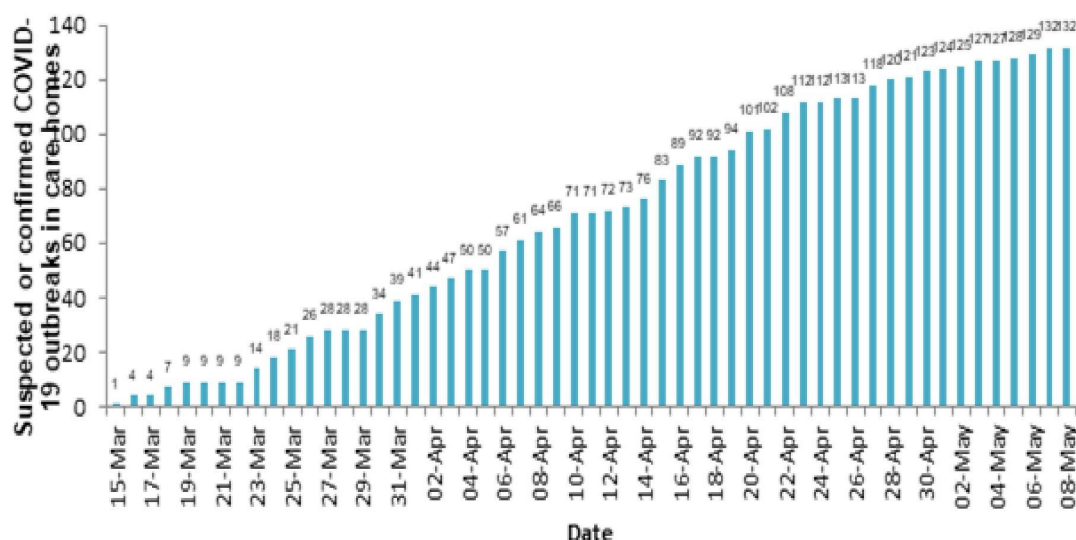
Testing to Support Care Homes

- 3.37 Testing in care home settings has always been a key priority in Northern Ireland since the beginning of this pandemic, and was a key focus of the first iteration of our Interim Protocol on testing Care home residents are amongst the most vulnerable people living in the community, and in Northern Ireland this impacts a significant proportion of the population with 16,000 beds and 40,000 staff in the sector across the province. Care Home outbreaks are associated with significant morbidity and mortality and early investigation has shown significant numbers of staff and patients who test positive for SARS-CoV-2 remain asymptomatic (over

one third in an early analysis of outbreak settings). Their infectiousness and role in transmission is unclear.

- 3.38 There is evidence that while overall community transmission of COVID-19 is reducing, the care sector is seeing a large number of cases and outbreaks. The number of new outbreaks in Northern Ireland since mid-March is shown in Figure 8.

Figure 8: Cumulative suspected or confirmed COVID-19 outbreaks reported to PHA per day



Source PHA

- 3.39 It is against this background that testing care homes has always been a critical part of our COVID-19 response.
- 3.40 We have continued to expand our testing in care homes (both residents and staff) as our testing capacity has increased and as the evidence and learning has emerged in relation to the SARS-CoV-2 virus and its behaviour.
- 3.41 The current testing approach in Northern Ireland is that all care home staff and their families, and all residents, will have access to testing if they have symptoms. All staff and residents are also tested in homes when two or more people - staff or residents - have symptoms, as this is a possible outbreak scenario. Testing is

underway for all residents and staff in homes where there have been previous outbreaks that have not been resolved. Additionally, all new admissions to care homes from hospital or community settings, including from supported living accommodation, should have their COVID-19 status checked 48 hours before admission to the care home.

3.42 We are working to continually extend our testing capacity, and the next phase of this ongoing expansion of care home testing will involve:

- Testing kits made available for use in homes through satellite operations from the three national testing sites currently operating in NI.
- Four Mobile testing units which will operate as part of the national testing programme and will be deployed to support this important programme in care homes. Capacity for each mobile testing unit will be in the region of 200 to 300 tests per day. The mobile units will be used to support the programme for cleaning (non-outbreak) care homes and in care homes where there are other clusters/outbreaks as required.
- Trust and PHA/HSCB teams supporting care homes, bolstered by the deployment of testing capability from the NI Ambulance Service and up to 40 nurses from the HSC system.
- Scheduled completion of testing of all residents by June 2020. Provisional figures – based on returns from circa 95% of care homes – indicate 3,762 residents have been tested to date. That's over 25% of the care home population.
- A rolling programme of testing for staff. Further details of staff testing provision will be confirmed in the near future.

3.43 The care home testing policy is kept under active review. One option being considered at a national level is that there should be regular **testing** of ALL residents and staff in care homes, regardless of whether they have symptoms or signs suggesting COVID-19 infection, with the aim of helping to keep these homes free of COVID-19. Widespread testing in care homes will allow early isolation and appropriate management of patients positive for COVID-19 to avoid onward transmission.

- 3.44 Care homes with no outbreaks are supported to ensure they maintain high infection control standards and practice social distancing and personal hygiene measures.

Testing to Support Supported Living Communities

- 3.45 From 11 May 2020, testing for COVID-19 has been extended into Supported Living Communities. All staff and residents will be tested where two or more people (staff or service users) meet the criteria to be a possible or confirmed case. Outbreaks occurring in such settings are to be reported to the Health Protection Team in the PHA. Trusts should support these settings with swab taking, interpretation of results and infection control measures.

Testing and Contact Tracing

- 3.46 Large-scale, integrated contact tracing and testing will play a key role in managing the rate of COVID-19 transmission, and maintaining R below 1 when social distancing measures are relaxed.
- 3.47 The Scientific Advisory Group for Emergencies (SAGE) has indicated that a successful contact tracing programme requires around 80% of contacts of symptomatic cases to be traced and isolated rapidly, ideally within two days of symptom onset for the index case. This requires between 3 and 30 contacts per symptomatic case to be identified and traced. A proportion of contacts will require testing, in particular those who have symptoms consistent with infection at the time they are identified as close contacts and those who go on to develop symptoms during their advised period of self-isolation.
- 3.48 The Northern Ireland contact tracing service, known as '*Test, Trace, Isolate, Support*' commenced on 18 May 2020. The service is located in the PHA and its design is informed by learning emerging from a prototype service run by the PHA during April. Further scaling up of the contact tracing service will continue during May and June 2020.
- 3.49 The '*Test, Trace, Isolate, Support*' Strategy (under development) is designed to break the chain of transmission of the SARS-CoV-2 virus by identifying people

with COVID-19, tracing people who may have become infected by being in close contact with them and supporting those people to self-isolate so that if they have the disease they are less likely to transmit it to others. This programme will be expanded in the coming weeks in preparation for a possible second wave of the pandemic.

- 3.50 Testing required for our '*Test, Trace, Isolate, Support*' programme will be undertaken through the HSC / SACT laboratory network (Pillar 1 testing) and also through the National Testing Programme (Pillar 2 testing), through fixed test centres, home delivery service, and satellite or mobile testing capability. In tandem with the other UK countries, Northern Ireland expanded eligibility for testing to symptomatic members of the public on 18 May 2020. Members of the public who have symptoms and who wish to book a test can access a bespoke digital portal, known as the 'Citizen's Portal', to make arrangements to be tested through the National Testing Programme. Their close contacts who are symptomatic will also be tested through similar arrangements.

Genomics

- 3.51 Genomics is the study of whole genomes of organisms and incorporates elements from genetics. It is an approach that involves scanning the genes from many different people and looking for genetic markers that may be used to predict the presence of a disease. The goal of a genomic study is to understand how genes contribute to a disease and to use that understanding to help develop preventative and treatment strategies.
- 3.52 The Belfast Hub (QUB and BHSCT) is part of the UK consortium (COG-UK) which will perform whole genome sequencing and will sequence samples from local confirmed cases of COVID-19 in Northern Ireland. The key aim of this UK consortium is to sequence the shifting genetics of COVID-19 in 'real-time' which will contribute to mapping its spread and detect mutations. Combined with clinical and epidemiological data and intelligence, this important scientific knowledge will help guide public health interventions and policies at a local and national level.

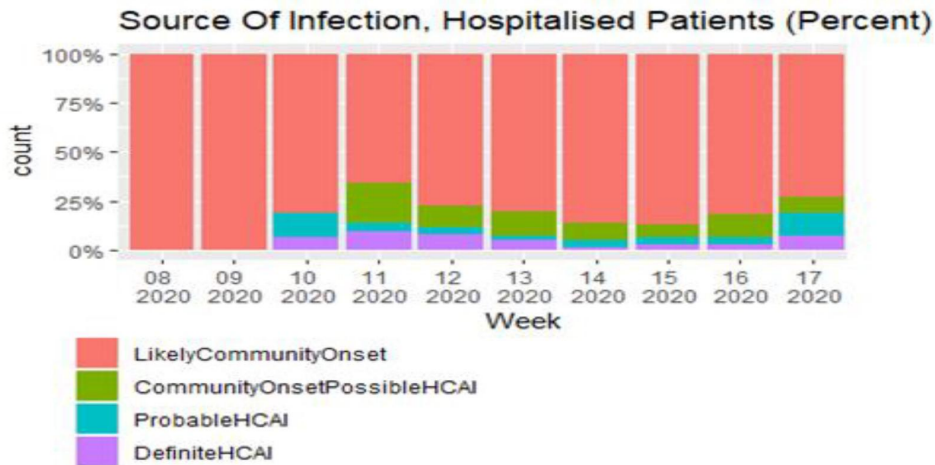
- 3.53 As of the end of April a total of 10,567 SARS-CoV-2 genomes have been sequenced nationally. In Northern Ireland, 120 genomes have been sequenced to date, with an additional 950 sent to Wellcome Trust Sanger Institute (WTSI) for sequencing since HSC laboratory testing began. As protocols become established there is an expectation to scale-up to work on over 190 genomes per week in Northern Ireland.
- 3.54 QUB is planning to undertake and expand the COVID-19 viral genome collection and viral genome analyses. UU (Northern Ireland Centre for Stratified Medicine/ C-TRIC /GMI) will coordinate the recruitment of the human host/patients from the COVID-19 positive individuals (with appropriate controls) and coordinate Single-Nucleotide Polymorphism, Genome Target, Whole Gene Sequencing and RNA-sequencing generation with Genome Medicine Ireland partners. A key objective will include the correlation of host genotype, viral genotype, phenotypic and other data with: (a) predisposition to COVID-19 infection, (b) severity, (c) treatment response if appropriate (drug/vaccine/intervention), and (d) disease epidemiology.

Data Linkage

- 3.55 Data linkage is a process which temporarily brings together two or more sets of administrative or survey data from different organisations to produce new information which can be used for research and statistical purposes. Linking health data sets improve understanding of immunity, co-morbidities, outbreaks and potential control strategies and can be undertaken using organisations like the Honest Broker Service, Biobank etc.
- 3.56 Data linkage work related to COVID-19 is currently being undertaken by the PHA where expert data analysts are joining information relating to the first positive COVID-19 laboratory test (from HSC laboratory systems) to the HSC Patient Administration System (PAS) records for all healthcare settings. This data linkage has facilitated an analysis of hospital admissions by age, gender, deprivation, local council area and the changing pattern of disease caused by COVID-19. This work is ongoing, however early findings of this analyses shows

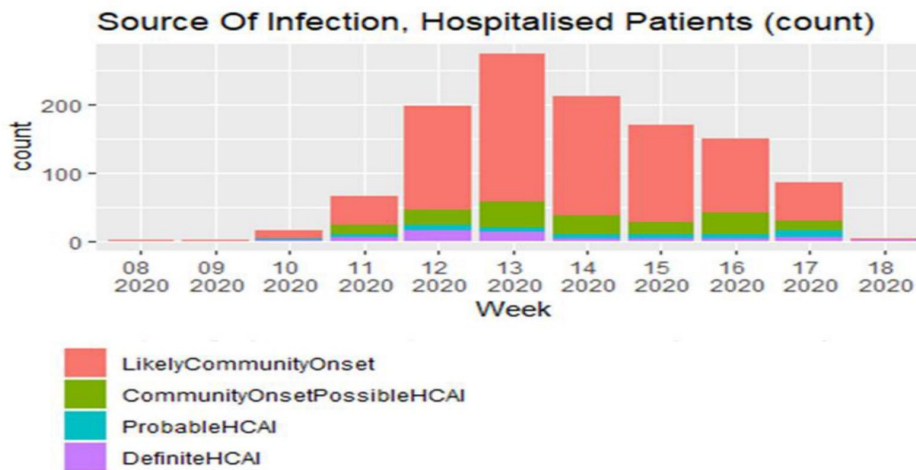
some evidence of an increase in healthcare acquired infection over time shown in Figures 9 and 10.

Figure 9: Healthcare Acquired Infection – Hospitalised Patients (%)



Source: Personal Communication from Declan Bradley PHA

Figure 10: Healthcare Acquired Infection – Hospitalised Patients (count)



Source: Personal communication from Declan Bradley PHA

Research Programmes

- 3.57 A number of research programmes are currently underway to examine several aspects of SARS-CoV-2 and testing for COVID-19 in Northern Ireland, these include:

1) Viral detection

SARS-CoV-2 detection using Loop-Mediated Isothermal Amplification (LAMP) is a single-tube technique for the amplification of DNA and a low-cost alternative to detect certain diseases.

COVID-19 Genomics Screen (COG-UK) which has sequenced over 120 viral genomes from people in Northern Ireland. A further 950 Northern Ireland samples are being sequenced at the WTSI (Cambridge).

2) Antibody detection

Assessment of new antibody kits and serological antibody kinetics. This would include the development of new antigen diagnostic tests with Fusion Antibodies. This may be through finger prick (dried blood spot), sampling and integrated digital devices for screening and point-of-care testing.

3) Host responses

Human genome/genetic analyses of SARS-CoV-2 positive patients to identify comorbid and other risk factors involved in disease predisposition and severity through investigation of host immune responses. Finger prick (dried blood spot) sampling as a possible compliment to antibody testing serological diagnostics and integrated digital devices for screening.

4) Epidemiology

Epidemiological studies of people in Northern Ireland are ongoing, and are supported by PCR and serological testing. Further information on PCR testing can be found at paragraph 3.8 and seroprevalence at paragraphs 3.25 to 3.30. A clinical study of COVID-19 antibody responses in children is underway in the Royal Belfast Hospital for Sick Children.

4. Communication

4.1 We will communicate the outputs of the EAGT to a wide range of stakeholders including but not limited to:

- Those eligible for testing including frontline staff, health and care workers and the general public;
- HSC organisations and other service delivery partners (for example in primary care, pharmacy and dental services, Trust and non-Trust based care settings);
- Media; and
- Other government agencies and Departments, including the Northern Ireland Executive.

4.2 We will use a range of communication channels to ensure that information is shared widely, appropriately and on a timely basis.

4.3 We will also continue to promote ongoing communication and collaboration at a national level to ensure that we are sighted on new test developments across the UK and in ROI.

4.4 Our strategic communications approach on testing continues to evolve and our programme of work will include the development of a Communications Strategy to support the continued roll-out of the Testing Strategy.

4.5 We experienced early challenges in scaling up our testing capacity, including the critical dependency of all testing capacity on the availability and supply of reagents used in the testing process. In view of this our communications approach will aim to strike the right balance to reassure the public (and particularly key workers) on our scale-up of testing and ongoing developments, but without overpromising.

Expert Advisory Group on Testing – Membership

Brid Farrell (Chair, Public Health Agency)

Lourda Geoghegan (Department of Health)

Gillian Armstrong (Department of Health)

Dan West (Department of Health)

NR (Department of Health)

Ian Young (Department of Health)

NR (Public Health Agency)

NR (Public Health Agency)

NR (Public Health Agency)

Brian Smyth (Retired Public Health Doctor)

Sarah Buckley (Pathology Network Manager)

NR (Belfast Health and Social Care Trust)

NR (Southern Health and Social Care Trust)

Stuart Elborn (Queens University, Belfast)

Myles O'Hagan (Business Services Organisation)

Eddie Ritson (Health and Social Care Board)

NR (Belfast Health and Social Care Trust)

NR (Belfast Health and Social Care Trust)

Karin Jackson (Northern Ireland Blood Transfusion Service)

NR (Department of Health)

Muhammad Sartaj (Public Health Agency)

NR (Public Health Agency)

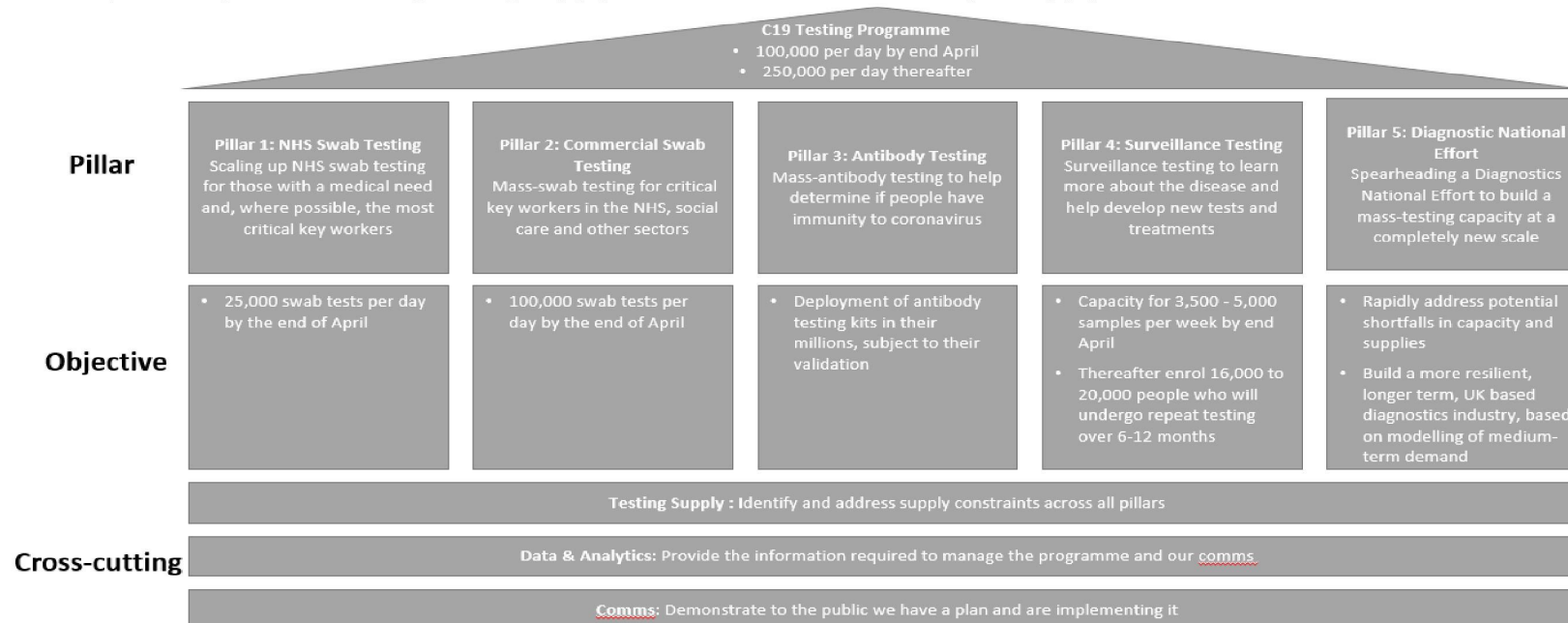
NR (Public Health Agency)

Key Stakeholders

- Department of Health
- Public Health Agency
- Northern Ireland Pathology Network
- Northern Ireland Blood Transfusion Service
- Health and Social Care Board
- Health and Social Care Trusts
- Queens University Belfast
- University of Ulster
- Agri-Food and Biosciences Institute
- ALMAC
- Business Services Organisation Procurement and Logistics Service
- Department of Health and Social Care, London
- Public Health England
- Department of Health and Social Services, Wales
- Department of Health, Republic of Ireland
- Industry and Commercial Partners
- Western Health & Social Care/ Clinical Translational Research and Innovation Centre
- United Kingdom Chief Medical Officers
- Oxford University
- Regulation, Quality and Improvement Authority (RQIA)

Department of Health and Social Care⁶**Covid-19 Testing Strategy**

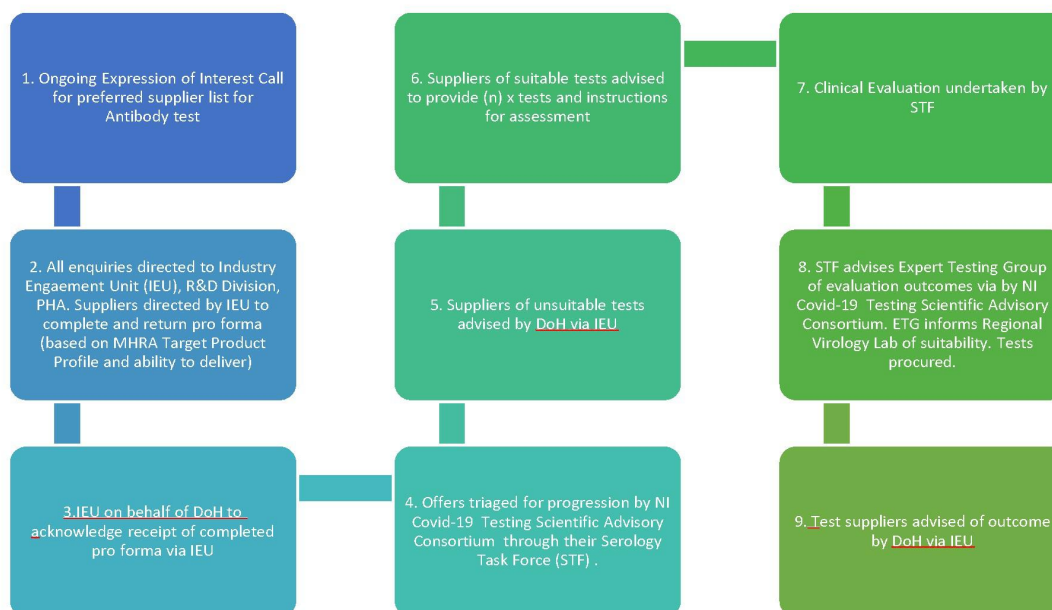
Our testing strategy outlined our ambition to deliver both the near term objective – 100,000 tests per day – and medium term objective – 250,000 tests per day – coordinated activity is being delivered across five key pillars, underpinned by a cross-cutting Testing Supply team focussed on continuity of supply.



⁶ Coronavirus (COVID-19) Scaling up our testing programmes

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878121/coronavirus-covid-19-testing-strategy.pdf

Engage with Industry (Pillar 5): Industry Engagement Framework



List of Abbreviations

AFBI	Agri-Food and Biosciences Institute
BHSCT	Belfast Health and Social Care Trust
BSO PaLS	Business Services Organisations Procurement and Logistics Service
CO	Cabinet Office
COVID-19	Coronavirus
DoH	Department of Health
HCW	Health and Care Worker
HSC	Health and Social Care
HSCT	Health and Social Care Trust
LAMP	Loop-Mediated Isothermal Amplification
NHS	National Health Service
NHSCT	Northern Health and Social Care Trust
NIBTS	Northern Ireland Blood Transfusion Service
NICR	Northern Ireland Electronic Care Record
NISRA	Northern Ireland Statistic & Research Agency
POC	Point of Care
PCR	Polymerase Chain Reaction
QUB	Queen's University Belfast
ROI	Republic of Ireland
RVH	Royal Victoria Hospital
RVL	Regional Virology Laboratory
SACT	Scientific Advisory Consortium on Testing
SAGE	Scientific Advisory Group for Emergencies
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus-2
SEHSCT	South Eastern Health and Social Care Trust
SHSCT	Southern Health and Social Care Trust
UK	United Kingdom
UU	Ulster University
WTSI	Wellcome Trust Sanger Institute
WHSC/C-TRIC	Western Health & Social Care Trust/ Clinical Translational Research and Innovation Centre