

## TESTING STRATEGY

**JULY 2020**

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## SECTION 1 – MINISTERIAL FOREWORD

As we emerge from lockdown and with the prevalence of Covid-19 reducing from the peak we saw just a few weeks ago we need to make preparations for what may lie ahead. With that in mind I am setting out our testing priorities for the next phase.

Testing is not a panacea it has to have a purpose and our job is to ensure it is used appropriately so that it does not introduce harm, such as through the generation of false positives or negatives. More needs to be done to communicate why, where and how people should or could be tested.

Early in the epidemic we defined, designed and delivered a population testing system from near enough a standing start. This is no longer the case. Whilst an incredible amount has been achieved from the grit, hard work and determination of many people in setting up our COVID-19 testing infrastructure more needs to be done in preparing ourselves for what might be a difficult winter.

We now have a national testing infrastructure that means anyone who needs a test can access one. In turn this enables us to deploy contact tracing to control the transmission of the disease as lockdown measures are eased. Test, Trace, Protect is fundamental to helping us find a way to live with the disease until a vaccine or treatment is available.

There are still areas where we know we need to improve and we are working to deliver an optimum pathway of 24 hours for test turnaround times. We also need to respond to new testing technologies and be ready to seize the opportunities that these offer.

So as we look ahead to the Winter there are four clear priorities:

- **Controlling and preventing transmission of the virus by supporting contact tracing** – to prevent and protect spread of the disease amongst the population and to trace the spread of coronavirus, understand transmission dynamics and to ensure that testing can support targeted action through local outbreaks in communities or within businesses.
- **Protecting Our NHS services** – to prevent, protect and deliver testing to support the safety of staff, patients and clients.
- **Protecting vulnerable groups and managing increased transmission rates** – to safeguard and control infection in groups, communities or settings where there are greater risks.

**Developing future delivery** – to utilise health surveillance and new technologies to improve our understanding of the virus through the use of intelligence and to innovate new ways to test across the population.

This strategy builds upon the latest evidence which has been submitted from our Technical Advisory Group and the work of SAGE and it's subgroups. However, we know that data and evidence is still evolving, where questions remain about the virus

and our individual immune response. The testing strategy will be iterative and continue to evolve as evidence emerges.

## **SECTION 2 - OVERVIEW AND PRIORITIES**

As we move forwards from the first wave of the COVID-19 epidemic, our approach to testing is evolving rapidly, both for viral detection and for testing the protective immune responses to it. This strategy sets out how testing will work alongside the easing of lock down measures to ensure that we can keep the number of daily cases low, but also sets out how we will continue to build capacity for the possibility of a second wave until an effective vaccine with long-term protective efficacy becomes available and widely used.

We must also be clear that testing is just a part of our overall approach to preventing the transmission of the disease across Wales. We all need to play a part to ensure that we follow government guidelines in areas such as social distancing and hand hygiene, in order to keep us all safe and reduce risk.

Testing is not something that is just done and counted. There should be clear outcomes attached to testing which are underpinned by strong clinical evidence in order to achieve the desired impact. Testing on its own does not remove or reduce the extent to which the virus is circulating in our communities, but helps us to trace the virus and gather health surveillance to respond effectively.

This strategy has been shaped and developed to consider the available evidence, to identify potential risk factors and to ensure that we can focus our capacity and resources to continue protecting public health. Our strategy has been developed with the seven principles set out by the Royal College of Pathologists very much in mind (see Annex). Testing for SARS-CoV-2 has a number of purposes, it can be used for:

- Identifying COVID-19 cases to support contact tracing and thereby the spread of disease;
- diagnosing COVID-19 to help with treatment and care;
- population health surveillance, so that we can understand the spread of the disease; and
- business continuity, enabling people to return to work or education safely.

### **Where we are now**

Our current testing approach has focussed on people in hospitals, care homes, and symptomatic critical workers. We now have a testing infrastructure that supports mass testing of symptomatic people across the population enabling our NHS Test, Trace, Protect service. We are asking people to report symptoms, testing anyone in the community who is showing symptoms of COVID-19. We are then tracing those they have come into close contact with to control the spread of the disease. We are also deploying testing rapidly to help manage outbreaks and clusters.

We currently have two different forms of testing in Wales.

- RT-PCR (virus detection) test, that detects the presence of viral RNA. The test is usually done using a nasal swab taken from the nose or back of the throat. This kind of testing can highlight if someone currently has the infection.
- Antibody test, that detects the antibody response to the SARS-CoV-2 virus, and is used primarily to determine whether a person has been previously infected. At the current time the use of tests are focused on the serosurveillance of defined target cohorts for the purpose of understanding the cumulative level of historical infection.

At the current time, **RT-PCR testing** remain the primary front line test for the diagnosis of infection with SARS-CoV-2 virus.

As agreed by the Technical Advisory Group, the principles for RT-PCR include:

- That clinically-led testing associated with the medical needs of an individual should have primacy over testing for other purposes.
- The utility of additional RT-PCR testing be considered in the wider context of other testing that is taking place, including the 'test, trace and protect' programme.
- The performance of the RT-PCR is at its best when its use is targeted, for example, when used to support diagnosis in symptomatic individuals. It is unsuited to the non-targeted screening of asymptomatic individuals, especially in populations with a low prevalence of infection. Use in asymptomatic individuals should, wherever possible, be on the basis of effective targeting, for example following tracing that has indicated a high-probability of exposure and thus likely infection.
- The purpose of testing (either 'single' or 'repeat') within defined target settings or cohorts should be clearly defined and agreed prior to the implementation of that testing.
- Criteria for the cessation of repeat testing within defined target setting or cohorts should be clearly defined and agreed prior to the implementation of that testing.

**Antibody testing** to SARS-CoV-2 antigens may assist in the identification of higher risk environments and support the implementation of risk mitigation measures in those settings. Examples would be settings or occupations associated with high contact rates. At the current time the use of tests for antibody should be focused on the serosurveillance of defined target cohorts for the purpose of understanding the cumulative level of historical infection in those cohorts and in some cohorts through repeat testing to help understand their risks going forward.

National priority areas for antibody testing include school staff, healthcare workers and the social care sector that are set out in the strategy. However, to help inform intelligence and the public health response through local plans, we will work with University Health Boards through a National Clinical Advisory Group to consider the potential for any wider application of antibody tests. This will include considering where there could be further public health gains in their usage, such as in high contact workplaces or amongst vulnerable groups.

#### **Four National Priority Areas for Testing in the current phase**

In preparing for the Winter we need to ensure that we can utilise our testing capacity better understand the disease at an individual and population level and continue to build and strengthen our response (e.g. contact tracing) and analytical functions (e.g. surveillance). We also need to be agile and flexible to respond to any changing circumstances, such as the emergence of flu, as we move towards the winter period. Our approach to testing in this phase is therefore focussed upon four key priority areas:

- 1. Controlling and preventing transmission of the virus by supporting contact tracing** – to prevent and protect spread of the disease amongst the population and to trace the spread of coronavirus, understand transmission dynamics and to ensure that testing can support targeted action through local outbreaks in communities or within businesses.
- 2. Protecting Our NHS Services** – to prevent, protect and deliver testing to support the safety of staff, patients and clients.
- 3. Wider uses of testing** – to safeguard and control infection in groups, communities or settings where there are greater risks.
- 4. Developing future delivery** – to utilise surveillance and new technologies to improve our understanding of the virus through the use of intelligence and to innovate new ways to test across the population.

To underpin this strategy we will work with Local Health Boards and partners to develop Local Delivery Plans which set out clear deliverables, timeframes and current and future planning arrangements. This will take into account a rapid review through the Academy of Medical Sciences about how health and social care services can prepare for Winter pressures.

### **SECTION 3 – PROTECTING AGAINST THE TRANSMISSION OF THE VIRUS BY SUPPORTING CONTACT TRACING**

Reducing the onward transmission of the virus requires that we know who is infected and in turn requires those individuals and their close contacts to self-isolate to break the chain of transmission. In the main we have used symptoms as the gateway to testing and we will continue to do so. Since 18th May, anyone in Wales with symptoms of COVID-19 can be tested. Delivery of our Test, Trace and Protect strategy is helping to break the chains of transmission of the virus. This approach requires high levels of public understanding – of the symptoms, of the need to seek a test, of the process by which they can take a test. In turn testing must be quickly and easily accessible.

Not everyone with the virus will display symptoms, and not all those with symptoms come forward for testing. To ensure that we can effectively control any new transmissions, we wish to encourage the maximum take up of testing, including among those who are experiencing mild symptoms. We expect to see an increase in testing during the autumn and winter, as seasonal illnesses are evident, such as respiratory infections, which are consistent with symptoms of COVID-19.

When outbreaks or incidents emerge we need to be able to rapidly deploy testing capacity with fast turnaround of results to help in the analysis of the outbreak. This will help to determine what steps may be needed to control the outbreak or limit the possibility that a cluster or incident develops. Local Health Boards (LHB) have a critical role to play in population testing and managing the risk of transmission. Each LHB will need to develop a Local Testing Plan reflecting the national priorities and actions set out in this strategy.

### **3.1 Sampling Capacity and Accessibility**

We need everyone with symptoms to come forward for a test and be able to access one ideally on the same day. As we move into the Autumn this will require an expansion in the range and reach of our national testing infrastructure.

At present we have:

- Mass Testing Centres (MTCs) – 8 across Wales in Newport, Ebbw Vale, Cardiff, Abercynon, Swansea, Carmarthen, Llandudno and Deeside.
- Community Testing Units (CTUs) – 19 across Wales in a variety of settings.
- Mobile Testing Units (MTUs) – 18 units across Wales with 12 across Local Health Boards and 6 for rapid response.
- Home Testing Kits (HTKs) – including access to a dedicated portal for care homes.

We want to build a resilient, flexible and sustainable delivery model which will be responsive to current and future needs. Contact tracing combined with the other testing purposes could potentially require us to need as many as 20,000 tests a day. From this total the contact tracing demand is estimated at 4,500 - 11,000 per day.

Estimating the need for testing is affected by a number of variables, the spread of the disease, the incidence of new cases and transmission rates in the community, the prevalence of symptoms and the emerging evidence on how testing can best be deployed to prevent infection. We will continue to review new scientific advice, our modelling and international experience and we will keep this evidence under review and adapt our estimates of need accordingly.

We currently have sampling capacity that more than meets our current requirement, with our Welsh laboratories holding capacity for over 15,000 per day and we also have access to wider UK capacity, which is being used for population testing, testing in care homes and for key workers. Welsh capacity is being used to respond to clinical need and outbreak management. We are not using all of this capacity, reflecting the low prevalence of the disease at present. But it is vital that we maintain the capacity to respond to spikes in testing need arising from outbreaks. However, we know that the end to end process and the effective staffing and resources will require contingency plans with partners to meet any spike in demand.

We want to ensure that testing is regularly and frequently available across Wales and we will work with Local Health Boards, local authorities and Third Sector partners to develop effective outreach with communities across Wales. This includes

a targeted focus within areas of higher deprivation, within our more rural or isolated communities and with protected characteristic groups.

To meet these needs we will:

- Work with UK Government to bring a new Lighthouse Laboratory to Wales.
- Continue to review our modelling and keep this evidence under review and adapt our estimates of need accordingly to support an effective response.
- Publish a dashboard of daily data that will inform capacity and needs levels.
- Scale the number of tests that are available to book across the population and ensure that people who are symptomatic can quickly and easily gain access to testing.
- Work with Local Health Boards to ensure that access and outreach are delivered through the use of mobile and community units within towns and communities across Wales through pop up provision.
- Explore community based provision through local sites and utilise access to home testing kits in community settings which can provide rapid results.
- Put in place local testing plans across all Local Health Boards in order to identify contingency planning ahead of the winter.
- Launch a major communications push on seeking a test when symptomatic to help people understand why, how and when they should access tests and what the results means for their contacts, friends or families.
- In support of this undertake targeted communications and outreach with Local Health Boards, with a focus on local demographics and with protected characteristic groups.
- Build our understanding of public attitudes towards testing, and using help to identify areas that can be supported or strengthened with regard to our public health response and risk communication, such as helping people in higher risk groups or settings.

### **3.3 Planning for and Managing Outbreaks**

In the event of outbreaks (as defined in the Wales Outbreak Control Plan 2020), which may include within local communities or within a closed setting such as a care home, school or workplace, we will ensure that our testing programme is able to effectively respond. This will help to identify measures to isolate people with positive results and minimise the spread of the disease.

Analysis of results linked to outbreaks can give us an insight into the nature of the outbreak and therefore give us a clearer indication of how to respond

To achieve this we will:

- Work with partners to maintain flexible capacity to respond rapidly to any outbreak, or changes in prevalence.  
Support local outbreak response and management through use of genomic data.
- Provide access to testing for asymptomatic people where there are signs of local incidents and outbreaks, where deemed necessary by specialist health protection teams in the community or microbiology and infection prevention and control teams in an inpatient setting.

- Utilise genomics to support testing and continue to use real-time rapid turnaround and close-to real-time sequencing to support national and local outbreak responses.
- Provide our Local Health Boards with access to five Mobile Testing Units which will act as a rapid response and be directed to support effective controls and tracing.
- Access a national reserve of rapid response vehicles across the UK in a case of a larger and more sustained outbreak.
- All LHBs will need to have mobilisation plans that enable them to deploy testing capacity at pace in response to possible outbreaks.

### **3.4 Rapid Turnaround Times**

The testing process involves five critical components: communications (people aware about how to access support); requesting (book to sampling); sampling (including logistics through to laboratories); testing (including laboratory capacity and turnaround times); and results reporting. There are a number of partners involved and each plays a critical role to deliver timely results to enable a rapid and responsive tracing system.

Testing at scale with rapid turnaround enables action to be taken by individuals and organisations to minimise the risk of spread of the virus. Rapid testing is also crucial for both our economy and businesses, in order to get individuals with symptoms but who do not have COVID-19 back into employment and to identify where there is the potential to spot any emergent trends or potential outbreaks.

We will:

- Review and optimise the end-to-end process, with a focus on requesting, sampling and reporting.
- Work with partners to ensure that we achieve rapid turnaround times within 24 hours from test to processing.

### **3.5 Education Settings**

Once education settings (including early years, schools and higher/ further education) open from September onwards it will be vital to ensure that there is flexibility in the testing regime to respond to any potential increased transmission rates. Each setting will be developing relevant guidance and the testing approach will underpin part of an approach to protect both pupils and staff in these settings.

We will:

- Provide each education setting with a supply of home testing kits and a positive result will require those in contact with the individual to self-isolate at home.
- In the event of a Covid-19 outbreak a mobile testing unit will be sent to test a class, year group or entire setting, as necessary.

- Where there are two or more confirmed cases in a two-week period, consider further measures, including for larger number of pupils and staff may have to self-isolate at home.
- For surveillance use antibody tests with a sample of school staff tested in the first phase during June and July and target some new school staff.

## **SECTION 4 – PROTECTING OUR NHS SERVICES**

The challenge facing the NHS as it begins the second phase of its response to the outbreak is to maintain the capacity to provide high quality services for patients with COVID-19, whilst increasing other urgent clinical services and important routine diagnostics and planned surgery. A key objective is to minimise the transmission of COVID-19 infection within hospitals and within other healthcare settings and connecting services, including ambulance, primary and community care.

We are working with LHBs to agree a whole system testing approach for Wales and we will continue to review our testing policy for health and care settings as the evidence evolves. We will support Local Health Boards through our NHS Planning Framework to mobilise testing for both staff and patients. In line with the Technical Advisory Group advice, when the prevalence of the disease is low, as it is now, care needs to be taken in using RT\_PCR tests as a screening tool. Low prevalence of the disease is likely to generate a higher rate of false positives and false negatives. This has implications for the use of tests as a screening tool for staff and patients alike, including:

- For critical worker screening, this may lead to significant unnecessary exclusion from work which has to be balanced against the risk to patients of transmission particularly where they are vulnerable and at risk of more severe illness.
- In the context of pre-surgical screening, this may lead to significant unnecessary postponement of surgery.

However, the balance of risks needs to be considered carefully, where testing can also provide reassurance and support positive wellbeing for healthcare patients and staff. This is a vital consideration as we plan for the effective use of both RT\_PCR and antibody tests within settings.

### **4.1 NHS Services**

#### Patients

We want our NHS services to be accessible and open to all, which will require us to build in safeguards through testing to minimise the risk for patients.

We will:

- **Emergency Admissions:** all patients will be tested on admission. For patients who test negative, further testing will be undertaken if COVID-19 symptoms are present or develop.

- Elective Admissions: when prevalence in the community is high there is merit in providing testing for elective admissions (including day surgery), where patients will be required to self-isolate and pre-admission testing undertaken (conducted a maximum of 72 hours in advance), this will take into account the type of procedure or treatment to be undertaken.
- Outpatients / diagnostic interventions: utilise testing and isolation which will be determined, based on patient and procedural risk. When using the test to inform discharge for individuals whose symptoms of COVID-19 have improved, then a negative RT\_PCR, taken 14 days after onset and/ or a detectable antibody level is consistent with an absence of infectivity.
- Discharge: all patients being discharged to a care home or a hospice will continue to be tested prior to discharge to ensure that they do not transmit the virus into closed settings.

### Staff

We will continue to protect and maintain a safe working environment for our NHS staff. Testing also provides an important opportunity to support positive wellbeing and confidence within the workforce.

We will:

- Asymptomatic: additional available NHS testing capacity will be used to routinely and strategically test asymptomatic frontline staff as part of infection prevention and control measures.
- For surveillance, to use antibody tests with healthcare staff to help understand the spread of the disease within healthcare settings.

## **4.2 Health and Care Staff in the Community**

There are a number of health and care professions working with potentially vulnerable people within community services, who are going into people's homes. These include domiciliary carers, social care workers, midwives, district nurses or GPs, substance misuse and mental health services in the community who are potentially increasing the risk of being asymptomatic carriers. To ensure that we can build in appropriate safeguards we will

- Work with local health boards and local authorities to utilise antibody testing for health and care staff who are accessing people's homes who are shielding or are attending closed settings, such as care homes, substance misuse and mental health services, shelters or schools.
- We will roll out a pilot within a primary care Cluster with GPs, Dental Surgeries and Pharmacies to consider the application of asymptomatic RT-PCR testing within community settings.
- Utilise findings in the initial phase to consider a future testing approach.

## **SECTION 5 – PROTECTING VULNERABLE GROUPS AND MANAGING INCREASED TRANSMISSION RATES**

RT-PCR tests are not designed to be a screening tool. As already stated when the prevalence of the disease is low there is an increased rate of false positives and false negatives. However there are cases when testing asymptotically may be the right approach. For example testing in the context of an outbreak or incident may be used asymptotically to help in analysing the spread of the virus and determining actions needed to limit spread further. More generally the case for asymptomatic testing rests on a risk assessment of the presenting situation.

Asymptomatic testing will have greater value where there is clear and certain gain – where individuals would expose high risk contacts either through work or home. These high risk contacts could be those with comorbidities, the elderly or where there is a closed community with a high likelihood of rapid transmission or where the use of Personal Protective Equipment (PPE) is difficult.

Implementing a blanket approach to asymptomatic testing will therefore not lead to the required outcomes and we will be looking to target testing where our health surveillance highlights increased risk.

### **5.1 Care Homes**

People living in care homes and other similar residential settings are amongst the most vulnerable, with many relying on close personal care. Since 15 June we have been testing all staff on a weekly basis, which is highlighting that prevalence rates are low. There are risks to consider in relation to false positives which could potentially impact on future testing results. Therefore we will actively monitor any risks.

We will:

- Test all care home staff on a weekly cycle and provide continued access to a dedicated care home portal.
- Target where there are any new cases and act immediately, which would include deploying our mobile testing units to test all residents in care homes in cases where a positive test is found.
- For surveillance use antibody tests with a sample of social care staff.

### **5.2 Local Approaches to Asymptomatic Testing**

The safety and protection of the most vulnerable people in our communities is at the heart of the Welsh Government response to the pandemic. Testing helps us to define risk, provide reassurance and to ensure that we are effectively controlling any potential outbreaks when used at the right time. We want to support LHBs and their partners to develop an approach which will identify how they can utilise asymptomatic testing to safeguard and protect local populations. For example there is likely to be increased risks for tourism during the summer months which may increase risk rates.

Asymptomatic testing decisions have to consider the impact of false positive tests. We will therefore take a dual approach:

- As outlined Section 3 to manage when local outbreaks have been confirmed, the use of asymptomatic testing will be made available.
- When we see an increase in transmission rates at a localised level through the use of surveillance, then a case would be developed to consider the use of asymptomatic testing.

Through testing plans and intelligence each LHB will identify how this flexibility can be met, but the following two areas should be considered for decision making for vulnerable groups and settings:

- High Contact Workplaces – there are certain workforce settings that hold greater risk to the virus spreading, particularly within some occupations which involve working very closely with others (within arm's length and often touching) and risk exposure to disease on a daily basis. There are also risks for BAME and older workforces and Office of National Statistics analysis identifies high risk professions.
- Vulnerable Groups – these settings which may hold many vulnerable people are inherently high risk and the easing of restrictions in the community will increase the risk of new incursions of the disease through residents and staff. This could include residents within shared accommodation and community based services in high risk settings. For example supported housing, homelessness hostels, prisons, refuge accommodation (including Drug and Alcohol Centres), Immigration Centres, Mental Health Secure Units and Learning Disability Shared Accommodation.

In the situation where there are emergent patterns and increased transmission rates across Wales, which may be in relation to specific settings or population groups, we will work through an established Clinical Advisory Group to enable a national approach and enable decision making. This will consider use of both antibody and RT-PCR testing in situations.

In the incidence that private testing is requested which is outside of the scope for asymptomatic testing on a local level. It will be for the individual or the business to assure themselves that the test they are using is effective and is validated and proven. Advice can be received from Public Health Wales. People who are symptomatic should always apply for a test through NHS provision.

We will:

- Work with LHBs and partners to develop local testing plans, taking account of risks within their areas and plan for asymptomatic testing where there is evidence that it would be of benefit.
- Work with the National Clinical Advisory Group to utilise surveillance and intelligence to consider the use of any future asymptomatic testing.

- Utilise genomics data to examine transmission in key groups and settings, look for the presence of mutations that could affect diagnostic tests which will help to inform local modelling.

## **SECTION 6 – DEVELOPING FUTURE DELIVERY**

We will continue to strengthen and develop our testing approach to ensure that this is sustainable in the future, that we plan for future peaks, so that it can be flexible and responsive to local needs and to ensure that we can adapt to emergent evidence and the development of new technologies. This will require strong partnership working in order to adapt to these challenges and strong governance to ensure that we collectively respond as a system across Wales.

Moving forward will require us to utilise the data collectively to identify trends and to respond quickly to emergent trends. We will utilise our data to improve our understanding of the virus and how this impacts upon the future delivery of testing approaches across Wales as we move towards the autumn and winter period.

### **6.1 Health Surveillance**

Health Surveillance collects a constant set of data on a defined population, and is used to answer questions and problems arising in the area of health under surveillance. Specific uses of the health intelligence gained will help us to estimate disease prevalence over time, detection of clusters and information for planning health services.

An antibody testing programme will provide important information on the prevalence of COVID-19 in different work groups and help us to better understand how the disease spreads. This will work alongside RT-PCR testing which confirms whether or not someone currently has the virus. We are commencing antibody testing for Covid-19 in Wales and using a range of sero-surveillance studies to better inform our understanding of the virus which will help to build an evidence base for us to develop a testing programme.

We will:

- Present findings from tests for school staff who have supported vulnerable children and children of key workers in hubs across Wales.
- Continue to roll out anti-body findings undertaken with healthcare workers and analyse findings and to develop testing through the social care sectors, including care homes.
- Take part in the SIREN study, led by Public Health England which is a prospective longitudinal study over 2 years, which will determine if prior infection in health care workers confers future immunity to re-infection.
- Participate in a cross UK study with ONS to find out how many people have the infection and how many are likely to have had the infection, even if they have not realised it at the time.
- Combine anonymised information on COVID-19 and other anonymous information about our population to provide us with a much greater depth of knowledge, enabling us to respond more effectively.

- We will also work with PHW to undertake a range of sero-surveillance studies including:
  - Using residual blood samples from Welsh Blood Service, to monitor age-specific sero-prevalence in donors over time;
  - In healthcare workers, using a selected sample cohort as a sentinel to monitor extent, trends and local variation across teams;
  - In women attending maternity services, to monitor sero-prevalence and sero-incidence in this specific group; and
  - Linked to the GP sentinel surveillance system utilise our SAIL system to bring together a variety of sources together.

Over the last 4 years Wales has invested considerably in the development of Pathogen Genomics capacity through the Genomics Partnership Wales and the Genomics for Precision Medicine strategy. Based on the evidence generated and its wider value, going forward the genomics work will support Test, Trace and Protect in order to use rapid turnaround sequencing to gather intelligence regarding local trends to:

- Provide surveillance/situational reports on the number of clusters of cases and their disease trajectories
- Provide analysis summaries for use as indicators by Welsh Government
- Identify imports from the UK and abroad
- Provide a system to place cases that cannot be linked to other known cases/contacts into known genomic clusters of cases
- Provide analyses to exclude the presence of a case in a cluster (e.g. where an individual is linked to 2 clusters of cases by epidemiological information)
- Pilot the use of phylodynamic models to estimate R and the number of cases from genomic data in real time.
- Track and interpret viral mutations observed in the population.
- Identify possible new introductions of virus into Wales and utilise Retrospective sequencing to examine outbreaks and other relevant questions relating to COVID-19 in Wales in the first half of 2020 to support future preparations and planning.
- Generate further population data that can be integrated with other population-health data held in SAIL to enable population-health analyses that integrates viral pathogen sequence data.
- Utilise retrospective/slower turnaround sequencing to support analysis of the first wave, in order to provide information to support future planning (e.g. by providing parameters for epidemiological modelling).
- Ensure that Wales will continue to play its part in the use of genomics for pandemic response at a UK-level, as part of the COVID-19 Genomics UK consortium..

## 6.2 New Technologies

We are working across UK to consider and assess innovative testing technologies with the potential to increase testing capability and turnaround times. New technologies are likely to be needed to provide for new use cases and to overcome supply constraints such as swabs and reagents. These include:

- Lateral Flow testing for serology to be used to increase the intensity of serosurveillance in target cohorts and settings.
- Improve available RT-PCR tests to enhance performance for the off-CE-marked uses (asymptomatic and infectivity testing) and explore use of multiplex tests for rapid results.
- Saliva based testing could make diagnostic testing more accessible (overcomes potential swab supply constraints).
- Utilising end-point PCR technology to achieve high test volumes in a short space of time, we are validating the uses to confirm it is effective and appropriate for COVID-19 testing.
- LAMP is a technique that can be used both inside labs and in settings, these tests can be run on open-source machines, generic plate readers or smaller, specialist devices. LAMP is a technique that can be used both inside labs and in PoC settings (e.g. care homes, airports, A&E triage). The validation has been tested and we will work across UK to consider pilots and the potential roll out for practical use.
- Consider use of syndromic testing as we enter the winter respiratory viral season and consider how this will be targeted towards cohorts in the population.
- Utilise testing of wastewater to provide early warning of upticks in cases at a local level, with the potential use of metagenomics to match the virus in wastewater samples to sequenced isolates collected as part of the genomics work being undertaken from patient samples.
- Work with Health Technology Wales to provide rapid evidence summaries and research programmes on emerging evidence for testing.
- Develop testing linked to the Zoe app, which is the COVID-19 Symptom Tracker.

## **SECTION 7 – NEXT STEPS**

This strategy will have significant implications for Local Health Boards and their partners in order to plan and operationalise how this is delivered through Local Delivery Plans. This will be carefully managed and we will underpin the delivery with a clear and accountable governance structure and provide access to expertise from a national perspective.

There is already effective joint working and practice being shared across partners. We will continue to ensure that this intelligence is shared and deliver a team Wales approach to ensure that we can optimise capacity and reduce complexity in the system.

This strategy will need to be regularly updated and reviewed and this will help to provide a roadmap for the next phase up until September 2020. We will provide bi-weekly updates on progress and review how delivery is being managed and taken forward during this time.

### **7.1 Roles and Responsibilities**

To deliver this strategy there are a number of key roles and responsibilities which align with our Test, Trace and Protect Strategy:

Individuals – following public health advice, hand washing, social distancing, reporting symptoms and self-isolating when necessary.

Welsh Government – provide strategic direction, oversight, determine priorities and provide resources to enable testing.

Public Health Wales (PHW) – our expert National Public Health body providing leadership and specialist advice on public health approaches. Responsible for coordinating contact tracing, advising on sampling and testing, laboratory analysis of tests, health surveillance and providing expert health protection advice and analysis of the spread of the virus in our communities through a range of health surveillance indicators.

Local health boards and local authorities – providing a strategic overview and delivery for local decisions and testing capacity. Provide testing facilities to support Test, Trace, Protect and environmental and public health responses to local outbreaks and clusters or preventative action in areas regarded as high risk. Developing Local Testing Plans with partners to help deliver the Testing Strategy and to actively engage and communicate with local populations.

Industry, Health Technology Wales, Life Science Hub, Universities, Office of National Statistics – to develop surveillance, data and new technologies to strengthen our testing approach based on the latest evidence and science.

UK Government and other Devolved Nations – to develop joint ways of working and to effectively share practice and evidence.

## Annex

### **Seven Core Principles of Testing**

The following seven principles underpin any form of diagnostic assessment and must be applied to a national testing strategy.

1. The test is the right one, at the right time, and with the correct result. This result includes the appropriate clinical interpretation and, where not specifically designed and validated for home use, a test carried out by skilled trained laboratory professionals to recognised and accredited quality and service standards.
2. Testing must be carried out for a purpose: for diagnosis, for screening or for gathering data to understand the spread, or level, of disease in a population. Any testing programme must be clear as to its purpose, and the tests chosen appropriate for that purpose.
3. Problems in testing result in problems with care. With an infectious disease, this can have significant impact on disease spread, risk assessment, morbidity, mortality and population health. These problems arise from a range of issues including poor specimen taking, poor labelling or poor transcription of details, slow turnaround of results, poor quality control, ineffective communication of the result, inappropriate application of the result, and lack of clinical input or oversight. Many of these issues have been seen in recent times, all of which must be urgently addressed.
4. Data connectivity is a cornerstone of testing. It is a key aspect of improving quality, and great strides have been made in this area through the rapid connection of labs via NPex across much of the UK. Consistent test coding will aid this, and should be rolled out at speed. Links that connect primary and secondary care and public health bodies should be strengthened to ensure all results are available to clinicians when required, form a part of individuals' permanent health records and can be used, in an appropriate and legal framework, for public health purposes.
5. Testing standards must be upheld. Testing will be carried out in many settings, but must be carried out as part of a quality assured system, meeting accredited standards in regulated or approved settings. Accredited standards will apply to both laboratory and point-of-care testing. Different technologies will be used, depending on the clinical setting, clinical pathways and public health need.
6. People being tested should be informed about why they are being tested, and the implications and limitations of their results. They should have access to those results. Individuals should be informed if their data becomes part of a research programme and of their rights to be excluded if they so wish, within the context of public health needs.
7. At societal level, the more people who understand about the testing being performed, the more informed their consent will be. Information needs to be in plain language and accessible to all in a range of formats. National and international awareness is raised by media, professional bodies and programmes such as Lab Tests Online, but broader education, including in schools, has a role also. It is

important that sampling is not mistaken for testing – the language used must be accurate to give the public confidence in test results.