



HM Government

# Webinar: Update on Innovation in Testing and Pillars 3&4 of the National Testing Strategy



# Our National Effort for Diagnostics

Lord Bethell of Romford

Parliamentary Under Secretary of State, Department of Health and Social Care

# Today's Agenda

<b>13:10- 13:25</b> <b>Strategic Update and Forward Look</b>	Update on Pillar 3 – Tim Brown, Director, COVID-19 Response: Antibody Testing  Update on Pillar 4 – John Hatwell, Director, COVID-19 Response; Paul Elliott, Chair in Epidemiology and Public Health Medicine at Imperial College London  Q&A
<b>13:25-13:45</b> <b>Triage and Evaluation System</b>	Triage and Evaluation System- Dan Bamford, Deputy Director COVID-19 Testing Programme (New Tests)  Q&A
<b>13:45-14:15</b> <b>Diagnostics Innovation Team</b>	Diagnostics Innovation Team – Piers Ricketts, SRO Diagnostics Innovations Team; Anna Dijkstra, COVID-19 Testing Supply  Q&A
<b>14:15-14:25</b> <b>New Crowdsourcing Challenges</b>	Update on Point of Care Tests – Lindsey Hughes, Deputy Director and Lead for COVID-19 Testing Supplies Novel Solutions Team  Latest challenge/s and update on the previous challenges – Doris Ann Williams, CEO BIVDA
<b>14:25-14:30</b> <b>Close</b>	Doris-Ann Williams, Chief Executive of BIVDA



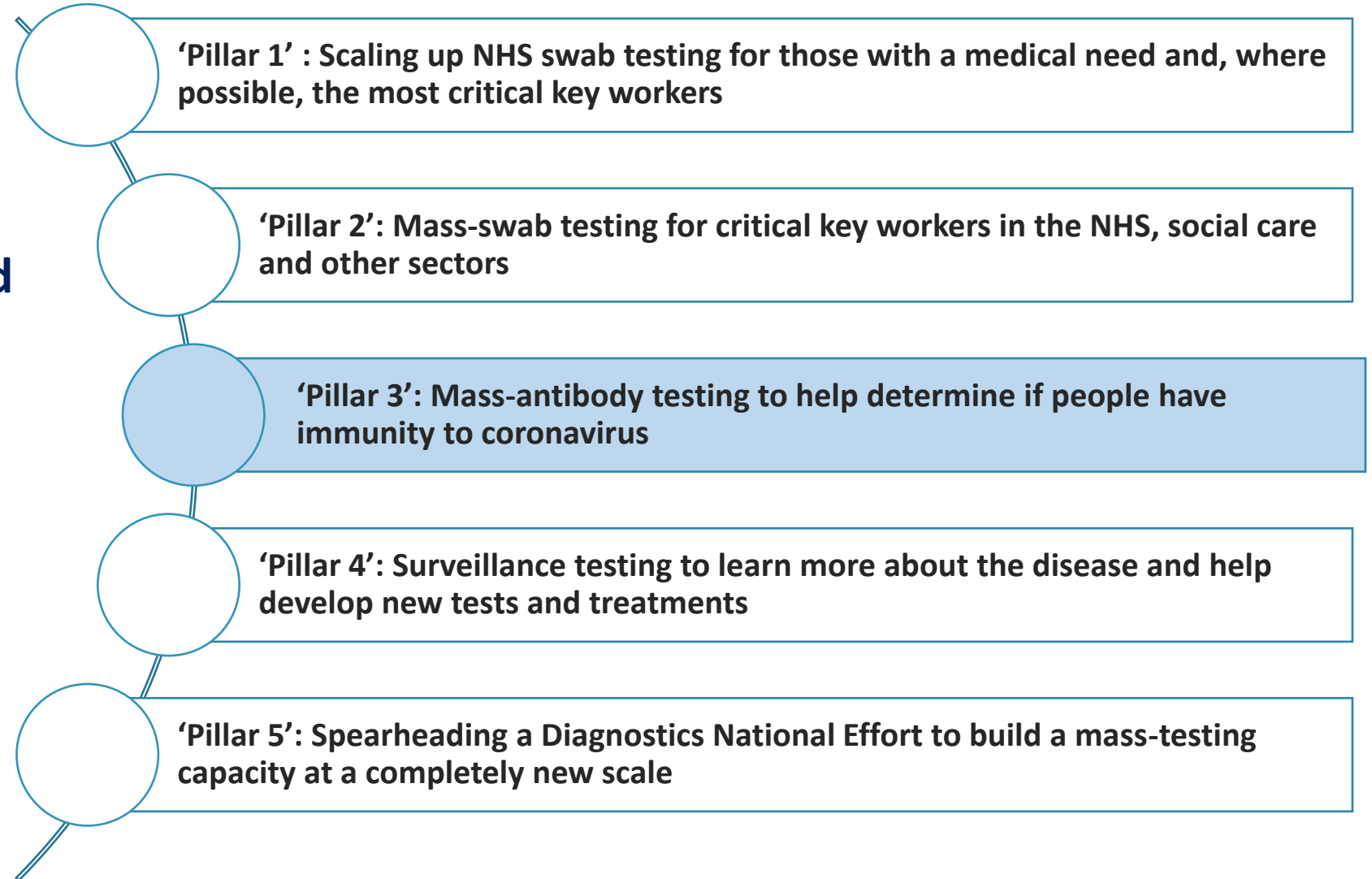
# Update on Pillar 3

Tim Brown, Director, COVID-19 Response: Antibody Testing



# Our National Testing Strategy

**The strategy was announced by the Secretary of State on 2<sup>nd</sup> April and has 5 key strands**



### Pillar 3 approach to antibody test devices

- The Government is currently pursuing two main types of antibody test device:
  - Lab-based tests (ELISA or other immunoassay) for use within NHS and other laboratories.
  - Self-use finger-prick tests (lateral-flow tests) for use within a home or community setting.
- MHRA has published [target product profiles](#) online outlining the specifications we require for different products types.
- We have been scanning the market for available solutions which meet our specifications, and want to hear from industry about testing options. We have signed contracts with several assay providers and are in negotiations with other suppliers.
- We are also backing efforts to develop a homegrown test. A business consortium, UK Rapid Test Consortium (UK-RTC), including Oxford University, Abingdon Health, BBI Solutions and CIGA Healthcare has launched, in order to design and develop a new lateral flow test.

### Deployment to date

- [The Health Secretary announced](#) in May that the Government would roll out lab based testing for NHS and care staff, as well as patients and care residents based on clinical advice.
- Testing using existing NHS pathology lab infrastructure is up and running with an initial [capacity of 40,000 tests a day](#).
- For care staff, antibody testing will be rolled out in a phased way across regions in England. We are working with local leaders in Greater Manchester to design the initial rollout and we expect to start testing soon. We will then develop plans with local leaders to implement testing in the rest of England, based on local needs and their ability to combine this with swab testing.
- Public messaging on what having a positive antibody test means is clear – don't assume any level of immunity and continue to follow government advice on social distancing.



# Update on Pillar 4

John Hatwell, Director, COVID-19 Response

Paul Elliott, Chair in Epidemiology and Public Health Medicine at Imperial College London

# Pillar 4: Surveillance testing

## Purpose

**Robust population surveillance programmes help us understand:**

- **Rate of COVID-19 infections**
- **How the virus is spreading across the country.**

They help us to assess:

- Assess the impact of measures taken to contain the virus
- Inform current and future actions, and
- Develop and assess the effectiveness of new tests and treatments.

## Progress

- Since February we have launched multiple surveillance studies to aid our understanding of the prevalence of the COVID-19 virus and its spread:
  - PHE serological testing survey
  - ONS COVID-19 Infection survey
  - REACT-1 and REACT-2 with Ipsos MORI and Imperial College
  - UK Biobank seroprevalence survey
  - Care home surveys
  - Schools infection survey
- In addition to the surveillance the REACT project also aims to test **user acceptance, usability, consistency and accuracy of lateral flow tests (LFT) used at home**



# REACT projects (SARS-CoV-2 antigen & antibody)

## REal-time Assessment of Community Transmission (REACT)

- **REACT-1**
  - Antigen testing
- **REACT-2**
  - Antibody testing

### Study 1

Usability, acceptability and performance of LFTs self-testing in **health service workers**

### Study 2

Usability, acceptability and performance of LFTs self-testing in **public volunteers**

### Study 3

Usability, acceptability and performance of LFTs self-testing in the **community**

### Study 4

Usability and validity of LFT self-testing in **key workers (mainly police personnel)**  
Plus seroprevalence and antigen testing

### Study 5

Nationally representative sero-prevalence study using self-administered LFTs

LFT – Lateral flow test

# REACT-1 Study

- Baseline prevalence of current infection **during May**
- Viral RNA/swab self-taken
- Ages 5+
- England & local authorities (lower tier =315)
- Participants selected from NHS register, representative of cross-section of population
- Using wet swabs (PHE labs) and dry swabs in cold chain with Eurofins labs
- Over **120,000 individuals** included
- Findings provide crucial reference data for future (repeated) surveys
- Repeat monthly to generate national and local prevalence trends & reproduction rate (R) over ~30 days
- **Establish level of current symptomatic and asymptomatic SARS-CoV-2 infections**

## Coronavirus (COVID-19) Home Test

Thank you for taking the time to complete your coronavirus home testing kit and helping to keep yourself and others safe.

Please read these instructions thoroughly and follow the steps carefully to help you get the most accurate result.

**BEFORE YOU START, READ THROUGH THESE PAGES TO MAKE SURE YOU UNDERSTAND EACH STEP.**

Check that your kit contains these items:



# REACT-2, study 4



- Usability and validity of lateral flow antibody test by key workers (police and fire service) (N=5,500)
- Re-tested by healthcare professional
- Participants attend a regional test centre (Keele, Warwick, London, Derby, Manchester and Bournemouth)
- Participants will have **plasma** tested for **antibodies** with the Abbott system
- Study 4 also assessing suitability of **saliva** for **antigen** testing (directly compared with nasopharyngeal swab) and (potentially) **antibody** testing
- Results of the nasopharyngeal swab test are reported back
- Dry blood spot cards being collected for **antibody** testing
- Airwave participants (police personnel) also have a clinical chemistry panel and blood count



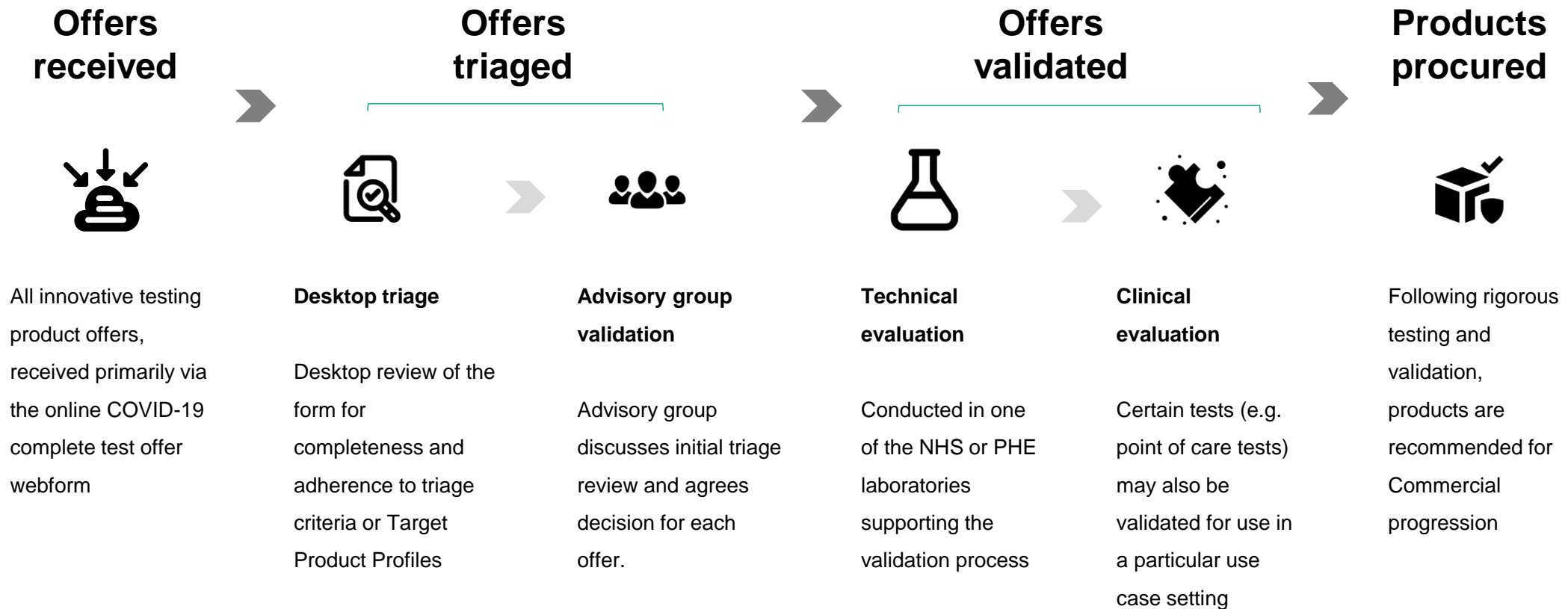
# Q&A



# Triage and Evaluation System

Dan Bamford, Deputy Director COVID-19 Testing Programme (New Tests)

# Current Triage and Validation Process



A detailed description of the current triage and validation process has been published<sup>1</sup>

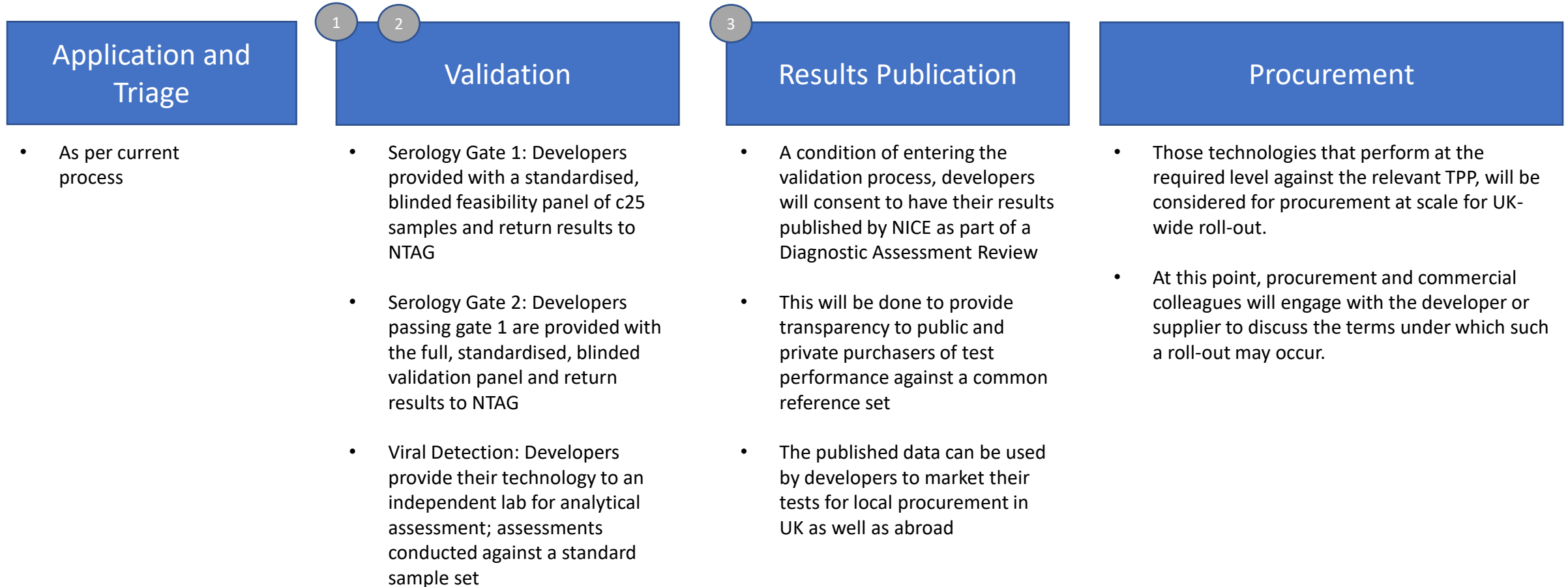
# Key challenges faced across the validation process

	Issue	Solution
1 Clinical material constraints	<ul style="list-style-type: none"><li>Constraints around sample availability and standard validation materials have impacted the development cycles for test developers</li></ul>	<ul style="list-style-type: none"><li>Signposting industry to NHS labs and organisations (e.g. NHSBT and NIBSC) that have clinical materials available to support test development</li></ul>
2 Enabling a decentralised model of validation	<ul style="list-style-type: none"><li>Conducting all of this evaluation work centrally can increase the time to procurement</li></ul>	<ul style="list-style-type: none"><li>Making standardised validation sets for Serology and Viral Detection available</li><li>Blinding these validation sets so developers can conduct their own validation work (initially Serology)</li></ul>
3 Publishing comparable results	<ul style="list-style-type: none"><li>Purchasers of tests (public and private) do not have access to independent, comparable validation data to inform purchasing decisions</li></ul>	<ul style="list-style-type: none"><li>With test developer consent, publish the results of nationally-commissioned validations</li></ul>



# Developing an improved validation process

Standardised validation panels will be available by the end of June, enabling a move to an improved model of validation. We are keen to hear feedback on this proposed model.





# Q&A



# Diagnostics Innovation Team

Piers Ricketts, SRO Diagnostics Innovations Team

Anna Dijkstra, COVID-19 Testing Supply

# Diagnostics Innovation Team: scope of work

- The Diagnostics Innovation Team was formed in mid-May to consider and assess innovative testing technologies with the potential to increase the UK's Covid-19 testing capability beyond the level of 200,000 tests per day announced last month.
- New technologies are likely to be needed to provide for new use cases and to overcome supply constraints such as swabs and reagents.
- The scope of the team's programme is therefore to assess the different technologies available in order to understand how they can boost the UK's diagnostic testing capacity and in what timescale.

A number of use cases are under development. These have not been finalised but could include the following:

Mass asymptomatic testing

Population monitoring

Localised outbreaks/  
one-off tests

Flu season/ surge  
requirement

Rapid tests to meet  
eligibility criteria

# Areas of Focus

We are examining innovations which can bring significant increases in testing volumes but all are complex and require evaluation

	Test Type	Advantages and disadvantages
New process to increase scale	Saliva-based sampling	<ul style="list-style-type: none"> <li>Patients and public provide a saliva sample rather than a naso-pharyngeal swab;</li> <li>Significant benefits in user experience and increased volumes (avoids swab production constraints) but requires clinical and real world evaluation and new workflows.</li> </ul>
	Guanidine for viral inactivation	<ul style="list-style-type: none"> <li>Guanidine in sample tube inactivates the virus and hence enables incoming samples to be handled more easily in greater numbers;</li> <li>Caustic substance so needs risk case approval and service evaluation.</li> </ul>
	Pooling of samples	<ul style="list-style-type: none"> <li>High scale – multiple samples can be pooled and processed in a single test. Several methodologies available;</li> <li>Most likely suited to low prevalence sample groups and can create complex logistics in the lab.</li> </ul>
	‘End point’ PCR	<ul style="list-style-type: none"> <li>Lab-based technology may provide significant increase in scale;</li> <li>Has been used for small number of Covid-19 tests in the US;</li> <li>Significant work required for validation, procurement and logistics;</li> <li>Use case needs to be specified depending on sensitivity</li> </ul>
High scale but lower sensitivity	New Viral detection assays (e.g. LAMP)	<ul style="list-style-type: none"> <li>High scale, high probability, and relatively simple fast and cheap;</li> <li>Can be produced near to patient;</li> <li>Potentially low sensitivity, use case still to be agreed.</li> </ul>
Higher sensitivity low scale	‘Point of care’ devices	<ul style="list-style-type: none"> <li>Simple, portable systems delivering quick turnaround (e.g. ~1hr) and often can be scaled to increase volume</li> <li>A lot of systems still being developed and not ready for scale-up</li> </ul>
	Viral Sequencing	High throughput (volume and speed) to support surveillance and research.

# Saliva-based sampling

Mass asymptomatic testing

Population monitoring

Localised outbreaks/ one-off tests

Flu season/ surge requirement

Rapid tests to meet eligibility criteria

- Saliva based testing could make diagnostic testing more accessible (overcomes potential swab supply constraints) and cheaper.
- Other advantages of using saliva-based testing instead of the swabs are that sample collection is relatively easy, minimally invasive/ painful and can reliably be self administered.
- Likely to provide greater sample reliability given the difficulties associated with swabs (especially in self-testing).

- Scientific evaluation now complete;
- Clinical and service evaluation taking place mid-June to mid-July;
- Supply chain investigated – large volumes of sample tubes should be possible.

# Guanidine for viral inactivation

Mass asymptomatic testing

Population monitoring

Localised outbreaks/ one-off tests

Flu season/ surge requirement

Rapid tests to meet eligibility criteria

- The presence of active virus in testing samples is a potential health risk and limits the number of labs that can safely handle the samples, thus reducing testing capacity.
- The use of viral inactivation is common in standard NHS viral testing. It enables the sample to be handled and processed in a lower risk setting, meaning you can provide greater testing capacity through use of lower category labs etc.
- Viral inactivation can be achieved through the use of Guanidine (commercial buffers or homemade) and other technologies such as heat inactivation and RNA extraction kits.
- As we look to increase COVID-19 testing capacity through the use of viral inactivation we need to understand how BAU NHS viral testing, using viral inactivation, can be maintained.

- Risk assessment undergoing final sign off
- Pilot plan being developed to facilitate concordance testing.
- Develop implementation plan and work with channels / logistics teams based on final policy decision.
- Continue working with suppliers to understand their implementation activities, dependencies, risks and timelines.
- Commence leakage testing.



# Pooling of samples

Mass asymptomatic testing

Population monitoring

Localised outbreaks/ one-off tests

Flu season/ surge requirement

Rapid tests to meet eligibility criteria

- Theoretically, sample pooling provides an opportunity to increase testing throughput whilst reducing reagent consumption. This is especially true in populations with low prevalence
- Sample pooling is being applied internationally in the testing of Covid-19, most notably in Germany, China, Singapore, Malaysia and Israel
- There are many different ways in which sample pooling could be applied, varying by point of pooling, method of identifying positive samples and testing output
- However, the practical application of sample pooling can be complex in terms of lab logistics, so determination of use cases is important.

- 4-week UK validation of applicable orthogonal pooling methodology starts week commencing 8 June.
- Other pilot locations being explored (GOSH and Crick Institute).
- International discussions and case studies being compiled on international implementation of sample pooling

# End Point PCR

Mass asymptomatic testing

Population monitoring

Localised outbreaks/ one-off tests

Flu season/ surge requirement

Rapid tests to meet eligibility criteria

- Utilising end-point PCR technology may be an attractive pathway to achieving high test volumes in a short space of time.
- However, validation is required to confirm it is effective and appropriate for COVID-19 testing.
- In parallel with validation, the use case must be developed to reflect the sensitivity of the technology
- Significant work also required in relation to logistics and procurement

- Initial sensitivity results expected by 12 June
- Proof of concept in UK planned to be in use by end of July but requires significant programme of work



# LAMP

| Loop-mediated isothermal amplification

Mass asymptomatic testing

Population monitoring

Localised outbreaks/ one-off tests

Flu season/ surge requirement

Rapid tests to meet eligibility criteria

- LAMP is a technique that can be used both inside labs and in PoC settings (e.g. care homes, airports, A&E triage)
  - There are two workflows under consideration: one with RNA extraction (similar to PCR), the other direct from swabs. The tests can be run on open-source RT-qPCR machines, generic plate readers or smaller, specialist devices
  - The key benefits vs RT-qPCR are:
    - speed of result (<30 mins for positive tests)
    - speed of sample preparation (can be done without RNA extraction step)
    - cost (potentially 1/3rd of cost per sample)
    - applicability in POC settings
    - can co-exist with PCR as they use different supply chains and reagents
- The clinical validity is well established. The intent now is to:
    - model the additional capacity that use of LAMP would create and assess best use of that capacity
    - assess the benefits and implications of use cases and move into real world testing
    - evaluate potential supply chain constraints
  - Two pilots are underway as a real world test for use in identifying Covid positive patients coming through A&E
  - Application in airport settings is being explored, as per Vienna Airport



# Genetic sequencing

Mass asymptomatic testing

Population monitoring

Localised outbreaks/ one-off tests

Flu season/ surge requirement

Rapid tests to meet eligibility criteria

- Genetic sequencing has a similar workflow to LAMP and PCR, requiring sample collection, conveyance to a lab and processing. The RNA of the sample is then genetically sequenced, with the benefits of:
    - accuracy of detection (near 100%)
    - high throughput
    - diagnostic benefits (avoiding re-test if used in combination with sample pooling; tracking the chain of transmission though detecting mutations and strains)
  - As well as use in lab settings, it potentially has mobile applications, e.g. care homes, airports, hospitals. However it is not as fast and is more costly than LAMP, and shares the same supply chain as LAMP. Assessment is ongoing as to the trade-offs between using different technologies in different settings.
- Clinical validation and capacity modelling is ongoing.
  - Mobile applications are being explored.
  - From receipt of sample through to a result is likely to be 2-2 ½ hours (vs 3-4 for PCR, but 1-1 ½ hours for LAMP)
  - The intent is to move to piloting, though is unlikely to form part of the testing network for 2 months minimum. However the potential gains of accuracy and capacity make it an important technology.



# Q&A



# Update on Point of Care Tests

Lindsey Hughes

Deputy Director and Lead for COVID-19 Testing Supplies Novel Solutions Team

# Update on point of care or near patient tests

- Original #TestingMethods Challenge launched 10<sup>th</sup> April
- Call for new tests via the testing triage service
- Intelligence from NHS diagnostics community
- Offers of new tests welcomed via the triage process



# Use cases for point of care or near patient tests:



Increase hospital lab capacity



A&E triage



Hospital admissions  
(urgent and non urgent)



NHS staff testing



Out of hospital testing



Test and trace

# Progress to date:

- Identified 27 platforms at various stages of development
- 2 devices already deployed in the NHS
- Small number in pilot and/or require further clinical validation
- Real world testing/validation to be undertaken in potential use case settings
- Continue to monitor development of the remainder
- Supporting role out will give intelligence on utility in non clinical settings
- NICE to perform rapid assessment of cost effectiveness of the use cases to support policy development and inform further evidence generation



# New Crowdsourcing Challenges

Doris-Ann Williams

Chief Executive of BIVDA



## New challenge: COVID Plus: Multiplexing with other pathogens

As we move towards the winter flu season, we must consider how to include COVID 19 viral detection into the wider respiratory virus and/or gastrointestinal virus testing regimes. We are seeking testing kits that will deliver multiplexed or syndromic respiratory and/or gastrointestinal viral detection and that will operate on either existing rapid turnaround laboratory platforms, existing near patient care platforms, or new technologies that can be deployed into NHS and PHE testing laboratories.



These should be ready to deploy within four to six weeks.

**Add your examples here: [testingmethods.crowdicity.com](https://testingmethods.crowdicity.com)**

**#TestingMethods2020**

**#Covid-19**



# Close

Doris-Ann Williams

Chief Executive of BIVDA

