



HM Government

Webinar: Opportunities to contribute to the National Diagnostics Effort for COVID-19

Our national effort for diagnostics

Rt Hon Matthew Hancock MP

Secretary of State for Health and Social Care



Today's Agenda

12:25-12:35

Our national approach

Dr Sam Roberts - Director of Testing Supplies

12:35-12:55

Our needs for pillar 1 & 2:
Consumables:

Dr Beverley Jandziol – Government Commercial Lead for the Testing Programme

Prof Chris Molloy – Co-Ordinator of the National Hub Labs and CEO of the Medicines Discovery Catapult

Mark Stevenson – Executive Vice President and Chief Operating Officer of Thermo Fisher Scientific

Q&A

12:55-13:15

Our needs for pillars 1& 2:
enabling open RNA extraction and
PCR platforms alongside NHS labs

David Wells – Head of Pathology, COVID-19 Testing Cell

Ewan Cameroon – South of England Head of Diagnostics, NHS England and Improvement

Dr Sonia Gandhi – The Francis Crick Institute

Q&A

13.15 – 13.20

How to respond and our future
communication

Paul Chambers – Department of Health and Social Care

13:20-13:40

Pillar 5: Developing the UK's
diagnostics industry - call for novel
solutions in key areas

Prof Jo Martin – President of the Royal College of Pathologists

Q&A

13:40-13:45

Close

Dr Sam Roberts – Director of Testing Supplies



What we need from you

Update on our National Testing Strategy

Dr Sam Roberts

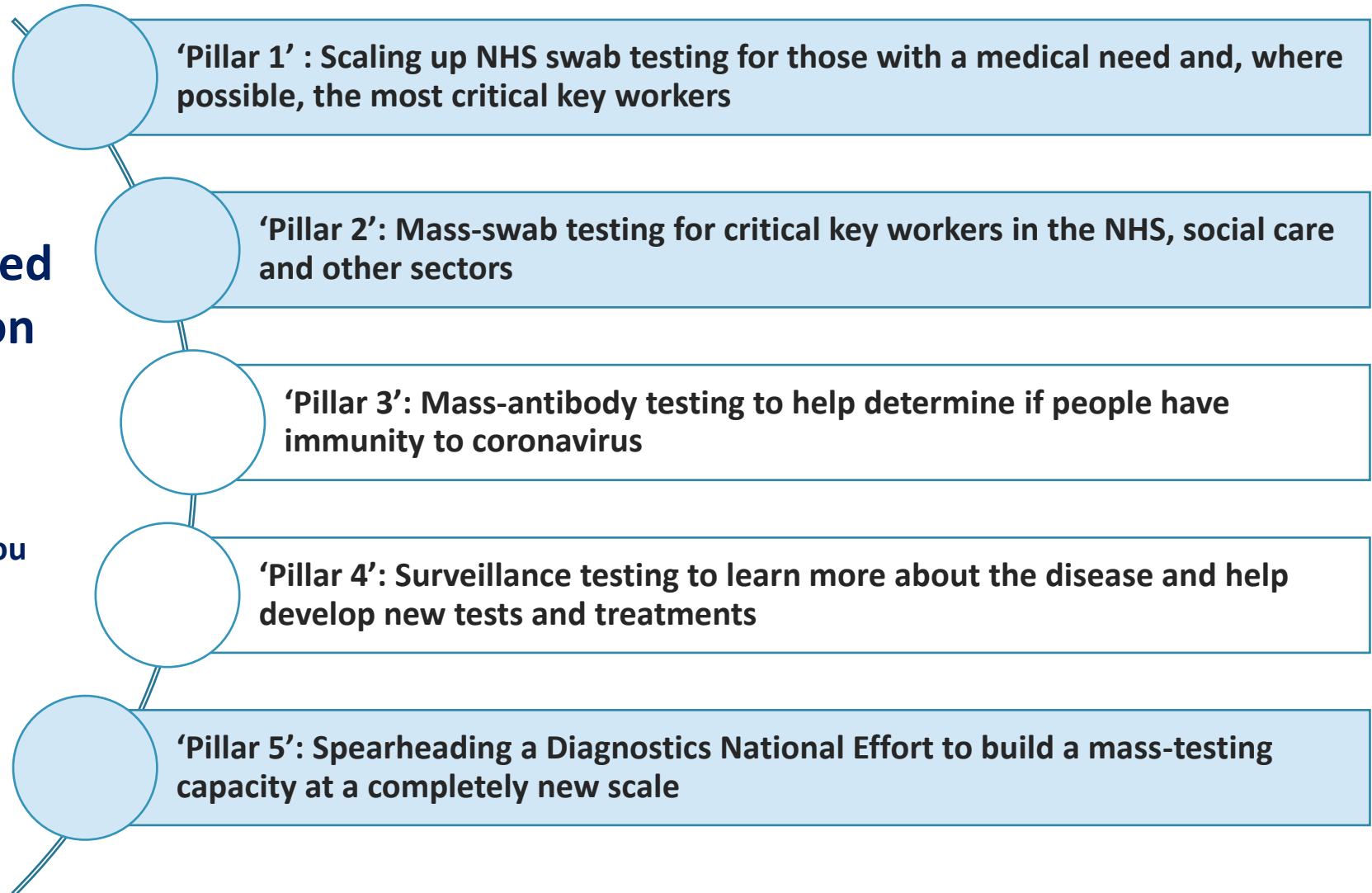
Director of Testing Supply



Our National Testing Strategy

The strategy was announced by the Secretary of State on 2nd April and has 5 key strands

The webinar today will focus on how you can contribute to pillars 1,2 and 5



We are not currently prioritising the following:

Given this time of national emergency we are not prioritising approaches which will take stretched resources away from testing patients and staff.

Please do not get in contact at this time if you:

- Are seeking initial validation of a new PCR assay
- Have lab capacity that meets the criteria above but has potential to deliver <2000 tests a day within 3 weeks
- Are proposing approaches that 'hack' closed system assays which would then require NHS revalidation of those sites or assays



Our needs for pillar 1 & 2

Current consumable requirements

Dr Beverley Jandziol

Government Commercial Lead for the Testing Programme



COVID-19 PCR Testing Consumables

So what's on our wish list?

Equipment	Sampling Kits	Reagents	Other Consumables
Open PCR systems with high throughput (loan or purchase)	Swabs e.g. nasopharangeal with min breakpoint of 80mm	RNA extraction	Various plates e.g. Deep 96 well plates
KingFisher Flex with 96 deep well head (5400360) - loan or purchase	Tubes e.g. 75-100mm to accommodate bar codes	Probes & Primers	Pipette tips (various)
	Viral transfer media e.g. UTM / VTM or Liquid Ames Medium approved for viral transport		Handsafe long cuff gloves

- Sustainable supply
- Particular interest in UK based manufacturing opportunities
- 'Fit for purpose' alternatives to current specs



COVID-19 PCR Testing Consumables - Swabs

Specifications:

	Type	Length	Breakpoint	Shaft material (not wood or Calcium alginate)	Tip material	Packaging	Sterility
Preferred	Throat and Nose Nasopharyngeal	min. 150mm / 6"	Dry swab range: 80- 100mm	Plastic shaft	PurFoam Rayon Cellular Foam	Peel Pouch	Sterile
Alternatives that can be considered	Nose (if long enough to reach throat)	min. 130mm		Plastic shaft	Foam Dacron Flock	Tube	Sterile



COVID-19 PCR Testing Consumables - Reagents

Extraction Kit	Extraction Reagents	PCR Kit	PCR Reagents
Abbott mSample prep system DNA	Abbott RNA Sample Purification Reagents	Abbott RT SARS-CoV Control Kit	Altona Diagnostics AltoStar® Internal Control 1.5
Altona Diagnostics AltoStar® Purification Kit 1.5	Biomerieux NucliSENS easyMAG Extraction Buffer	Abbott RT SARS-CoV-2 Amplification Reagent Kit	Applied Biosystems TaqPath 1-Step RT-qPCR Master Mix
Ausdiagnostics Mastermix Demi RNA Reagent Cassette	Biomerieux NucliSENS easyMAG Lysis Buffer	Abbott m sample preparation system	Ausdiagnostics Positive controls
Ausdiagnostics MT-Prep Viral/Pathogen Extraction Kit B	Biomerieux NucliSENS easyMAG Magnetic Sillica	Altona Diagnostics RealStar SARS-CoV-2 RT-PCR Kit 1.0 RUO	BD TNA Strips
Biomerieux NucliSENS easyMAG disposables/cartridges	Elitech Elite InGenius SP200 Extraction Reagent	Altona Diagnostics RealStar SARS-CoV-2 RT PCR Kit 1.0	Cepheid Analyer
Biomerieux NucliSENS easyMAG Instrument starter pack	Hologic Panther Fusion Extraction reagent-S	Applied Biosystems TaqMan Fast Virus 1-Step Master Mix	Hologic IC RNA Primers
Hologic Panther Fusion DNA/RNA Enzyme Cartridge 96 tests	Hologic Panther Fusion Elution Buffer	Ausdiagnostics Demi RNA mastermix cassette	Hologic IC RNA Probes
Launch Duplica NA body fluid kit	Hologic Panther Fusion Oil	BD BD Max Cartridges	Hologic Panther Fusion Internal control-S
Life technologies Mag MAX CORE NA Purification Kit	Hologic Panther Fusion Specimen Lysis Tubes	EliTech Gene finder COVID-19 plus real time amplification assay	Hologic Panther Fusion Reconstitution Buffer-I
Omega Biotek MagBind Viral DNA/RNA kit	Promega Magnesil blue	Hologic Multi-Tube Unit Lit Assy	Hologic Panther Fusion Universal Fluids
Qiagen QIAAsymphony DSP Virus/Pathogen Mini and Midi Kit	Qiagen NeuMoDx™ Lysis Buffer 4	Hologic Auto Detect Kit, APTIMA, AS	Hologic Panther Fusion Assay fluids
Qiagen Sample Prep Cartridges, 8-well	Roche MagNa Pure bacterial Lysis Buffer	Hologic Assay Fluids Kit, APTIMA, AS	Qiagen NeuMoDx™ LDT Probe/Primer Strip
Roche MagNa Pure Compact DNA Isolation Kit	Roche MagNa Pure 96 Internal Control Tube	Hologic LDT cartridges	Qiagen NeuMoDx™ LDT Master Mix, RNA
Roche MagNa Pure 96 Processing Cartridge	Roche MagNA Pure 96 External Lysis Buffer	Qiagen NeuMoDx™ Cartridge	Qiagen NeuMoDx™ Wash Solution
Roche MagNA Pure 96 DNA and Viral NA Large and Small Volume Kit	Roche MagNA Pure 96 Bacterial Lysis Buffer	Qiagen Rotor-Gene probe RT-PCR Kit	Qiagen NeuMoDx™ Release Solution
Roche MagNa Pure 24 Processing Cartridge	Roche MagNA Pure 96 System Fluid	Qiagen QuantiTect Multiplex RT-PCR NR Kit	Qiagen QIAstat-Dx Respiratory Panel
Roche MagNa Pure 24 Total NA Isolation Kit	Roche MagNA Pure (beads)	Qiagen Quantifast multiplex RT-PCR + R Kit (RNA)	Qiagen QIAstat-Dx respiratory 2019-ncov panel
Thermo Fisher KingFisher Pure Viral NA Kit	Severn biotech Kingfisher Buffer	Qiagen Rotordisc	Qiagen Rotordisc sealing
Thermo Fisher Magmax Viral Pathogen Kit	Thermo Fisher Magmax Viral / Pathogen Binding Soutlion	Qiagen OTV	Roche Kit Cobas 6800 / 8800 Wash IVD
Hain GXT Extraction kit (ver 1.0)	Thermo Fisher Magmax Viral / Pathogen Wash Solution	Roche Omni Reagent Cassette	Roche Kit Cobas 6800 / 8800 SPEC DIL reagnet IVD
	Thermo Fisher Magmax DNA/RNA Binding Beads	Roche Kit Cobas 6800 / 8800 SARS-COV-2 test	Roche Kit Cobas 6800 / 8800 Lys reagent IVD
	Thermo Fisher Magmax Proteinase K		Roche Kit Cobas 6800 / 8800 negative control buffer
	Thermo Fisher Magmax Elution Buffer		Roche Kit Cobas 6800/8800 Lys Reagent IVD



Our needs for pillar 1 & 2

The National Covid-19 Testing Labs

Prof Chris Molloy

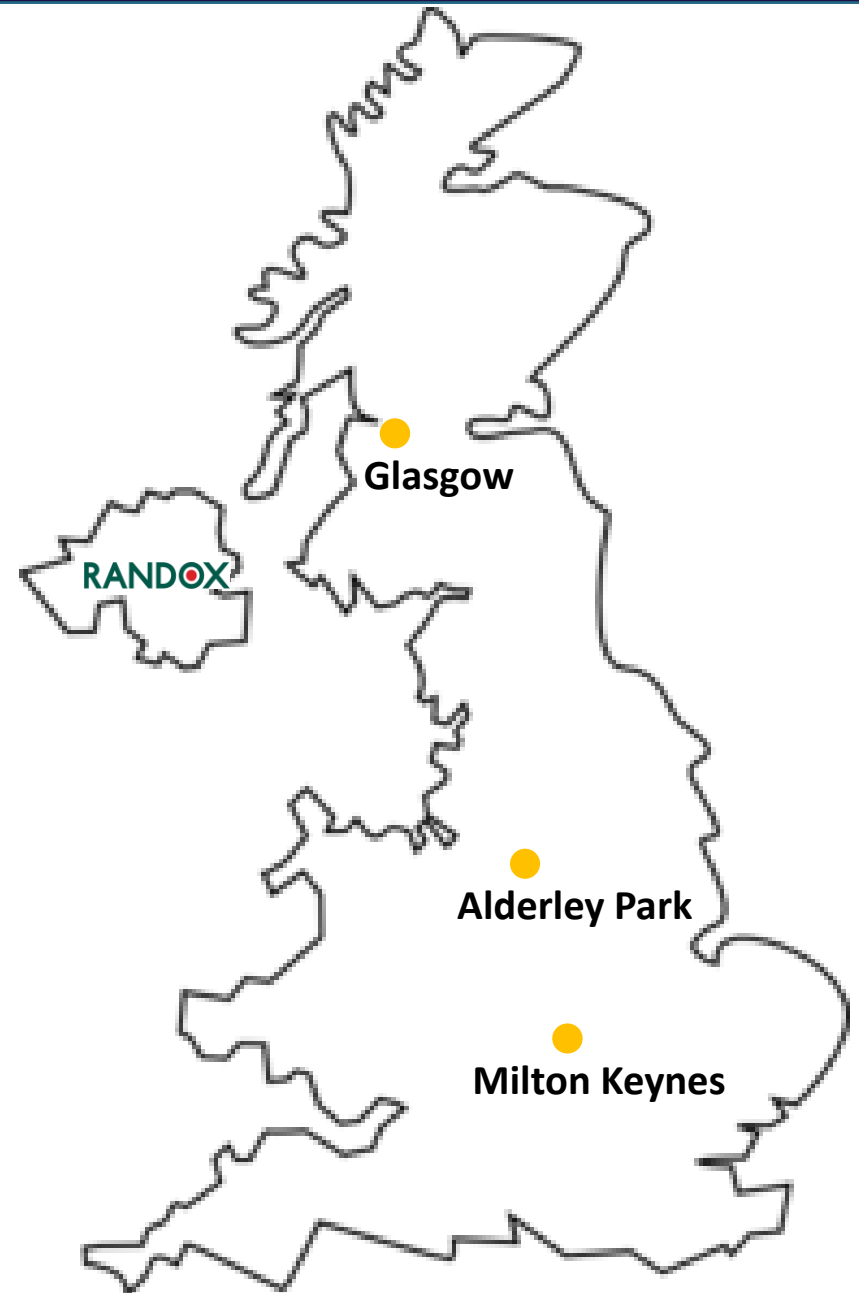
National co-ordinator and CEO Medicines Discovery Catapult,

Lighthouse Labs

- **Three new high throughput national facilities**
- **Brought to life by**
 - UK Biocentre
 - Medicines Discovery Catapult
 - University of Glasgow
- **Industrialising**
 - Thermo Fischer TaqPath assay with high capacity data analysis
 - Built on industrial principals, automation and expertise
 - To be staffed by skilled employees and volunteers 24/7
 - Establishing a robust supply chain of equipment and consumables

Supported by

- Industry : AZ/GSK/Thermo with access to resources and experimental data
- Academia : Nationwide in supply of materiel, advice & volunteers
- NHS / PHE : Clinical expertise and assay validation



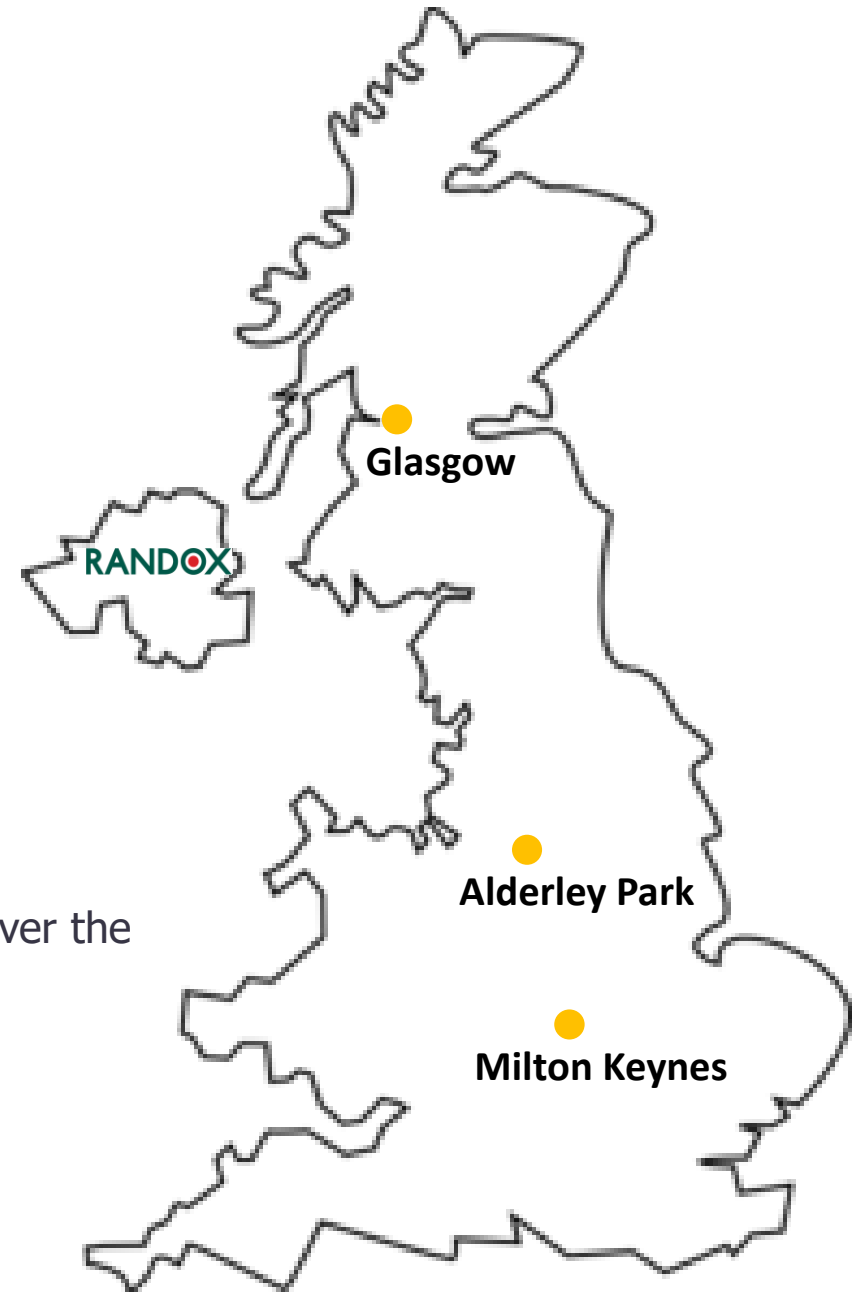
Lighthouse Labs

Status

- Milton Keynes – live
- Alderley Park – first clinical samples this week
- Glasgow – systems validation, with clinical samples next week
- Randox - live

Capacity

- Currently thousands per day, rising to tens of thousands *per day* over the next weeks as high capacity automation is brought to bear
- Workforce is growing. We are asking for volunteers through covidtestingassistance@dhsc.gov.uk



Our needs for pillar 1 & 2

Industry support for pillar 2 – strength of consumables supply and reagents requirements

Mark Stevenson

Executive Vice President and Chief Operating Officer of Thermo Fisher Scientific

Industry support for pillar 2: Consumables supply and reagents

Situation

- Super labs built in three locations across the country have sample processing and qPCR instruments with capacity for collectively > 100,000 patient samples per day
- Need to ensure consistent and reliable supply of consumables and reagents

Industry Response

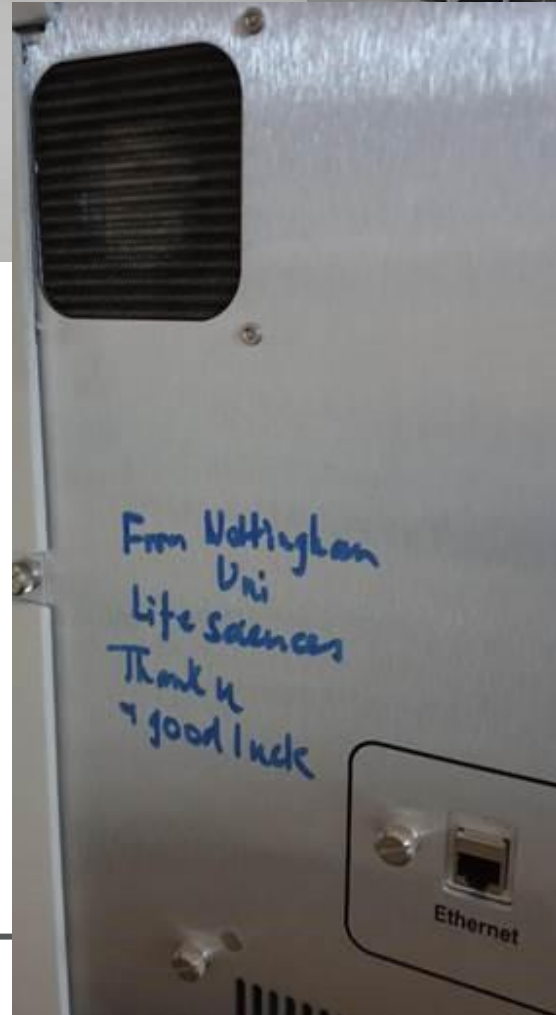
Overall Approach

- Use of private / public partnership : Amazon, Boots, Royal Mail and Randox, Thermo Fisher Scientific, alongside the Wellcome Trust and top UK universities
- Amazon and Royal Mail providing logistics, while Boots has been supporting initial trials by supplying volunteer healthcare clinicians as testers
- 24/7 lab operations for the three laboratories – as well as repair, maintenance and technical support

Ensuring supply of reagents kits

- Selected one lab testing platform, ≈100 Thermo Fisher's Applied Biosystems 7500 Real-Time PCR System with 40 Kingfishers. With 2 runs per day over 3 shifts > 100K samples per day.
- Validated all labs on Thermo Fisher's Applied Biosystems TaqPath COVID-19 RT-PCR Kit. The TaqPath COVID-19 RT-PCR Kit contains both the assays and controls required for the real-time PCR detection of RNA from the SARS-CoV-2 virus.
- RNA extraction reagents and assays been manufactured at scale (>5 million per week) to meet 100k daily demand; Evaluating supply redundancy. Manufacturing site in Warrington, Cheshire, is currently making qPCR assays for other applications, will start COVID-19 qPCR assays.
- Evaluating options to strengthen supply chain on swabs and transport media.

Building out a new lab testing center: UK BioCentre at Milton Keynes



Glasgow and Alderley Park

Both will be online by the end of the week and will ramp quickly



Our needs for pillar 1 & 2

Open RNA extraction and PCR platforms alongside NHS labs: Lab requirements

David Wells

Head of Pathology, COVID-19 Testing Cell



Lab requirements

- Additional lab capacity including RNA extraction *and* PCR equipment that uses open source consumables (i.e. those that can be used on a variety of equipment) and should meet the following criteria:
 - Sample reception area for accepting and logging samples adhering to national infection control procedures;
 - Sample tracking capability (e.g. barcoding) for the end to end pathway;
 - Access to Category 3 compliant facilities or Category 2+ if risk assessed and confirmed by HSE, if handling clinical samples prior to viral inactivation. Further information can be found [here](#)
 - Automated RNA extraction equipment (validated by the NHS or Public Health England)
 - Access to a Real Time PCR assay machine using an assay validated by the NHS or Public Health England.
 - Automated result analysis systems in line with national policy and working in conjunction with the SOPs in place within the partnering NHS pathology network
 - Quality processes in place including validation and verification methodologies
 - Specialist workforce available e.g. PhD students or post docs with relevant experience that can work in rotas according to the needs of the NHS

If you can help in one of these areas, please fill in this [web form](#) to tell us more about your solution.





Our needs for pillar 1 & 2

NHS labs experience - Plugging your lab into the local NHS

Lt Col (Retd) Ewan Cameron L/RAMC

BA(Hons) DipM DLSHTM MSc Public Health FRSPH FCMI MIHM VR

South of England Head of Diagnostics, NHS England and Improvement

NHS Labs Experience end Feb - Present



The Experience

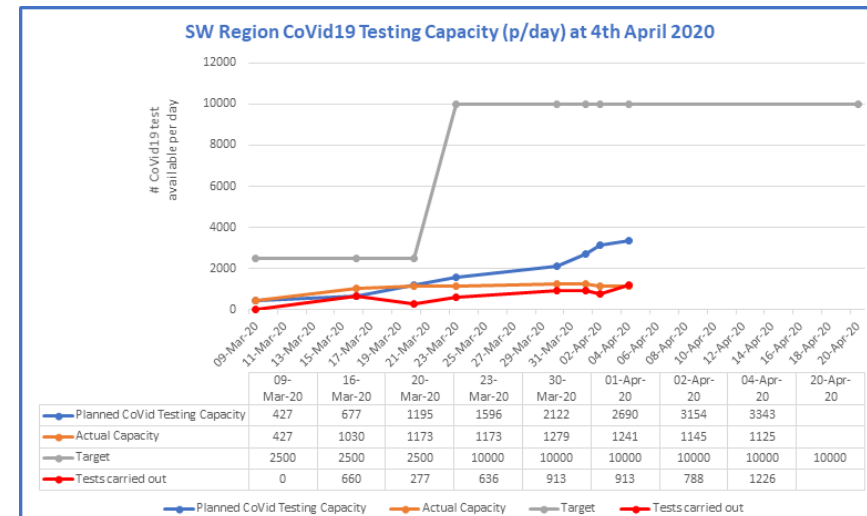
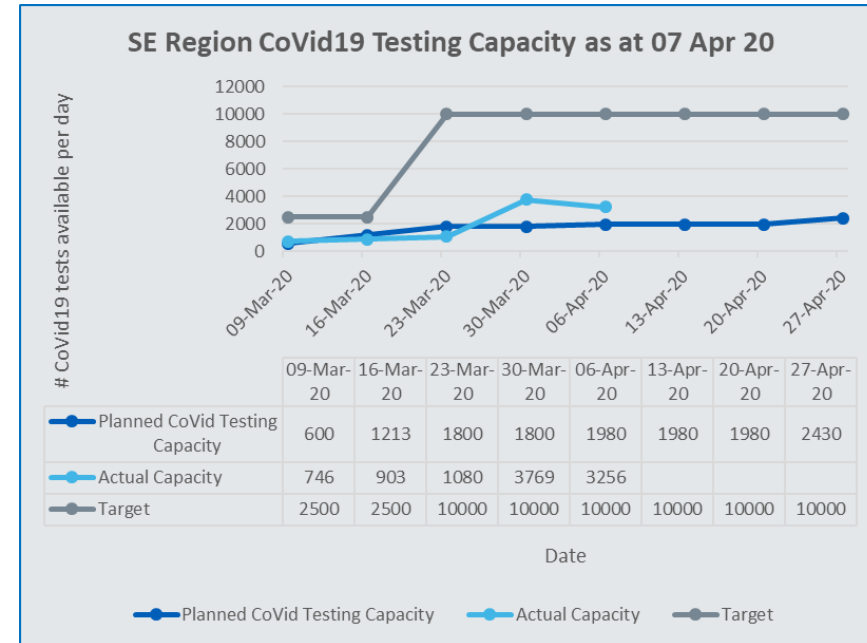
1. Global competition for PCR consumables including the NHS has dried up labs capacity to source consumables.
2. Dips in capacity due to insufficient laboratory consumables (extraction, reagents, ensigns and plastics) and swabs.
3. Immense frustration at headlines, jam tomorrow and inability to deliver due to supply chain constraints.
4. Staff have 'pulled out all the stops' to deliver the service.
5. We have the people, we have the platforms to achieve 10k per Region target but not the specific consumables.

Plugging Your Lab in to the NHS

1. Developing Local solution with local pathology networks within the National framework.
2. Perseverance.
3. Recognising local, Regional and National structures.
4. Successes include:
 - Local veterinary lab supporting
 - Novel solutions extraction challenges
 - Working with AHSNs

The Ask

1. We need industry to provide us with sufficient laboratory consumables across all our platforms.
2. Private labs with capacity to approach NHS at Local and National levels

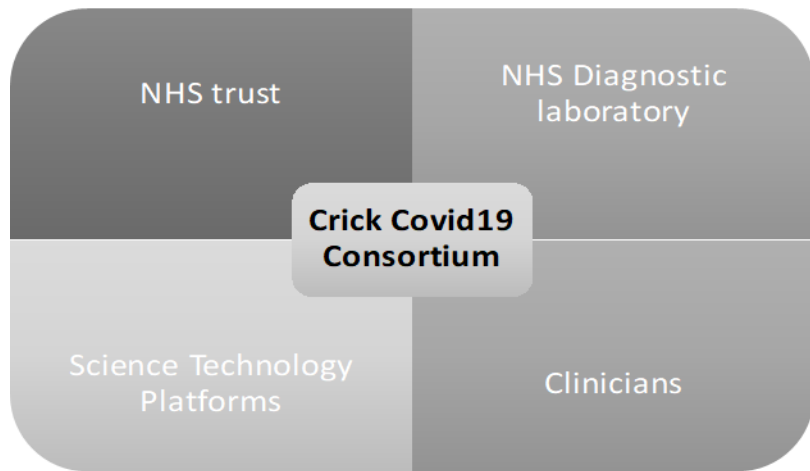


Our needs for pillar 1 & 2

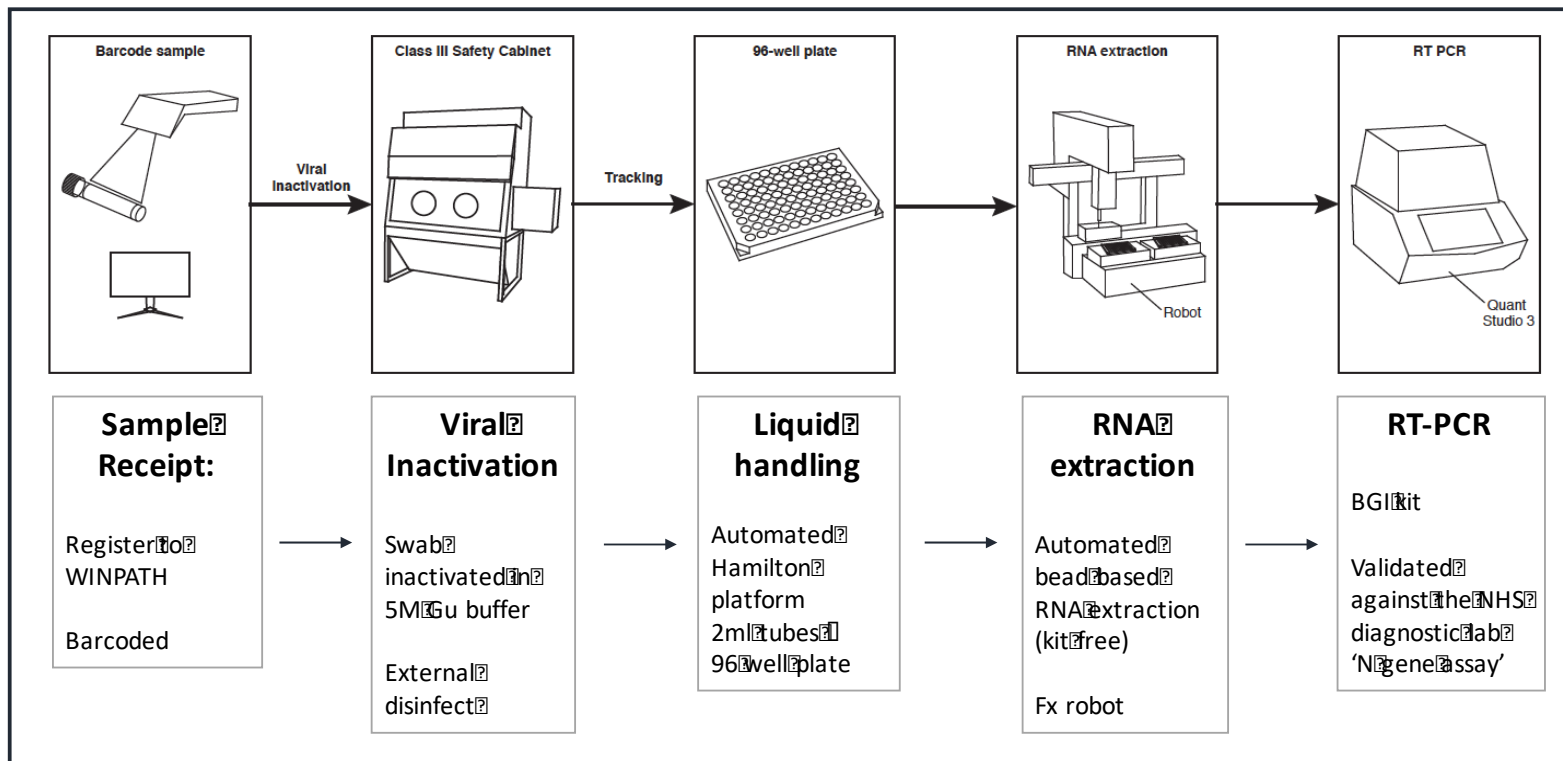
Experience of decentralised approaches for the national effort – practical steps for organisations

Dr Sonia Gandhi

The Francis Crick Institute



- Repurposing research institute for Covid19 diagnostic testing
- Key Partnerships: NHS/academic
- Deliver flexible and scalable pipeline



- ### Critical Components
- Samples
 - 12 CL3 Hoods and staff
 - 4 adaptable robotic platforms
 - 6 PCR machines
 - End-end data management (interfacing with NHS system)
 - Clinical team: clinical scientists 2nd level reporting; consultant virologists 3rd level reporting

Running these calls and future communications

Process for submitting proposals, triage and future calls

Paul Chambers

COVID – 19 Testing Cell



Running these calls and future communications

The response from industry has been huge – but in order to ensure we can quickly respond to specific/deliverable offers – we are ramping up resource and putting new system in place

If you have a **specific offer** in response to **specific calls**

- All information on <https://www.gov.uk/coronavirus-testing>
- Link through to specific web forms to collect info we need
- Dedicated triage and case management team – backed by expert panels

If responding to our future pillar 5 calls or have other offers

- Respond to email address below
- Separate triage teams will review - and respond asap – but unless a specific offer on immediate need – may take a bit of time.

For further information

- Gov.uk continue to be updated with further calls
- Future webinars, and information will be run on other strands, including work on antibody testing

covid19triageservice@nhsbsa.nhs.uk
[0800 9159965](tel:08009159965)





Pillar 5: Developing the UK's diagnostics industry

Call for novel solutions in key areas

Prof Jo Martin

President of the Royal College of Pathologists

We are seeking novel solutions in four key areas

Dry swabs for use in virus detection

A key element of speeding up the end to end testing process is the availability of swabs that can be used easily and reliably to detect the virus in a range of different swabbing applications and age groups including for use in home testing and which can be used with multiple extraction platforms.

Transport media that inactivates the virus

In order to increase laboratory throughput we are looking at ways to minimise processes including the need to handle test samples in Category 2+/3 facilities. We are looking for transport media solutions that inactivate the virus reliably or do not add significant steps to the laboratory process or impact on viral detection

Desktop PCR equipment for point of care testing

Taking samples and transporting them to testing labs takes time and may not always represent the best approach within clinical pathways. We are looking for the potential to add testing capacity through reliable and standards based testing at the point of care with desktop PCR machines that allow for fast, accurate and safe results for the operator.

RNA extraction: new methods

RNA extraction capacities are currently challenged even with automated platforms. We seek new methods of extracting viral RNA or enabling viral detection without an extraction step would help remove this bottleneck, as long as they are “ready to go” and can be integrated into existing or optimised PCR testing chains



How you can get involved in this work

- In partnership with Crowdcity, we have launched a **testing methods sourcing platform** to collect ideas on these four specific challenges <https://testingmethods.crowdcity.com/>
- If you have a solution that addresses any of these challenges, please register and add them to the platform. We want to know:
 - What is your idea/offer?
 - Have you validated this method, if so, how and what were the results of the validation?
 - How quickly could this be deployed and what are the dependencies?
 - What is the likely production volume?
 - What are the risks and barriers to using this at scale?
 - Who are you already partnering with on this?
- Even if you don't have a solution, you can comment to other people's solutions; we hope you'll be willing to share but you can also make a confidential submission
- Every solution and comment will be considered
- We will pause the platform on the evening of Tuesday 14th April to have an initial review of the solutions put forward



Close

Dr Sam Roberts

Director of Testing Supply

