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

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker/Role</th>
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<tbody>
<tr>
<td>12:25-12:35</td>
<td><strong>Our national approach</strong></td>
<td>Dr Sam Roberts - Director of Testing Supplies</td>
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<tr>
<td>12:35-12:55</td>
<td><strong>Our needs for pillar 1 &amp; 2: Consumables:</strong></td>
<td>Dr Beverley Jandziol – Government Commercial Lead for the Testing Programme</td>
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<td></td>
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<td>Prof Chris Molloy – Co-Ordinator of the National Hub Labs and CEO of the</td>
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<td>Medicines Discovery Catapult</td>
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<td>Mark Stevenson – Executive Vice President and Chief Operating Officer of</td>
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<td>Thermo Fisher Scientific</td>
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<td></td>
<td>Q&amp;A</td>
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<tr>
<td>12:55-13:15</td>
<td>**Our needs for pillars 1&amp; 2: enabling open RNA extraction and PCR</td>
<td>David Wells – Head of Pathology, COVID-19 Testing Cell</td>
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<td></td>
<td>platforms alongside NHS labs</td>
<td>Ewan Cameroon – South of England Head of Diagnostics, NHS England and</td>
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<td>Improvement</td>
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<td>Dr Sonia Gandhi – The Francis Crick Institute</td>
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<td></td>
<td>Q&amp;A</td>
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<td>13.15 – 13.20</td>
<td><strong>How to respond and our future communication</strong></td>
<td>Paul Chambers – Department of Health and Social Care</td>
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<td>13:20-13:40</td>
<td>**Pillar 5: Developing the UK’s diagnostics industry - call for novel</td>
<td>Prof Jo Martin – President of the Royal College of Pathologists</td>
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<td>solutions in key areas**</td>
<td>Q&amp;A</td>
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<tr>
<td>13:40-13:45</td>
<td><strong>Close</strong></td>
<td>Dr Sam Roberts – Director of Testing Supplies</td>
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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 2\textsuperscript{nd} April and has 5 key strands

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

- **Pillar 1**: Scaling up NHS swab testing for those with a medical need and, where possible, the most critical key workers
- **Pillar 2**: Mass-swab testing for critical key workers in the NHS, social care and other sectors
- **Pillar 3**: Mass-antibody testing to help determine if people have immunity to coronavirus
- **Pillar 4**: Surveillance testing to learn more about the disease and help develop new tests and treatments
- **Pillar 5**: Spearheading a Diagnostics National Effort to build a mass-testing capacity at a completely new scale
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?

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

- Sustainable supply
- Particular interest in UK based manufacturing opportunities
- ‘Fit for purpose’ alternatives to current specs
## COVID-19 PCR Testing Consumables - Swabs

### Specifications:

<table>
<thead>
<tr>
<th>Type</th>
<th>Length</th>
<th>Breakpoint</th>
<th>Shaft material (not wood or Calcium alginate)</th>
<th>Tip material</th>
<th>Packaging</th>
<th>Sterility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred Throat and Nose Nasopharyngeal</td>
<td>min. 150mm / 6&quot;</td>
<td>Dry swab range: 80-100mm</td>
<td>Plastic shaft</td>
<td>PurFoam Rayon Cellular Foam Dacron Flock</td>
<td>Peel Pouch</td>
<td>Sterile</td>
</tr>
<tr>
<td>Preferred Alternatives that can be considered Nose (if long enough to reach throat)</td>
<td>min. 130mm</td>
<td>Plastic shaft</td>
<td>Plastic shaft</td>
<td>PurFoam Rayon Cellular Foam Dacron Flock</td>
<td>Tube</td>
<td>Sterile</td>
</tr>
</tbody>
</table>
## COVID-19 PCR Testing Consumables - Reagents

<table>
<thead>
<tr>
<th>Extraction Kit</th>
<th>Extraction Reagents</th>
<th>PCR Kit</th>
<th>PCR Reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott mSample prep system DNA</td>
<td>Abbott RNA Sample Purification Reagents</td>
<td>Abbott RT SARS-CoV Control Kit</td>
<td>Altona Diagnostics AltoStar® Internal Control 1.5</td>
</tr>
<tr>
<td>Altona Diagnostics AltoStar® Purification Kit 1.5</td>
<td>Biomerieux NucliSENS easyMAG Extraction Buffer</td>
<td>Abbott RT SARS-CoV-2 Amplification Reagent Kit</td>
<td>Altona Diagnostics RealStar SARS-CoV-2 RT-PCR Kit 1.0 RUO</td>
</tr>
<tr>
<td>Ausdiagnostics MasterMix Demi RNA Reagent Cassette</td>
<td>Biomerieux NucliSENS easyMAG Lysis Buffer</td>
<td>Abbott m sample preparation system</td>
<td>Applied Biosystems TaqPath 1-Step RT-qPCR Master Mix</td>
</tr>
<tr>
<td>Ausdiagnostics MT-Prep Viral/Pathogen Extraction Kit B</td>
<td>Biomerieux NucliSENS easyMAG Magnetic Silica</td>
<td>Abbott RT SARS-CoV-2 Amplification Reagent Kit</td>
<td>Applied Biosystems TaqMan Fast Virus 1-Step Master Mix</td>
</tr>
<tr>
<td>Biomerieux NucliSENS easyMAG disposables/cassettes</td>
<td>Altona Diagnostics AltoStar® Internal Control 1.5</td>
<td>Altona Diagnostics RealStar SARS-CoV-2 RT-PCR Kit 1.0</td>
<td>BD TNA Strips</td>
</tr>
<tr>
<td>Biomerieux NucliSENS easyMAG Instrument starter pack</td>
<td>Hologic Panther Fusion Extraction reagent-S</td>
<td>Altona Diagnostics RealStar SARS-CoV-2 RT-PCR Kit 1.0</td>
<td>Cepheid Analyzer</td>
</tr>
<tr>
<td>Hologic Panther Fusion DNA/RNA Enzyme Cartridge 96 tests</td>
<td>Hologic Panther Fusion Elution Buffer</td>
<td>Altona Diagnostics DnaRNA mastermix cassette</td>
<td>Hologic IC RNA Primers</td>
</tr>
<tr>
<td>Launch Duplica NA body fluid kit</td>
<td>Hologic Panther Fusion Oil</td>
<td>Hologic Panther Fusion Internal control 5</td>
<td>Hologic Panther Fusion Oil</td>
</tr>
<tr>
<td>Life technologies Mag MAX CORE NA Purification Kit</td>
<td>Hologic Panther Fusion Specimen Lysis Tubes</td>
<td>Hologic Assay Fluids Kit, APTIMA, AS</td>
<td>BD BD Max Cartridges</td>
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<tr>
<td>Omega Biotek MagBind Viral DNA/RNA kit</td>
<td>Promega Magnesil blue</td>
<td>Hologic Panther Fusion Reconstitution Buffer-1</td>
<td>Hologic Panther Fusion Internal control 5</td>
</tr>
<tr>
<td>Qiagen QIAxSymphony DSP Virus/Pathogen Mini and Midi kit</td>
<td>Qiagen NeuMoDx™ Lysis Buffer 4</td>
<td>Hologic Panther Fusion Universal Fluids</td>
<td>Hologic Panther Fusion Universal Fluids</td>
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<tr>
<td>Qiagen Sample Prep Cartridges, 8-well</td>
<td>Roche MagNa Pure bacterial lysis Buffer</td>
<td>Hologic Panther Fusion Assay Fluids</td>
<td>Qiagen NeuMoDx™ Wash Solution</td>
</tr>
<tr>
<td>Roche MagNa Pure Compact DNA Isolation Kit</td>
<td>Hologic Assay Fluids Kit, APTIMA, AS</td>
<td>Qiagen NeuMoDx™ LDT Probe/Primer Strip</td>
<td>Qiagen NeuMoDx™ Wash Solution</td>
</tr>
<tr>
<td>Roche MagNa Pure 96 Processing Cartridge</td>
<td>Qiagen NeuMoDx™ Cartridge</td>
<td>Qiagen NeuMoDx™ LDT Master Mix, RNA</td>
<td>Qiagen NeuMoDx™ Wash Solution</td>
</tr>
<tr>
<td>Roche MagNa Pure 96 DNA and Viral NA Large and Small Volume Kit</td>
<td>Qiagen Rotor-Gene probe RT-PCR Kit</td>
<td>Qiagen NeoMoDx™ Release Solution</td>
<td>Qiagen NeuMoDx™ Wash Solution</td>
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<tr>
<td>Roche MagNa Pure 24 Processing Cartridge</td>
<td>Qiagen Rotor-Disc</td>
<td>Qiagen Rotor Disc sealing</td>
<td>Qiagen NeuMoDx™ Wash Solution</td>
</tr>
<tr>
<td>Roche MagNa Pure 24 Total NA Isolation Kit</td>
<td>Qiagen Rotor-Disc</td>
<td>Qiagen Rotor Disc sealing</td>
<td>Qiagen NeuMoDx™ Wash Solution</td>
</tr>
<tr>
<td>Thermo Fisher KingFisher Pure Viral NA Kit</td>
<td>Qiagen OTV</td>
<td>Roche Kit Cobas 6800 / 8800 Wash IVD</td>
<td>Roche Kit Cobas 6800 / 8800 Wash IVD</td>
</tr>
<tr>
<td>Thermo Fisher Magmax Viral Pathogen Kit</td>
<td>Qiagen QuantiTect Multiplex RT-PCR NR Kit</td>
<td>Roche Kit Cobas 6800 / 8800 SPEC DIL reagent IVD</td>
<td>Roche Kit Cobas 6800 / 8800 SPEC DIL reagent IVD</td>
</tr>
<tr>
<td>Hain GXT Extraction kit (ver 1.0)</td>
<td>Qiagen Quantifast multiplex RT-PCR + R Kit (RNA)</td>
<td>Roche Kit Cobas 6800 / 8800 Lys reagent IVD</td>
<td>Roche Kit Cobas 6800 / 8800 Lys reagent IVD</td>
</tr>
<tr>
<td>Thermo Fisher Magmax DNA/RNA Binding Beads</td>
<td>Qiagen Quantifast multiplex RT-PCR + R Kit (RNA)</td>
<td>Roche Kit Cobas 6800 / 8800 Lys reagent IVD</td>
<td>Roche Kit Cobas 6800 / 8800 Lys reagent IVD</td>
</tr>
<tr>
<td>Thermo Fisher Magmax Proteinase K</td>
<td>Qiagen Rotordisc</td>
<td>Roche Kit Cobas 6800 / 8800 negative control buffer</td>
<td>Roche Kit Cobas 6800 / 8800 negative control buffer</td>
</tr>
<tr>
<td>Thermo Fisher Magmax Elution Buffer</td>
<td>Roche Kit Cobas 6800/8800 Lys Reagent IVD</td>
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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
**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

- 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

### Situation

<table>
<thead>
<tr>
<th>Status</th>
<th>Industry Response</th>
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| **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
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 2\(^{nd}\) level reporting; consultant virologists 3\(^{rd}\) 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](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**
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 Crowdicity, we have launched a **testing methods sourcing platform** to collect ideas on these four specific challenges [https://testingmethods.crowdicity.com/](https://testingmethods.crowdicity.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