



## National Measurement Laboratory (NML) at LGC: Response to the COVID-19 pandemic

As the UK National Measurement Laboratory (NML), our role is to ensure confidence and quality in the chemical and bio-measurements measurements made in the UK. We are using this expertise, working with healthcare providers, industry, universities and the global measurement and standards communities to help support efforts against the COVID-19 pandemic in the following ways:

### International standardisation

#### Viral Diagnostics

The ability to accurately and precisely measure nucleic acids (DNA, RNA) is crucial for COVID-19 testing. We have developed an SI-traceable reference measurement procedure to support COVID-19 diagnostic testing using our nucleic acid measurement expertise.

The NML is leading, with the support of other measurement institutes, a fast-tracked **inter-laboratory study for SARS-CoV-2 genome measurement** through the Nucleic Acid Analysis Working Group (NAWG) of the International Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (**CCQM**). This study measures genes targeted by diagnostic tests to SARS-CoV-2, using materials developed in the UK and China and will involve more than twenty National Measurement Institutes and approved guest laboratories from around the world. It will support countries to ensure globally standardised testing by assisting diagnostic manufacturers with test development and providing quality assurance of routine COVID 19 testing.

In our role as a nominated **expert laboratory for external quality assurance provider INSTAND eV**, we are supporting their new Proficiency Testing (PT) scheme for SARS-CoV-2 genome detection (600+ participants). This involves assigning reference values for virus quantification and evaluating material homogeneity, as well as participating in the PT schemes to support testing laboratories.

We are contributing to international guidance documentation for assay design and standards assessment, through active involvement in the steering committee of the newly formed **“Coronavirus standards working group”** (through the Joint Initiative for Metrology in Biology, USA, with global participation).

#### Serology Diagnostics

The development of antibody- based tests to help monitor the overall prevalence of the virus and help assess the likely immunity of the population to SARS-CoV-2 is of paramount importance to ease the lockdown restrictions around the globe.

We are participating in a second **CCQM inter-laboratory study** led by the Canadian National Measurement Institute together with other global national measurement laboratories for antibody characterisation to support the development of Covid-19 serological (antibody-based) tests, as well as assisting in the development of reference materials and methods to improve their accuracy.

#### International documentary standards

A recently completed European (EMPIR) project for improved bio-analytical measurements led by the NML has helped develop 3 international (**ISO**) **standards** for the counting of biological entities, **important for diagnosing respiratory infections and identification of microbial pathogens**. One of these (ISO 20395:2019 Requirements for evaluating the performance of quantification methods for

nucleic acid target sequences – qPCR and dPCR) has been made [freely available by ISO](#) to support the development and implementation of effective COVID-19 testing. This standard has, amongst others, already been central in the implementation of the quality assurance for field labs testing for coronavirus. The European Commission also [highlighted](#) this work as one of their research and innovation projects and initiatives that will help tackle the spread of coronavirus and preparedness for other outbreaks.

### Supporting the healthcare system nationally

We are providing regular support to the NHS and PHE around validation of molecular diagnostic viral method performance.

We are collaborating with local UK NHS hospitals and testing laboratories (**Great Ormond Street NHS Foundation Trust (UK), Health Services Laboratory (UK)**) where we have assisted in the clinical development and utility of COVID-19 testing to ensure the robustness of different assays for increased volumes of patient samples at the front line.

### Collaborating with academics and supporting research

We are partners in multiple **joint collaborative academic research proposals** that will use the NML's mass spectrometry and molecular biology resources and expertise to help with the development of improved molecular and antibody testing for COVID-19 pandemic.

This includes our involvement in the [Mass Spectrometry COVID-19 coalition](#), which is a global initiative led by the University of Manchester, UK, set up to inform serological testing, support vaccine and therapeutic development (mapping viral proteins and their interactions) and develop methods to determine disease prognosis and the lifetime of infectious particles in the environment.

We are also a partner in the new **COVID-19 National Diagnostic Research and Evaluation Platform (CONDOR)**, funded by the National Institute for Health Research and UK Research and Innovation. CONDOR will create a single national route for evaluating new diagnostic tests in hospitals, GPs and care homes. Led by Manchester University NHS Foundation Trust and the University of Oxford, in collaboration with four NIHR Medtech and In vitro diagnostics Co-operatives and co-led by the Chief Medical Officer, Prof Chris Whitty, CONDOR is one of a number of COVID-19 studies that have been given **urgent public health research status by the Department of Health and Social Care**. In our national role **we will provide independent validation** of the new molecular point of care tests and of emerging serological tests.

### Helping industry

We are working with industry on **critical and emerging businesses needs** where chemical and bio-measurement expertise is required to support their activity in response to COVID-19 e.g. the production of PPE, alcohol hand wipes and diagnostic kit development.

### Broader Communications/Publications

Provided scientific content and consultation on script for a **TEDEd Animation** on [“How do virus tests actually work?”](#)

Attended/contributed to **Royal Society policy briefing** on COVID-19.

Co-authored an opinion piece [“Diagnostic tests for covid-19—improving accuracy and global harmonisation”](#) for **The British Medical Journal**.

Co-authored a correspondence piece ["The COVID-19 MS Coalition—accelerating diagnostics, prognostics, and treatment"](#) for **The Lancet**.

