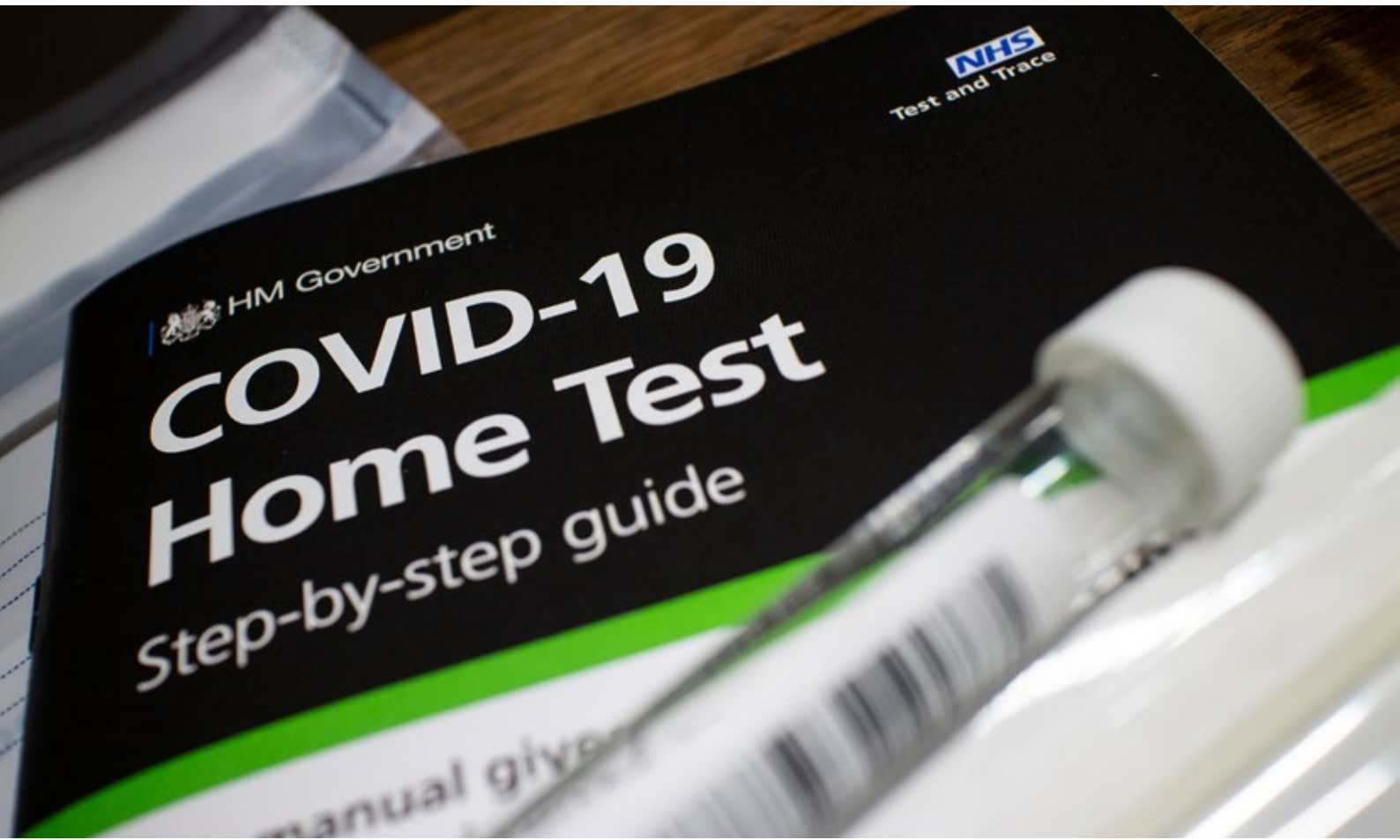


RELIABLE TESTING FOR COVID-19

Since the UK Government's decision to introduce antigen and antibody testing for Covid-19 in May, medical laboratories and testing organisations have made it a priority to extend their scope of accreditation to include Covid-19 diagnostic testing. In response, UKAS, the UK's National Accreditation Body, has made it their mission to help organisations deliver high-quality, reliable tests. Dina Patel speaks to Lorraine Turner, Technical Director at UKAS, to find out how UKAS is helping medical laboratories and testing organisations through a new fast-track accreditation process to ensure that the public has access to reliable tests



In May, the UK Government announced that anyone who has symptoms of Covid-19 can ask for a free test to check if they have the virus. The test usually involves taking a swab of the inside of your nose and the back of your throat using a long cotton bud, and needs to be completed within five days of symptoms appearing. This is called an antigen test. Antibody tests that check if you have already had the virus are also available. The test works by taking a blood sample and testing for the presence of antibodies to see if you have developed an immune response to the virus.

Testing is important because it allows contact-tracing systems to work effectively. Contact-tracing

systems work by notifying you when you have been in contact with someone who later reports positive for Covid-19. Testing helps to identify those who have been infected and need to isolate or be treated. Testing NHS workers also lets them know if it is okay for them to go to work. Antibody testing can be used to determine the level of immunity in a population, which could help to determine if lockdown rules can be eased.

Lorraine Turner, Technical Director at UKAS, speaks to *Quality World (QW)* about how UKAS is assessing the technical competence of laboratory staff and the facilities, equipment and testing methods used through a newly created fast-track accreditation process.

“Covid-19 testing had to be made available before accreditation was in place. UKAS developed a fast-track process to enable medical laboratories to extend their scope to cover testing for Covid-19”



QW: What is your role at UKAS?

Lorraine Turner: I am the Technical and Business Development Director at UKAS. I have a broad range of responsibilities that include leading UKAS's delivery of accreditation in healthcare and the design and development of new accreditation activities. I also have responsibility for the external affairs and technical and quality governance teams.

I started my career in local government as an analytical chemist and joined the civil service as Technical Officer for NAMAS (National Measurement Accreditation Service), which merged with the National Accreditation Council for Certification Bodies (NACCB) to form UKAS in 1995. Over the past 25 years, I have developed expertise in the use of accreditation to provide trust and confidence across many areas of science and industry. I work with a wide variety of stakeholders nationally and internationally to develop standards, guidance and policy to deliver accreditation. I also advise key stakeholders of both the established and potential benefits of using accredited services as an integral part of the UK's quality infrastructure. Most recently, this has included both the House of Lords Science and Technology Select Committee on forensics and Department of Health and Social Care, NHS England and NHS Improvement, and Public Health England regarding the situation with the Covid-19 pandemic.

QW: How has UKAS responded to the pandemic?

LT: Before lockdown commenced, UKAS started planning the switch to conducting remote assessments for all its customers. UKAS has been guided by the need to protect the health and safety of all its staff, assessors and customers, while maintaining trust and confidence in accredited testing services. Recognising the pressure that healthcare scientific

and diagnostic services were facing at this challenging time, UKAS worked with NHS England and NHS Improvement and the devolved governments to re-profile assessment activities for those services most affected by the pandemic.

Testing for Covid-19 had to be set up quickly and while it is normally the case that all tests performed are covered by accreditation, Covid-19 testing had to be made available before accreditation was in place. UKAS developed a fast-track process to enable medical laboratories to extend their scope to cover testing for Covid-19. I have been working closely with the Department of Health and Social Care as part of the Laboratory Capacity Review group to provide advice on accreditation and quality assurance, and to review the many offers of help the government has received to support and expand the testing capacity.

QW: Why is testing important for patients and the public?

LT: Matt Hancock, the Secretary of State for Health and Social Care, has said that during the Covid-19 pandemic, good quality testing can help provide us with certainty and is a big part of how we're going to defeat this disease. Consequently, helping laboratories deliver high quality, reliable tests is a priority for UKAS.

While the government has encouraged the rapid expansion of Covid-19 testing methods and capacity during the pandemic, this cannot be at the expense of ensuring the quality of the results. Recently, it has often been said that a bad test is worse than no test. It is, therefore, vital that all aspects of any new test methods and procedures are rigorously evaluated and verified if patients, regulators, and the public are to trust them. By assessing the technical competence of laboratory staff and the facilities, equipment and testing methods used, accreditation helps generate confidence in the quality and reliability of test results.

QW: How many applications has UKAS received from organisations wishing to gain accreditation for Covid-19?

LT: To date, UKAS has received over 70 applications from laboratories seeking to extend their scope of accreditation to include Covid-19 diagnostic testing, with a steady stream of new applications each week.

Given the novelty of the disease and the government's priorities on diagnosing the number of cases in the community, most of these applications have been for Covid-19 antigen testing. As priorities change and new testing methods are developed and evaluated, I expect the number and proportion of applications for Covid-19 antibody testing to increase.

At the beginning of June, the first two accreditations were awarded for Covid-19 antigen testing. St Helen's and Knowsley NHS Trust gained accreditation against ISO 15189 Medical laboratories – Requirements for quality and competence, for general patient diagnosis, and the Metropolitan Police was awarded accreditation to ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories, for testing its own staff.

Since then, around a dozen organisations, including NHS Trusts and private laboratories, have gained accreditation for Covid-19 antigen testing. The UKAS assessment team is working hard to process the remaining applications as quickly and as thoroughly as possible. These applications are at various stages of the assessment process, and more successful grants of accreditation are expected to be announced in the coming weeks.

QW: What does achieving this accreditation mean for laboratories?

LT: Accreditation introduces a vital level of quality assurance to the testing process and demonstrates the ability of a laboratory to perform valid test procedures and provide

“Accreditation introduces a vital level of quality assurance to the testing process”

reliable results. This means regulators, patients and clinicians can have confidence that accredited testing services are delivered with the highest levels of competence, quality and reliability. For medical laboratories, accreditation ensures the competence of the whole process, including pre- and post-examination activities, such as diagnosis and interpretation by clinicians.

It is often easy to forget that many laboratories are also businesses. Where accreditation is compulsory/mandatory, ►

ACCREDITATION

such as for testing for asbestos, achieving accreditation can open doors to previously closed marketplaces. Equally, in cases where accreditation is not a legal requirement, it can be a practical requirement/need of doing business, as many contract tenders will specify accreditation as part of the tendering process.

By incorporating recognised industry best practices, achieving accredited status can also have many internal benefits for a laboratory. These range from streamlined processes that improve efficiency and the bottom line, to raising levels of staff training and morale, as accreditation is often seen as a badge of honour.

QW: What are some of the biggest challenges in the accreditation process for laboratories and testing organisations?

LT: Every laboratory is different in terms of its facilities, equipment and personnel, the testing procedures it performs, which of those (if any) are already covered by its scope of accreditation and why it is seeking to gain accreditation. Consequently, each laboratory's journey to accreditation will be different and face different challenges, depending on whether it's a relatively minor extension to scope for an experienced and well-resourced laboratory, a radical departure from a laboratory's existing scope, or a first time accreditation for a new laboratory.

The biggest challenges faced by laboratories providing Covid-19 testing have been to ensure that these new testing methods are valid and that the laboratories can achieve their expected performance. Understanding the capability of new methods takes time, and this testing was needed urgently. Laboratories have had to work hard to gather evidence and data to demonstrate their capability at the same time as having to test large volumes of patient samples.

For laboratories that are new to accreditation, there is the need to ensure they have their supporting processes fully documented and that they have a means to monitor their performance to ensure reliable results can be delivered on an ongoing basis.

QW: How can they overcome these challenges?

LT: The key to any laboratory successfully passing an accreditation assessment is being able to demonstrate that they have the necessary technical competence, staff, methods, equipment and safeguards in place



Photo: 10 Downing Street

Organisations that are conducting Covid-19 antigen testing

UK Biocentre, which runs the National Institute for Health Research's National Biosample centre in Milton Keynes, is at the forefront of the Covid-19 national testing effort. It was designated by the government as one of the first three laboratories required to analyse tens of thousands of Covid-19 samples daily.

The centre is one of the first Lighthouse labs - the biggest network of diagnostic testing facilities in the UK - and specialises in managing high volumes of samples. To date, more than 500 scientists have analysed over three million swab samples and the centre is ramping up testing to further increase throughput to help the country get on top of the coronavirus.

Dr Tony Cox, CEO at UK Biocentre, said: "From a standing start, we began using a manual process to test Covid-19 samples within four days. We rapidly redesigned our laboratories and installed robotic equipment enabling us to test more than 30,000 samples every day. Scientists here oversee the liquid handling robots, the RNA extraction, the PCR reagent process and other

state-of-the-art kit and machinery that now fill our laboratories. It is this industrial scale testing that gives us the capacity to test tens of thousands of samples each day."

In May, UKAS granted St Helen's and Knowsley NHS Trust accreditation against ISO 15189 Medical laboratories - Requirements for quality and competence, for general patient diagnosis. The NHS Trust is using the accredited Covid-19 test for general patient diagnosis.

The Metropolitan Police has also been awarded accreditation to ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories, for testing its own personnel. These accreditations are specifically for Covid-19 antigen testing and are the first to successfully come through via UKAS's new fast-track Covid-19 assessment process.

To date, around a dozen laboratories across both the public and private sector have been accredited by UKAS for Covid-19 diagnostic testing. An updated list of these businesses and organisations can be found by searching for the phrase "SARS CoV-2" on the UKAS website (ukas.com).

to perform the testing process in such a way that it meets the criteria laid out in the relevant standard. For most laboratories, this is ISO/IEC 17025 – Testing and calibration laboratories, while ISO 15189 Medical laboratories – Requirements for quality and competence, is more suited to medical laboratories. The first step is to read and understand the requirements of the standard and implement measures to make sure your laboratory meets them.

QW: How does the new remote assessment process maintain the vigilance of assessment under the new Covid-19 restrictions?

LT: The Covid-19 pandemic has highlighted that the need for competent, reliable and verifiable testing is as important as it has ever been. It is vital that laboratories maintain accreditation during this time, so that regulators, patients, clinicians and the general public continue to have confidence in the fitness for purpose of their testing activities.

To help laboratories mitigate the current social distancing restrictions, UKAS has been conducting all assessments remotely since March and is expecting this to continue until at least October. Although the actual assessment process has altered slightly, its objectives and standards of performance have remained the same. No corners have been cut, or assessment criteria compromised. Laboratories will still have to prove they have the same level of competence across the same aspects as they would if an assessment was being conducted on-site.

The witnessing of the relevant testing activity is an important part of the accreditation assessment process. Normally this would be done in person by the UKAS assessment team, but testing can be witnessed remotely

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in several ways, including live streaming and narrated video.

Where necessary, to support the setup of the national testing programme for Covid-19, UKAS has performed on-site assessments for applicant laboratories.

Jeff Ruddle, Strategic Development Director at UKAS, recently explained in an article for the CQI how UKAS is helping conformity assessment bodies with remote assessments (quality.org/knowledge/remotessessments).

QW: What is the next biggest challenge for UKAS going forward?

LT: During the current national emergency, UKAS is fully committed to maintaining the role, level and status of accredited organisations as a vital part of the UK’s quality infrastructure. This will continue to be the case as lockdown is incrementally lifted, when efforts will be focused on helping UKAS-accredited organisations successfully navigate and make the most of the new political and economic landscape. We want to take the learning from this period of implementing remote assessments to develop the use of technology further and to support the development of the risk-based approach to assessments. The need for independent assurance of competence remains as strong as ever, even though the way that assurance is provided might change.

UKAS’s development team have already received a number of enquiries for new schemes seeking to provide confidence in new processes and services that have arisen as a result of this pandemic; for example, to support safe working environments and cleaning/decontamination procedures. ■