OPINION

THE BIG QUESTION

Better recognition for biomedical scientists: *p.14*

JUNE ALMEIDA

IMAGING PIONEER

Looking back at the first person to see a human coronavirus: *p.30*

IN VITRO DIAGNOSTICS

PRODUCT REGULATION

How regulatory changes could impact on laboratories: *p.40*

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CONTENTS

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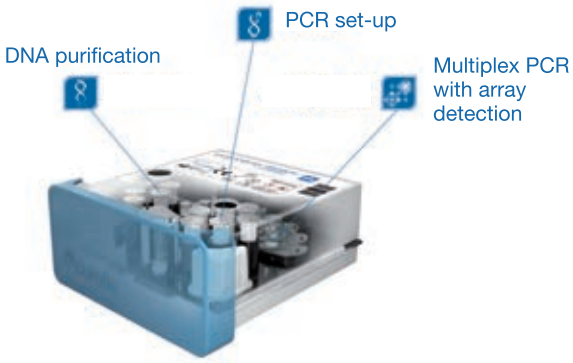

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SUPPORTING MEMBERS

David Wells, IBMS Chief Executive, on how the Institute will support, progress and promote biomedical science.

It was great to see our member-elected Council come together and discuss the current and future strategy of the IBMS last month. Ours is a truly democratic professional body – run by the membership, for the membership.

It was agreed that we have made great strides with the terms "support, progress, promote" at the core of all our actions and that we must take these mission words forward – but with the new and emerging professional landscape in mind.

We all agreed that the IBMS needs to be more responsive and agile when it comes to our members' education needs. We must support more access to HCPC registration through better uptake of our entry routes and allow our HCPC-registered members to pick and choose the breadth of their specialist portfolios on a modular basis.

We also need to support our members by further increasing the wider public's understanding of the benefits that the profession and biomedical science deliver to society.

We want more of our members to progress, through better and more relevant training and qualifications, while allowing a more agile and inclusive approach. The IBMS supports greater diversity and intends to champion our members' values, such as sustainability and high professional standards.

The IBMS itself also needs to progress, by opening its doors to the full range of the biomedical science profession within the UK and globally. Our members in healthcare and academia will be strengthened with a deeper membership base in industry, research and diagnostics – so our voice can be louder and more representative of the profession at large.

Alongside better support and progress, the IBMS must also continue to promote the importance of our profession and build upon our profile post-pandemic, to develop a policy and engagement capability at a government level.

We also need to promote our highest qualifications, widen the disciplines that these are available in and increase the potential numbers of our members who can access them.

Through high-quality input and reflection, the discussion came to form an ambitious strategy from an equally ambitious Council. Looking around the table, it was clear that our professional body was in very capable hands. I have no doubt that the IBMS will be going from strength to strength in the coming years – delivering valuable services to our members and the profession at large.

David Wells
Chief Executive

Institute of Biomedical Science is the professional body for the biomedical science profession.

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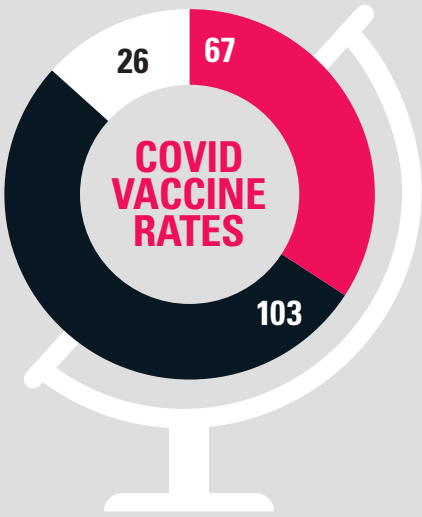
SCIENCE NEWS IN NUMBERS



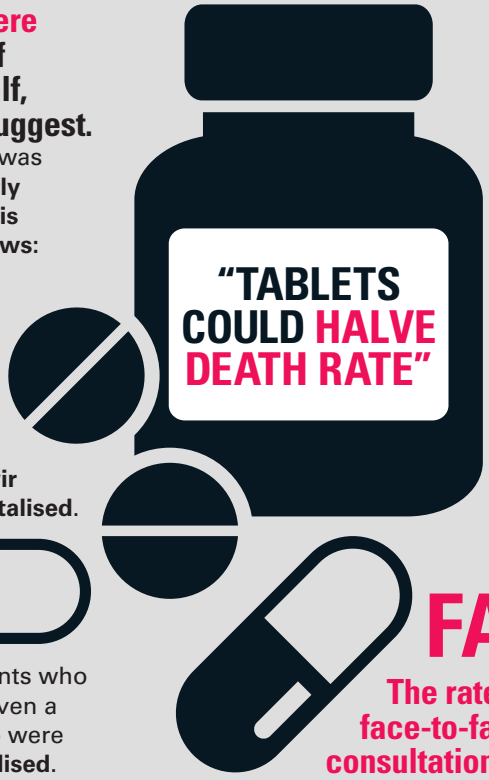
An experimental drug for severe COVID-19 could cut the risk of hospitalisation or death by half, interim clinical trial results suggest.
In a study, the tablet, **molnupiravir**, was given **twice a day** to patients **recently diagnosed with the disease. Analysis of the 775 patients in the study shows:**

0 people given **molnupiravir died.**

7.3% of those given **molnupiravir** were **hospitalised.**

8 people given a placebo **later died** of **COVID-19.**

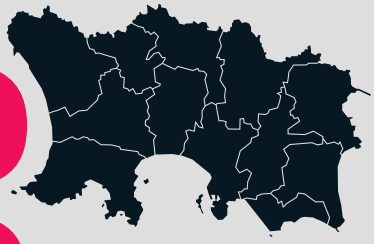
14.1% of patients who were given a **placebo** were **hospitalised.**



Of the 196 countries and territories administering vaccines and publishing rollout data, 67 are high-income nations, 103 are middle-income and 26 are low-income.

FACE-TO-FACE

The rate of face-to-face GP consultations in England has changed little since the winter lockdown, NHS Digital data show.
A total of **58% of patients were seen face-to-face** in August, which was the first full month following the ending of restrictions. That compares with **54% in January** and **more than 80%** before the pandemic.



750

DEATHS FOR JERSEY

Jersey has recorded the lowest annual deaths since 2014.
In 2020, **750 residents died**, states the Annual Mortality Report. **Cancer and circulatory system diseases** were the main causes of death and **people who died with COVID-19 made up 7% of the total**, making it the **fourth highest cause of death.**

₹50k

The Indian government's decision to pay 50,000 rupees (£498) as compensation for every death due to COVID-19 has been approved by the country's top court. India has **officially recorded more than 447,000 COVID-19 deaths**, but experts believe that the figure **may be up to 10 times higher.**

SCIENCE NEWS

CANCER

"No urgent referral for 60% of red flags"

Six out of 10 patients in England with "red flag" symptoms indicative of possible cancer didn't receive an urgent referral for specialist assessment within two weeks, as recommended in clinical guidelines.

Nearly 4% of patients in the sample of 48,715 consultations were subsequently diagnosed with cancer within the next 12 months, new research shows.

Scientists used information on diagnoses, investigations, and treatment of general practice patients supplied to the Clinical Practice Research Datalink – a large database of routinely collected anonymised UK primary care health records.

The red flag symptoms are: swallowing difficulties; postmenopausal bleeding; iron deficiency anaemia; rectal bleeding; blood in the urine; a breast lump.

Overall, 40% of patients received an urgent referral within two weeks of seeing their GP. Of the patients who received an urgent referral, 10% were diagnosed with cancer within the year. Of the patients who didn't receive an urgent referral the figure was 3.6%.

→ **bit.ly/3AghpcS**

GASTROENTEROLOGY

OESOPHAGEAL CANCER INCREASE IN UNDER 50S

Oesophageal adenocarcinoma cases have tripled in under 50s over the past 30 years, a new study has found.

The research, conducted in the Netherlands on almost 60,000 patients, found new cases of oesophageal adenocarcinoma had risen from 0.34 to 0.92 per 100,000 population between 1989 and 2018.

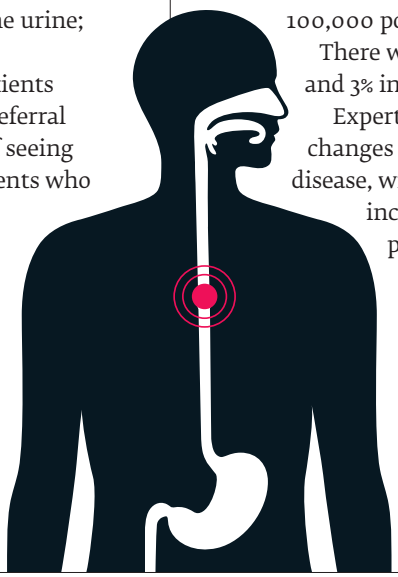
There was an average increase of 1.5% in males and 3% in females.

Experts believe the rise in cases reflects changes in lifestyle-related risk factors for the disease, with increases in unhealthy habits, including smoking, poor diet and reduced physical exercise.

Ali Al-Kaabi, lead author, said: "Gastro-oesophageal reflux, obesity and smoking are important risk factors for oesophageal adenocarcinoma.

"We also know that rates of these risk factors have all increased in young adults over the past 30 years."

→ **bit.ly/3iymqYo**



PRESCRIBING

TRIAL CAMPAIGN TO REDUCE OPIOIDS "IS EFFECTIVE"

A campaign that urged GPs to "think twice" before putting a patient on opioid medicines is effective in reducing opioid prescribing in primary care, according to a major study.

Although the reduction in opioid prescriptions issued by individual GPs was small, when aggregated they had a large effect.

The campaign was trialled in West Yorkshire and the researchers say over a year, it resulted in 15,000 fewer patients being given opioids – and a net saving to the NHS of £700,000.

If it were replicated across the UK, the campaign could lead to 406,000 fewer patients taking opioid medications.

The study involved a "feedback" intervention that continued for a year, where GPs were given two-monthly updates on the number of people at their practice prescribed opioids.

Opioids are often given as painkillers, but the Royal College of Anaesthetists says there is little evidence they help with long-term chronic pain – although they work for acute pain and end-of-life care.

In April, NICE issued guidance on supporting patients who experience chronic or persistent pain, which states that they should not be started on commonly used drugs, including opioids.

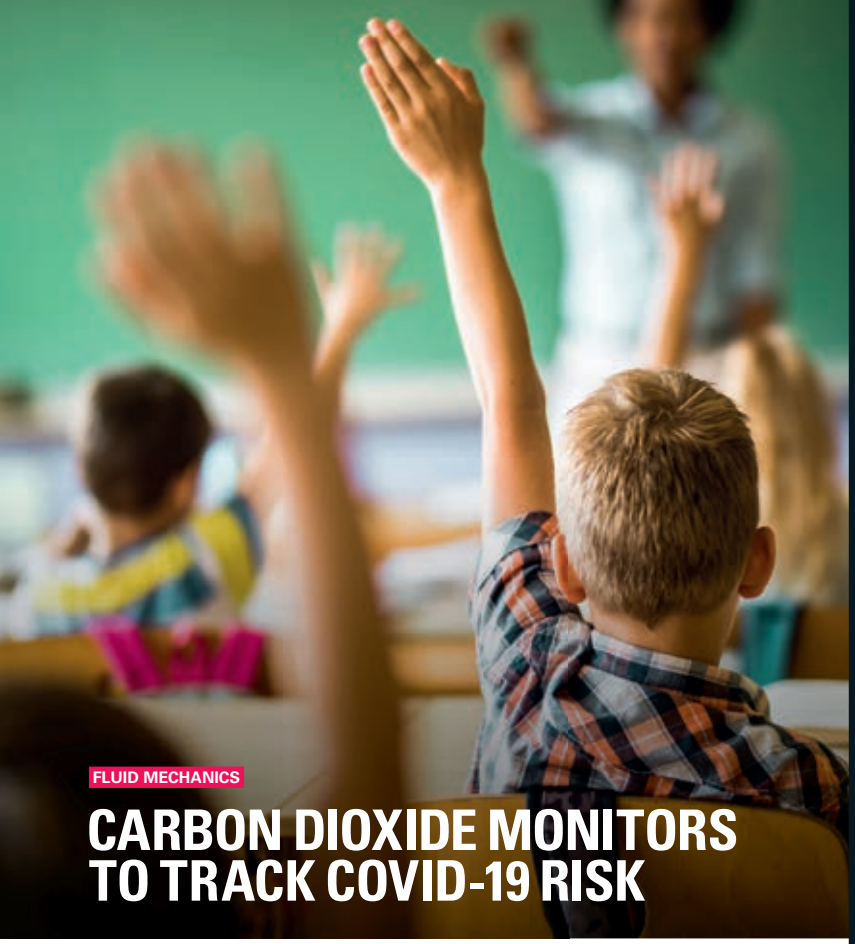
The number of prescriptions issued by GPs in England for opioids increased by 37% from 1998 to 2016, with the quantity of oral morphine doubling.

→ **bit.ly/3oAYBTw**

37%

THE NUMBER OF **PRESCRIPTIONS ISSUED BY GPS** IN ENGLAND FOR **OPIOIDS** INCREASED BY **37%** FROM 1998 TO 2016

IMAGES: ISTOCK/SHUTTERSTOCK/SCIENCE PHOTO LIBRARY



FLUID MECHANICS

CARBON DIOXIDE MONITORS TO TRACK COVID-19 RISK

Scientists have developed a way of using carbon dioxide monitors to help estimate the risk of catching COVID-19 and other airborne diseases in near-real time.

They say it could help track the evolving risk of transmission in indoor spaces, such as schools and offices, and may also lay the groundwork for air quality monitoring in the future.

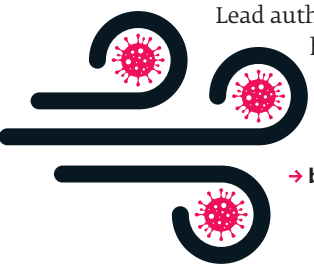
Such systems could predict transmission rates of airborne diseases, such as COVID-19 or seasonal flu, and work in concert with ventilation systems to adjust the air within buildings to keep the risk of transmission low.

The research builds on work from the same authors, published earlier this year, which provided a guide to the risk of airborne transmission in different indoor settings.

Using data from super-spreader events, they produced a mathematical model that estimated the average length of time it would take to become infected when sharing a space with someone who had COVID-19.

From this they produced a safety guideline, setting limits on time spent in shared spaces, and adjusted by factors including the size of room, numbers of infected and susceptible people, what they were doing, ventilation and mask use.

The researchers say there is overwhelming evidence that the virus which causes COVID-19 is mainly spread by airborne droplets, breathed out by infected people. Measuring CO_2 tracks how much air people are breathing out and the rate at which it is removed by ventilation.



Lead author Martin Z Bazant said: "CO_2 monitoring has been used for decades to assess the quality of air handling in buildings, and can now be re-purposed to assess the risk of indoor airborne disease transmission."

→ **bit.ly/3uOMlzR**

WHAT'S HOT AND WHAT'S NOT

HOT

GLYCEROL

Applied topically or ingested in drinking water, glycerol is effective at combating psoriasis, a new paper reports.

HOT

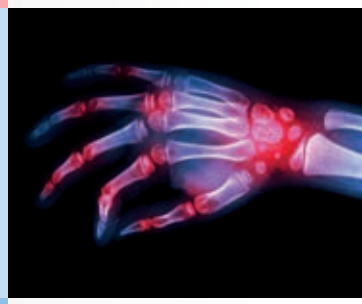
THE SUN

Scientists David Julius and Ardem Patapoutian, who discovered how our bodies feel the warmth of the sun or the hug of a loved one, have won the Nobel Prize.

HOT

BLUE CRABS

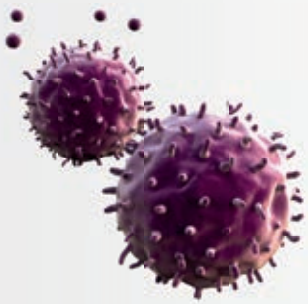
Scientists at the University of Maryland Centre for Environmental Science have sequenced the genome of the blue crab, which will be made publicly available.



NOT

RHEUMATOID ARTHRITIS

Researchers at The University of Toledo have developed an experimental vaccine that shows significant promise in preventing rheumatoid arthritis.



NOT

T-CELL TESTS

A study by scientists at Uppsala University and Karolinska Institutet says T-cell tests are unreliable in establishing whether someone has previously had COVID-19.

NOT

TICKS

A novel virus that can infect humans and cause disease and is transmitted by tick bites has been identified by scientists in Japan. It has been named Yezo virus.

IMMUNOLOGY

IMMUNITY AFTER CATCHING COVID

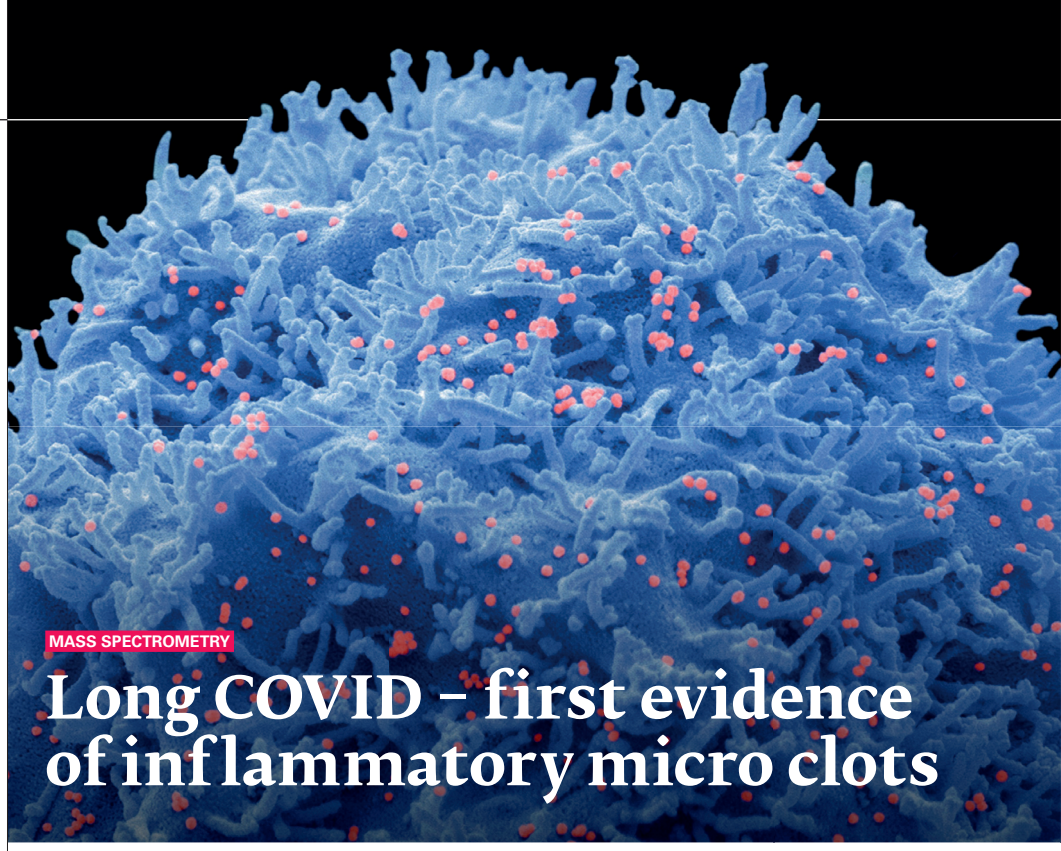
There has been uncertainty about how long immunity lasts after someone who is unvaccinated is infected with SARS-CoV-2.

Now a team of scientists led by Yale School of Public Health and the University of North Carolina at Charlotte has published a study indicating strong protection following natural infection is short-lived.

"Reinfection can reasonably happen in three months or less," said Jeffrey Townsend, the Elihu Professor of Biostatistics at the Yale School of Public Health and a lead author of the study. "Therefore, those who have been naturally infected should get vaccinated. Previous infection alone can offer very little long-term protection against subsequent infections."

The study is the first to determine the likelihood of reinfection following natural infection and without vaccination.

→ **bit.ly/3mqZc7x**



MASS SPECTROMETRY

Long COVID – first evidence of inflammatory micro clots

New research indicates that an overload of various inflammatory molecules "trapped" inside insoluble microscopic blood clots could be the cause of some of the lingering symptoms of long COVID.

The finding was made by Professor Resia Pretorius from Stellenbosch University.

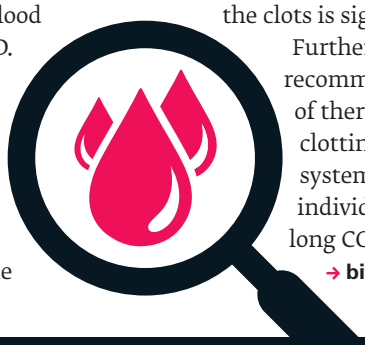
She said: "We found high levels of various inflammatory molecules trapped in micro clots present in the blood of individuals with long COVID. Some of the trapped molecules contain clotting proteins such as fibrinogen, as well as alpha(2)-antiplasmin."

Alpha(2)-antiplasmin is a molecule that prevents the breakdown of blood clots, while fibrinogen is the main clotting protein. Under normal conditions the body's plasmin–antiplasmin system maintains a fine balance between blood clotting and fibrinolysis.

With high levels of alpha(2)-antiplasmin in the blood of COVID-19 patients and those suffering from long COVID, the body's ability to break down the clots is significantly inhibited.

Further research is recommended into a regimen of therapies to support clotting and fibrinolytic system function in individuals with lingering long COVID symptoms.

→ **bit.ly/2WFlgRQ**



UNDER THE MICROSCOPE

This month: HeLa cells

I have heard of this.
Many people will have. It is an immortal cell line that is used in scientific research.

Has it been in the news?
Yes. A life-size bronze statue of Henrietta Lacks, the Black American woman after whom the HeLa cell line was named, has been unveiled at the University of Bristol to honour the 70th anniversary of her cells first being used.

Who was Henrietta Lacks?
She was a young wife and mother who died in 1951 of an unusually aggressive form of cervical cancer. During surgery, a sample of cells was taken from the tumour and sent to a laboratory where they were found to be the first living human cells ever to survive and multiply outside the human body. Henrietta's cells were taken without her or her family's knowledge or consent, and it was only in 1975 that, by chance, the family found out about her legacy.

What have they been used for?
They have made possible some of the most important medical advances of all time, including the polio vaccine, chemotherapy, gene-mapping, IVF and cloning. They are used in almost every major hospital in the world.

Sounds like she left an incredible legacy.
She certainly did. Professor Jeremy Tavare, Dean of the Faculty of Life Sciences at the University of Bristol, said: "Many of our biomedical science researchers whose work uses human cells have used Henrietta's cells in their research or with collaborators, including myself. We all owe Henrietta an enormous debt of gratitude."

Where can I learn more?
Visit **bit.ly/3a6mlkH**

CARDIOVASCULAR DISEASE

Blood marker for peripheral artery disease

Researchers at Washington University School of Medicine have shown that high levels of a specific protein circulating in the blood are an accurate marker for a severe type of peripheral artery disease that narrows the arteries in the legs and can raise the risk of heart attack.

The protein, called circulating fatty acid synthase (cFAS), is an enzyme that manufactures saturated fatty acids. Until recently, fatty acid synthase was thought to be found only inside cells.

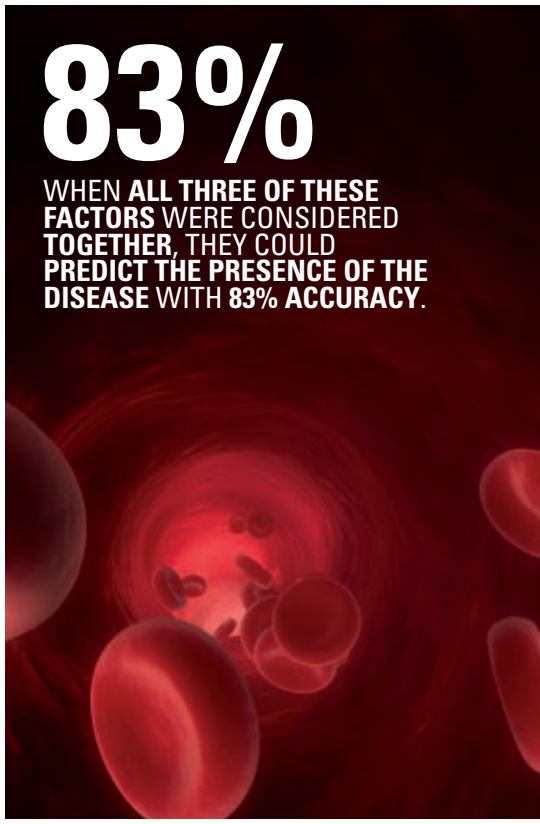
The new study suggests that fatty acid synthase also circulates in the bloodstream and may have an important role in the plaque formation characteristic of cardiovascular disease.

The team collected blood samples from 87 patients before they underwent vascular surgery to treat chronic limb-threatening ischaemia.

The researchers found that cFAS levels in the blood were independently associated with the disease. A diagnosis of type 2 diabetes and smoking status also were strongly and independently correlated with chronic limb-threatening ischaemia.

When all three of these factors were considered together, they could predict the presence of the disease with 83% accuracy.

→ **go.nature.com/3mpF1a4**



A vital leap forward in cardiac testing

Speed meets accuracy where it matters most – the wait is over for hs-cTnI at the point of care.

When ruling out a potential myocardial infarction (MI), every minute spent waiting on test results comes at a cost. Patients and their families are anxious, and clinicians and laboratory professionals are pressured to identify the problem quickly and accurately. Increased time to results adds congestion to an already busy emergency department. But what if ED staff had access to high-sensitivity troponin right at the point of care?

Consider the value of adding a new tool at the clinician's disposal that can provide high-sensitivity troponin I (hs-cTnI) results in just 8 minutes from a single fingerstick and patient interaction. The solution is intuitive, easily integrates into the existing workflow, and gives laboratory partners centralised control over decentralised testing, so ED throughput can be improved for efficiency and confidence.

The Atellica® VTLi Patient-side Immunoassay Analyser, powered by Magnotech® Technology, will transform your chest pain assessment process to benefit patients, clinicians, and your operational workflow. Because when it comes to assessing patients with symptoms of an MI in the ED, trust, time, and resources aren't just valuable – they're vital.

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SIEMENS Healthineers

TECH NEWS

INTEGRA BIOSCIENCES

PIPETTING ROBOT

Integra Biosciences is giving labs an opportunity to win an Assist Plus pipetting robot.

The Assist Plus automates multichannel pipettes and is ideal for a variety of different applications, from PCR to immunoassays.

It is designed to free up time, help streamline daily pipetting tasks and minimise the risk of errors or operator-to-operator variability.

For information and to enter the competition, visit the website.

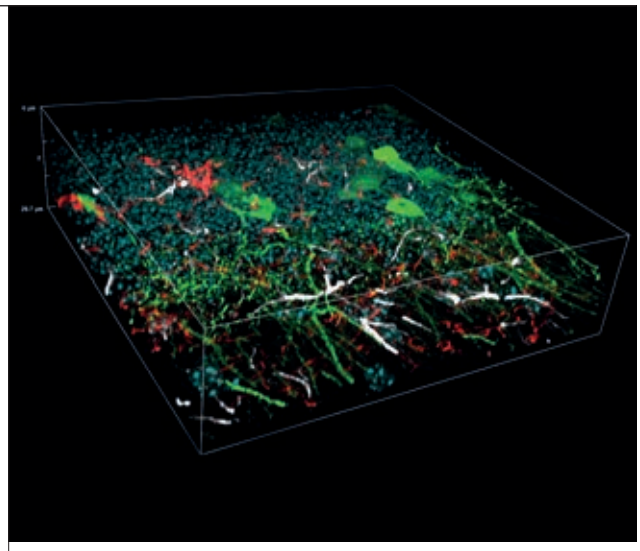
→ **integra-biosciences.com**

CN BIO

ONCOLOGY SERVICE

CN Bio, a leading organ-on-a-chip company that designs and manufactures single- and multi-organ microphysiological systems, has launched its oncology service in response to the global need to improve cancer drug discovery approval rates. The ability of existing approaches to mimic the dynamic drug concentrations in the human body is limited, but the oncology service enables the creation of human and animal PK profiles and applies them to 3D tumour models and organoids.

→ **cn-bio.com**



CRESTOPTICS

MICROSCOPE MODULE

CrestOptics, a manufacturer of high-end microscopy solutions and advanced systems for fluorescence microscopy and diagnostic applications, has launched DeepSIM – a super-resolution module designed to enhance the imaging capabilities of confocal microscope systems.

The DeepSIM module can be used with Crest's X-light V3 spinning disk, or alternative confocal systems, to offer high-resolution images for life science researchers.

→ **crestoptics.com**

THIS MONTH WE ASK

"How can biomedical scientists get better recognition for what they contribute to healthcare?"

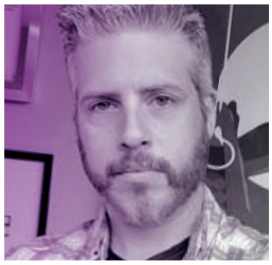
THE BIG QUESTION

Nigel Coles

Pathology Quality Manager
Birmingham Women's NHS Foundation Trust

All healthcare organisations are set up in such a way that it puts people in groups – groups that have the same, or similar, tasks and functions, for example pathology, clinical biochemistry, automation section and so on. That is not so surprising as healthcare is extraordinarily complex; it relies on 1.5m human beings trying to help 60m other human beings. Each of these wants to have a home, as Maslow has been telling us for nearly 80 years. We have safety and security in our groups and for that to happen we want order and predictability, which reinforces silo working.

As a biomedical science workforce, we must recognise ourselves first and the huge contribution we make to people's lives by recognising our unique skills. Once we recognise that in ourselves, we can move out of silo and help, support, lead and challenge other areas of healthcare by interacting, engaging and integrating with other silos. In today's connective world, silo working does not have to be the problem it once was. Every day there are numerous opportunities to collaborate with other clinical groups and professions, but you do need confidence to do it. Take those opportunities – the benefits are massive, both personally and for your profession. The skills you have are unique, use them – they are skills other groups are looking for. As you voice your opinion, recognition will develop, providing you state clearly "I am a biomedical scientist". But if we stay in our silos, recognition for biomedical scientists remains in the other people's hands.



Dr Chris Moore

Programme Leader BSc Biomedical Science
UWE Bristol

This is a tough one because there are different levels of recognition that I believe biomedical scientists deserve. On one hand, we have those students who undertake a biomedical science degree at a university that is accredited by the IBMS – that is a badge of honour that is not recognised enough, and it isn't valued enough that they studied somewhere that has the profession in mind, especially when any university can call a cluster of human health-related modules "biomedical science", but without the rigours and competencies that the IBMS and the NHS needs in its staff.

Then there are those who are already in the role and spend a great deal of their careers at the same banding as a graduate nurse or physiotherapist and are seen by the end users, the patients and the public, as generic lab technicians, rather than the (often) discipline specialists that they really are. The career progression, specialisation and clinical involvement of biomedical scientists feels like it is still in its infancy, when it could provide so many benefits to diagnostics and health management if there were closer relationships with the clinical personnel.

For simple recognition from a practical perspective though, it wouldn't hurt trusts to consider not sticking the pathology labs in basements or separate buildings when designing hospitals though – patients and visitors should be able to see this remarkable step in the diagnostic process as easily as the nurse by the bedside or the radiographer in the booth.

Allan Wilson

Lead Biomedical Scientist in Cellular Pathology
Monklands Hospital

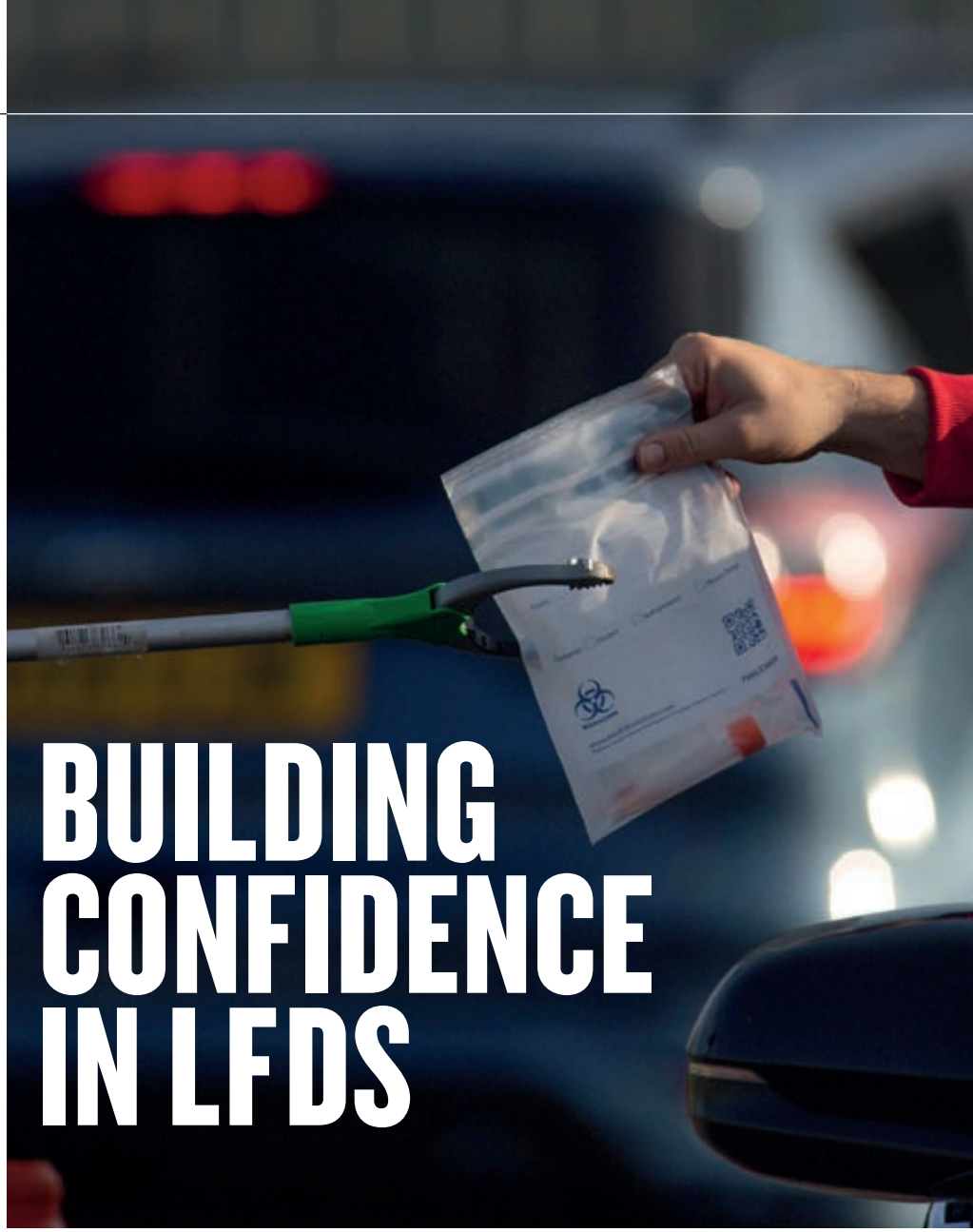
The pandemic and focus on laboratory testing and biomedical scientists has undoubtedly raised the profile of laboratory medicine and the vital role that laboratories play in delivery of healthcare. However, it is not clear if this has led to a wider recognition of the vital contribution that biomedical scientists contribute to healthcare.
A logical second question is who do we want this recognition to come from? From my interactions with the media during the pandemic, I think there are four groups that we should be targeting: the media, the public, politicians and other healthcare professionals.

I would argue that we have made inroads with the media and politicians and we are now in regular contact with a range of media groups and have seats at a range of political tables. The public is a harder nut to crack, but not impossible – we need to be more vocal about what we do in every aspect of our life – too often we describe what we do as "I work in a lab".

There is a lack of knowledge among most of our healthcare colleagues of what we do. If those groups we work closely with do not understand or recognise what we do, what chance is there for the general public? Again, I would argue for advocacy and stepping outside the lab to engage with every possible clinical group with which we can legitimately engage.

So, I offer you a challenge – be an advocate, step outside the lab door and shout loudly about what we do and what more we have to offer.

IMAGE: HENDRIK DAHL/IKON



BUILDING CONFIDENCE IN LFDS

New research has used a mathematical formula to clarify how lateral flow devices are more effective than sometimes portrayed. **Professor Iain Buchan**, Executive Dean of Liverpool's Institute of Population Health, explains the findings.

"Public health works really well when there is a very close partnership between service and science," says Professor Iain Buchan, Chair in Public Health and Clinical Informatics and Executive Dean at the University of Liverpool. "The most important thing is to have great science networked at national and international levels and great partnerships to embed and provoke the science at local levels.

"We've been able to move very fast in Liverpool because of the particularly close relationship between science and [the public health] service," he says, explaining that a long tradition of action-research for dealing with public health challenges in a deprived area prepared Liverpool to deliver world-first COVID-19 insights, such as how mass rapid-antigen testing works "on the ground".

Leading the university's Institute of Population Health, Iain's work focuses on data-intensive public health research for "major societal challenges", most recently responses to COVID-19. Moving from clinical medicine to public health in 1996, Iain has a long history of "turning people's numbers into actionable information, really trying to close that data–action gap". He says: "I saw a lot of underused data – I was one of the first people to describe the child obesity epidemic, using routinely collected health visitor data."

The latest research he has co-authored has found that lateral flow devices (LFDs) are more accurate than previously reported, demonstrating their reliability as a public health tool in reducing the spread of the virus. Working with researchers from University College London, Harvard University and the University of Bath, the research investigated validation studies of LFDs and showed the problem with reporting sensitivity values (the proportion of people with the infection who test positive) of LFDs relative to polymerase chain reaction (PCR) tests.

The study used a new formula for calibrating the sensitivity of LFDs, which showed they are likely more than 80% sensitive at picking up people who are infectious with the COVID-19 virus – i.e. a public health test for infectiousness and not a clinical test of for those who have been infected, but who may no longer be infectious, as is the case with PCR tests.

Different properties

Previous research into the effectiveness of LFDs has compared them with PCR, suggesting the latter is the "gold standard" to show if someone is positive or negative for COVID-19. But this research highlights that LFDs work in a very different way to PCRs – they are not equivalent.

LFDs detect material from the surface proteins of the virus and are very likely to give a positive result when someone is infectious. PCR tests detect the virus'

IMAGES: ALAMY

genetic material, which can be present for weeks after a person has stopped being infectious. In previous research, LFD sensitivity was being evaluated by ability to identify the same cases that PCRs picked up. If someone's LFD is negative but their PCR is positive this is because they are not at peak transmissible stage.

"It's important to... recognise that the two tests reflect different properties of the infection and have different testing utilities – clinical versus public health," the study reads. Iain adds that the results of the study weren't a surprise because it used a mathematical way of synthesising the differences between a public health test of infectiousness and a clinical test of having been infected.

"We had done a lot of initial research last November [2020], looking at the real-world performance of rapid antigen testing," Iain says, adding that the latest research findings were an "unsurprising projection of those results onto the virus' usual time course in a person's body". The research also makes an important distinction between viral load and viral shedding, where more research needs to be done, he says.

Using the data

The study's authors say that it's important health professionals and the public have clear information about the operating characteristics of the tests. "Criticisms of LFD for apparent low sensitivity have failed to take the viral biology and epidemiology into account," the study reads.

"This has confused policymaking and damaged trust in LFDs, despite the need for better tools to control transmission of SARS-CoV-2. It is our hope that recalibrated absolute sensitivity statistics will assist policymaking and help build public confidence in LFD as a tool to aid COVID-19 resilience and recovery."

The University of Liverpool has collaborated with the NHS and local government to put together a data legacy system for ongoing COVID-19 responses and recovery, called CIPHA (www.cipha.nhs.uk), that can be used quickly to understand the real-world, system-wide impacts of technologies such as diagnostic tests, symptom monitoring devices, new care pathways and artificial intelligence.

"This is a computational way of gathering a bigger, system-wide picture of what happens when you put a technology into a real-world setting, and it helps to target those resources for the best outcomes," Iain says. "For the first time, we've got updated data every 30 minutes from COVID public health systems combined with NHS and local authority social care. That allows different parts of a service to coordinate their actions in near real-time."

Future studies hope to improve the calibration further using series of daily repeated PCR and LFDs among substantial cohorts drawn from the general population. All of this strengthens the links between public health services responsible for communication, how people can access a test without digital means and many other factors, and clinical research. "Reverse-engineering practical actions [of research] helps close the data–action gap, and that provokes really good science," Iain concludes. BMS

LFD FACT FILE

- ✔ Lateral flow devices were first rolled out in Liverpool in November 2020, as part of a pilot to test everyone living or working in the city regardless of whether they had COVID-19 symptoms.
- ✔ Around a third of COVID-19 transmissions are from people before they start displaying classic symptoms.
- ✔ A pilot study of asymptomatic testing in Liverpool found the sensitivity of the LFD was estimated to be 40% and the specificity relative to PCR (the proportion of people without the infection who have a negative test) thought to be about 99.9%.
- ✔ NHS Test and Trace figures show that over 6 million LFDs were conducted on 2 to 8 September 2021 – a 52.2% increase from the previous week. Over 1.4 million PCR tests were conducted, an 18.9% increase from the previous week.
- ✔ For self-reported LFD positives that were matched to a confirmatory PCR, 90% were confirmed positive by a subsequent PCR.
- ✔ For assisted LFD positives that were matched to a confirmatory PCR, 79% were confirmed positive by a subsequent PCR.

SHINING A LIGHT ...ON LIGHTHOUSE LABORATORIES

We look back over the history of the lighthouse labs and whether better quality control and tighter regulation are needed.

An investigation was launched in October after a COVID-19 testing laboratory, mistakenly told up to 45,000 people that they did not have the disease.

Testing at the Wolverhampton lighthouse laboratory was suspended and an investigation launched.

The issue came to light when people had positive lateral flow tests, but negative follow-up PCR results from the lab between 8 September and 12 October.

The error meant that thousands of people infected with COVID-19 were wrongly told to stop isolating, and could have infected others.

When the news broke, the IBMS released a statement that publicly reiterates the need for a regulated workforce and laboratory accreditation for mass testing centres.

It said: "As the professional body for biomedical science, the IBMS expects any workforce undertaking diagnostic testing for COVID-19 to meet the same minimum requirements as any other medical laboratory workforce that is involved in diagnostic testing.

"Our members' established services have some of the highest quality testing programmes in the world. This has been achieved through the implementation of stringent training and registration processes for staff and robust quality management systems for testing – both of which have proven to provide high-quality and safe services for patients.

"The mass testing centres set up during the pandemic must assure the same quality of testing and competence of staff as pathology laboratories in the NHS and private healthcare sector."

The statement came just two months after the IBMS Council delivered a position statement on the need for registered staff and accreditation in laboratories doing COVID-19 testing (see box, overleaf, for an extract).

What are lighthouse labs?

Lighthouse laboratories – which take their names from the PCR testing technology that uses fluorescent light to detect the virus – are high-throughput facilities dedicated to COVID-19 testing for NHS Test and Trace.

Each lighthouse laboratory has been reviewed by experts and is supported by

"Our members' established services have some of the highest quality testing programmes in the world"

an external clinical virology advisor.

The lighthouse laboratories are managed through the Department of Health and Social Care (DHSC), NHS trusts, commercial suppliers, academia and not-for-profit organisations.

In June 2020, NHS Test and Trace had the capacity to carry out 2000 tests per day but, following the launch of the lighthouse labs network, by March this year the number had increased to more than 750,000 a day.

NHS Test and Trace is for England only, but similar programmes are in place in Scotland, Wales and Northern Ireland. These programmes are: Test and Protect in Scotland; Test, Trace, Protect in Wales; and Contact tracing in Northern Ireland, all of which rely to some extent on the work of lighthouse laboratories.

Criticism

As is the case with most massive infrastructure and logistics programmes, the rollout of the lighthouse laboratory network has had its issues.

Earlier this year *Panorama*, the BBC documentary series, aired an episode featuring covert filming from inside a lighthouse lab in Milton Keynes,

THE IBMS COUNCIL POSITION STATEMENT (AN EXTRACT)

Current COVID-19 testing landscape

The national response to the COVID-19 pandemic has required an unprecedented increase in the UK's capacity to provide timely and accurate PCR and serology testing for the SARS-CoV-2 virus. The UK government has aimed to control the virus by increasing testing numbers and by implementing the test, track and trace programme. The IBMS supports this strategy and is proud of the achievements that the biomedical science profession has delivered in such a short timeframe.

However, the pace of upscaling testing capacity across the healthcare sector must not lead to a reduction in the quality of the diagnostic testing process. Before we set up more mass testing centres, we must work together to assure the quality of testing and the competence of staff and make sure that current and any future centres will be more closely integrated with National Health Service (NHS) systems.

Established diagnostic testing facilities (i.e. pathology laboratories in the NHS and private healthcare sector) have typically evolved their processes over a number of years and have some of the highest quality testing programmes in the world. This has been achieved through the implementation of robust quality management systems that are proven to provide high quality and safe services through medical laboratory accreditation (e.g. to ISO 15189:2012 standards).

As the next phase of increasing testing capacity is undertaken, it is essential that the provision of a high-quality and safe testing service is at the centre of the national testing strategy. We should not sacrifice quality for quantity.

Quality matters

It is well known in laboratory medicine that the one thing worse than no result is the wrong result. The IBMS has published guidance on the role of the Quality Manager in Clinical Laboratories that outlines the minimum expectations of the quality management system in relation to the Quality Manager and their role. Of particular note are the recommendations for quality governance and clinical governance.

To ensure the process is undertaken to a suitably high standard the IBMS recommends that "the Quality Manager is a biomedical scientist and holds a recognised quality management qualification such as the Institute's Certificate of Expert Practice in Quality Management, in addition to a Master's level qualification such as an MSc or the Institute's Higher Specialist Diploma in either a scientific specialism or in Leadership and Management".

The IBMS expects that all testing facilities performing COVID-19 PCR and serology testing seek appropriate medical laboratory accreditation as soon as possible. There are now a number of laboratories that have achieved ISO 15189 accreditation for their COVID-19 testing processes, and the number pending an assessment to grant this is increasing. Laboratories that have medical laboratory accreditation are kite-marked as providers of a high-quality and safe service, often for very similar tests to the COVID-19 assays. Prior accreditation provides reassurance that there is minimal risk of poor quality practice while a laboratory awaits accreditation for new tests.

>To read the full position statement, which also covers statutory regulation, non-registered staff, scientific staff, laboratory directories and supporting IBMS members, visit **bit.ly/3ITaG4w**

The documentary included evidence of potential contamination, discarded tests and a high-pressure work environment.

Dr Tony Cox, CEO at UK Biocentre, a not-for-profit organisation that runs the lab, said: "This programme presents an incomplete and selective representation of our efforts. In fact, many of the allegations date from a time the lab was operating under a unique period of pressure at the start of this year due to the second wave of the pandemic."

While the IBMS backed the government drive to increase testing, following the programme a statement was released that outlined how essential it was that the provision of a high-quality and safe testing service is at the centre of the national testing strategy.

It said: "The IBMS proposes that the lighthouse laboratories consider recruiting additional HCPC-registered biomedical scientists to supervise staff, increasing the focus on quality control and assurance, and attain UKAS accreditation to assure safe practice. This would ensure testing that is fit for purpose, robust and focused on the patient.

"The ratio of registered scientists and non-registered support should be assessed in each individual situation; it will vary with the level of automation available and the stability of the assay and workflow, but should provide sufficient numbers of registered scientists that any supervision is real and not 'nominal'."

Closures and opening

In March this year, it was announced that a Loughborough lighthouse lab that had the capacity to process 50,000 tests every day was to close. The DHSC confirmed its six-month contract was not being renewed and a spokesman said an "improved system" meant the laboratory network capacity was being "consolidated".

A DHSC spokesperson said: "Our testing system has continued to evolve, turnaround time has improved and new technology means we can process hundreds of thousands of tests a day in one lab, and respond to increased demand as needed."

"The ratio of registered scientists and non-registered support should be assessed"

They continued: "This improved system means we are now able to consolidate our laboratory network to achieve the best value for money without reducing our overall national laboratory capacity."

However, six months after being closed down by the government, the lab was officially opened again, having been acquired by the global whole-genome sequencing company, Dante Labs.

Dante Labs, which has a partnership with NHS Test and Trace, said it would deliver "PCR testing and clinical whole-genome sequencing at scale".

The firm said it planned to have an initial processing capacity of 50,000 COVID-19 samples a day – the same as before it closed on 31 March.

A few months previous, there were issues around a lighthouse "mega lab" that was planned for Scotland that was expected to add 300,000 to the UK's daily testing capacity.

The lab was announced last November, with an expectation that it would be operational in early 2021, but it was delayed by months, as a building was not secured. Then in January this year work on the lab stopped.

A DHSC spokeswoman said: "Since the start of the pandemic, the UK has increased the capacity of our laboratories by more than tenfold.

"With the vaccine rollout under way across the UK, development of one of the planned very high throughput labs has been paused until the impact of the vaccine on the long-term demand for PCR testing can be assessed. Substantial testing capacity remains in place and this will not prevent anyone from getting a test."

The future

At the time of writing, on 18 October, the UK recorded 45,140 new infections – the highest jump in COVID-19 cases since mid-July. According to the latest data from Johns Hopkins University, the UK had 589.68 new cases per million –a figure more than twice as high as the US (255.24 cases per million) and more than five times higher than Germany (104.2 cases per million).

With the increase in cases as we head into winter, an uncertain few months are faced across the UK. But one thing is for certain, it is vital that the lighthouse labs have the highest quality of testing and levels of staff competence.

The IBMS position statement from August concludes: "The IBMS is proud of the expertise of our members who work at the heart of healthcare in laboratory medicine 24 hours a day, 365 days a year, contributing to over 70% of diagnoses in the NHS, processing over a billion samples every year. The biomedical science workforce have continued to go above and beyond to get the UK into a position to deal with this pandemic and are working tirelessly to help get patients and their medical teams the results that they need.

"The IBMS and our members want to ensure that all laboratory and rapid testing for COVID-19 is performed to the highest quality and in the safest manner possible. We would welcome working with any institutions, government bodies or testing organisations to help support these objectives." IBMS

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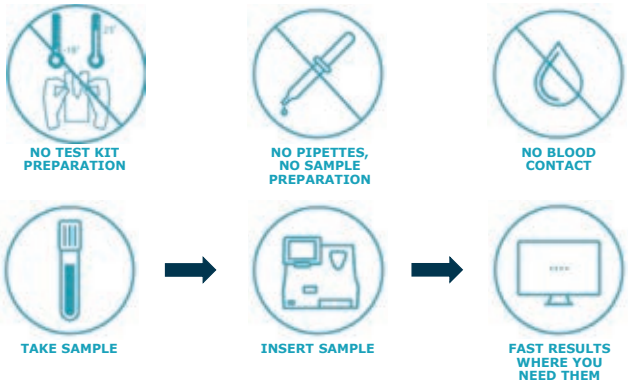

Full AQT90 FLEX test menu

Marker	Reportable range	Standard of traceability	Measuring time (min:sec)
TnI	10 – 25,000 ng/L	NIST, SRM 2921	18:19
TnT	10 – 25,000 ng/L	**	12:18
CKMB	2 - 500 µg/L	IRMM, 455	18:09
Myo	20 - 900 µg/L	Scripps, M0725	18:09
NT-proBNP	70 - 35,000 µg/L	**	10:10
CRP	5 - 500 mg/L	ERM – DA472/IFCC	20:18
ßhCG	2 - 5000 IU/L	IU/L WHO, 75/589	18:09
D-dimer	80 - 100,000 µg/L	Hytest, 8D70	20:10
PCT	0.12 - 100 µg/L (whole blood), 0.082 - 100 µg/L (plasma	**	12:11

**Traceable to in-house calibrators, which have been value-assigned to correlate with other commercially available assays. (Roche - TnT/NT-proBNP & B·R·A·H·M·S - PCT)

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[1] DIAGNOSTICS: RECOVERY AND RENEWAL Report of the Independent Review of Diagnostic Services for NHS England Oct 2020

GENOMIC MEDICINE

BREAKING NEW GROUND

Cancer Genomics Project Manager **Deborah Lakeland** describes the cultural change sweeping across healthcare provision in the UK and its importance in clinical laboratories.

Genomics medicine is a rapidly evolving field that promises huge benefits of personalised care, especially for patients with cancer. Greater understanding of the molecular basis of disease is enabling access to more comprehensive diagnosis, prognosis, and targeted treatments than was possible before. Predicting the risk of future cancer development or adverse reactions to drugs also means that interventions, such as cancer surveillance, can be undertaken earlier and alternative treatments utilised to reduce the potential risk of future harm.

Breaking new ground

Back in 2013, Genomics England was commissioned by the Department of Health to set up the 100,000 Genomes Project, with the aim of mainstreaming whole genome sequencing (WGS) in the NHS. For the first time, patients with rare diseases and cancers were able to access WGS as a new standard-of-care test. I joined the project in 2017 and was instrumental in developing the interdisciplinary working relationships, the sample pathways, and the laboratory processes, proving both in principle and in practice that WGS could be accessed by patients under the care of clinicians in the Royal Preston Hospital. Fast-forward another five years, and genomics is now a massive growth area worldwide that is redefining disease classification and personalising clinical care at pace and scale. There have been several factors driving this service transformation: worldwide collaboration is fostering a culture of genomics excellence, accelerated discovery of gene–disease and gene–drug pairs with increasing clinical utility detected by advanced sequencing technologies and translational research now readily adopted in clinics. Collectively, these improvements serve to reduce risk and improve both overall survival and progression-free survival in cancer care.

State of the art

In April 2021, the national Genomic Medicine Service (GMS) launched a National Genomic Test Directory with eligibility criteria for centrally funded tests, including everything from single-point mutations, to entire whole genomes (3 billion A, T, C, G bases) sequenced. The advanced test repertoire, updated annually, combined with pathways and service redesign, is increasing knowledge in the genomics database, whilst radically improving clinical management and patient outcomes. The GMS in the NHS is a world-leading model of care.

The GMS is delivered by seven regional genomic laboratory hubs and aims to deliver equitable access to genomic testing in England, thereby increasing the genetic diversity of the clinical database, and the clinical actionability of relevant gene variants in 180 common cancers. Where an inherited cancer predisposition is identified, patients undergo counselling and surveillance at the earliest opportunity to manage the risk of future cancer development. This care is then cascaded to affected blood relatives too. Where a gene relating to adverse drug reaction is identified, the anti-tumour medicine can be administered at a lower dose with close observations, or alternative treatments considered that are compatible with the patient genetic make-up. Tumours harbouring genetic susceptibility to anti-cancer immunotherapies are now associated with much improved clinical outcomes. Liquid biopsies are harnessing ever-

IMAGES: ISTOCK

increasing quantities of DNA, which can indicate which patients have complete pathological response to treatment, and provide early indication of therapy resistance and relapse, in advance of clinical presentation. Cancer-specific genomic instability scores, mutational signatures, and tumour mutation burden, from WGS, are now routinely informing clinical decisions.

Supporting the transformation

Innovative roles and new ways of working are developing within the Lancashire & South Cumbria (L&SC) Pathology Collaboration. As ambassadors for the new service, histopathology biomedical scientists are upskilling at the genomics–pathology interface, under the direction of a cancer genomics project manager, in secondments funded by the Cancer Alliance.

In close partnership with the North West Genomic Laboratory Hub, and the local molecular pathology subgroup, this vital work ensures more complex tumour tissue handling and assessment

"Genomics is now a massive growth area that is redefining disease classification and personalising clinical care"

is undertaken that meets the strict Genomics England acceptance criteria for test referrals.

Programmes underway include supporting implementation of the Genome UK strategy to sequence 500,000 genomes, with WGS mainstreaming as a standard-of-care test, developing new sample pathways that provide equitable access to advanced molecular analysis, and also the National Lynch Syndrome Transformation Project, which identifies more individuals carrying inherited cancer-predisposition genes.

Upskilling the workforce

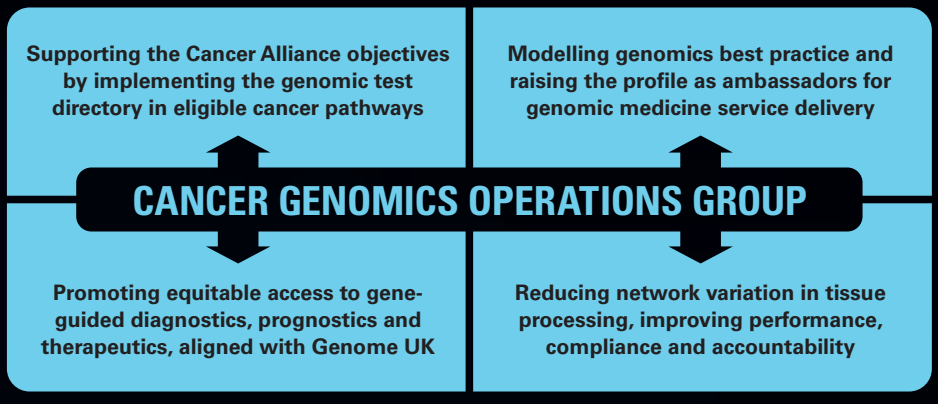
We are aligning secondary care clinical and technical services with the Cancer Alliance and Genome UK agendas, championing cutting-edge genomics and molecular diagnostics, prognostics and pharmacogenomics, defining best laboratory practice for tumour tissue processing in a genomic era, and auditing service outreach and clinical engagement with this service transformation, for all eligible inherited or acquired cancer cases. Collectively, we oversee operations in a regional standardised approach, through newly developed frameworks, monitoring performance and assurance. We celebrate successful practices, and identify risks or where improvements are needed, continually fostering essential network relationships, and service redesign. Business intelligence now flows unimpeded, between genomics and pathology stakeholders throughout the North West.

There are special projects, tailored by the geography in our region. Blackpool is a lung cancer specialist centre developing an algorithm to triage molecular requests, test assay limitations, and reduce service duplication, in partnership with the North West Genomic Medicine Service Alliance Pathology Accelerator Project and an industry-funded tissue navigator role.

Preston is a brain specialist centre, which will introduce WGS in the next phase of eligible clinical indications. We are working with local clinical histopathology leads to redesign pathways in the context of the single pathology service emerging for L&SC by 2023. We have identified regional Lynch and Genomics Champions, to facilitate Lynch genetic testing and surveillance, in line with National Lynch Transformation, and we are fostering cultural change through regional events and workshops.

The highly effective and enthusiastic team of biomedical scientists in the newly formed Cancer Genomics Operations Group (see box), is facilitating equitable access to state-of-the-art analysis across our network, and serves as exemplar practice that will likely be replicated in laboratories nationwide. BMS

THE CANCER GENOMICS OPERATIONS GROUP



ACCREDITATION AGILITY

Ben Courtney, the Healthcare Section Head at UKAS, outlines the service's response to the COVID-19 pandemic.

When a mandatory lockdown to contain the transmission of COVID-19 was announced by the UK Government in March 2020, organisations rushed to implement changes to their operations, policies and procedures in order to continue work with minimum possible disruption.

The United Kingdom Accreditation Service (UKAS) had an increased responsibility to ensure that confidence could be maintained in the quality of pathology services at a time of unprecedented uncertainty and change.

To support healthcare services impacted by the pandemic, UKAS, following agreement with NHS England and NHS Improvement (NHSEI) and the devolved nations, allowed accredited pathology customers a six-month postponement of assessments. Where assessments did take place, all but the most essential site visits were cancelled and converted to remote assessments. Many applications for conducting such assessments were trialled – Zoom, Skype, Facetime, WhatsApp, for example, but eventually Microsoft Teams was selected as being most suitable to provide the necessary flexibility and resilience. Additional resources were implemented for file sharing (e.g. dropbox), but SharePoint has become our standard application for transferring large volumes of information.

Remote assessment

Policies and procedures were rapidly developed to support remote assessment in extraordinary circumstances (UKAS Technical Policy Statement TPS73, for example), which were then adopted by international bodies, such as the International Accreditation Forum (IAF), the International Laboratory Accreditation Cooperation (ILAC) and the European co-operation for Accreditation (EA) into their range of guidance and support documents.

The success of remote assessment has been phenomenal and is as much a testament to the hard work of accredited pathology customers to engage with and support the process as it is to the development of the programme by UKAS. Customer satisfaction with the remote assessment approach has been regarded as "excellent" in customer satisfactory surveys throughput the pandemic. UKAS has yet to fully evaluate the success of remote assessment using the outcomes of subsequent on-site visits, but the numbers and themes of non-conformities identified remotely is not hugely different from that which would normally be expected. Remote assessment, therefore, remains a tool that will be retained for the future. It will form an integral part of a UKAS objective to implement an approach to assessment that is likely to result in changes to the frequency of assessment that will be determined by evaluating risk-based criteria for each customer.

New applications

With lockdown, UKAS also received an unprecedented number of new applicant

laboratories, working to support the national COVID-19 testing programme. In specifying accreditation for the private testing and sampling, UK Government has been instrumental in encouraging over 500 laboratories to apply for accreditation and set extremely demanding deadlines of around six months for these organisations to gain accreditation. The challenges that have consequently arisen have been significant but have driven equally significant changes in UKAS processes to ensure that the Department of Health and Social care (DHSC) target deadliness can be met.

The vast majority of the COVID-19 applicant laboratories are unfamiliar with accreditation and its requirements, so UKAS developed a three-stage approach to accreditation to guide them through the process (see box).

To support applicants through the process, a series of web-based training modules have been created to explain key requirements of the standards and other supporting guidance. These eLearning modules are broken down into short, easy-to-understand topics, with some useful guidance and answers to frequently asked questions. They guide the customer from application through to grant of accreditation and are freely provided to all applicants – it is our intention to further develop these modules and roll them out more widely to other applicant organisations in the coming months.

APPROACH TO ACCREDITATION

Stage 1 is the application stage and requires the applicant to submit basic documentary evidence to UKAS to show that it has a legal identity and prompts for basic quality system information.

Stage 2 is a gap analysis that is conducted by the applicant in response to 13 key questions posed by UKAS, which would be regarded as a key introduction and stepping stone to the requirements of International Standards.

Stage 3 is a full initial assessment to determine the laboratory's competence and compliance against the requirements of ISO 15189 and/or ISO/IEC 17025. Feedback and support is provided at all three stages to ensure the customer is able to navigate from application to grant in a controlled, stepwise manner.

In addition to the implementation of the eModules, UKAS has developed a provider assessment tool (PAT) that allows all reporting, documenting of improvement actions, evidence submission and evidence feedback to be conducted using a single template, rather than the multiple assessment reports and improvement action reports that are a feature of its normal process. This single report ensures that all information is retained centrally and speeds up not only the assessment, but also the independent decision-making process. UKAS is currently testing a unified reporting structure for all customers, which is expected to be rolled out in the autumn of 2021.

Finally, for the COVID-19 applicants, instead of a time-consuming exchange of evidence to clear non-conformities identified at initial assessment, UKAS is conducting a close-out assessment via Microsoft Teams, where the assessors can ensure that appropriate action has been taken by the applicant laboratory to address the issues – this is working well and is another of the efficiencies that have been developed during lockdown that UKAS is seeking to embed in its

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toolbox going forwards. The intention throughout has been to simplify and demystify the background processes associated with granting, maintaining and renewing accreditation, and UKAS will continue to critically review its procedures to ensure that they remain simple, efficient and effective.

Recruitment drive

Prior to November 2020, UKAS had approximately 650 accredited medical laboratory customers. The additional 500 applications submitted to UKAS by February 2021 challenged UKAS' resources, particularly considering the short timescales DHSC required UKAS and the private providers to meet. Government requirements to ensure all sampling and point-of-care testing providers were included in the scope of the legislation required UKAS to increase the numbers of available assessors, looking at areas of technical competency UKAS had not previously covered. It is acknowledged that during the course of 2021, the extensive private provider work has meant our currently accredited customers have experienced slower than expected turnaround times for their extensions to scope, evidence review and the conduct of profiled surveillance and reassessment visits. To resource the additional work, UKAS has needed to recruit an additional 15 assessment managers, which increases the team by approximately 40%. This recruitment is still on-going and UKAS would be very interested to receive applications from experienced biomedical scientists, particularly those with technical competencies.

UKAS is working hard to improve service delivery to customers during a period of unprecedented new applications. The recruitment of new assessment managers and subsequent training can take some time. To expedite improvement, UKAS has looked to external lead assessors, decision makers and movement of resources within the business to support healthcare. This is already taking effect with a significant reduction of outstanding decisions and assessments.

This has highlighted again the crucial work our peer technical and clinical assessors perform. This is an opportunity to thank all of those who contribute to UKAS assessments and have continued to do so throughout the pandemic. UKAS is looking at the opportunities that this presents to external assessors, without whom the assessments would not be possible. As part of a review of UKAS' available technical resource, UKAS would continue to encourage applications from individuals across all disciplines who have relevant technical and/or clinical experience. To improve resilience and turnaround times, UKAS can contract assessors on a paid basis (daily rate), as this is commonplace across the rest of UKAS' business activity. UKAS will be advertising these roles shortly, with a view to an individual being able to conduct as many assessments as they wish in a year, probably up to a maximum of 180 days.

A strong commitment

The last two years, in pathology and healthcare as a whole, have been challenging. All organisations have had to demonstrate agility and flexibility and respond accordingly to the pandemic, UKAS included. This has allowed more areas to be covered by accreditation and the significant increase in assessment of sampling and point-of-care testing has certainly improved the quality of the result and ultimately, patient safety. In achieving this, there has been a knock-on effect in service delivery of UKAS' established customers. This is a focus of UKAS' service improvement plans and there is a strong commitment to ensuring customer service levels are improved but at the same time ensuring UKAS can support the continual improvement of emerging areas of diagnostic testing and emerging models of healthcare testing delivery. BMS

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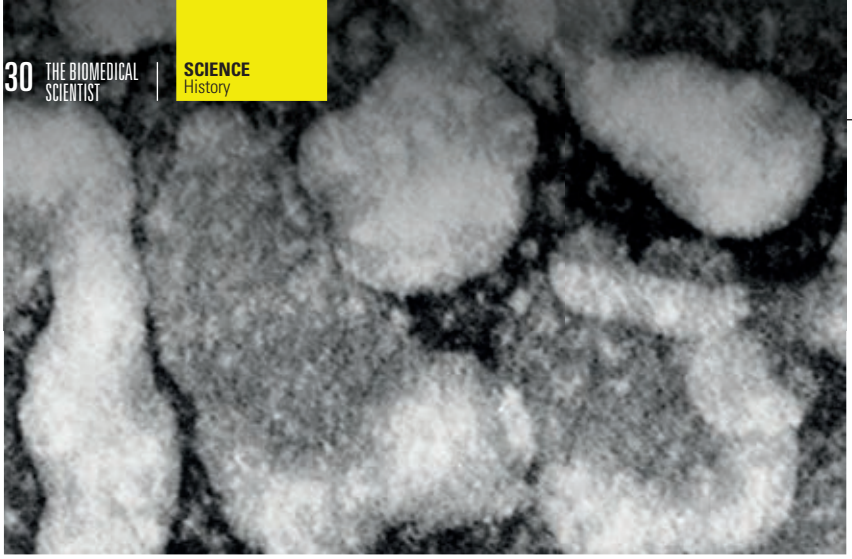


JUNE ALMEIDA

VIRUS IMAGING PIONEER

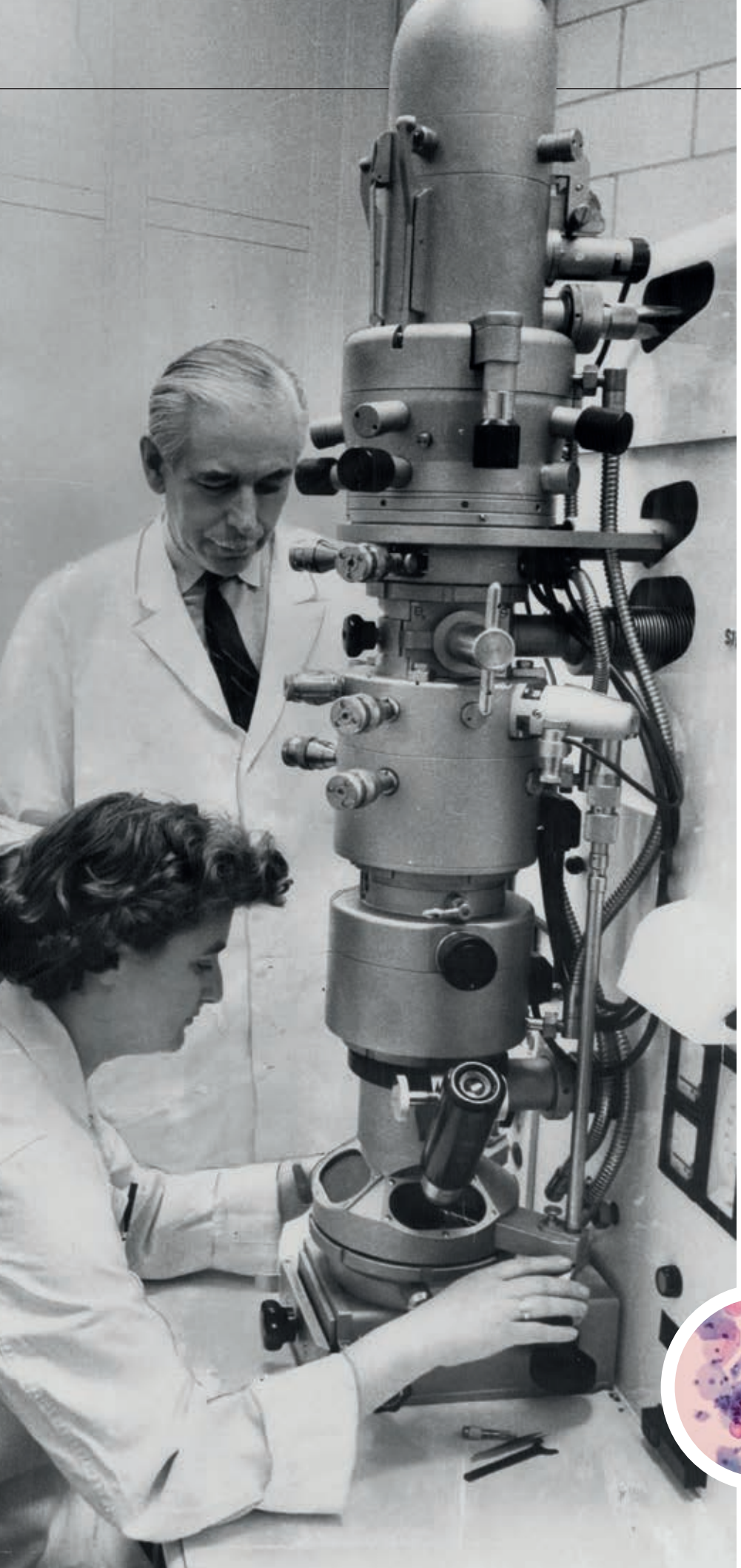
Beginning her career as a junior hospital technician, **Dr June Almeida** completed it as a world-renowned virologist whose techniques revolutionised diagnostic electron microscopy. She was also the first person to see a human coronavirus. **Here we look back over her life.**

June Dalziel Hart was born on 5 October 1930, in a second-floor tenement flat at 10 Duntroon Street, Glasgow, her mother a shop assistant and her father a bus driver (her younger brother Harry died from diphtheria aged six years in 1940). Flourishing academically at Whitehill Senior Secondary School, Dennistoun, where she won a school prize in science, financial constraints meant that June could not go to university.

So, having passed her "higher" examinations, she left school in 1947 to become a junior histopathology technician at Glasgow Royal Infirmary, earning 25 shillings per week.

Early days

In 1952 the Harts moved to London, where June joined the pathology department of St Bartholomew's Hospital as research assistant to Professor John WS Blacklock (1896–1973) and became an Associate of the Institute of Medical Laboratory



Left. Micrograph of coronavirus by June Almeida, 1966.
Centre. June Almeida sitting at a powerful electron microscope.
Below/right. Koilocyte cell criteria of human papilloma virus infection.

"Electron microscopy was an emerging field in the 1950s, but Almeida's expertise was apparent"

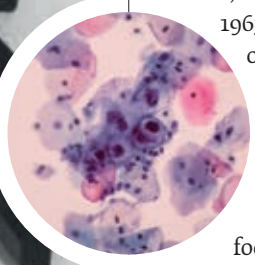
Technology – the forerunner of the Institute of Biomedical Science.

In 1956, having married the Venezuelan artist Henry (Enrique) Rosalio Almeida (1913–1993) two years before, the Almeidas emigrated to Canada, where June was appointed as research assistant to Dr A F Howatson in the Division of Biological Research, Ontario Cancer Institute (OCI), Toronto, and her work with the electron microscope (EM) began.

Electron microscopy was an emerging field of study in the 1950s, but Almeida's expertise was apparent, and her reputation grew, with her first peer-reviewed journal article submitted for publication only one year after starting work in Toronto. In his entry in the *Oxford Dictionary of National Biography*, consultant virologist Professor Jangu Banatvala suggests that in Canada and the North American continent the lack of a university degree did not obstruct career progression, when compared with the UK.

Landmarks

The EM technique of negative contrast staining was originally applied to purified virus preparations, but Almeida refined this method, enabling the use of crude preparations to study cell-associated viruses, and offering, as she wrote in 1963, "a new approach to the study of the morphology of basic cell components in the normal cell and the virus–cell relationship in infected cells".



Almeida's EM work was characterised by efficiency, focus and range. For example,

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Molecular Solution for Viral Meningitis Testing

Introducing the Bosphore Viral Meningitis Panel Kit v3 for the detection of Herpes simplex virus 1, Herpes simplex virus 2, Varicella-Zoster virus, Enterovirus (Coxsackie A and B, Echovirus, Poliovirus and Enterovirus 68 – 71) and Parechovirus.

Key points of the assay:

- Simple workflow
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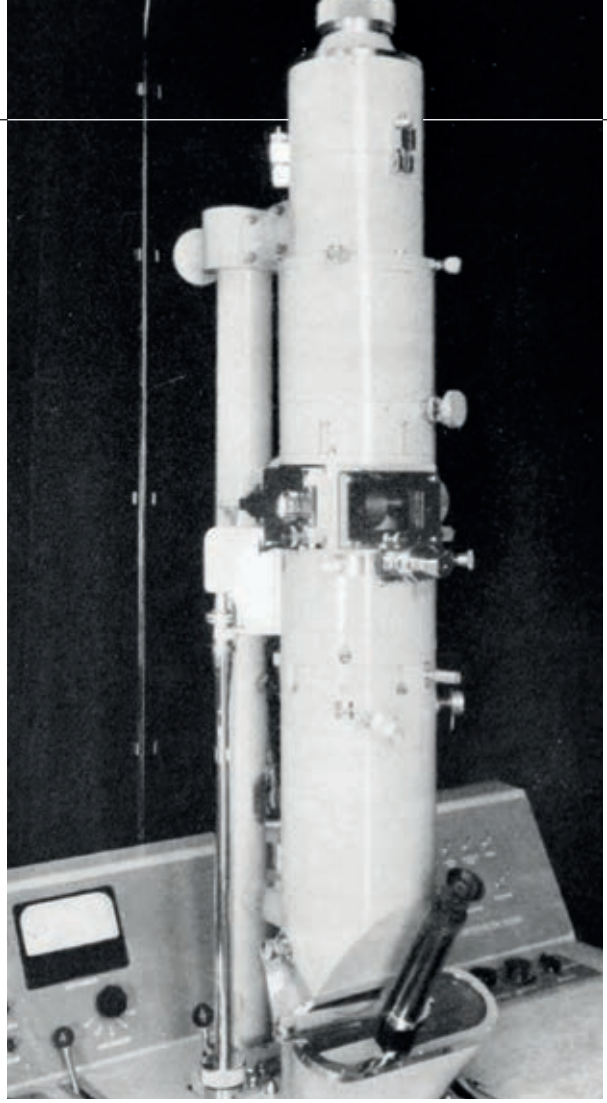


Left. Electron microscopy: proceedings of the Stockholm Conference, September 1956.

by 1962 she had helped identify the morphological characteristics of wart viruses – later designated human papilloma viruses – and determined their sites of production. In describing the morphology of the Herpesvirus varicella, Almeida made the crucial observation that "the viruses of varicella and herpes simplex appear to be indistinguishable by morphological criteria".

By 1963, when Almeida became a Fellow of the Royal Microscopical Society, she had been exploring the potential of immune-electron microscopy (IEM), which relies on the ability of a specific antibody to a specific viral antigen to clump together virus particles, which would otherwise be difficult to see. Almeida's insight was to realise that "IEM could help extend the range of what was possible with negative staining", and when she and her colleagues undertook IEM studies on wart and polyoma viruses "to their delight the technique made smaller viral particles much more visible than previously thought possible".

Coronavirus

In 1964, microbiologist Professor AP Waterson visited Toronto's OCI laboratory and, impressed by Almeida's high-quality work, offered her a post as scientific assistant in his department at St Thomas's Hospital, London. The Almeida family, now with a young daughter, returned to the UK.

It is a measure of Almeida's strength of character to learn of her reaction to the news, shortly after her arrival at St Thomas's in 1964, that a recently acquired EM was the sole preserve of a professor of pathology Robert Curran and could not be used without his permission.

She did not ask permission, often used it in Curran's absence, and the subsequent purchase of a second EM for Almeida's use solved this problem.

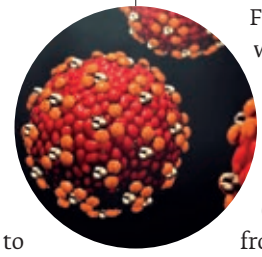
"The referees said the images were just bad pictures of influenza virus particles"

Meanwhile Dr David AJ Tyrrell (1925–2005), at the Medical Research Council's Common Cold Unit, Wiltshire, was investigating respiratory samples from pupils at a boys' boarding school in the Epsom area of Surrey, one of which – sample B814 – could be passaged in organ culture and produce common cold symptoms in volunteers. In his memoir Tyrrell recalls learning that Almeida "was seemingly extending the range of the EM to new limits... [and] she claimed that she would be able to find virus particles in our organ cultures with her new, improved techniques. We were not too hopeful but felt it was worth a try". The sample was sent by train to St Thomas's and Almeida "saw virus particles in the B814 specimens!" Noting that the viruses had a halo-type surrounding, "recourse to a dictionary produced the Latin equivalent, corona, and so the name coronavirus was born." The first photographs of a human coronavirus were published in 1967.

Significantly, Almeida had seen similar particles previously while studying infectious bronchitis of chickens and mouse hepatitis liver inflammation, but, as Tyrrell recalls, "her paper on the subject had been rejected because the referees said the images she produced were just bad pictures of influenza virus particles."

Rubella, hepatitis B and university degrees

Almeida's friend and colleague at St Thomas's, Professor Banatvala, notes that the IEM technique, "employed and pioneered by June Almeida... had a simplicity and originality that characterized her work", an important application of which permitted Almeida and colleagues to reveal for the first time the fine structure of rubella virus, allowing "rubella to be displayed in the electron microscope and [explaining] why the virus has hitherto been so difficult to characterise".



From 1967 to 1972 Almeida was Research Fellow and, from 1970, Senior Lecturer in the Department of Virology, Royal Postgraduate Medical School, London, achieving her MPhil (1970) and DSc (1971) degrees from the University of London.

IMAGES: GETTY/ALAMY/SHUTTERSTOCK/ISTOCK

Right. St Thomas's hospital, 1976, with Big Ben in the background.
Below. Histopathology of chronic active hepatitis, light micrograph.

During this time, Almeida's IEM work on detergent-treated virus preparations from patients with serum hepatitis (later called hepatitis B) led to the discovery of an internal component of the virus that was later designated the hepatitis B core antigen.

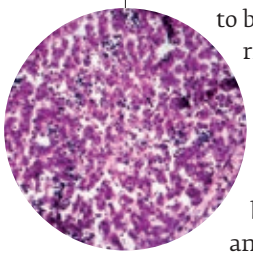
Rapid virus diagnosis and Hepatest

Almeida promoted the use of the EM in rapid virus diagnosis, emphasising its simplicity and noting that "the technique is of greatest importance when there is no available biological method for handling the virus in question". However, Almeida's virological contributions extended beyond electron microscopy. Following her appointment in 1972 as Principal Scientist at Wellcome Research Laboratories, Almeida undertook vaccine research and the production of diagnostic reagents such as the Hepatest.

The Hepatest was a haemagglutination technique performed in plastic microtitre plates, whereby the presence of the hepatitis B surface antigen in a patient's serum caused the agglutination of turkey red blood cells that had been coated with purified equine antibody to the hepatitis B surface antigen. A robust technique, widely used in virus diagnostic laboratories in the 1970s and 1980s, the Hepatest was also modified for use in the screening of blood donor samples for both hepatitis B surface antigen and antibody to hepatitis B surface antigen.

Later years

Between 1958 and 1983 Almeida authored or co-authored 103 peer-reviewed papers or chapters and was lead author of 64. Although she took early retirement in 1984, in the late 1980s she assumed an advisory role at St Thomas's Hospital Virology Department, visiting one day a week to collaborate with colleagues to produce early high-quality electron micrographs of the human immunodeficiency virus.



"She assumed an advisory role at St Thomas's Hospital to produce early high-quality electron micrographs of the human immunodeficiency virus"

Almeida combined academic rigour with feistiness, yet her strong personality was tempered with modesty about her achievements. For example, "when asked in 1993 how she came to make her breakthrough in hepatitis B research, she answered that she just 'happened to be in the right place at the right time'."

And Dr Janine Ayres – Almeida's friend and colleague at Wellcome Research Laboratories – recalls her brimming with self-confidence and having a wonderful mischievous sense of humour: "She was an excellent speaker who would entertain an audience who attended any of her lectures." Dr Ayres also makes clear that Almeida did not seem to need to stake a claim in an area of research and direct her own team within that area: "She seemed to be much happier working in collaboration with such teams using her techniques or developing new approaches to answer their questions. The hierarchy of academia or industry does not necessarily recognise such an approach, although her achievements more than warranted such recognition."

Finally

The advent of the coronavirus pandemic has stimulated public interest in the origin of this group of viruses, and Almeida's role in visualising for the first time a human coronavirus is rightly highlighted. However, it is also timely that a wider audience is also made aware of the many other contributions that Almeida made to the discipline of virology.

At a personal level, as her daughter recalls, June Almeida, who died in 2007, "was not only sociable, with many friends from all walks of life – from professors to secretaries, who she valued as individuals, not for their status – but she was always aware of her own humble origins, where less money restricted choices." BMS

A.MENARINI diagnostics

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NP or OP swabs sample collection

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Stir the swab in the collection buffer

3. TRANSFER
Pipette 30µL of sample into PCR tube

4. START
Results delivered in less than 20 minutes

Typical sensitivity levels and time to result of different methods for SARS-CoV-2 viral detection

	Typical LoD levels (Viral copies/reaction)	Typical Time to Result
Rapid Lateral Flow Antigen Test	4000-5000 copies	15 min
VitaPCR Rapid PCR test Gen 2	30 copies	20 min
Laboratory Real Time PCR test	10 copies	2-4 hours

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Additional kits are available to differentiate SARS-CoV-2 from other respiratory infections.

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A.MENARINI diagnostics

Below. Visitors looking at a lung model
Right. Visitors to the exhibition cinema

The **Francis Crick Institute** has opened *Outwitting Cancer – Making Sense of Nature's Enigma*, an immersive exhibition and the first to take place within a working science laboratory, home to cancer scientists from across the world. Here, Exhibitions Manager **Hana Dethlefsen** talks through the launch.

Q I understand this been in the pipeline for a while?

Yes – this exhibition was meant to open in 2020, but was delayed by about a year. In the meantime, the Manby Gallery was used as a vaccination centre, where more than 80,000 members of the public were vaccinated against COVID-19, including Prime Minister Boris Johnson, as well as the Leader of the Opposition, Sir Keir Starmer.

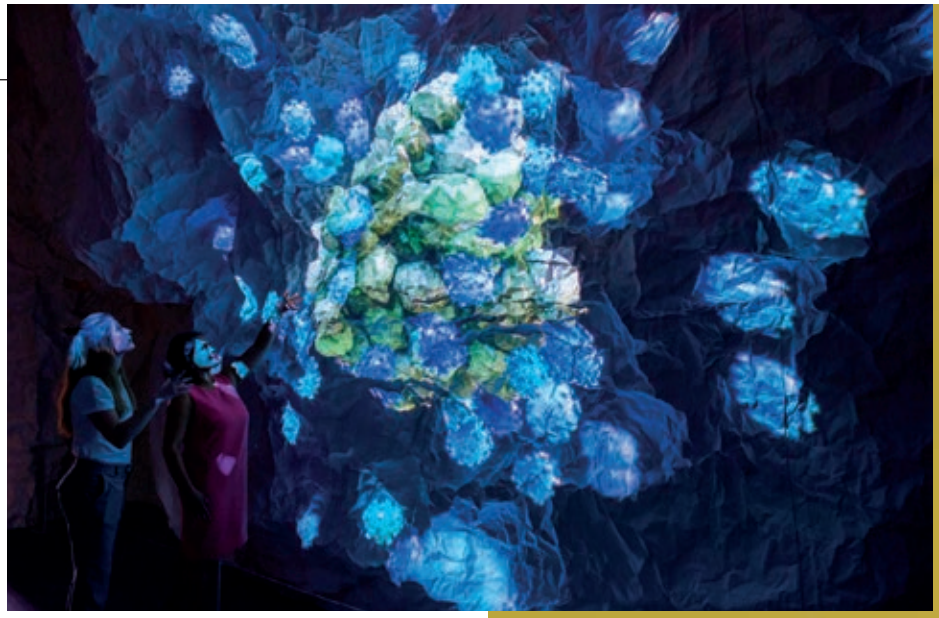
Q Why does the Crick put on exhibitions?

Public engagement is one of the Crick's strategic objectives. Now, more than ever, it's important for scientific institutions to be transparent about the process of science and to build trust with the public. It's important to show how science is done, how we generate evidence, how

IMAGES: FRANCIS CRICK INSTITUTE

AN IMMERSIVE EXPERIENCE

CANCER EXHIBITION AT THE CRICK



assumptions and ideas change over time and how progress is ultimately made. Our last exhibition welcomed more than 25,000 visitors in our Manby Gallery, and we hope we'll reach as many with this exhibition, too.

Q Is it challenging to communicate science through art?

What we do in the gallery isn't restricted to art, but it's certainly one of the tools we use to help make our science more accessible. Depending on the topic and how we choose to communicate it, the Crick has used multiple ways of interpreting and sharing the work that happens here in the building.

The *Outwitting Cancer* exhibition includes a large artistic installation – an immersive film and music experience developed by curator Yasmin Khan, filmmakers SDNA, and composer Mira Calix, using microscopy images from the Crick. We hope this immersive experience sets the emotional scene for the exhibition, priming visitors for the themes they will encounter later in the exhibition experience. Elsewhere in the exhibition, visitors will be able to watch filmed interviews, and experience images, objects, and text that explore the main themes of the exhibition.

"The impact of science on society is evident throughout history"

Q How and why did you pick the people who are featured in the films?

Our curator, Yasmin Khan, did a wonderful job of selecting a variety of researchers to represent the work being done here at the Crick, alongside relatable non-experts with a stake in cancer research (see box). Whether they are people living with cancer, having a previous experience of it, or having a professional interest in cancer research, our "non-experts" are experts in approaching the topic from a layperson's point of view – asking the types of questions our visitors would want to ask, but might be too shy or embarrassed to ask themselves. Yasmin wanted the exhibition to be relatable and uplifting, and so set up the pairings to explore the big questions – hopes, challenges and opportunities that are driving cutting-edge research into cancer.

Q Art and science have often historically been seen as opposing disciplines; is this starting to change?

Art and science are both ways of exploring the world, and although people may think of scientists as being rigid in their approach, I would think scientists know and can confirm that they need to be creative in their thinking to do the type of work they do. I know many researchers here at the Crick are talented in the arts, and that many explore their passions through various artistic means, including writing, music, dance and visual arts.

SHORT FILMS

A series of short films forms the backbone of the exhibition, and includes the following.

- **BBC journalist George Alagiah, who is living with bowel cancer, meets Vivian Li, a stem cell and cancer scientist, as she creates "mini-organs".**
- **Renowned cell biologist Mariann Bienz, who had a lung removed as part of her own cancer treatment, meets Charlie Swanton, Cancer Research UK's Chief Clinician, to talk about the evolution of tumours.**
- **Lawyer and brain cancer patient Adam Blain, meets scientist Simon Boulton to talk about the role of DNA in cancer.**
- **Cancer Research UK's Chief Scientist Karen Vousden talks to broadcaster and sex educator Alix Fox to bust some cancer myths.**
- **Crick scientist Erik Sahai meets Dr Georgette Oni, a trailblazing plastic reconstructive surgeon, as they discuss how cancer spreads.**
- **Dominique Bonnet, an expert in acute myeloid leukaemia at the Crick, gives journalist Tim Jonze, who is living with a rare blood disease, a behind-the-scenes tour of her labs.**

Bottom Left. Charlie Swanton and Yasmin Khan
Top Left. The exhibition cinema with visitors
Centre. Visitor reading *Onco'Zine*
Right. Intestinal organoids

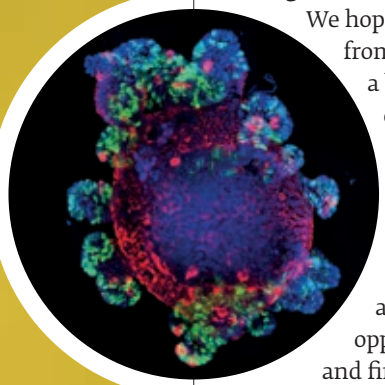
IMAGES: ©VIVIAN LI LAB-FRANCIS CRICK INSTITUTE

There have always been explorations of scientific themes and topics through art, and I don't see that changing.

Q Why is it important that people understand more about life sciences?

The impact of science on society is evident throughout history – we could be in the middle of a biomedical revolution where our understanding and management of human disease completely changes. We need to engage and inform the public early when scientific advances or applications of science arise and to have healthy democratic societies with the right values and openness to debate.

Q What do you hope people will come away from the exhibition having learned or thinking about?



We hope people will walk away from *Outwitting Cancer* with a better understanding of what cancer is, and why it's so hard to cure. The aim is to empower visitors to have positive discussions about cancer, to spark curiosity, and to provide the opportunity to dig deeper and find out more. BMS

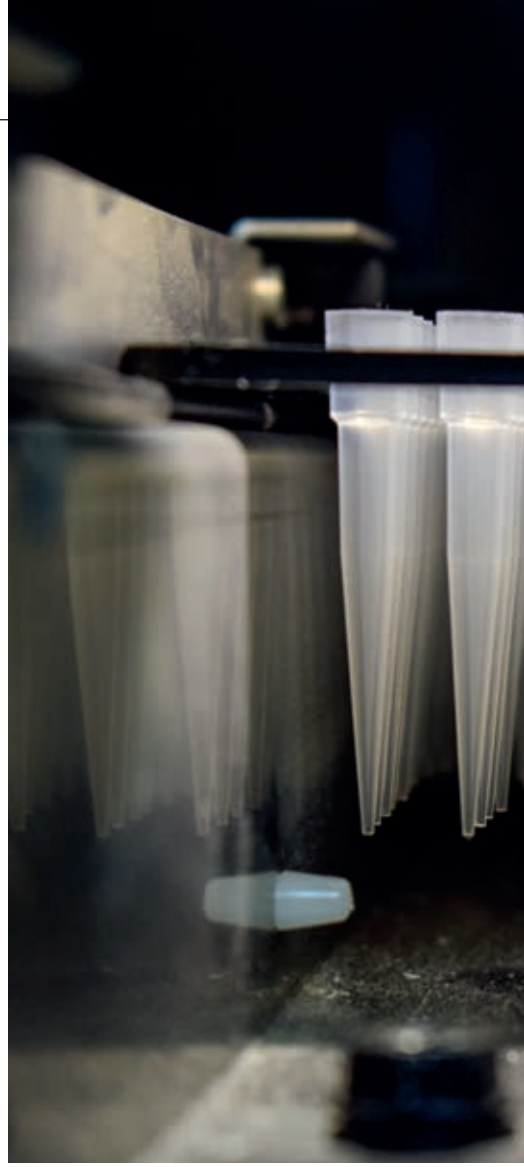
EXHIBITION INFO

Outwitting Cancer – Making Sense of Nature's Enigma is a free exhibition running until 15 July 2022 at The Francis Crick Institute in London.

The gallery will be open Wednesdays 10am–8pm and Thursdays, Fridays and Saturdays 10am–4pm. Alongside the exhibition there will be a lively programme of events and talks, as well as an in-depth digital experience with additional exhibition content. Visit crick.ac.uk/outwittingcancer or @TheCrick for further details.

PRODUCT REGULATION

Steve Lee from the Association of British HealthTech Industries looks at the potential impact on medical laboratory services.



Ensuring the safety and performance of products used in testing services is changing significantly and will continue to change over the next two to three years. These changes are already beginning to affect the availability of some products in the UK.

Many of the products used in medical laboratory testing services meet the definition of an *in vitro* diagnostic medical device (IVD) (see What are IVDs?) and are, therefore, subject to regulation of their safety and performance. Regulation is primarily concerned with enabling patient access to high-quality, safe and effective IVDs, and avoiding access to products that are unsafe. When appropriately implemented, regulation ensures public health benefit and the safety of patients, healthcare workers and others.

Until now, most IVDs have had a relatively low level of regulation with little independent scrutiny of products prior to them being placed on the market. The exceptions include products used to ensure the safety of the nation's blood supply. However, as the COVID-19 pandemic has highlighted, demonstrating the safety and performance of IVDs can sometimes be inconsistent and users often independently validate performance.

New regulations are intended to improve product safety and performance requirements with additional scrutiny before a product can be placed on the market. This should provide greater reassurance that products will perform as the manufacturer intends and should reduce the amount of user validation needed prior to commissioning a new product.

WHAT ARE IVDS?

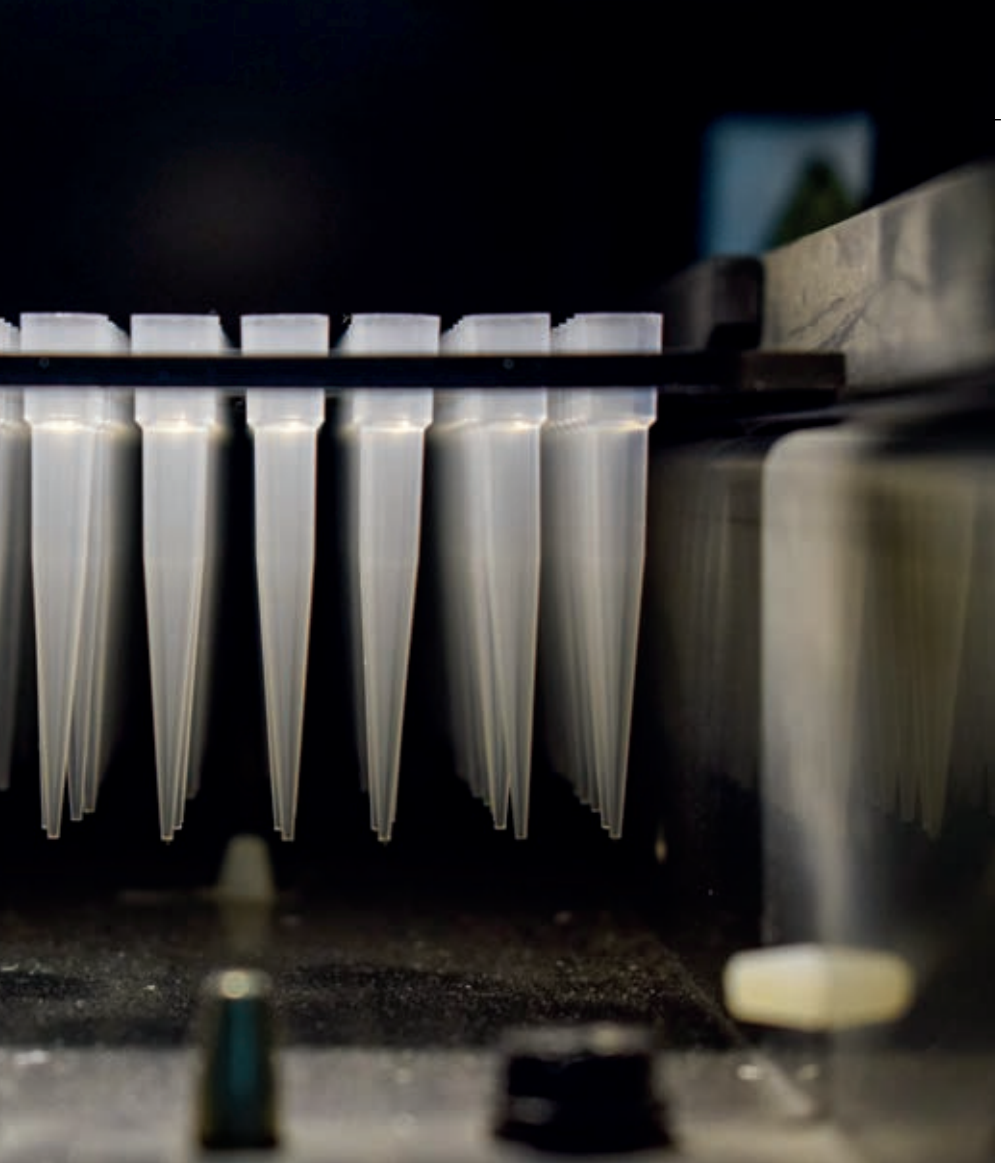
IVDs and their accessories can be intended for screening, monitoring, diagnosis, aids to diagnosis, prognosis, prediction or as a companion diagnostic for a medicinal product. IVDs can include reagents, calibrators, control materials, equipment, software and specimen receptacles intended to provide information on physiological or pathological states, congenital impairments, predisposition to medical conditions, predicted treatment response or compatibility with potential recipients.

However, not all existing products will be able to meet these new requirements and will either need to adapt to the new regulations or be removed from the market. For some manufacturers, the cost of meeting the new requirements may mean that they will no longer be able to supply them.

There are two major milestones to consider. The first milestone concerns the EU "CE mark", which will be accepted in the UK up until June 2023. The second milestone is the UK's own sovereign regulation for the "UKCA mark", which will be mandatory from July 2023.

New EU regulations

The first regulatory change to apply is the EU regulation on IVDs. IVDs placed on the market in the EU need to renew their CE mark to fit the new requirements. May 2022 marks the end of a five-year transition across to the new regulations and many manufacturers will be able to offer a seamless transition without



any noticeable effect on availability.

However, there are concerns that some manufacturers may not be ready for the new regulations because their attention has been focused elsewhere – not least in providing IVDs essential to tackling the pandemic. There are also significant concerns about the readiness of the EU infrastructure for assessing products for the new CE mark. For some products, manufacturers will decide that some, or all, of their products cannot meet the new requirements in an economically viable way, so will voluntarily remove these products from the market.

There are also significant changes to the exemption for IVDs that are made and used within a single EU or Northern Irish health institution, which means that not every EU or NI health institution will be able to continue using the exemption.

This means that some IVDs and some testing services will not be available to you either temporarily or permanently. There have been calls for a relaxation to give more time for the EU system to be ready for manufacturers and health institutions. The European Commission has recently responded with proposals for new dates that have yet to be ratified in the European Parliament. It remains to be seen if the proposed new dates will go far enough.

New UK regulations

Until June 2023 it will be possible for manufacturers to use either the CE mark, based on EU regulations, or the new UKCA mark, based on UK regulations.

From June 2023, it will only be possible to use the UKCA mark for products placed on the market in Great Britain. (Northern Ireland will continue to allow products with a CE mark.) The regulations that underpin the UKCA mark for IVDs will be changing too and we expect the transition for these regulations to end in June 2023. We do not yet know what these regulations will be, but we expect them to have similarities with the EU regulations for IVDs. Although we do not yet know what the regulations will be, it is possible that not all IVDs on the UK market will be able to meet them. This means that some IVDs and some testing services will not be available to you either temporarily or permanently.

The Medicines and Healthcare products Regulatory Agency (MHRA) has published a public consultation on the new UK regulations for IVDs. The consultation (**bit.ly/3DZuYQk**) closes on 25 November. Although the consultation looks daunting at first, it's possible to jump straight to chapter 17 and use a simplified version. This is a generational opportunity to influence how the medical products that you use should be regulated for safety, quality and performance. BMS

IMAGES: SHUTTERSTOCK

HOW TO STAY INFORMED

- **Ask your supplier** if they are prepared for the IVDR or are planning on removing some IVDs from their catalogue.
- **Will you need to** fully validate new tests prior to commissioning, or can you simply verify performance? Will this affect your UKAS accreditation?
- **If you rely on** the exemption for in-house manufacturing can the new exemption continue to apply? Do you know what the new exemption requires?
- **Will you be able to contribute to the UK consultation?** Will you contribute via your trust or your professional body (or both)? The MHRA website for devices regulation and registering for updates may be useful to help you stay informed.
- **If your testing service** may be affected negatively, do you have a plan B?

Steve Lee is Director of Diagnostics Regulation at the Association of British HealthTech Industries. He previously worked at the MHRA and trained as a biomedical scientist.

MY IBMS NEWS

VIRTUAL CPD EVENT

REGISTER NOW FOR THE BIOMEDICAL SCIENTIST LIVE

The second Biomedical Scientist Live virtual event is set to take place later this month.

The two-day event, brought to you by the IBMS, will be held on 24–25 November, with sessions from 16:00 to 18:30.

The event, which is now open for registration, is free for all IBMS members.

There is a packed line-up of speakers discussing the most vital and timely topics of the day.

Among the sessions in the programme will be a discussion on the future of face masks and interdisciplinary approaches to infection control and a session on how to launch innovative services.

Other topics include mentoring, sustainability in the lab and advanced clinical haematology practice, among much more.

This virtual CPD event provides the opportunity to knowledge-share with colleagues, hear from key speakers and enjoy demonstrations of best practice through a range of workshops, discussions and demonstrations.

The event returns after being launched in November last year to help IBMS members who were struggling to access CPD opportunities, due to events being cancelled in the pandemic.

Thousands of people attended the online event last November and gave very positive feedback.

For more information, to register and to see the confirmed speakers, visit the Biomedical Scientist Live website.

→ **live.thebiomedicalscientist.net**

NEW IBMS PODCAST

Hear scientist turned comedian

On this month's IBMSpod our special guest is the comedian, actor and writer Dave Spikey, who spent his early career working as a biomedical scientist in haematology at Bolton General Hospital.

It was during this period in the 1980s that he scripted and performed in a number of amateur pantomimes with a group of like-minded health workers called the Bolton Health Performers.

After winning a talent show called *Stairway to the Stars*, Dave went on to co-write and star in the hit comedy series *Phoenix Nights*, before working on a host of other TV shows and live tours, alongside writing and directing.

On the podcast Dave discusses his early days working in the lab and how, after working across a number of specialisms, he found his home in haematology.

To hear more about his career in biomedical science and stand up (and the funniest thing that ever happened to him in the lab) listen to the podcast now.

→ **ibms.org/resources/podcasts/ibmspod**

INSURANCE

IBMS FEES FROZEN FOR 2022

Due to the loss of the group medical malpractice insurance, IBMS Council has passed an agreement for membership renewal rates for 2022 to be held at the same rate as 2021.

The loss was outside the IBMS' control and the result of the hardening of the market and increased regulation. Because of this, insurers were unwilling or no longer able to provide group cover.

→ **Form more information, visit the IBMS website.**

PROMOTION

NATIONAL PATHOLOGY WEEK

The IBMS is supporting National Pathology Week 2021 from 1 to 7 November.

The annual week-long celebration includes activities and events promoting disciplines and professions within pathology.

By supporting this event, the IBMS is helping to showcase the roles and specialisms of IBMS members and help them to promote the profession to the public.

This year's theme is "All Together Now" and the Institute is excited to support this important awareness campaign to highlight the vital role of biomedical science.

→ **bit.ly/3BHHSSe**

THE BIOMEDICAL SCIENTIST LIVE

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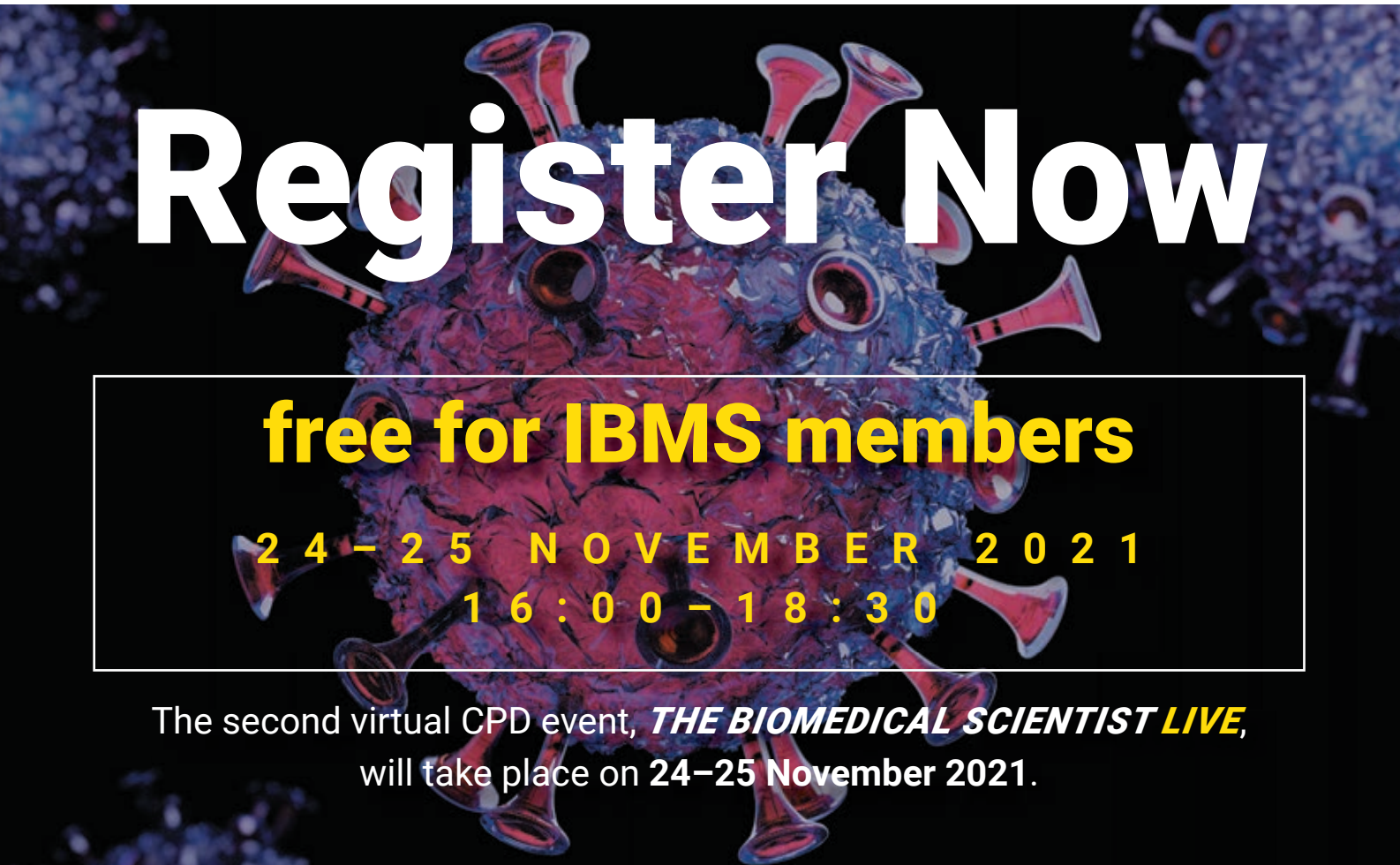


Register Now

free for IBMS members

24–25 NOVEMBER 2021
16:00–18:30

The second virtual CPD event, ***THE BIOMEDICAL SCIENTIST LIVE***, will take place on **24–25 November 2021**.

Featuring a packed line-up of knowledge-sharing sessions, including seminars, presentations, discussions and demonstrations.

#IBMSLIVE21
live.thebiomedicalscientist.net

IBMS Institute of Biomedical Science

SCAN ME

JOURNAL-BASED LEARNING EXERCISES

Institute of Biomedical Science Continuing Professional Development

Please select your choice of correct answers and complete the exercises online at: **www.ibms.org/cpd/jbl**

DEADLINE WEDNESDAY 2 FEBRUARY 2022

Disseminated intravascular coagulation: epidemiology, biomarkers and management

Adelborg K, Larsen JB, Hvas AM. *Br J Haematol* 2021; **192** (5): 803–18. doi: 10.1111/bjh.17172. Assessment No: 110421

01	Disseminated intravascular coagulation (DIC) can be a complication of infection, malignancy, trauma or obstetrical complication.	11	In a solid tumours cancer study in the US, the prevalence of DIC in patients with ovarian and brain cancers was the same.
02	In a study of DIC patients by Siegal *et al*, renal dysfunction was present in a third of patients.	12	The prevalence of DIC in patients with acute promyelocytic leukaemia (APL) is over four times the prevalence in patients with acute lymphoblastic leukaemia (ALL) in studies from the US and India.
03	In a study by Okajima *et al*, up to half of patients with cancer-related DIC were likely to develop clinically significant bleeding.	13	The ISTH scoring system for DIC differs between a basic score and if the patient is pregnant.
04	Standard criteria for diagnosis of DIC has allowed comparability between studies.	14	The revised Japanese Association for Acute Medicine (JAAM) score for DIC includes antithrombin as a parameter.
05	The incidence of sepsis-associated DIC appeared to be falling between 2004 and 2010.	15	In patients with thrombocytopenia, a marked fall in platelets may indicate hepatic cirrhosis in a differential diagnosis.
06	Tissue factor may be expressed on the surface of malignant cells in cancer-related DIC.	16	The thrombin generation assay does not discriminate between decreased prothrombin synthesis and increased consumption.
07	Decreased von Willebrand factor (VWF) levels and increased ADAMTS13 levels contribute to increased platelet aggregation during sepsis.	17	Thrombin–antithrombin (TAT) complex formation may be increased when antithrombin levels are low.
08	Decreased liver synthesis and degradation by elastase contribute to lower plasma levels of protein S in sepsis.	18	In the absence of bleeding, platelet concentrate may be considered if the platelet count falls below 50 x10^9/L.
09	Cancer is often associated with a decrease in fibrinolytic activity.	19	Poor clinical outcome has been associated with reduced levels of antithrombin in some studies.
10	Platelet counts may be in the reference range early in DIC due to an acute-phase reaction.	20	Prothrombin complex concentrates may be used in patients with major bleeding as a source of all clotting factors, plus protein C, S and antithrombin.

REFLECTIVE LEARNING

01	Discuss the use of scoring systems in the diagnosis and monitoring of DIC.	02	Discuss the use of global blood tests including viscoelastic assays and thrombin generation tests in monitoring DIC.

DEADLINE WEDNESDAY 2 FEBRUARY 2022

Next-generation sequencing-based clinical metagenomics identifies *Prevotella pleuritidis* in a diabetic adolescent with large parapneumonic effusion and negative growth of pleural culture: a case report. Galliguez T, Tsou PY, Cabrera A, Fergie J. *Br J Biomed Sci* 2021; **78** (2): 101–5. doi: 10.1080/09674845.2020.1827846. Assessment No: 110121

01	The authors consider this to be the first reported case of *Prevotella pleuritidis* causing pneumonia associated with parapneumonic effusion in children.	**11**	*Prevotella* species were previously categorised as *Bacteroides* species.
02	*Prevotella pleuritidis* was, according to the authors, previously isolated in 2017 from a child with a liver abscess.	**12**	Community-acquired pneumonia has an incidence rate of 53 per 10,000 in children up to five years of age living in developed countries.
03	The patient went into respiratory distress two days after presenting with a 24-hour history of right-sided chest pain.	**13**	According to the authors, a delayed start of appropriate antibacterial treatment is not thought to be a risk factor for parapneumonic effusion.
04	Three weeks after discharge the patient's symptoms had completely resolved.	**14**	The chest X-ray taken on Day 1 showed patchy consolidation on the right lower lobe.
05	The authors acknowledge that a limitation of their study is the lack of cell count analysis on the initial pleural fluid.	**15**	The patient was treated with ceftriaxone and linezolid, in place of the previous combination of cefepime and vancomycin.
06	*Prevotella pleuritidis* can be found as colonic commensal flora.	**16**	The authors highlight reports that show only 40–80% of respiratory pathogens were detected (in pneumonia) when using multiplex respiratory PCR.
07	The patient's haemoglobin levels fell each day from Day 4 to Day 10.	**17**	The patient in this case study was found to be positive for coronavirus OC43 on Day 3.
08	Following effusion drainage, the patient's condition declined from a respiratory standpoint.	**18**	Antimicrobial regimen for *Prevotella pleuritidis* can include metronidazole and carbapenems.
09	Next-generation sequencing-based clinical metagenomics can provide culture-independent unbiased detection, but not quantification of pathogens when using a shotgun approach.	**19**	The patient's sodium level increased each day from Day 1 to Day 9.
10	The authors feel this study is important as it confirms *Prevotella pleuritidis* as a pathogen that can contribute to pneumonia and parapneumonic effusions.	**20**	Mycoplasmas are among commonly seen pathogens associated with paediatric parapneumonic effusions.

REFLECTIVE LEARNING

01	How can next-generation sequencing and other molecular methodologies help to identify non-culturable/difficult to culture pathogens? Thinking of your own laboratory, what might the potential advantages and disadvantages be?

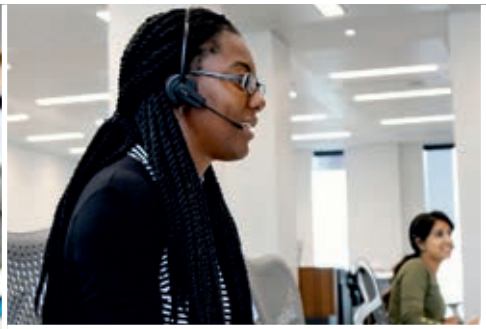
EVENTS AND TRAINING COURSES

IBMS Institute of Biomedical Science
Continuing Professional Development

More training courses, CPD and local events and activities are available on the IBMS website.

DATE	TITLE	VENUE CONTACT
November		
2 Nov	**Paediatric antimicrobial resistance and stewardship**	London and online I ecarruthers@bsac.org.uk
10–12 Nov	**ICC applications in laboratory practice webinar**	Online I cpt@ukneqas.org.uk
19 Nov	**Transmission electron microscopy webinar**	Online I cpt@ukneqas.org.uk
23 Nov	**Diagnostic cytology beginners/refresher webinar**	Online I cpt@ukneqas.org.uk
24 Nov	**Diagnostic cytology intermediate/troubleshooting webinar**	Online I cpt@ukneqas.org.uk
24 Nov	**Train the trainer**	London I c.ferrier@westminster.ac.uk
28 Nov–1 Dec	**British Society for Immunology Congress**	Edinburgh I congress@immunology.org
December		
1 Dec	**Medical laboratory assistant – introductory course**	Harrow I LNWH-tr.lrctcbooking@nhs.net
7 Dec	**BMT introductory webinar**	Online I cpt@ukneqas.org.uk
9–10 Dec	**Infection 2021: BSAC Winter Conference**	London and online I ecarruthers@bsac.org.uk
10 Dec	**Fresh muscle biopsies webinar**	Online I cpt@ukneqas.org.uk

SONIC HEALTHCARE UK



Sonic Healthcare UK says Thank You!

We at Sonic Healthcare UK wish to say a big thank you to all of our employees who have worked tirelessly throughout the pandemic and given their very best to ensure that critical healthcare was provided to patients without any disruption. This includes our couriers who made it possible for samples to reach their required destination as quickly as possible.

We also want to say a big thank you to all of those who work in healthcare, especially registered scientists, for the extraordinary efforts you have made over the last 18 months.

As a dynamic, rapidly expanding organisation, we are always searching for new talent. Why not be part of our success story by joining one of our friendly, professional and dedicated scientist and support staff teams? We offer a range of full-time permanent positions, as well as part-time, evening and weekend roles across the UK.

If you are ever looking for a new role, we would love to have you. Please visit: **https://www.tdlpathology.com/about-us/careers/**

SCAN ME

Photos may show pre-covid environments.

Medicines Discovery Catapult Services (MDCS) Lighthouse Laboratory based at Alderley Park in Macclesfield, Cheshire, was set up in April 2020 to provide PCR testing as part of the UK's COVID-19 response. We are now expanding to incorporate serology and COVID-19 antibody testing as part of our ongoing support to the national pandemic response. We are recruiting for the following positions in our friendly Serology department working 4 days on 4 days off pattern.

Main Duties – Specialist Biomedical Scientist
£40,000 per annum
12 month fixed term contract

- Supervision of a small team of Trainee Biomedical Scientists and Laboratory Technicians
- Overseeing the running of our Cobas 8000 analysers
- Be responsible for validating results using infinity Roche middleware

Main Duties – Senior Biomedical Scientist
£48,000 per annum
12 month fixed term contract

- Providing leadership, and daily support to the serology team of scientists and technicians
- Work closely with the Head of Labs and Laboratory Operations Team to ensure that the high-quality service is maintained
- Bring ideas from your experience to help shape the future of the laboratory

Our ideal candidate for each role will be:

- HCPC registered and ideally have an IBMS specialist portfolio
- Experienced in a serology or biochemistry/immunology discipline
- Experienced in UKAS accreditation and in maintaining quality standards (ISO 15189)
- Experienced in using Roche Cobas Equipment

Benefits package

- 25 days holiday inclusive of bank holidays per year (based on 4 on 4 off shift pattern)
- Generous company pension scheme - employee 5% and employer up to a maximum of 10% contributions
- Life assurance policy – 4 x annual base salary
- Free onsite parking
- Employee Assistance Programme
- Discounted shuttle bus service from Manchester to Alderley Park

Onsite facilities

- Restaurant, Cafes and gastro pub
- Gym and workout studio, running, walking, and cycling routes
- Good public transport links with the shuttle bus service

CATAPULT
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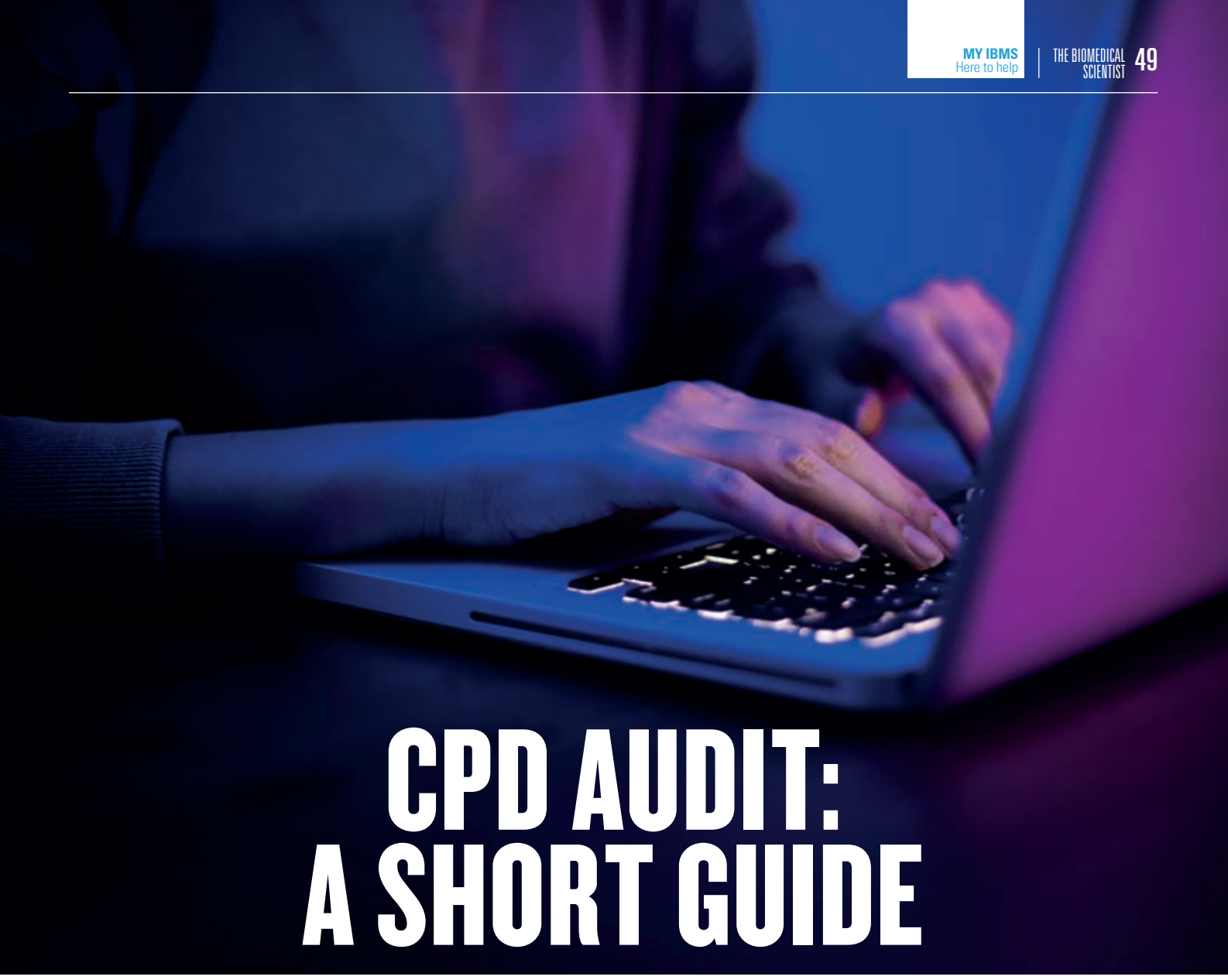
To apply for the position please visit our careers page at md.catapult.org.uk or send your CV and covering letter to recruitmentlhl@md.catapult.org.uk



CPD AUDIT: A SHORT GUIDE

Alan Wainwright, the IBMS Executive Head of Education, revisits the Health and Care Professions Council (HCPC) CPD audit.

The HCPC states that "Continuing professional development is the way in which registrants continue to learn and develop throughout their careers so they keep their skills and knowledge up to date and are able to practise safely and effectively. Our standards of continuing professional development set out what we expect and require of registrants' continuing professional development."

HCPC standards for CPD and what they require you to do:

1. Maintain a continuous, up-to-date and accurate record of your CPD.

2. Demonstrate that your CPD activities are a mixture of learning activities relevant to current or future practice.

3. Ensure your CPD has contributed to the quality of your practice and service delivery.

4. Ensure that your CPD benefits the service user.

5. Present a written profile, upon request from the HCPC (which must be your own work and supported by evidence), explaining how you have met the HCPC standards for CPD.

The following information has been extracted from the HCPC website. Full details of the CPD audit and how to respond can be found at hcpc-uk.org.

HCPC audit of CPD

Biomedical scientists are currently in the phase of renewing their HCPC registration. During each renewal the HCPC randomly selects 2.5% of each profession and asks them to submit their CPD profile.

The audit selection is computer-generated at random. If you are selected,the HCPC will notify you by email within 10 working days of the renewal window opening. As CPD is an ongoing requirement while you are registered, it is possible that you could be picked for audit on multiple occasions. However, the HCPC only audits registrants who have been registered for two years

or more. Recent graduates will not be selected for audit when they renew for the first time.

If you are selected you need to:

- Submit a CPD profile by the deadline, which shows the activities you have undertaken since your last renewal.
- Provide supporting evidence that shows your CPD meets the standards, including a dated list to help the assessors identify any gaps of more than three consecutive months that have not been accounted for.

CPD Profile

1 Practice history summary (up to 500 words)

- To check your CPD is relevant to your current/future practice (CPD Standard 2).
- Your summary should describe your role and the type of work you do and should include your main responsibilities, identify the specialist areas you work in and the people you communicate and work with most.

2 Your statement (up to 1500 words)

In this section, you are required to show how you meet HCPC standards of CPD. Drawing on the CPD activities you have carried out, you will need to show how you meet Standards 3 and 4, describing how your CPD activities improve the quality of your work and benefit service users.

One way to complete your statement is to choose four to six CPD activities you have carried out. For each one describe:

- what the activity was
- what you learnt
- how you think the activity improved the quality of your work and benefited your service users.

Choose activities that you think benefited you the most and for which you have some supporting evidence. When describing how your CPD has benefited the quality of your work, or benefited service users, you may need to describe how you believe that this has happened. Other ways might include using your professional development plan or similar (if you have one) or structuring your statement around each of the CPD standards.

3 List of activities

You are required to provide a dated list of CPD activities you have carried out since you last renewed your registration. Decide which activities show how you meet the HCPC standards for CPD.

4 Supporting evidence

You are asked to also provide evidence that shows that the CPD activities you have written about in the profile have taken place. You are also required to send the HCPC a summary of all your activities, but this summary should be only a sheet or two, with a very brief list of activities and dates.

5 Evidence

The HCPC identify three categories of evidence that are required:

1. Material you may have produced, for example: information leaflets and case studies.

2. Materials showing you have reflected on and evaluated your learning and work, such as: evaluation of courses or conferences you have attended.

3. Materials from others, including: testimonials or course certificates.

IMAGES: ISTOCK/SHUTTERSTOCK

HCPC DOS AND DON'TS

DO

- **Keep it simple. Use simple language to describe the CPD you have done, what you have learnt from it, and how it has benefited you and your service user(s).**
- **Choose four to six CPD activities over the last two years. Tell us what you did, what you learnt, and the benefits to you and your service user(s).**
- **Ensure the activities you discuss are a mixture of learning types and were undertaken in the last two years.**
- **Remember to include a dated list, in chronological order, of all the CPD activities you have completed in the last two years. This will demonstrate that you have met CPD Standard 1. Ensure that you explain any gaps of three consecutive months or more.**
- **Double check your profile before submitting it, ensuring all relevant documentation is included.**

DON'T

- **Try to describe in detail every activity you have undertaken over the last two years.**
- **Send evidence of all your CPD activities.**
- **Include identifiable information. This must be anonymised before including it with your CPD profile.**
- **Include CVs.**

Full details of the CPD audit and how to respond can be found on the HCPC website **hcpc-uk.org**

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