



Department for
Business, Energy
& Industrial Strategy

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NATIONAL MEASUREMENT LABORATORY

ANNUAL REVIEW 2017

LGC AS A NATIONAL MEASUREMENT LABORATORY

LGC delivers state-of-the-art measurement science in our role as a National Measurement Laboratory (NML). Designated for chemical and bio-measurement, we have established ourselves as one of the top measurement institutes worldwide in our field.

As the NML we form part of the UK National Measurement System (NMS), a consortium of laboratories funded by the UK Government Department for Business, Energy and Industrial Strategy (BEIS) that provides the core measurement infrastructure for the UK.

We have two key roles:

- ensuring trust and confidence in chemical and bio-measurements in the UK as identified by government strategy and industry needs;
- addressing measurement challenges of the future to foster innovation, promoting productivity and economic growth.

Our research areas span the sectors of advanced therapeutics, diagnostics, safety and security and are delivered through the four core streams of:

- measurement research
- calibration facilities
- reference materials
- training and consultancy.

We play a leading role internationally to develop best practice and harmonise measurements across the world, in turn providing further confidence in the UK's science and technology capabilities.

Through improved chemical and bio-measurements we support manufacture and trade, protect consumers, and enhance skills development and quality of life.



EXECUTIVE SUMMARY

Welcome to this Annual Review of our National Measurement Laboratory activities for 2017.

This year the government announced its ambitious plans to boost research and development within the UK, with the launch of the Industrial Strategy white paper, and accompanying sector initiatives and Challenge Fund (ISCF). We also saw the publication of the much anticipated UK measurement strategy. These developments come at the same time as the UK prepares for exiting the EU and we have revamped components of our programmes to respond to this changing landscape and to maximise alignment and impact. This includes direct involvement in ISCF projects, such as our £2.25m award to provide measurement infrastructure to support UK manufacturing of future medicines; a capability that will build on our expertise in the areas of oligonucleotides, biopharmaceuticals, cell-based therapies, nanomedicines and single cell and tissue imaging.

This year has seen a number of successes across all of our areas of activity. For example, we are now one of only a few laboratories worldwide to gain ISO/IEC 17025 accreditation for the high accuracy quantification of extracted DNA by digital PCR (dPCR), thus enabling us to support molecular diagnostic companies and reference materials providers to develop products for the benefit of their end-users. Similarly, our nanoparticle capabilities are informing new regulatory frameworks to enable the safe implementation of these versatile materials. NML-led interlaboratory studies are providing best practice for direct mass spectrometry analysis approaches that remove the need for sample preparation and support fields such as food authenticity. Finally, a novel generic approach to increase sensitivity and reduce measurement variability of routine immunoassay measurements in biological fluids has been developed and will be applied to monitor biomarkers in patients with Alzheimer's disease.

This year we have also focussed significant energy on increasing our engagement levels with measurement stakeholders. This includes the development and launch of two collaborative partnership programmes – 'Analysis for Innovators (A4I)' and 'NHS England Knowledge Transfer Partnerships (KTP)' – that provide new direct routes for stakeholders to access the unique

measurement facilities that reside within the NML. Both programmes are run across the National Measurement System, with A4I targeted at UK industry and the NHS KTP allowing healthcare scientists the opportunity to create, expand or implement innovative ideas to improve the quality of patient care. We value our ongoing relationships with our UK partner and collaborator organisations, be they industry, clinical, academic or otherwise and will work ever closer with these to ensure translation of our measurement capability for maximum economic and social benefit.

In addition, we continue to perform an important role within the international metrology community, supporting global consistency and traceability of measurement through our activities under the auspices of the International Bureau of Weights and Measures (BIPM), the organisation that maintains a coherent system of units. UK industry works in international markets and our participation in these activities is essential in allowing us to provide services and products that are accepted globally.

I would like to thank the teams responsible for delivering our work over this year for their hard work and commitment to maintaining the quality and consistency of chemical and bio-measurements.

Derek Craston
Chief Scientific Officer



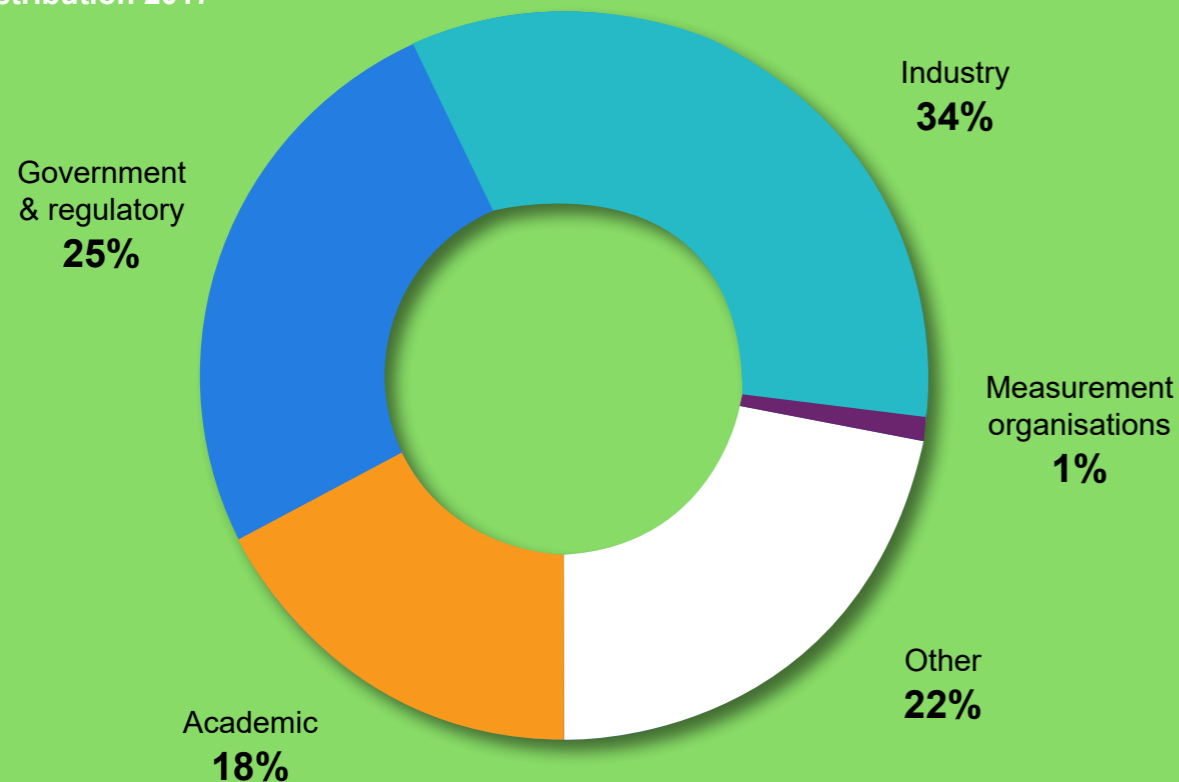
CONFIDENCE IN MEASUREMENT

For governments, society and individuals to have confidence in the decisions that are based on the thousands of routine measurements made each day they must also have confidence in the measurements themselves.

We work closely with government, academia and private sector organisations to understand, address, and manage the measurement challenges they face in order to provide practical and effective measurement solutions.

These measurements cover a vast array of applications, from clinicians making a medical diagnosis, to laboratories providing forensic evidence to support the justice system or tests to safeguard the quality of our water.

NML stakeholder distribution 2017



2017 achievements in numbers

- 23 peer-review publications
- 7 new CMC claims
- 24 reference materials
- contributed to 22 ISO standards
- 6 CCQM studies
- 359 delegates across 14 countries trained

2017 stakeholders in numbers

- 480 stakeholder interactions
- 302 unique institutions

THE NML AND THE GLOBAL MEASUREMENT COMMUNITY

We regularly coordinate and participate in international comparison studies between National Measurement Institutes under the auspices of the Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM), and are regarded as one of the top institutes for our designation within the global measurement community. Successful participation in these studies supports our Calibration and Measurement Capabilities (CMCs) claims which underpin our measurement services.

In 2017 we successfully participated in 6 studies (leading on 1) spanning the full range of our capabilities. Among these were a study to demonstrate competence for quantifying multiple organic analytes (amino acids), where we had the best results of any participant, and the ongoing study to measure concentration and abundance of low level cancer mutations in the presence of high levels of normal DNA.

Excellent performance at CCQM has maintained the NML's world-leading position and also led to 7 new and revised CMC claims.

- **Inorg 033R** essential elements in food and food supplements [revised]
- **Inorg 053** potassium in food and food supplements
- **Inorg 054** carbon isotope ratios in food and food supplements
- **Org 050** tacrolimus purity and reference value (CRM/ERM-AC022)

We received the first flexible broad scope claim within the organic area.

- **Org 051-053** PDBEs, PAHs, PCBs, low polarity pesticides (<500Mwt), perfluorinated carboxylic acids (<C12) and perfluorinated sulphonates (<C12) in soil, sludge and sediment



REFERENCE MATERIALS

Reference materials (RMs) are the cornerstone of accurate and traceable measurements – they are measurement standards which can be used to validate analytical methods, establish traceability and support quality control.

We have a portfolio of over 150 materials covering high purity standards, carbon isotope ratios, food, environmental and clinical materials, and alcohol standards. This year we released new materials to underpin therapeutic drug monitoring for transplant patients, protect food authenticity and safety, and support regulation around consumer products.

New materials released in 2017:

- Pure tacrolimus (ERM-AC022a)
- Human blood - sirolimus (ERM-DA111a)
- Electronic cigarette liquid – nicotine and water (ERM-DZ002a)
- Yeast - total chromium and chromium (III) (ERM-BD213a)
- Peanut flour (LGCQC1020)

Replacement materials released in 2017:

- Horse meat (LGC7220)
- Beef meat (LGC7221)
- Pork meat (LGC7222)
- Sheep meat (LGC7223)
- Chicken meat (LGC7224)
- Turkey meat (LGC7225)
- Goat meat (LGC7226)
- 1 % horse meat in beef (LGC7240)
- 10 % horse meat in beef (LGC7241)
- 1 % pork meat in beef (LGC7242)
- 10 % pork meat in beef (LGC7243)
- 1 % chicken meat in sheep (LGC7244)
- 5 % chicken meat in sheep (LGC7245)
- 1 % turkey meat in sheep (LGC7245)
- 5 % turkey meat in sheep (LGC7247)
- 1 % beef meat in sheep (LGC7248)
- 5 % beef meat in sheep (LGC7249)
- 15 % alcohol standard (ERM-AC405d)
- 40 % alcohol standard (ERM-AC405d)

We have accreditation to ISO Guide 34 as a Reference Material Producer.

This year we released our Metagenomic Control Material for Pathogen Detection (ATCC® MSA-4000™) in partnership with ATCC (American Type Culture Collection). The material contains a selection of bacterial DNA species commonly observed in clinical infections, such as sepsis, and includes organisms known to be resistant to antibiotics. Using our dPCR expertise, we performed quantification of the bacterial DNA present at a range of concentrations to provide customers with improved precision. This material will help researchers better understand their sequencing methods and molecular diagnostic approaches for detecting and monitoring common human diseases.

In 2017, we became one of the few laboratories worldwide to gain ISO/IEC 17025 calibration accreditation for purity of organic materials by quantitative NMR (qNMR).

Our current scope, which we shall further extend in 2018, spans organic analytes of high purity (>90%) with a molecular weight of <1000 g/mol. This accreditation enables us to provide faster high accuracy reference material characterisation and measurement research for customers across the agricultural biotechnology, biopharmaceutical, chemicals, consumer products and forensic industries.



COUNTING ON BIOLOGY FOR THE FUTURE

We are in the midst of a bio-revolution: advances in genomic and informational technology coupled to advanced measurement at the cellular and molecular level are transforming our understanding of biology. This will affect the future of many sectors, including healthcare, environment, agricultural biotechnology and food, supporting applications ranging from monitoring viral load or circulating tumour cells in patients to identifying the presence of genetically modified foods.

However, the new methods and technologies currently being developed will only achieve their full potential if we can ensure they are safe and can be implemented reproducibly. Accurate measurements of biological analytes (e.g. nucleic acids, proteins and cells) are crucial to their development.

There is currently a lack of reference methods and standards to support

the comparability and traceability of biological measurements. This delays progress in translating research into commercial applications and ultimately use in the clinic, and impacts upon accreditation, regulatory development and compliance. This in turn influences efficacy of products and can compromise patient and consumer safety.

For biomolecular analytes, where the numbers involved are very small, the seven base quantities of the International System of Units (SI) are not a particularly useful measure to achieve comparability and traceability. Instead, biologists can best be served by counting individual entities. The NML has established itself as a pioneer in quantitative biological analysis, developing novel and highly accurate reference methods and driving and supporting key initiatives in this area to establish the necessary measurement framework,

inform best practice and develop the underpinning standardisation activities.

Using these approaches we are now working closely with stakeholders from private industry, public institutions and standards organisations across a number of national and European collaborative initiatives (projects such as SPIDIA4P and EMPIR Biostand [see boxes]).

These projects develop and revise the standards and guidance documents needed to support the progress of biotechnology and clinical diagnostics and mitigate the use of inaccurate and unreliable tests.

This will help the biotechnology industry optimise and assess their processes, enabling data comparability, reducing risks and costs and ultimately supporting regulatory confidence and compliance to facilitate international trade.

In 2017, we became one of the few laboratories worldwide to gain ISO/IEC 17025 accreditation for quantification of extracted DNA in solution by droplet digital PCR, demonstrating our world-leading capability to effectively and accurately measure DNA. This accreditation supports our new dPCR facility in providing reference material characterisation and quantitative measurement research for customers across the diagnostics, therapeutics, agricultural biotechnology and food industries.

We are currently involved in revising and developing the following written ISO (International Organization for Standardization) standards, developed by international experts to help support innovation and provide solutions to global challenges:

- ISO 17511 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (revision)
- ISO/NP TS 20914 Medical laboratories – Practical guide for the estimation of measurement uncertainty (new standard)
- ISO 20395 Biotechnology – Guidelines for evaluating the performance of targeted nucleic acid quantification methods - part 1: qPCR and dPCR (new standard)
- ISO 17822-2 In vitro diagnostic test systems - Qualitative nucleic acid-based in vitro examination procedures for detection and identification of microbial pathogens - Part 2: Quality practices for nucleic acid amplification (new standard)

The NML-proposed text describing how cellular or biomolecular entities can be counted in a traceable way will be included as part of the revision of the SI Brochure (9th edition) alongside the revision of the SI which is expected to be ratified at the General Conference on Weights and Measures (CPGM) in 2018.

The successful development of personalised medicine, the diagnosis and treatment of disease at the individual level, relies on the quality of the samples being analysed. The European project SPIDIA4P focuses on standardising the way in which clinical samples should be collected and handled (pre-analytics) to enable correct disease diagnosis. This is being done by developing pre-analytical technical specifications and external quality assessment (EQA) schemes. We will contribute our measurement expertise to this programme, providing nucleic acid material to EQA schemes, and contributing to European (CEN) and international (ISO) standards development.

BioStand is an NML-led project which aims to develop standards to support molecular diagnostic laboratories in demonstrating conformity with regulatory requirements worldwide. This European-funded project will use best practice guidance generated in previous NML-led international metrology projects (Bio-SITrace, INFECT-MET) and will work closely with international standards committees for biotechnology (ISO TC276) and clinical laboratory testing and in vitro diagnostic test systems (ISO TC 212).

MEASUREMENT SUPPORTING THE NHS: NEWBORN SCREENING

We are working in collaboration with NHS England through a Knowledge Transfer Partnership (KTP) to support the Newborn Blood Spot Screening programme. The Newborn Screening programme impacts on every child born in the UK, identifying babies who may have rare and reference material.

The KTP brings together the mass spectrometry expertise and experience in reference method and reference

material development at the NML with the clinical experience of Dr Rachel Carling, Consultant Clinical Scientist, Director of Service and Clinical Lead, Viapath, Guys & St Thomas' NHS Foundation Trust.

This work aims to further improve the methodology which underpins the screening programme, supporting harmonisation of the results. It will further disseminate best practice for statistical and mass spectrometry-based

approaches to clinical measurement to other laboratories involved in the screening process. These improvements are aimed at reducing the possibility of false positives occurring, which cause unnecessary stress to parents and increase workloads of clinicians.

The NHS Chief Scientific Officer's Knowledge Transfer Partnerships (KTP) is a 12 month programme started in 2017 that runs in partnership between NHS England and three UK National Measurement System (NMS) laboratories (LGC NML, National Physical Laboratory (NPL) and the National Institute for Biological Standards and Control (NIBSC)). It provides clinical leaders in healthcare science access to the unique capabilities within the National Measurement System to identify new approaches to measurement within their fields of expertise, ultimately helping to improve patient care.

Due to the success of the first programme, a second round will be launched in 2018. This will allow for a greater number of KTPs targeted to the areas of mutual interest between the NHS and the research and innovation infrastructure within the UK.

"I am delighted to be working with the National Measurement Laboratory, and by extending the collaboration to include the UK Newborn Screening Laboratory Network, I am confident that we can further improve the methodology which underpins the screening programme."

Dr Rachel Carling,
Consultant Clinical Scientist, Director of Service and Clinical Lead, Viapath, Guys & St Thomas' NHS Foundation Trust

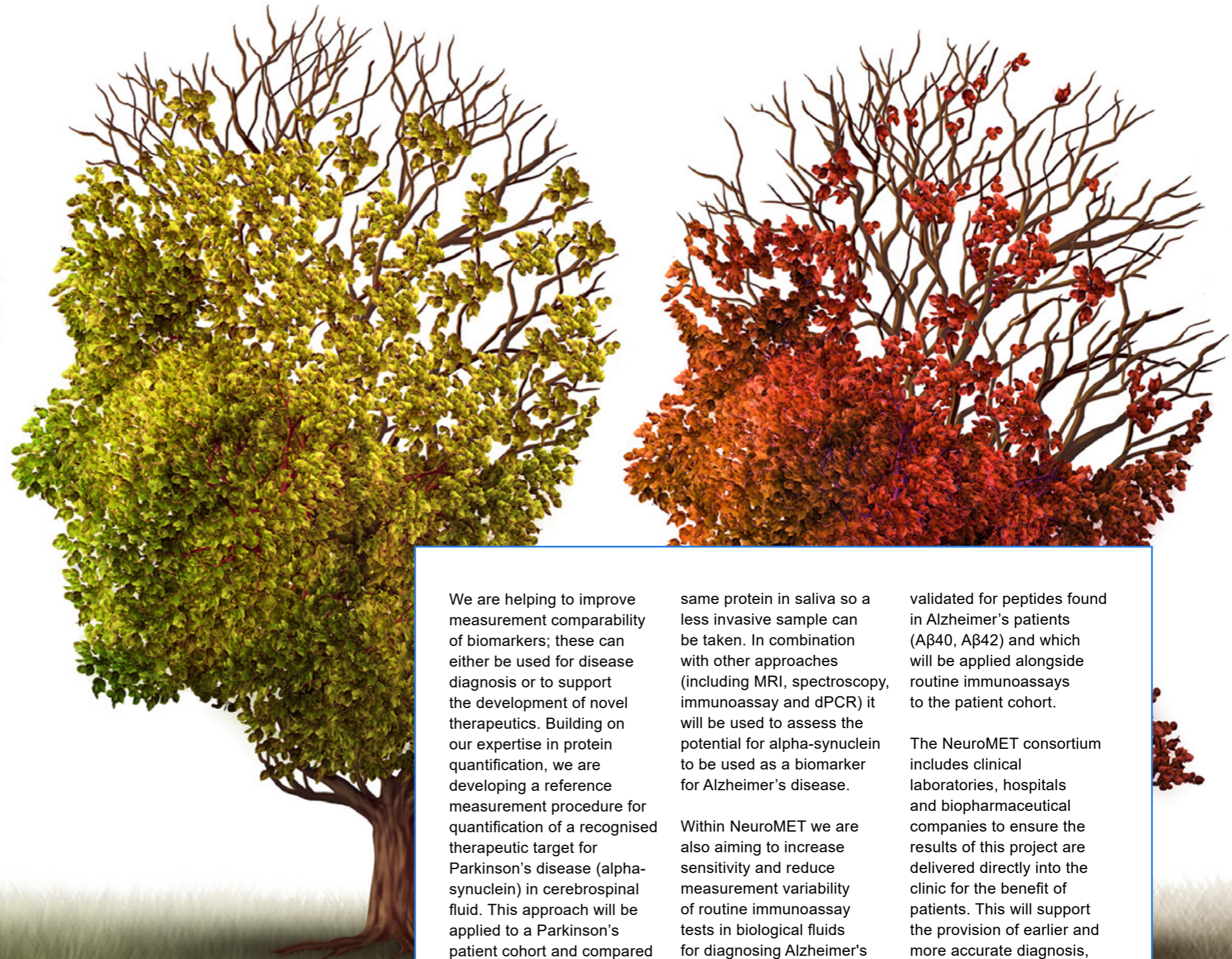


A PATIENT-CENTRED APPROACH: BETTER MEASUREMENTS FOR NEURODEGENERATIVE DISEASES

Neurodegeneration is a currently incurable, debilitating process. Alzheimer's and Parkinson's disease are two of the most common neurodegenerative diseases and present a growing global challenge due to our ageing population. While the symptoms may be different, there are similarities between the underlying changes to the brain in each disease as both involve the build-up of specific proteins in the brain and the destruction of brain cells. In the late stages of both diseases, the neurodegeneration can ultimately lead to dementia, a condition affecting over 46 million people globally

and costing around \$800 billion per year in social and medical care.

The NML is leading a European-funded multidisciplinary project (NeuroMET) to develop a clinical and measurement framework to improve the accuracy of neurodegenerative disease measurements. Working together with patients, the project will develop diagnostic protocols, reference methods and patient-centred outcome measures that are linked for the first time with clinical laboratory data.



We are helping to improve measurement comparability of biomarkers; these can either be used for disease diagnosis or to support the development of novel therapeutics. Building on our expertise in protein quantification, we are developing a reference measurement procedure for quantification of a recognised therapeutic target for Parkinson's disease (alpha-synuclein) in cerebrospinal fluid. This approach will be applied to a Parkinson's patient cohort and compared with results from routine immunoassay tests. In addition, our method will be tailored to quantify the

same protein in saliva so a less invasive sample can be taken. In combination with other approaches (including MRI, spectroscopy, immunoassay and dPCR) it will be used to assess the potential for alpha-synuclein to be used as a biomarker for Alzheimer's disease.

Within NeuroMET we are also aiming to increase sensitivity and reduce measurement variability of routine immunoassay tests in biological fluids for diagnosing Alzheimer's disease. The NML has developed a novel generic approach which has been

validated for peptides found in Alzheimer's patients (A β 40, A β 42) and which will be applied alongside routine immunoassays to the patient cohort.

The NeuroMET consortium includes clinical laboratories, hospitals and biopharmaceutical companies to ensure the results of this project are delivered directly into the clinic for the benefit of patients. This will support the provision of earlier and more accurate diagnosis, more effective treatment and improve monitoring of disease progression.

A CHALLENGE FOR OUR TIME: ANTIMICROBIAL RESISTANCE

Without action, antimicrobial resistant infectious diseases are estimated to account for a staggering 45% of global deaths, potentially as many as 1 every 3 seconds, by 2050, while also ending advances in medicine in areas such as surgery and cancer treatment.

Today our physicians are not armed with the diagnostic tests to quickly guide treatment to reduce and treat resistant pathogens. Where examples exist for more rapid methods, for

example to screen patients for MRSA, method uptake is slow as laboratories are unclear about test accuracy and support for quality assurance is in its infancy. As part of the NML-led European-funded project (AntiMicroResist), we have developed a novel reference method for MRSA and produced a prototype reference material which will be distributed as part of an external quality assurance scheme. This will be used to assess laboratory and method performance and

ultimately support screening approaches for MRSA to help inform treatment choice.

Working with hospitals and key stakeholder charities we are supporting the standardisation of comparable and traceable measurements in this area to deliver a step change in how microbial resistance is evaluated, treated and managed in the future.

ANTIBIOTIC RESISTANCE



The NML is helping to ensure that research into a cure for HIV is based on sound fundamental measurements. Recent work by NML scientists comparing different molecular methods (qPCR, dPCR) for quantification of HIV DNA has raised some concerns around the current popular choice of calibrator used to compare results between HIV clinical studies. It appears to lose HIV DNA copies during cell growth, potentially producing misleading estimates of how much HIV DNA is present and affecting whether novel strategies towards curing HIV are deemed successful or not.

Based in part on our work, the NIH AIDS Reagent Program, which provides critical reagents and resources to support research in the areas of AIDS therapeutics and vaccine development, has recently highlighted the potential instability of the calibrator on its reagent database to support the research community and enable the best chances of success.

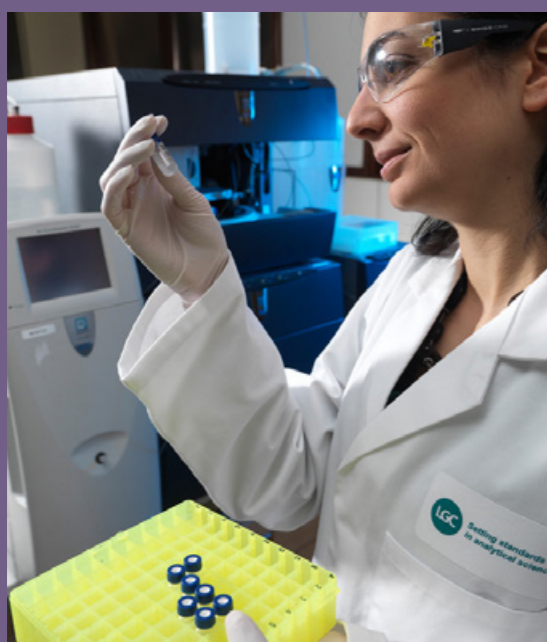
Biofilms are central to some of the most urgent global challenges. A biofilm is an association of micro-organisms in which cells stick to each other on living or non-living surfaces. They form in virtually every imaginable environment on Earth and they are a leading cause of antimicrobial resistance, forecast to be a major cause of death by 2050. The UK's world-class expertise in research in this area was recognised this year through the launch of the new National Biofilms Innovation Centre (NBIC), a multi-site Innovation and Knowledge Centre led by the University of Southampton.

Over the next five years, the NML will provide measurement support for the NBIC, focusing on the measurements required to determine the mechanisms of biofilm formation in hospital-acquired infections that can lead to antimicrobial resistance.

MEASUREMENT SUPPORTING INNOVATION

As the NML we support innovation within measurement science, providing novel measurement solutions to bridge the gap from fundamental research to application in industry.

By responding to new measurement challenges as they develop, we can support industry to make positive changes, improve processes and technologies more quickly and effectively, and reduce the risks associated with development. This will help to increase productivity and improve quality of life across the UK.



RELIABLE DIRECT MASS SPECTROMETRY: REMOVING THE NEED FOR SAMPLE PREPARATION

Ambient ionisation technology can be used to rapidly analyse samples without the need for sample preparation or chromatography, for example to analyse pharmaceuticals directly from tablets, detect explosives or determine the authenticity of food and drinks. With the recent growth and availability of commercial direct ambient ionisation sources, these techniques have been adapted across a wide range of industries, including healthcare, forensics, security and food.

However, there are significant measurement challenges with this type of technology, particularly around repeatability and robustness of the techniques and the effects of background interferences which are typically greater than those observed using traditional approaches. The NML led a second interlaboratory study (the first study was in 2015) involving 15 laboratories to assess these specific characteristics and help ensure that ambient ionisation applications are effective and reliable.

These results, which were presented at the annual British Mass Spectrometry Meeting, confirmed the best approach for obtaining repeatable data for ambient ionisation experiments (the use of a matched internal standard). The data obtained from this study has been well received in the ambient ionisation community and is being used along with the data from the first study to progress the NML's ongoing work in transportable mass spectrometry.

Scotch whisky is responsible for a quarter of all UK food and drink exports. The protection of this premium product from food fraud or adulteration is crucial in maintaining the global market.

The NML has been working with the Scotch Whisky Research Institute and King's College London to test the feasibility of transportable ambient ionisation mass spectrometry to provide useful fingerprint information on various types of Scotch whisky. These signatures will aid detection of counterfeit and adulterated Scotch whisky and this approach has the potential to be developed across the wider drinks industry.



NANOMATERIALS

Nanomaterials and nanotechnology developments are having an increasingly significant impact on human life, from enabling more targeted cancer treatments to improving the efficacy of vaccines or the delivery of agrochemicals. However, their small size can lead to potentially toxic effects. To protect human health and the environment, it is crucial that we are able to characterise nanomaterials effectively and understand their behaviour within biological systems.

Significant efforts are being made to ensure the appropriate regulatory frameworks are in place to support this enabling technology. National and international standardisation efforts play a critical role

in ensuring that the full potential of nanotechnology is realised and that it is safely integrated into society.

As the NML we have been instrumental in developing new international documentary standards (ISO) to support this field. For example, we provided expert input into a newly released Technical Specification (ISO TS 19590:2017) that outlines a novel method (single particle inductively coupled plasma-mass spectrometry, spICP-MS) for determining the size distribution and concentration of nanoparticles in aqueous samples. We have been invited to provide the UK expert view for a new standard on the analysis of nano-objects using a gentle

separation technique (field flow fractionation, ISO TS 21362). These standards have been produced as a response to the worldwide demand for suitable methods for the detection and characterization of nanoparticles in food and consumer products.

In addition, we provided the particle size reference measurements for a new silica reference material (ERM-FD101b) released this year by the European Commission (EC JRC Directorate F (Health, Consumers and Reference Materials)). This material will support the implementation of the EC definition of 'nanomaterial'.

The NML is co-ordinating the first international measurement comparison study between National Measurement Institutes (under the auspices of the CCQM) on the determination of number concentration of nanoparticles (colloidal gold). An interlaboratory comparison using the same material that is open to industrial and academic laboratories with an interest in nanoparticle analysis will be run in parallel through VAMAS (Versailles Project on Advanced Materials and Standards) in collaboration with NPL. This will allow a comparative evaluation across users and measurement institutes and may lead to the development of new international written standards to support regulation around nanoparticles.

We were invited to contribute to a workshop on regulatory preparedness run by the EU-funded project NanoReg 2, informing regulators and industry on reference material production and the current state-of-the-art for single particle nanomaterial analysis using inorganic mass spectrometry (spICP-MS) measurement.

ANALYSIS FOR INNOVATORS

"Using NMS services increases company survival rates, particularly for young companies. Support from NMS laboratories can increase employment by 10%–15% within two to four years."

- Frontier Economics Study (The impact of public support for innovation on firm outcomes (BEIS Research Paper Number 3))

ANALYSIS FOR INNOVATORS

Innovate UK Alongside NPL, NEL and STFC, the NML is a partner in the new Innovate UK funding programme 'Analysis for Innovators' (A4I). A4I provides companies with access to state-of-the-art measurement and analytical technologies. It focuses on solving measurement problems within existing business to improve competitiveness and productivity.

This year we have been working with five micro and small UK companies to address challenges in healthcare, food and bioscience development. These projects address challenges in quality control to reduce wastage, product improvement to provide regulatory support, and the extension of current products to access new markets.

Following the successful uptake of A4I, a second round of this programme will be launched in 2018.

The Coconut Collaborative

Ensuring consistent food quality throughout the supply chain is critical for the success of food businesses. The NML worked with the Coconut Collaborative Ltd, a manufacturer of coconut yogurt, and STFC, to develop a rapid and robust screening approach to detect rancidity in coconut cream. The unwanted use of a barrel of coconut cream tainted by rancidity in the manufacturing process renders it unsuitable for sale and consumption and can lead to entire batches of coconut yogurt being rejected. The novel screening approach developed at the NML (multi-spectral imaging), which replaces the current manual 'taste test', will help avoid annual costs in excess of £500k through reduced production and material charges.



"The A4I project collaboration has been incredibly valuable to the Coconut Collaborative Ltd. It has enabled us to work in a time efficient way with world class institutions and scientists to develop and prove a principle for solving a very unique but real rancidity measurement problem. We are impressed with the encouraging results."

James Averdieck, Managing Director

Sistemic



Cell therapies are seen as the future of treatment in a number of areas including diabetes and cardiovascular disease. However, one of the types of cell being used to generate cell therapy products (pluripotent stem cells, PSCs) has the potential to form tumours, raising concerns around product safety. The NML enhanced the sensitivity and specificity of the Sistemic Ltd novel prototype miRNA-assay to the levels required for market (<10 cells per million). This assay will ensure producers can accurately assess PSC contamination in their cell therapy products.

"We are delighted to have worked with LGC, utilising their expertise as the National Measurement Laboratory for chemical and bio-measurement. The successful outcome of this project has the potential to facilitate the clinical progress of pluripotent stem cell-derived cell therapy products, allowing them to be developed to safer clinical products more quickly."

David Mallinson, Vice President of Scientific Operations, Sistemic

AirQualityResearch



Novel technologies and solutions for wastewater management are necessary

for the UK to meet its sustainability goals, reducing water wastage and reusing resources where possible. Air Quality Research Ltd currently develops bespoke chemical-free, energy-saving products for bacteria control and chemical contamination, providing safe fluids for use in the home and industry. By working with the NML, they sought to increase further the efficiency of their treatment process for application to wastewater treatment for process industries, reducing costs and improving their potential for water reuse.

"We value the measurement support provided by the NML, to enable us to solve this technical challenge. As a small innovation company with a platform technology, finding the right solution to this measurement challenge is almost as difficult as the challenge itself! We have been very impressed with their approach and look forward to a continued collaborative relationship."

Peter Kukla, Managing Director of AQR

MEASUREMENTS FOR FUTURE MEDICINES

The NML has been awarded £2.25m by the Industrial Strategy Challenge Fund (ISCF) to support the manufacture of future medicines through better measurement.

The UK has seen unprecedented health outcomes and life expectancy gains over the last 30 years based on sound medicinal improvements. Recent advances are set to see this trend continue through the development of a host of new types of medicines: so-called advanced therapy medicinal product (ATMPs) based on genes, cells or tissues, in addition to novel oligonucleotide and protein based therapies. However, due to their complexity, manufacturing processes for many of these products are setting new challenges in terms of guaranteeing consistency of manufacture to ensure their safety. Such novel processes will rely, of course, on the accurate measurement, characterisation and behaviour of these medicines, both at their place of manufacture and within our bodies.

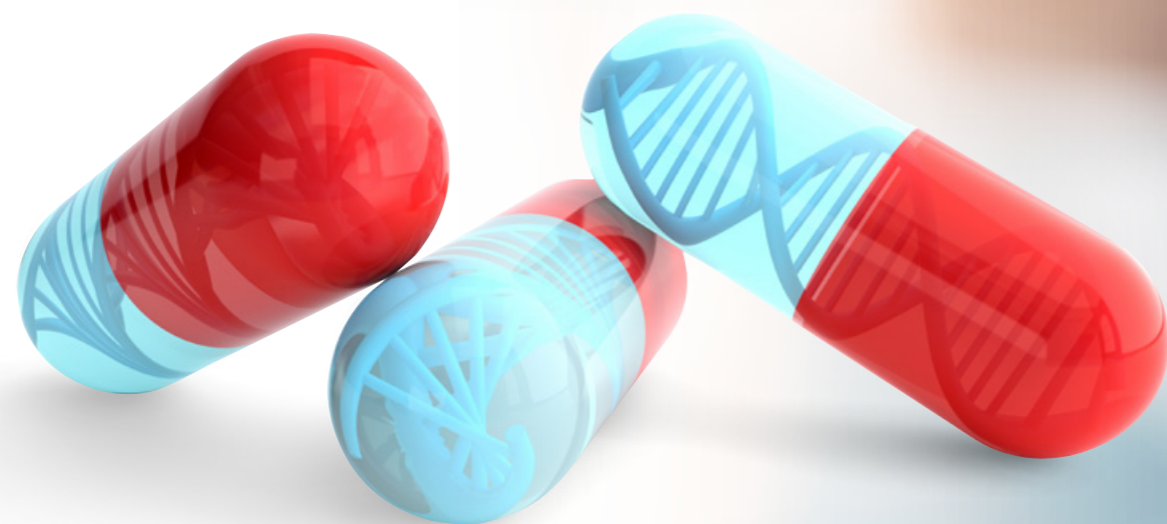
The 'Measurement for Future Medicines' project, started at the end of 2017, will further establish the NML's state-of-the-art capabilities and promote best measurement practice in manufacturing and clinical settings to enable the accurate and reproducible manufacture of future medicines.

This work builds on our measurement expertise in the areas of oligonucleotides, biopharmaceuticals, cell-based therapies and single cell and tissue imaging. Through close collaboration with regulators, the Cell & Gene Therapy Catapult, academic centres of excellence and industry partners, this project will help underpin productivity gains and innovation improvements in this area.

It will ensure the UK maintains its world-leading position within the pharmaceutical sector and continues to drive international best practice, ultimately leading to greater confidence in the safety of our medicines.

The NML is a partner, alongside NPL, NIBSC and Imperial College London's SynbiCITE, in a new virtual laboratory funded by the ISCF to establish a UK Centre for Engineering Biology, Metrology and Standards. The new £7m virtual laboratory aims to develop and provide relevant reference materials and methods to help convert innovation in synthetic biology into valuable products and services. The NML will provide specialist expertise in biological standardisation of genomic measurements.

Establishing industry-led measurements and standards will safeguard the quality and safety of products, and allow companies to maintain competitiveness and enhance innovation in fields such as the discovery and manufacture of new antibiotics.



PEOPLE

Philip Dunn was elected an Associate Member of the International Union of Pure and Applied Chemistry (IUPAC) Commission of Isotopic Abundances and Atomic Weights (CIAAW), making him only the ninth person with the UK affiliation since 1902.

Jim Huggett was made a Fellow of the Royal College of Physicians of Edinburgh (FRCP (Edin)) in recognition of the medical focus of the research he and his team have conducted on the development and standardisation of molecular diagnostics.

Denise O'Sullivan was invited on to the Steering Committee for the International Metagenomics and Microbiome Standards Alliance (IMMSA), an association of microbiome-focused researchers from industry, academia and government, that will be coordinating cross-cutting efforts to address microbiome and metagenomics measurement challenges.

Heidi Goenaga Infante was invited by the Analytical Chemistry division of IUPAC to join their task group that will critically evaluate the current sampling and analysis methods and standardised protocols available for nanomaterials.

Julian Braybrook was awarded an honorary Doctor of Science for his contribution to chemistry by Kingston University. Julian received the degree from Professor Lucy Jones, Vice Dean of Life Sciences, Engineering and Chemistry.

Fahmina Fardus-Reid was awarded her PhD from Kingston University with the thesis title "Extending metrological traceability in qNMR beyond the first dimension".

John Entwisle was awarded Chartered Scientist certification by the Science Council in recognition of his current responsibilities for characterisation of ethanol certified reference materials (CRMs) as a UKAS calibration analyst and as a technical manager for the alcoholic beverage analysis area.

Tamara Lekishvili passed the International Cytometry Certification Examination (ICCE)

and became a Certified Cytometrist.



KNOWLEDGE TRANSFER & DISSEMINATION

TRAINING FOR THE FUTURE

LGC has over 20 years' experience in delivering analytical quality training programmes to customers worldwide. The courses focus on providing analysts with the tools to ensure the validity of their measurement results.

In 2017 we delivered:
- 31 courses
- in 14 countries
- to 359 delegates
- from 94 organisations

We have an extensive programme of courses delivered from our headquarters in Teddington or at customer sites and customised, if required, to meet specific training requirements.

Topics covered include:

Method validation – Learn how to demonstrate that test methods are fit for purpose

Evaluating measurement uncertainty – The principles and practice of estimating measurement uncertainty in testing laboratories

Statistics for analysts – Getting the most from data generated in the laboratory

Designing effective experiments – Learn how to plan, execute and analyse efficient experiments

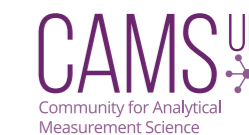
Understanding ISO/IEC 17025 requirements for analytical laboratories – Improving awareness of the technical requirements of ISO/IEC 17025

Using proficiency testing in the analytical laboratory – Learn how to get the maximum benefit from participation in proficiency testing schemes

Reference material production – Planning effective reference material characterisation studies to meet the requirements of ISO Guide 34

Our courses consistently receive excellent feedback from delegates and we have a high level of repeat customers. Over 96% of delegates who completed a course feedback questionnaire in 2017 stated that the training met their expectations.

Details of all our training programmes are available at www.lgcgroup.com/training.



The NML is playing a key role in a new initiative focused on developing new talent and providing the UK with a community for chemical and bio-analytical measurement science. CAMS-UK is an industrially-led membership network developed in response to the Royal Society of Chemistry (RSC) Analytical Division analytical landscaping exercise in 2015 and the subsequent 2016 Engineering and Physical Sciences Research Council (EPSRC) review of analytical science.

CAMS-UK is designed with the intention of bringing cohesiveness to the analytical measurement science community and aims to:

- Raise the profile of UK analytical measurement science training and research
- Facilitate industrially-led innovation in novel point-of-use measurement technologies
- Provide a talent pool with industry-ready transferable skills for the future
- Facilitate access across the UK community of analytical measurement laboratories, training providers, research and commercial innovation organisations.

Gaining significant momentum over the last 18 months CAMS-UK has secured financial support from the Analytical Chemistry Trust Fund. With industry, UK Research and Innovation and government organisation interest, CAMS-UK is due to launch formally in January 2019.

SELECTED PUBLICATIONS

The quality and credibility of our science is demonstrated in part through our publications in peer-reviewed journals. In 2017 LGC experts published 23 scientific papers. Here is a selection:

Busby E et al. Instability of 8E5 calibration standard revealed by digital PCR risks inaccurate quantification of HIV DNA in clinical samples by qPCR. *Sci Rep* (2017) 7:1209. DOI: 10.1038/s41598-017-01221-5

Pang S & Cowen S. A generic standard additions based method to determine endogenous analyte concentrations by immunoassays to overcome complex biological matrix interference. *Sci Rep* (2017) 7:17542. DOI:10.1038/s41598-017-17823-y

Bath SC et al. Iodine concentration of milk-alternative drinks available in the UK in comparison to cows' milk. *Br J Nutri* (2017) 118(7):525-532. DOI:10.1017/S0007114517002136

Torma AF et al. Candidate liquid chromatography mass spectrometry reference method for the quantification of the cardiac marker 1-32 B-type Natriuretic Peptide. *Clin Chem Lab Med* (2017) 55(9):1397-1406. DOI: 10.1515/cclm-2016-1054

Petrov P et al. Interference-free determination of sub ng·kg⁻¹ levels of long-lived ⁹³Zr in the presence of high concentrations (μg·kg⁻¹) of ⁹³Mo and ⁹³Nb using ICP-MS/MS. *Anal Bioanal Chem* (2017) 410(3):1029-1037. DOI:10.1007/s00216-017-0635-9 *part of ABC's 16th Anniversary Edition showcasing research from the diverse and exceptional Editorial Board*

Dunn PJH et al. CCQM-K140: carbon stable isotope ratio delta values in honey. *Metrologia* (2017) 54 Tech Supp. DOI:10.1088/0026-1394/54/1A/08005

Nunez S et al. A species-specific double isotope dilution strategy for the accurate quantification of platinum-GG adducts in lung cells exposed to carboplatin. *J Anal Atom Spectrom* (2017) 32:1320-1330. DOI:10.1039/C7JA00078B *part of themed collection in memory of Professor Joe Caruso*

Taylor A et al. Atomic spectrometry update: review of advances in the analysis of clinical and biological materials, foods and beverages. *J Anal At Spectrom* (2017) 32:432-476. DOI: 10.1039/C7JA90005H

Lekishvili T & Campbell JJ. Rapid comparative immunophenotyping of human mesenchymal stromal cells (hMSCs) by a modified fluorescent cell barcoding (FCB) flow cytometric assay. *Cytometry A* (2017) DOI:10.1002/cyto.a.23248

Cryar A, Groves K & Quaglia MJ. Online Hydrogen Deuterium Exchange Travelling Wave Ion Mobility Mass Spectrometry (HDX-IM-MS): a systematic evaluation. *J Am Soc Mass Spectrom* (2017) 28(6):1192-1202. DOI:10.1007/s13361-017-1633-z

Do you have a measurement-related question?

Are you looking for measurement support to address your measurement challenges?

Contact us to access expertise in a range of chemical and biological measurement technologies and related topics such as analytical quality assurance, method validation, measurement uncertainty, reference materials and proficiency testing.

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