
TAKE-AWAY DIAGNOSTICS
DELIVERING THE FUTURE?
FUTURE DIAGNOSTICS

PHOTOGRAPHY: RICHARD GLEED

After a rise in at-home tests and a fall in non-COVID-related hospital attendances during the pandemic, will a new era of diagnostics be ushered in as we return to normality? We look at the evidence.

When pubs and restaurants were forced to close at the start of this year, sales of takeaways and delivered foods shot up by 317%, compared with pre-pandemic 2020. In the first six weeks of the COVID-19 outbreak in the UK, the veg box market more than doubled, after which came the arrival of the "makeaway" – restaurants delivering meal kits for customers to cook, assemble and serve at home. The hospitality sector has seen a takeaway revolution.

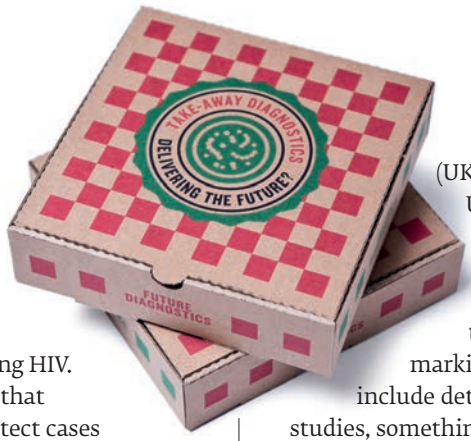
It's a far cry from the world of lab diagnostics, but could a similar change be underway in biomedical science? Earlier this year, the UK Department of Health and Social Care noted that 138 SARS-CoV-2 viral detection and antigen tests were under evaluation and 120 lateral flow devices for home-based testing had been evaluated, (although only 30% of the latter met the standards for phase 2 validation).

Meanwhile, the Nuffield Trust reported that in England in April 2020, Accident & Emergency attendances were at their lowest since records began in 2010 and numerous innovative services have been launched to help diagnose and treat patients without the need to step foot in a hospital – from drive-through phlebotomy in Sheffield to sexual health photo diagnosis in Derbyshire.

Post-pandemic, might a public reluctance to attend hospital, together with a growing awareness of home-based diagnostic tests and POCT lead to a drift away from accredited laboratories?

Home-based testing

A 2018 evaluation of home-based testing cited a 2006 UK study that found 104 home-testing or postal kits covering 24 conditions, including tests for faecal



occult blood, prostate-specific antigen, diabetes, urinary tract infections, and sexually transmitted infection tests including HIV.

It is acknowledged that self-test kits could detect cases that would otherwise be missed by providing convenience and avoiding embarrassing consultations. A recent US study of 326 rural college students reported that removing perceived barriers to HIV/sexually transmitted infection testing "by leveraging at-home testing is one potential method to increase screening uptake among this at-risk population".

But while a UK pilot study into home-based self-testing for SARS-CoV-2 antibodies using lateral flow immunoassays showed high levels of acceptability, there were limitations with kit usability, such as difficulties with the lancet and pipette, a need for clearer instructions and more guidance on result interpretation.

However, Dr David Ricketts, Head of Laboratory Process Improvement at Health Services Laboratories, says that "laboratories will need to focus on making things more patient-friendly, rather than modelling services to fit in with the current capability of their current service." David adds that, subject to appropriate government funding, he would welcome a trend for more do-it-yourself testing kits for other microbes/conditions. But he cautions that "from my experience of repeated at-home lateral flow testing, there are still many pre-analytical issues related to lay people doing these tests, even for something so simple as the current COVID-19 test."

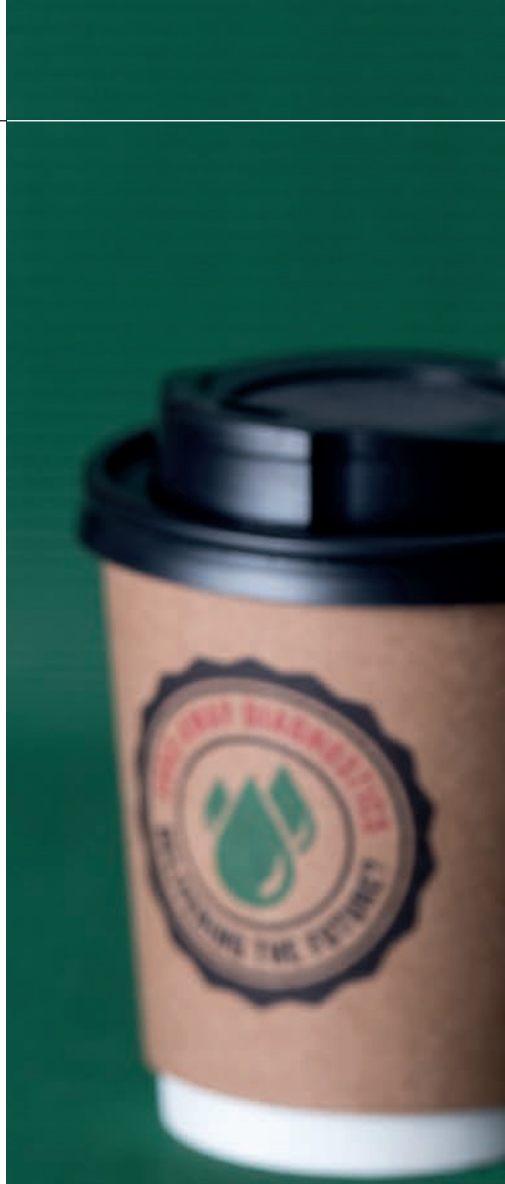
Regulation and quality control

How might future non-lab-based testing developments impact regulation of the diagnostic pathology landscape? "All such *in vitro* devices", explains David, "will need to be CE/UK Conformity Assessment (UKCA) marked." The UKCA is the product marking system intended for the GB market to replace the European CE marking, "and this will include detailed usability studies, something we have not traditionally been used to doing outside of for healthcare professionals' use, which has been the traditional market."

Biomedical scientist, advisory panel member and assessor for the IBMS and the Science Council, Sheri Scott has over 20 years' experience in clinical biochemistry and POCT and is Senior Lecturer and course lead at Nottingham Trent University. "I have recently supervised an undergraduate research project looking at home testing kits for glucose monitoring," she says. "The kits are relatively cheap and easy to obtain, but often results can be expressed in different units. Four out of five of these kits had no quality control material or demonstrated any form of certification."

Dr Guy Orchard, Consultant Biomedical Scientist and Head of Education and Training Tissue Sciences at St John's Histopathology Department, Guy's and St Thomas' NHS Trust, urges caution: "Regulation and highly stringent quality control checks must be assured. Since this is not something that generally develops overnight, but evolves over time, I harbour some reservations about this possibility."

Guy thinks that kit manufacturing processes need to be standardised across the board, providing robust platforms that are closely monitored and checked to ensure adequate quality outcomes: "Laboratory-based diagnostic tests have the assurance of being nationally accredited with annual cycles of reassessment. This in turn ensures adequate practice and performance outcomes. How easily is this achievable in a home-testing environment?" While Guy acknowledges significant benefits to be



FAST FACTS

- A report on the global POCT market predicts that it will be worth £34bn by 2026, with an expected annual growth rate of 8.4%
- There are 27 different areas within the POCT sector from common blood glucose testing kits to activated clotting time testing kits
- The global at-home testing kit market, worth £6.29bn in 2019, is projected to reach £11.36bn by 2027, according to the *Global At-Home Testing Kits Market Share and Forecast by 2027* report.
- The IBMS has established a course, comprising six two-week modules, for an IBMS Certificate of Expert Practice in Point of Care Testing
- In 2019, for the first time at IBMS Congress, a programme of nine sessions was dedicated to POCT. It will return to Congress in 2022.

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derived from home testing in respect of condition monitoring, "it should be seen as a complement, not an alternative, to acute pathology laboratory testing."

In terms of home sample collection for sending into the lab, David notes, "there are many blood collection systems for taking capillary samples and sending them via the post. These will prove a challenge to labs as they will have to process an increasing number of paediatric-size tubes, which need more manual input but are more patient-friendly."

POCT

With recent advances and increases in POCT, could this also be an area that leads away from laboratory-based diagnostic testing? A prospective non-randomised UK study of molecular POCT for SARS-CoV-2 infection reported that POCT "is associated with large reductions in time to results and could lead to improvements in infection control measures and patient flow compared with centralised laboratory PCR testing." But Sheri is unequivocal: "No. POCT has been on the increase for many years but it cannot replace the high-quality, reliable results produced in accredited laboratories by qualified biomedical scientists, or the requirement for the delivery of abnormal results by trained professionals who understand those results." Sheri acknowledges that rapid results in A&E or glucose monitoring prior to insulin dosage at home, can have their place, "but if these results are inaccurate or poorly understood, the risks to the patient are high. The medical laboratory will be needed to ratify any abnormal results detected by POCT or home-testing kits."

And there are diverse areas where POCT appears to confer benefits. For example, a Spanish study with a monitoring series of almost 25 years reinforces the role of community-based HIV POCT in improving early HIV diagnoses in key populations, and highlights the importance of monitoring these data for

inclusion in a regional or national HIV surveillance system. UK researchers, noting the importance of distinguishing between COVID-19 and influenza, suggest a role for POCT being performed promptly "to allow the patient to be triaged according to the test result and therefore minimising the subsequent exposure risks and potential for healthcare-associated infections". A recent UK study assessing the cost-effectiveness of antimicrobial resistance (AMR) POCT strategies that optimise the treatment of *Neisseria gonorrhoeae* (NG) found that "once developed, AMR POCTs could have wide-ranging implications for clinical decision-making globally, including the potential reuse of antibiotics previously abandoned for the treatment of NG, ensuring the right treatment is given to the right person at the right time (precision medicine)."

POCT quality assurance

So, what are the main challenges to quality assurance and quality control that innovative non-laboratory-based diagnostic technologies present? Sheri believes that the main challenges are ensuring the results from such technologies are accurate, reproducible and understood by either the patient or the person conducting the test: "To mitigate these issues," says Sheri, "regulation of POCT is needed by the lab to ensure the most appropriate equipment and technology is sourced; the results are checked for accuracy; the staff performing the tests are trained and competent; the kits and reagents are stored according to requirements; the test is conducted in the conditions required; and that the POCT results are validated by the lab to confirm their comparability to results obtained in the lab. Less can be done regarding home-testing kits, but some form of regulation is needed."

David says slicker logistics will be needed "to allow more self-collect samples to be taken and facilitate different internal processes as these will not be as easily automated. The IT connectivity will be a key element, not only on the lab side but at the interface with the user too".

The future

Given the rise in non-laboratory-based diagnostic testing, where will medical laboratory science be in 2031, and will biomedical scientists be ready to meet the accompanying challenges? While Sheri anticipates a continued rise in POCT with a greater test variety, "this will not replace our medical laboratories.

"A cautious pragmatic approach is undeniably the safest way"

For a profession that is largely behind closed doors, the increase in POCT opens opportunities for interprofessional collaboration and development. We can be closer to the patient and work with other healthcare professionals to ensure POCT is reliable, and the technology is appropriate, used correctly and provides consistent and comparable results. Biomedical scientists need to be prepared to work with the other healthcare professionals to ensure this."

Guy says: "I feel that home-testing kits that rely on broad-based outcomes, such as negative or positive results without any quantitative evaluation, are more likely to be employed. The introduction of quantitative results is subject to a wider number of variables and therefore more prone to misinterpretation. This could also cause unnecessary and increased anxiety amongst the public using the home-testing kits."

Guy also anticipates a further expansion of home-testing kits, "simply to act as a preliminary screen for further investigation that may subsequently follow. It is also the case that such kits may improve efficiency and reduce patient waiting times for initial medical practitioner consultations. This in turn may help improve diagnostic turnaround times for testing, and overall improve patient management pathways in the future. However, a cautious, pragmatic approach is undeniably the safest way for these new home-testing kits to progress".

Finally...

Will diagnostics go the same way as the hospitality, with an increase in takeaway and home-based testing? They are relatively new features on the unfolding diagnostic landscape, but as biomedical scientists have demonstrated in their response to COVID-19, they are well prepared to meet the challenges posed by navigating this new territory. BMS