

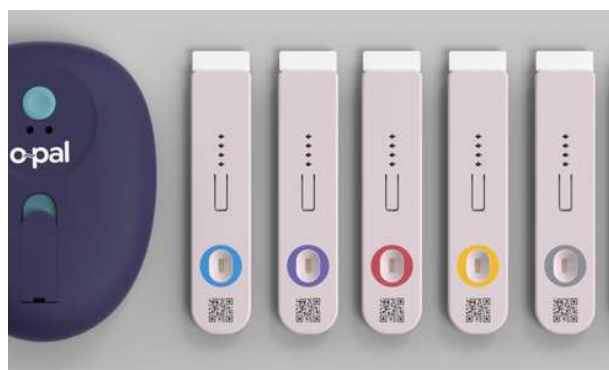


population-level data was flawed due to inaccurate reporting. Recognising the need to capture data at the point of test our development includes the automated upload of sample data to a secure server: if the medical need justifies it, every test taken can be recorded. If privacy concerns are paramount *e.g.*, in pregnancy testing then test results will not be recorded.

This transformation is enabled because our innovation allows the lateral flow test to be entirely digital- which also increases test precision beyond that possible with visual reporting. The éclateral digitalised health test integrates electrical components into the chemical matrix of a conventional lateral flow test. This feature translates the traditional visual lateral flow device results to an electrical measurement, using our o-pal mobile handheld reader. This has resulted in a digital health test device that is user-friendly for at-home use, delivering results in thirty minutes or less, depending on the analyte.

The Digitalisation Process:

The o-pal reader is at the core of the service, a low cost and clinical grade device which provides the electrical current and captures the electrical measurement of the analyte at the T line, and the control nanoparticles at the C line. Our o-pal tests will also incorporate an S line, which will measure a non-varying analyte in the sample to control for the amount and type of sample that was loaded into the test cassette. The Reader transmits test information by Bluetooth to the user's smartphone, where the dedicated o-pal App can transmit the result to a healthcare professional at a remote location or display the result to the user. By design, the use of our smartphone App enables accessibility to people who have not been able to use LFTs before, such as blind and partially sighted users. In addition, for all users, digitalisation provides an extra layer of accuracy and convenience, including for clinicians and healthcare teams who can prescribe tests to be taken at home, but can interpret the results from their offices. When showcasing this technology's effectiveness with SARS-CoV-2 samples, the potential benefits of digitalisation become evident. Every test taken gets reported, and the number of false negatives drops by more than 40%, resulting in improved clinical sensitivity. The innovative solution holds promise for the detection of analytes and antigens at levels that may not be visible to the naked eye for a diverse array of diagnostic applications (see reference 1). Our areas of focus extend to the CRP test, aiming to reduce unnecessary antibiotic usage, as well as female-centric health concerns like menopausal hormone testing or even a simple pregnancy test that can be used by blind women who cannot read first or second generation LFTs, but who will be able to hear the result using the accessibility



settings on their smartphone together with the o-pal app. We are taking steps to address the associated privacy concerns that have led to an investigation by the UK's Information Commissioner's Office into data collection by for example, fertility Apps. We clearly distinguish between medical tests, where data needs to be shared with healthcare professionals, and wellness tests where the data solely belong to the user and can only be seen by them.

Digitalisation Benefits

Data Integrity

Our lateral flow tests are encased in a cassette containing electrodes to engage communication between each lateral flow test strip and the o-pal reader. Each cassette carries a unique barcode, is strictly designed for single-use and is linked exclusively to the user's account when they scan the barcode. Any attempt to reuse a cassette or for it to be read by another individual is prevented both physically – the reader includes a mechanism that renders the cassette unusable – and digitally: each cassette's barcode is unique and cannot be reused. As the system records the initiation of each test, and a cassette cannot be used twice, this ensures complete traceability. All test results are captured and associated with the specific user and dual barcode scanning means that even the Reader used for each test is known, which can be important in high-volume settings if devices are being used in healthcare or residential care settings.

Applications

Healthcare Professional

The unambiguous nature of electrochemical measurements allows for the addition of sample controls to each lateral flow test, enabling both clinical confidence that the test was taken correctly but also enabling absolute quantification of the analyte against an invariant biomarker- although the nature of each sample loading biomarker may need to vary from test to test. This level of precision can be invaluable in healthcare settings, particularly when monitoring disease progression or treatment efficacy and here it is important to note that the user or patient can be prevented from seeing the result until they have been spoken to by a healthcare professional if the result means that there has been a change in their condition, or will be a change in their medical treatment.

For patients using a test at their home, each test result can be assessed by a clinician remotely, providing peace of mind to individuals. This telemedicine approach reduces the need for in-person healthcare visits, streamlining the diagnostic process and potentially reducing the burden on healthcare systems.

Clinical Trials

This secure data handling process, in conjunction with the elimination of optical readouts and data anonymisation is suitable for double-blinded clinical trials.

The digitalisation of test results, incorporating pseudonymisation, combined with our robust traceability strategy, ensures the integrity and accessibility of data to support a wide spectrum of applications (see reference 1), including clinical trials or for personal use at home. There is an enhanced traceability strategy with a single-use cassette being assigned to each user before commencing the test. The



Application Note



test results remain confidential until they are uploaded to a secure server, which is password protected, encrypted, and IP locked.

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Home Users

There is a growing need for clinical grade diagnostic tests from the comfort of one's own home. Clinical-grade, user-friendly solutions are an advantage of the éclateral technology whilst ensuring its affordability.

Since LFTs are visually interpreted they are ultimately subjective and are therefore difficult to analyse for non-specialists. Analysis becomes even more difficult for users who are visually impaired which in turn reduces the accessibility of LFTs. Replacing the visual aspect of testing with digital access to results will encourage individuals to have the confidence to track their wellness, monitor their progress and gather health data over time, all within the privacy of their own home.

LFT data is also not private in its current form as it can easily be visually interpreted by others, preventing users from having sole access to their medical device records. Because prioritising data privacy is paramount, privacy and data control are a critical aspect of éclateral's offering. A home users'



personal wellness information is protected and can only be accessed in ways they permit.

Future uses

Providing the ability for early disease detection we look ahead to support various fields in healthcare, wellness, and disease monitoring. The possibility to function as a global health tracking tool for infectious diseases and future pandemics, and for localised public health management, will enable the identification and management of pockets of reinfection before they escalate into widespread outbreaks.

The nature of the o-pal rapid test system and the digitalised service, captures test results at the point of the sample collection so anonymised health information can be recorded at scale. This capability extends to a wide range of applications, including inflammation detection, female health, and hormone testing, and acting as a measure around antibiotic resistance.

Applying these capabilities across many other areas of health and wellness whilst bringing clinical grade diagnostic tests into the home, we hope to help relieve pressures in primary care and on healthcare systems globally.

REFERENCES

1. Lee, L.G., Nordman, E.S., Johnson, M.D. and Oldham, M. F. A Low-Cost, High-Performance System for Fluorescence Lateral Flow Assays. *Biosensors* 3(4):360-73 (2013).



Paul Ko Ferrigno

Paul is the CEO and Co-founder of éclateral. He has been involved in commercialising technological innovations since 2008 when he founded Aptuscan (acquired by Avacta Group in 2012). He also invests in the future through work on multiple Boards for charitable, educational and grassroots sports organisations.



Bethan Larkin

Beth has recently graduated with a First Class Degree in Biological Sciences BSc (Hons). She is one of the team of scientists, passionate about making a difference in people's lives.



Benjamin Edwards

Ben (M.Chem, PhD), a scientific researcher at éclateral has helped contribute to two patents while developing the electrochemical methods and assay chemistry needed for technology development.



Sara Monem

Sara, Business manager at éclateral, brings with her experience from the Met Office in sales and digital marketing.