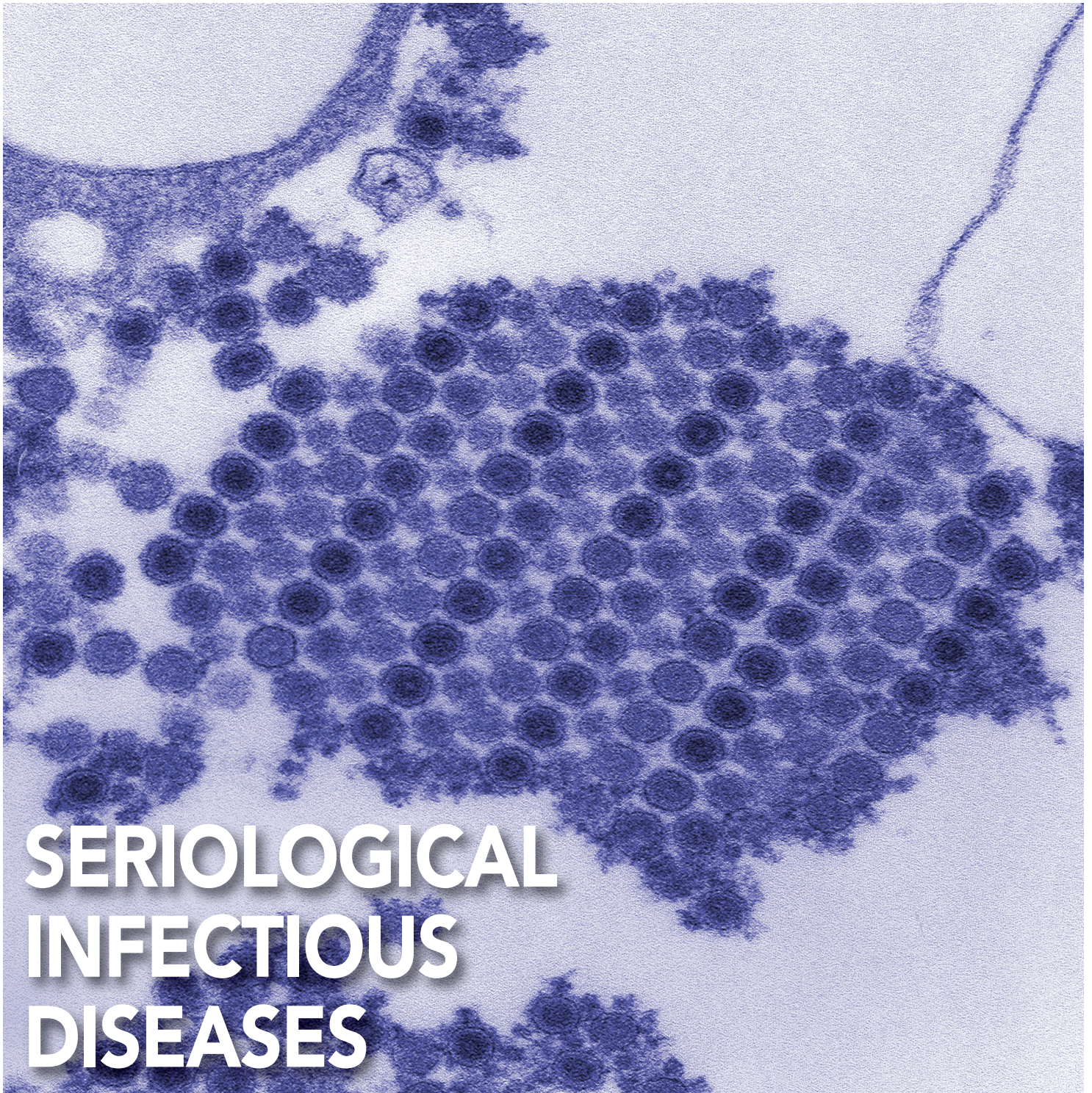




**PRECISION, RELIABILITY, HIGH-SPEED  
THROUGHPUT AND RANDOM ACCESS**

.....  
SYSTEMS FACILITATE CONTINUOUS  
FLOW AT A RATE SET BY DEMAND  
.....

**ENHANCED DIAGNOSTIC CAPABILITIES  
WHILE LOWERING THE COST ENVELOPE**



**SERIOLOGICAL  
INFECTIOUS  
DISEASES**

# Serological infectious diseases: a solution that meets a gap in the market

Jamie Laughlin explores the benefits of a novel, innovative solution for serological infectious diseases testing recently introduced at South West London Pathology, part of St George’s University Hospitals NHS Foundation Trust.

The ideal immunoassay platform must not only be sensitive and specific, but must also demonstrate versatility across a wide range of infectious disease markers, exhibit a high degree of automation, throughput, speed, accessibility, standardisation, ease of use and flexibility. In the past decade, several immunoassay platforms have been commercialised that have been able to meet some of these criteria. Overlying this automation is a requirement for reagent inventory management including optimised sample workflow and sophisticated results reporting that provides ‘value-added’ clinical interpretation.

There is, however, no denying that a niche market opportunity has existed for a significant period of time around low-to medium-volume specific assays that are more esoteric in nature. The historical solution for the laboratory might have consisted of various different devices, each devoted to perhaps one or only a few analytes, and each requiring a qualified member of staff to operate. Alternatively, these could be passed to a reference laboratory.

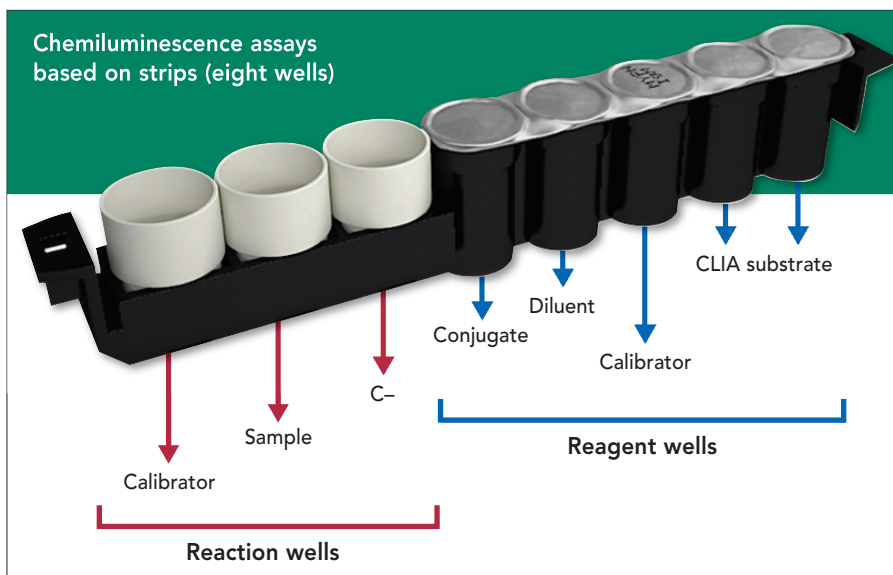
Today, automated chemiluminescence immunoassay (CLIA) analysers are widely used in clinical laboratories. They offer excellent precision and reliability, high-



The random-access VirClia analyser, available from Launch Diagnostics.

speed throughput, random access, and the technical simplicity of full automation. The implementation of the Roche fully automated tracked solution, coupled to a DiaSorin LIAISON XL has covered successfully a large repertoire of serological assays required at South West London Pathology (SWLP). This forms an integrated delivery system for serology within the network. This total laboratory automated (TLA) solution increased productivity, decreased and standardised turnaround time (TAT), improved safety, and allowed manpower to be reallocated for optimisation of those tasks that could not be fully automated/tracked.

Laboratories should recognise that TLA is not a panacea and standalone analysers make sense for lower volumes, especially when they offer versatility to analyte detection. There are, however, a number of more esoteric tests that continued to be sent to external reference laboratories at significant costs. The need, therefore, was for a standalone, task-orientated automated system. With the consolidation of laboratories, particularly in the area of microbiology, repatriation of assays is seen as a cost-saving mechanism, as well as an opportunity to improve quality and control the process



The strip-based technology employed by VirClia.

more effectively end to end. The solution should also demonstrate minimal touch points and support single-piece flow (ie random access).

### Random-access analysis at South West London Pathology

The launch of the VirClia produced by Vircell and distributed by Launch Diagnostics in the United Kingdom has created an opportunity for SWLP to repatriate, improve quality and offer a more comprehensive range of in-house infectious disease markers to the benefit of the user and, more importantly, the patient.

The challenge facing SWLP was to use automation to enhance early diagnosis and preventive medicine, providing improved care to the individual patient. The purpose of automation is to save time and improve performance through the elimination of human error. The VirClia system is a flexible monostest solution, offering the benefits of CLIA (ie higher sensitivity to detect lower levels of antibodies). The minimal touch points and Lean methodologies incorporated into the workflow adds to its usefulness. It allows for a pull-through specimen process approach rather than the more inefficient push approach, which has a tendency to produce bottlenecks.

Efficient systems facilitate continuous flow, at a rate set by patient/GP/clinician demand, which has been made possible by the design set-up of the VirClia. Competitive systems such as the popular Dynex DS2 encourage batching that leads to bottlenecks. The ultimate Lean solution must support single-piece flow, which is a feature of the VirClia solution.

It has the added advantage of short incubation times, ready-to-use reagents, with each strip containing all the reagents required to perform the test. Barcode identification ensures a complete audit trail and the system has a capacity of up to 24 tests per run.

The VirClia is commonly referred to as a discrete analyser, otherwise known as a random-access analyser which is selective and performs only those assays ordered on each sample. This represents a paradigm shift from batch analysis on automated enzyme-linked immunosorbent assay (ELISA) platforms (eg Dynex DS2) to fully random-access analysis.

The benefits of the VirClia in the microbiology laboratory at SWLP have included replacing manual assays such as *Mycoplasma pneumoniae* particle agglutination antibody tests (MGAT) with automation, eliminating potentially dangerous, error-prone manual procedures with automated processes requiring minimal user involvement,

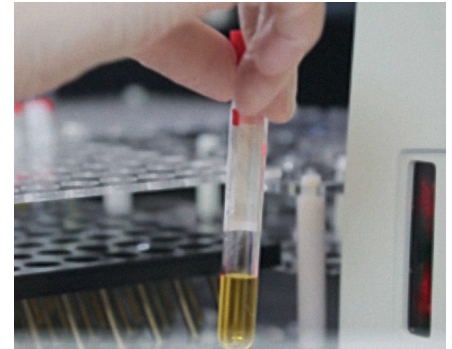


Intelligent racks make it possible to automatically manage the location of sample tubes.

increasing productivity, decreasing TAT, improving safety, minimising error, improving sample handling, and allowing practical reallocation of laboratory staff freed from manual tasks. The reaction wells and specific reagents of the assay are supplied as individual cartridges (eight wells) under the principle of one test per cartridge that fits perfectly in a standard 96-well microplate. Each strip includes a calibrator and a negative control that enables the validation and interpretation of results for each individual sample, and is not based on stored curves.

The wide range of assays available for

### The VirClia random-access analyser is selective and performs only those assays ordered on each sample



The inbuilt barcode reader streamlines loading and decreases sample tracking errors.

the diagnosis of infectious diseases on the VirClia offers broad coverage of over 80 parameters, including *Bartonella*, chikungunya and dengue, and provides highly sensitive solutions that give results in less time than other techniques.

The availability of Zika IgM and IgG is one of the many benefits being utilised to reassure pregnant mothers returning from high-risk areas with the minimal of delay.

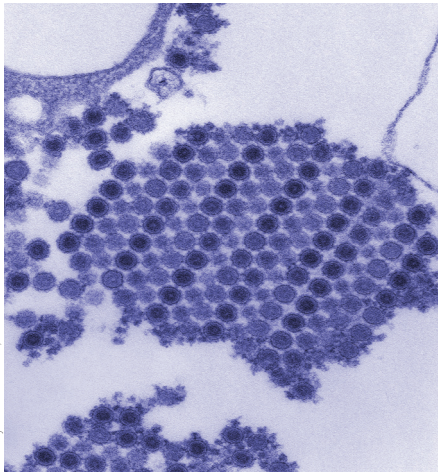
Its broad coverage also offers an opportunity for income generation by offering these tests to external customers. The competitive nature of pathology is contributing to innovative business strategies around income generation among NHS laboratories. The proliferation of well-funded, equipment-based private laboratories, especially in the London area, requires innovation and business development from the traditional NHS laboratories to ensure their continued survival.

One needs to recognise that antibody-based detection methods remain a mainstay for the diagnosis of infectious

## Benefits noted by technical staff

- Intelligent racks – it can automatically manage the location of the sample tubes with barcode technology.
- Flexible primary sample tube size (standard tubes of 12, 13 or 16 x 75 mm). This is particularly useful when the service covers a large geographical area serving multiple trusts – by offering the service to external users there will be variation in tube sizes received.
- Allows pipetting from primary sample tube; no further manipulation is needed.
- Requires minimal manipulation (ie touch points, therefore reduces the risk of human error).
- Its ability to mix and match different assays within one run (ie flexibility in its assay menu).
- True STAT ability for urgent samples.
- Intuitive software.
- Onboard camera – allows remote troubleshooting via VPN link
- High-precision micro-syringe aspirates 1µL with less than 3% coefficient of variation (CV).
- Convection incubator eliminates 'edge effect' by evenly heating each well.
- Ergonomic design (ie sliding sample tray for easy loading and unloading of samples).
- Inbuilt barcode reader streamlines loading and decreases sample tracking errors.
- Small footprint.

## RANDOM-ACCESS IMMUNOASSAY



CDC/Cynthia Goldsmith, James A Comer and Barbara Johnson

The wide range of assays available on the VirClia offers broad coverage of over 80 parameters, including chikungunya virus (pictured; digitally coloured transmission electron micrograph).

diseases and the evaluation of protection against them. With the erosion of global boundaries, farming practices and lifestyle changes, there has been substantial increase in the emergence of new viral agents over the past few decades, most recently the Zika virus. The length of time between the emergence of an infectious agent and the availability of a diagnostic test can inversely influence the extent of spread and damage, due to the delay in instituting rational interventions. The ever-

increasing repertoire of tests offered by the VirClia parent company has been refreshing and instilled confidence within SWLP about the usefulness of this analyser.

The challenge for too many NHS laboratories is to enhance their diagnostic capabilities while simultaneously lowering the overall cost envelope. Testing needs to be 'smarter', optimising workflow/efficiencies and utilising concepts that have been around in the commercial world for decades.

### Conclusions

Many modern instruments have designed quality at the source (ie the processing and mechanisms associated with it); however, the workflow, random access and minimal hands-on time continues to vary tremendously between these instruments, highlighting the importance of these key parameters in the selection of an instrument.

Laboratories today and in the future are being asked to increase productivity and the services offered while at the same time reduce overall cost including staffing. Integral to the success of this remit is smart automation with optimal workflow/hands-on time with inbuilt mistake-proofing in the process and a flexible wide-ranging assay platform. The VirClia has shown its effectiveness in

all of the aforementioned areas. Huge improvements in turnaround, hands-on time and cost reductions have been demonstrated.

Manual testing is clearly of the past century for a modern laboratory, except for a few extremely specialised tests – even here, SWLP Microbiology is challenging this. The elimination of manual serology has all but happened due to the launch of flexible automated platforms with a vast array of infectious disease targets that complement the full integrated tracked solutions SWLP has to offer.

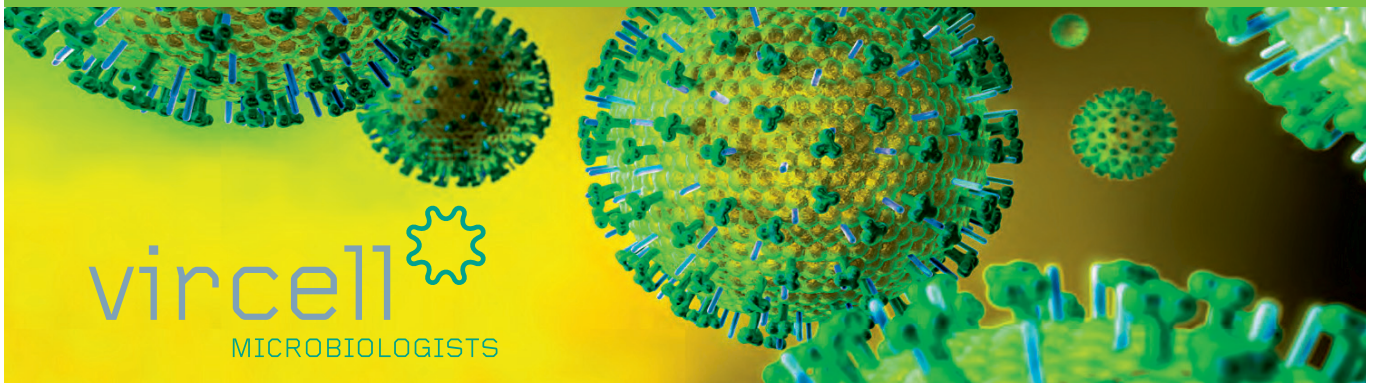
The VirClia system has created a robust, cost-effective solution which ultimately benefits the patient. Its versatility, and the wide range of analytes available, means clinical laboratories can process their analysis on a daily basis, without the need to accumulate samples or refer them to outside reference centres.



Jamie Laughlin is Head of Operations, South West London Pathology, St George's University Hospitals NHS Foundation Trust.

Further information is available from:  
Launch Diagnostics  
Tel: +44 (0)1474 874426  
Fax: +44 (0)1474 872388  
Web: [www.launchdiagnostics.com](http://www.launchdiagnostics.com)

**CONTACT LAUNCH DIAGNOSTICS LIMITED FOR FURTHER INFORMATION ABOUT THE VIRCLIA® CHEMILUMINESCENCE MONOTEST SYSTEM IN THE UNITED KINGDOM**



Vircell is a leading microbial biotechnology company which develops, manufactures and markets ready-to-use kits for the diagnosis of infectious diseases in humans by techniques ranging from traditional cell culture, ELISA, Chemiluminescence and molecular biology.

LAUNCH DIAGNOSTICS LIMITED  
Ash House, Ash Road,  
New Ash Green, Longfield, Kent,  
DA3 8JD  
Tel: 01474 874 426



**LAUNCH**  
DIAGNOSTICS

Contact Launch Diagnostics for more information,  
**01474 874 426**

or visit our website:

**LAUNCHDIAGNOSTICS.COM**

