

Adapting to rapidly changing diagnostic needs

A synopsis of three perspectives on molecular laboratory design

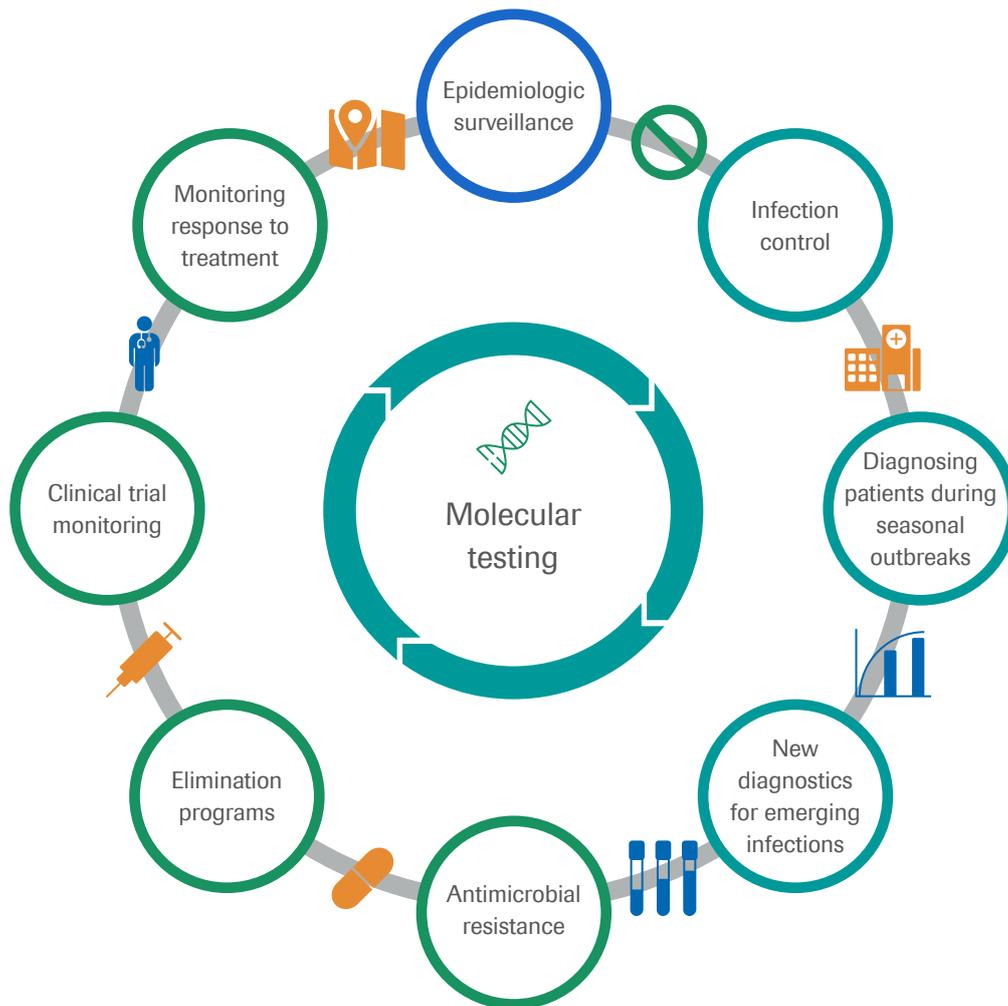


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Demands on the modern molecular laboratory

Although relatively new to the diagnostic toolbox, molecular testing is now critical in supporting healthcare and is not only used for patient screening, diagnosing infection and other disease states, monitoring patients' response to therapy, but also for epidemiologic surveillance, infection control, antimicrobial stewardship and clinical trial monitoring.¹ Molecular methods determine appropriate treatment of infections, and are essential in disease elimination programs, such as HCV elimination, which rely on detection of viremia and patient monitoring.²



The scope of molecular testing.

Molecular diagnostic laboratories also must respond to changing demands in infectious disease testing, including demand for influenza and norovirus which are typically seasonal, Chikungunya and Dengue, which can be weather dependent, and outbreaks such as the recent COVID-19 that can emerge rapidly.^{3,4} In response to the SARS-CoV-2 outbreak, molecular diagnostic tests were the first approved to detect and diagnose the virus and there was high demand for testing to be quickly scaled up and widely accessible.⁵

Operational implications for molecular laboratories

The modern diagnostic landscape means that there can be large variations in the demand for testing. Day-to-day laboratory challenges include:

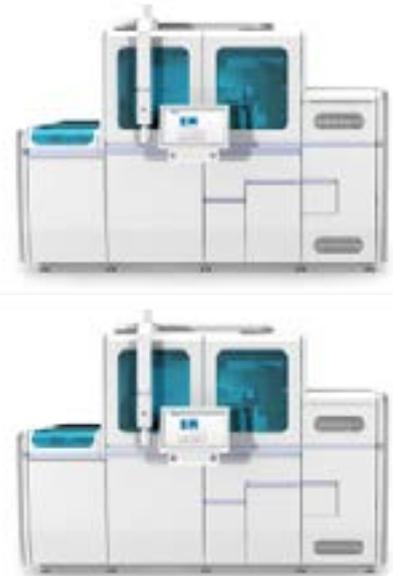
<p><i>Pre-analytical challenges</i></p> <ul style="list-style-type: none">▪ Sample frozen▪ Barcode unreadable▪ Too little material▪ Wide variety of sample types▪ Transport delays▪ Biosafety requirements	<p><i>Staff issues</i></p> <ul style="list-style-type: none">▪ Staff shortages▪ Training required▪ Hands on time needed▪ Morale▪ Skill gaps	<p><i>Technical issues</i></p> <ul style="list-style-type: none">▪ System Availability▪ Keeping SOPs updated▪ Capacity▪ Automation▪ Validation and QC
<p><i>Consumable requirements</i></p> <ul style="list-style-type: none">▪ Stock availability▪ Supply chain▪ Ordering▪ Different consumables for different instruments	<p><i>IT</i></p> <ul style="list-style-type: none">▪ Connecting all outputs to the LIS▪ Reliability▪ Results transmission to end user▪ Request/coding errors▪ Manual sample tracking	<p><i>Testing portfolio</i></p> <ul style="list-style-type: none">▪ Range of available tests▪ Workflow efficiency▪ Flexibility▪ Reflex testing and specimen tracking

Laboratories may look for solutions to streamline their testing processes, reduce the complexity of the molecular testing and minimise the operational challenges within a laboratory. If the laboratory can optimise its sample handling and testing strategies by reducing complexity, training requirements, and potential for sample contamination, then it may increase output and better adapt to changing demands and deliver patients results more quickly, aiding clinicians in improving patient care.^{6,7}

Molecular laboratory solutions

One of the ways in which molecular laboratories can streamline testing processes is by automating and consolidating testing workflows, reducing the need for hands-on processing. This can be readily achieved using pre-analytical processing platforms that are integrated with the molecular testing platform.

Areas of molecular laboratory testing that can be consolidated/automated include pre-analytics (e.g. fully automated specimen tracking, pre-processing and aliquoting), serology and molecular sample storage and retrieval (e.g. fully automated specimen tracking), allowing fully automated molecular testing.



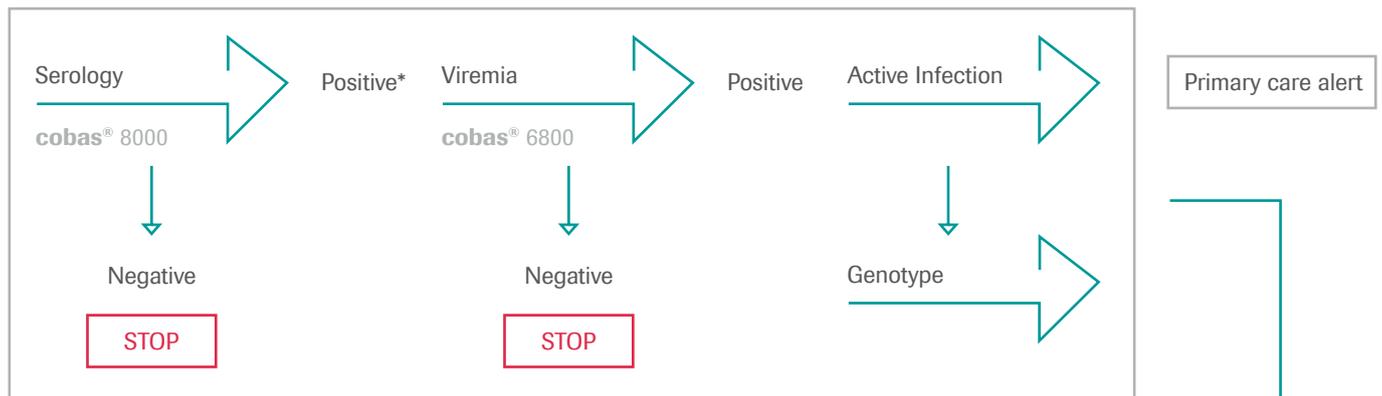
Pre- and post-consolidation and automation of molecular testing.^{8,9}

“Integration in molecular laboratories is being driven by the advent of new technologies allowing for greater automation including pre-analytics, integration and standardisation”

– Dr. Benito Regueiro, Head of Service, Professor of Microbiology, University of Santiago, Hospital Álvaro Cunqueiro

Dr Benito Regueiro, Head of the Clinical Microbiology Department at the University Hospital Complex of Vigo, Galicia, Spain, recently oversaw the consolidation of serology testing with the Molecular Work Area, using tests like HCV and HIV on Roche cobas Systems, at the Hospital Alvaro Cunqueiro Laboratory.

In addition to simplifying the testing process and sample handling, this strategy allows reflex testing of a positive serology result to determine whether there is active infection, and if so, to perform the necessary genotype testing (for HCV).



*Verify in »lanus« if new diagnosis or lack of previous viremia

RESULTS:
Negative serology: No contact
Positive serology/negative viremia: Infection resolved
Positive serology/positive viremia: Active infection/hospital derivation/treatment

Linking serology and molecular testing for HCV.¹⁰

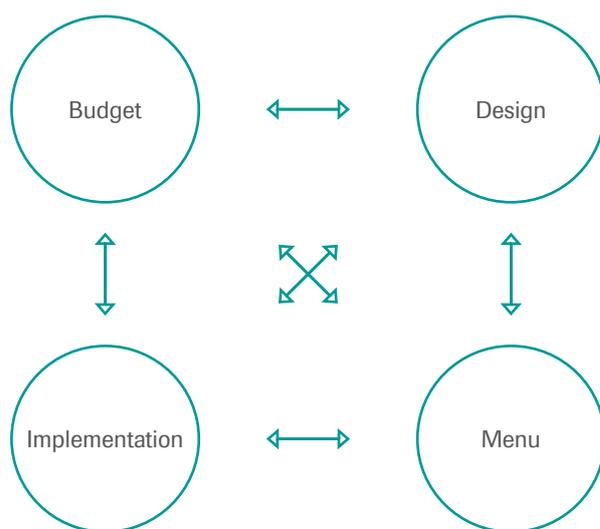
“Our integrated lab model had been recently successfully tested during the recent pandemic, and the Roche cobas p 612, cobas® 6800 System and cobas e 801 solution in our integrated lab had performed great work, we consistently reach 1300 PCRs daily”

– Dr. Benito Regueiro, Head of Service, Professor of Microbiology, University of Santiago, Hospital Álvaro Cunqueiro

Dr André Frontzek, Technical Director in the Department of Molecular Diagnostics at MVZ Dr Stein + Kollegen, Mönchengladbach, Germany, worked with Consulab, a consultancy company, to assess the impact of laboratory design on testing efficiency. This collaboration influenced the decision by his laboratory to consolidate and automate their workflows for HBV, HCV, CMV, norovirus, Chlamydia trachomatis and Clostridium difficile testing. Following consolidation onto the cobas® 6800 platform hands on time was reduced by 54%, reagent costs by 23% and overall costs reduced by 25%, despite a 29% increase in testing volume between 2014 and 2018.⁹

Implications for molecular laboratory design

The four main considerations when planning to automate and consolidate molecular testing are: design, budget, implementation and menu. All of these aspects are closely interrelated with one another. For example, issues with design can impact on the availability of menu options, leading to issues when consolidating testing workflows, which, in turn, impacts budget. These issues can be resolved when all parties involved in the planning and implementation – laboratory managers, business managers, diagnostics manufacturers – work together to ensure an optimal transition and maximum success.



Interconnected considerations for laboratory design.⁸

Design: Molecular testing laboratories have historically been organised into separate environments for specimen processing, pre-PCR, amplification and post-PCR steps. Molecular testing is often managed separately from serology testing. Consolidation and automation can allow separate work areas to be integrated into an open plan molecular work area, designed to increase simplicity and maximise the automation.

Budget: Immediate costs involved in transitioning from a traditional laboratory to a highly automated laboratory (e.g. acquiring the new technology, new reagents and training) are inevitable. However, in the long-term, consolidation should maximise the use of reagents, streamline costs and reduce staff requirements per test needed.

Implementation: All parties need to carefully consider how testing will be managed during the transition period, allow for training time on the new technologies in advance of the transition, and decide which workflows will be implemented into the new system first.

Menu: Switching from in-house laboratory developed tests to commercial assays is not always simple but working closely with the diagnostic company can help to ensure that evolving laboratory needs (e.g. multiplex panels or resistance subtyping) are met and prioritised for implementation. Diagnostic companies must work together with molecular laboratories to ensure that the testing menu availability allows them to keep up with the healthcare testing needs in their laboratory, allowing them to best support patients, healthcare and the community.

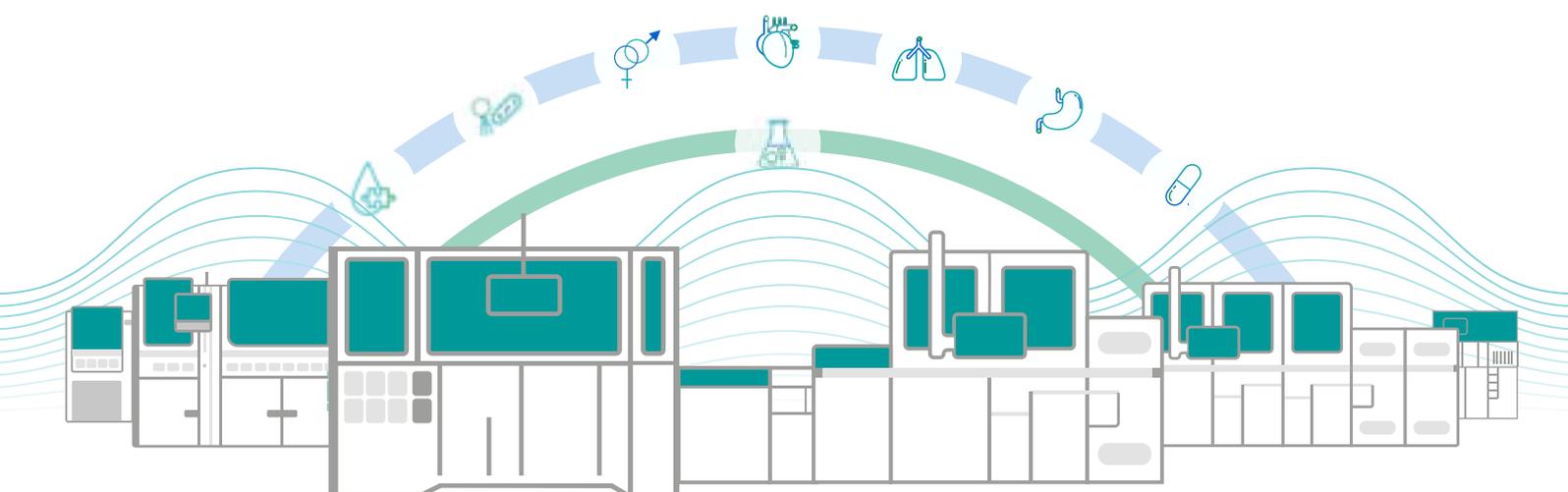
The Molecular Work Area

The Molecular Work Area empowers laboratories to address their current challenges while also unlocking future possibilities. By consolidating real-time PCR testing in a single fully automated solution, laboratories can better handle the unique challenges of complex sample types while opening the possibility to automate greater than 90% of a molecular laboratory's testing volume.*

The Molecular Work Area delivers automation, consolidation, integration, and standardisation, providing scalable throughput, minimising operator hands-on time and delivering consistently rapid turnaround times. With a broad menu of the right assays, including the option for menu extension using a dedicated open channel, testing can be integrated and consolidated onto a single platform while an intelligent workflow management solution ties it all together.

With seamless physical and virtual connectivity, laboratories of all sizes can standardise common reagents and streamline workflows to usher in a new era of efficiency in the molecular laboratory.

*May vary based on assay availability in your country



Summary

The SARS-CoV-2 pandemic has highlighted the need for molecular laboratories to be able to deliver a high volume of testing and adapt quickly to dynamic needs. In addition to responding to fluctuating pressures, the molecular diagnostic laboratory needs to offer the core testing options required to deliver ongoing essential healthcare testing. Therefore, simplicity and flexibility are key to maintaining the capacity to respond to changing demand.

The Molecular Work Area from Roche helps to meet the diagnostic needs of patients and respond to unpredictable patterns of infection with increased resilience through unmatched workflow automation, consolidation, integration and standardisation.

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9. Roche Diagnostics images on file.
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