Automation of Testing Methods in Microbiology and Virology

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The science of Clinical Microbiology, diagnostically, has always been about reacting to the presence, or presumed presence, of a bacterial, viral, or fungal infection for the sole purpose of identifying a pathogen and its susceptibility to potential treatment agents (antibiotics/anti-viral/anti-fungal). The overhead of traditionally manual microbiology methods for time and materials, such as culture planting/plating, incubation time, biochemical screening tests, etc. while still widely accepted and "mainstream", are arguably becoming cost-prohibitive and more antiquated when compared to the advances that are rapidly occurring in automation. Molecular testing can simplify specimen requirements for a variety of tests because it involves less invasive collection methods, as well as requiring much smaller specimen volumes. Molecular methods can detect the presence of pathogens directly from a sample which eliminates the need to culture out the sample over a period of hours, days, or even weeks.

Advances in automation/instrumentation

The microbiology laboratory is seeing an explosion of automated techniques. Compared to just a few years ago when clinical microbiology involved many very specialized tasks with little room for automation, unlike the clinical chemistry laboratory where the repetitive tasks lend to simplified automation. More and more systems are emerging for the clinical microbiology laboratory that can automate most of the testing processes, including inoculation of culture plates, detection of growth on culture media, susceptibility testing, and the extraction and detection of nucleic acids from specimens.

Molecular diagnostics is revolutionizing the entire laboratory industry, and the Microbiology department will play one of the most important roles. Rapid advancement of testing methods has opened the door to improving this function at the molecular and genetic level of these pathogens by supplementing or supplanting traditional manual methods. Rapidly evolving test methods will provide new capabilities in identifying strains of pathogens based on their molecular specificity, thereby predicting resistance and susceptibility to existing treatments, as well as helping to develop new treatments (antibiotics) that will be specific to the genetic makeup of the pathogen, minimizing the need for broad-spectrum treatments, the overuse of which has contributed to "superbugs."

Microbiology laboratories generally perform tests for many different specimen types including:

- Blood
- Urine
- Respiratory Specimens
- Tissues
- Throat swabs

Looking at the above list, and it's not complete, one can see that these different specimen types

are heterogeneous and laboratories will be asked to look for a host of different organisms depending on the type of specimen and what the physician orders.

The historical, manual, workflow of the microbiological laboratory is that the specimens are received in the laboratory, accessioned, and put on different types of growth medium depending on the culture type. Different application techniques are used to apply the specimen to the various culture media depending on the sample type. Cultures are then incubated for the necessary amount of time depending on the test ordered and sample provided. Finally the culture plates are reviewed by the laboratory technologist and the organisms or pathogens that are recovered are worked up according to the laboratory standard operating procedure. This is a very manual and subjective process that not only has remained largely un-evolved, it hardly lends itself to easy automation, until recently. Once the pathogens are identified, they would be reported back to the physician using the laboratory information system.

Now compare this to the modern, automated molecular laboratory and the manual processes have all but disappeared. When specimens arrive in these facilities, they are accessioned into an automation line then the automation of instrumentation and molecular information management solution (MIMS) kicks in.

Advances in instrumentation and automation platforms are absolutely making traditional microbiology methods automated and more accurate/precise. We're seeing the advent of new automation platforms, as well as the consolidation of existing platforms to be more tightly integrated with each other, as well as with the MIMS. MIMS Software will be required that is purpose built to flexibly define and automate specific workflows and reporting protocols for the unique and specific specimen types and testing methods, such as PCR, FISH, Immuno, and DNA extraction, which is quickly becoming a Microbiology standard. The MIMS will need to be capable of supporting and evaluating many more data elements beyond simple organism ID and antibiotic susceptibility. Features such as imaging, reflexive interpretation, textual and discrete data evaluation, along with highly customizable report formatting and data consolidation will prove to be the most important capabilities in a molecular information management solution. It will also need to be much more capable of integrating with multiple instruments, departments, and even other collaborative technology platforms. Adoption of technology beyond HL7 to tighter application-level integration such as REST API and web services, has become increasingly critical. Traditional lab information technology will struggle to support these requirements, as microbiology is an "afterthought" in many vendor platforms. Many vendors will simply try to modify existing platforms unsuccessfully because of the design limitations of a traditional "microbiology function" within a large and complex LIS. Even the old 'mainstay' best-of-breed systems will be limited by older technology and overall system design.

For a lab to benefit from automation, everything in it has to be bi-directional. The MIMS pushes information out—to instruments, to other applications, to outreach solutions, to other facilities—and at the same time captures information and pulls it back in and is case specific. This way, data lives not only with the patient case information that's accessible for the final reporting, but also in the database of the MIMS so that the laboratory can do true data management, statistical reports, and data churning. These elements are crucial when you consider the expansion of areas that are concerned with microbiology testing such as Homeland Security, the WHO (just look at the Ebola outbreak as a relevant example), etc.

Changes in the industry will favor laboratories that implement automation. It is predicted that overall testing volumes will continue to increase ten to fifteen percent per year due to an aging

population, testing innovations, infection control demands, and the growing challenges resulting from detection and identification of multidrug-resistant microorganisms. Laboratory expansion is on the rise, especially in the specialized area of microbiology testing.

While larger laboratories have the potential to benefit on a greater scale from total laboratory automation, smaller laboratories will see significant increases in efficiencies by automating processes and testing procedures.