Quest Diagnostics™

Addressing the challenges
of microbiology lab services

How hospitals can benefit from laboratory collaboration

Introduction

Microbiology testing is emerging as a rapidly expanding segment of healthcare.[1] There is an increasing demand for advanced molecular diagnostics due to multidrug-resistant bacteria and a higher prevalence of various infectious diseases[1], such as HIV/AIDS, tuberculosis, and hepatitis infections. Clinicians need timely and more clinically relevant results.

Advanced information technology and data analytics, the use of nanotechnology for molecular diagnostics development,[2] and the trend toward automation are also contributing to the growth of the industry, and together they increase the efficiency of diagnostic methods.[2]

Despite these efficiencies, microbiology testing poses numerous challenges for hospitals. Under the Protecting Access to Medicare Act (PAMA), hospital labs may see a reduction in reimbursement for routine tests; in preparation for this reduction, many are cutting laboratory spending and budgets.

A sampling of microbiology test payment rate changes under PAMA[3]

Test	2017 NLA*	2018 PAMA Rate	Payment Difference	Percent Change in Payment
Chlamydia antibody	$16.22	$14.60	-$1.62	-%9.99
CMV antibody	$19.74	$17.77	-$1.97	-%9.98
Hepatitis Be antibody	$15.87	$14.28	-$1.59	-%10.02
HIV-1/HIV-2 1 result antibody	$18.80	$16.92	-$1.88	-%10.00
Lyme disease antibody	$21.25	$19.31	-$1.94	-%9.13

*NLA= National limitation amount

At the same time, the industry is experiencing a staffing shortage that shows no signs of abating, as fewer microbiology lab professionals are trained and more are expected to retire.[4] This dearth of expertise could make it more difficult for hospital labs to keep up with changing practice standards, such as annual CLSI (Clinical and Laboratory Standards Institute) antimicrobial susceptibility testing standard updates.

As a result, many hospitals are looking beyond the hospital lab, seeking alternative solutions for microbiology testing services. Collaborating with a commercial clinical lab, for example, can enable them to maximize resources, better manage costs, and enhance quality, as clinicians and patients benefit from a more comprehensive testing menu, the latest testing technology, and faster results.

A growing need for microbiology testing

Diagnostic molecular biology has become the fastest-growing area in lab-based medicine.[5] This growth is due, in part, to increasing demand. While noncommunicable diseases are the leading cause of morbidity and mortality in most countries, infectious disease remains a major public health concern in the US and around the world.[6]

More than a dozen new infectious diseases have appeared over the past 25 years,[7] necessitating the development of new tests. Vector-borne diseases, for example, have increased since 1980, with the arrival of more diseases spread by insects, such as West Nile virus.[8]

In the meantime, traditional diseases that had been steadily declining with improved diagnostics and monitoring (such as tuberculosis), are resurging[7]—due to antibiotic resistance, and other reasons. As a result, an annual average of more than 13 million deaths worldwide are caused by infectious disease.[5] Thus the demand for advanced microbiology testing options remains high.

$ 2,706.1M

Total market for microbiology testing in 2016; expected to reach $5,409.1 million by 2023[1]

>12

new infectious diseases in the US over 25 years[7]

In addition to rising rates of infectious disease, in the US baby boomers are aging, meaning that over the next 10–20 years, a greater number of patients will require a greater number of diagnostic tests, and that includes microbiology testing. Some infectious diseases are even more common among patients in this age group; for example, the Centers for Disease Control and Prevention recommends that everyone born between 1945 and 1965 be screened for hepatitis C.[9]

Advancing diagnostic technologies

Precision diagnostics and precision medicine, along with rapid developments in genomics and bioinformatics, are also accelerating the growth of diagnostic molecular biology. As precision medicine moves toward the point of care, its progression will be accompanied by advances in molecular methods.[5]

More specifically, traditional culture-based infection diagnostic techniques are gradually being replaced by advanced molecular detection methods,[5] including nucleic acid-based techniques. Whereas the first assays were focused on the detection and identification of microbial pathogens (bacterium, virus, or other microorganism), these new technologies also detect antibiotic resistance determinants and assess microbial epidemiology on a genetic level.[10] Said another way, these more advanced tests will play a major role in both circumventing antibiotic resistance and furthering pharmacogenomics, allowing clinicians to tailor treatment based on both the host (the individual patient) and the pathogen.[5]

While clinical microbiology has lagged behind a number of other lab disciplines in the area of automation, the past few years have seen more changes and advances than the previous few decades.[11] Total lab automation systems are now available to handle specimens, incubate, streak plates, and digitally image cultures, reducing labor costs and improving turnaround time. One study revealed that an automated system's software could read chromogenic plates to detect methicillin-resistant *Staphylococcus aureus* with 100% sensitivity over more than 57,000 samples, in many cases detecting positives that technologists missed.[11]

> Advanced microbiology testing and automation can help improve patient care, enabling faster diagnoses, reducing length of stay, and potentially decreasing the number of healthcare-associated infections.[5]

Microbiology diagnostics: an overview[12]

Technique	Advantages	Disadvantages
Conventional cell-based (e.g., culture, microscopy)	• Inexpensive • Provides qualitative and quantitative data	• Pathogens have to grow in artificial media • Labor-intensive and time-consuming
Immunological (e.g., ELISA, microarray)	• High-throughput capacity • Rapid • Relatively low cost • Easy to perform • Provides qualitative and quantitative data	• Detection limit for organisms/ antigens with low abundance • Difficulties in generating selective antibodies
Nucleic acid based (e.g., hybridization, PCR, sequencing)	• Rapid • Easy to perform • Provides qualitative and quantitative data • Can reveal novel organisms • High-throughput capacity	• Detection limit for organisms with low abundance • Limit number of probes in one experiment/limit capacity for multiplexing • Moderately expensive/expensive
Other (e.g., MALDI-TOF mass spectrometry)	• High-throughput capacity • Rapid • Generates easily interpretable spectra • Provides qualitative and quantitative data • Low overall operating costs	• Detection limit for organisms with low abundance • Host proteins and normal flora might overlap mass spectra • High initial investments and maintenance costs • Lacking differentiation of closely related species

The challenges of microbiology lab services for hospitals

While the need for microbiology testing—and the technologies used—is advancing, hospital labs offering these testing services face numerous challenges.

For starters, microbiology lab services are labor-intensive—and costly. In most labs, staff salaries generally account for 60%–70% of the total expense budget.[13] Many microbiology tests cannot be automated easily,[11] so there is a direct link between workload and the number of clinical laboratory scientists needed to perform it.

Unfortunately, while microbiology lab professionals are needed, the industry is experiencing a staffing shortage. According to the National Accrediting Agency for Clinical Laboratory Sciences, while US labs need to fill more than 7,000 jobs annually, clinical lab education programs are producing only about 6,000 qualified lab professionals each year.[4] On top of that, as more baby boomers exit the workforce, 19% of microbiology lab professionals are expected to retire between 2015 and 2020.[4] These staffing shortages may result in the hiring of technologists with less training, requiring hospitals to invest in training for them.

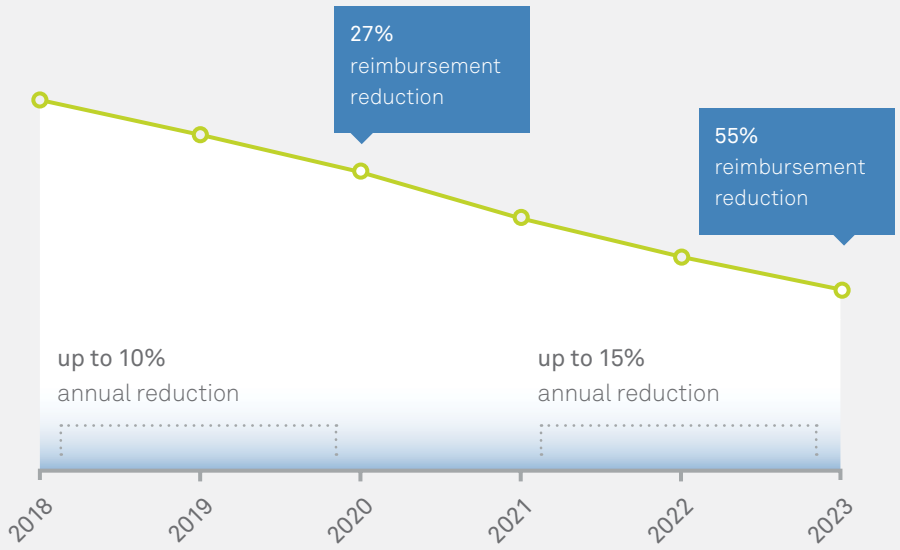
19%

of microbiology lab professionals are expected to retire between 2015–2020[4]

In addition to staffing considerations, hospital labs are now seeing declining reimbursement rates for routine microbiology tests. Under PAMA, clinical labs may experience Medicare cuts of up to 30% over the next 3 years.[14]

How the Centers for Medicare & Medicaid Services set payment rates[15]

Reimbursement rates for each test can be reduced up to 10% annually from 2018–2020, then up to 15% from 2021–2023, until the median price is reached.

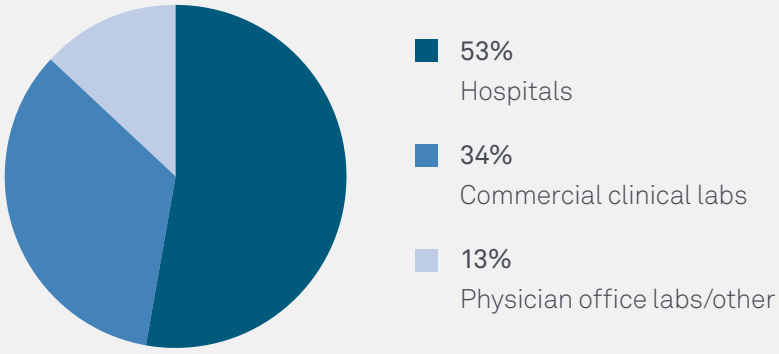


To offset this loss in revenue, many hospitals have imposed capital constraints—meaning fewer investments in advanced testing technologies and a surge in reagent rentals.[16] These cost-control efforts can also mean that certain routine microbiology diagnostic tests remain culture-based, which can ultimately affect both patient care and satisfaction.

Beyond the hospital lab: an alternative solution for microbiology lab services

To address cost, equipment, and staffing constraints, many hospitals are choosing to collaborate in order to fulfill the microbiology testing demands of their clinicians and patients.

Where clinical lab testing is performed in the US[17]



Relying on a commercial clinical lab for some or all of these services can provide numerous benefits to hospitals, clinicians, and patients.

1. Ensure quality and efficiency—a commercial clinical lab with microbiology expertise uses state-of-the-art equipment and standard or best-practice instruments for optimal results. Hospitals benefit from the latest technology without needing to invest in-house or make annual equipment updates.
2. Access a more comprehensive microbiology testing menu—using a commercial clinical lab can provide access to a broader menu of microbiology tests and the most up-to-date testing technology (e.g., MALDI-TOF, a highly accurate technology that shortens turnaround time for organism identification from 24–48 hours to minutes, allowing hospitals and clinicians to address a broader range of patient needs faster, thereby enhancing care quality.
3. Provide needed support in critical areas—a commercial lab can supply a team of microbiology experts to help hospitals address infection-control concerns and support antimicrobial stewardship efforts. This team can also provide antimicrobial reporting, which can be customized to suit local needs and made available for infection control and infectious disease specialists.
4. Maximize resources and better manage costs—relying on a commercial lab for microbiology testing services allows hospitals to devote resources to other critical tasks while leveraging cost savings from the larger lab's volume and technology. In general (not specific to microbiology), using a commercial lab can save hospitals 10%–20% annually,[18] and smaller hospitals with 300–500 beds can save roughly $15 million over 5 years.[19]

Conclusion

As the need for microbiology lab services—and the advanced diagnostic technologies required to perform them—continues to increase, hospital labs may be faced with dwindling reimbursements and staffing shortages. **This is especially problematic, as microbiology testing accounts for 10% of overall lab volume and 20% of overall lab expense.**[20]

To make better use of hospital resources and manage costs, many hospitals are turning to commercial clinical labs to perform some or all of their microbiology testing. Larger labs offer more comprehensive test menus, complete with the latest technology, helping to ensure both accurate results and faster turnaround times. These labs continually invest in advanced technologies, stay current with changing standards and testing methods, and staff clinical experts. In this way, they can help hospitals focus resources on other critical tasks while reducing length of stay and healthcare-associated infections—for improved patient care and better outcomes.

Address microbiology lab challenges with Quest Diagnostics

As a world leader in diagnostic testing, information, and services, Quest has unsurpassed experience in lab management, helping hospitals reduce costs, improve turnaround times, and increase operational efficiency.

- A comprehensive microbiology test menu, from routine to specialized
- A medical and scientific staff of more than 650 MDs and PhDs
- Educational resources, including an online education center, live webinars, and CME courses

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