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Strategic use of molecular point-of-care tests can improve respiratory testing outcomes

By Annanya Shetty, PhD

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LEARNING OBJECTIVES

Upon completion of this article, the reader will be able to:

1. Identify the key differences between traditional rapid antigen tests and molecular point-of-care (POC) tests, including their relative sensitivity and specificity.
2. Describe the components and functions of the hub-and-spoke model for respiratory testing within a healthcare system.
3. Evaluate the factors that influence the selection and implementation of molecular POC testing platforms, including turnaround time, connectivity, and portability.
4. Analyze how molecular POC testing and laboratory-based testing support diagnostic stewardship by reducing unnecessary testing and improving clinical decision-making.

Point-of-care (POC) testing stands to be transformative for diagnosing respiratory infections, provided it passes certain clinical performance thresholds. The advent of highly reliable molecular POC platforms is now giving clinical laboratory teams greater flexibility in their respiratory testing strategies. The need for greater flexibility in respiratory testing is underscored by the substantial burden of respiratory diseases worldwide, which analyses indicate may reduce average life expectancy by more than one year.[1]

With POC platforms delivering fast and accurate results, clinical labs can consider a hub-and-spoke model in which POC platforms are strategically placed in outpatient and other key settings to detect the most common pathogens, while more complex and comprehensive testing is performed in

the central laboratory. While the central clinical lab is always the hub, spokes may include urgent care facilities, pharmacies, physician offices, emergency departments, and even nursing facilities, where studies have demonstrated benefit to patients from earlier recognition of emerging outbreaks.[2]

Respiratory testing becomes particularly challenging during peak season, when overlapping symptoms and rising demand can strain laboratory resources while increasing the need for rapid results.[3,4] Strategically implemented molecular POC testing can help relieve clinical labs of some of this pressure, without sacrificing diagnostic quality.

Establishing the appropriate combination of POC and lab-based testing must also be informed by diagnostic stewardship programs. The hub-and-spoke model could contribute to ensuring that the right test is given to the right patient at the right time, and that all tests are offered with the expectation that their results will be actionable for each patient's case.

Pitfalls of POC testing

In recent decades, some POC tests have proved challenging to implement among the clinical laboratory community due to analytical sensitivity and specificity issues.[5] While the concept of POC testing has always been an appealing one, delivering results to physicians and patients more quickly while also enabling better and more timely clinical decision-making, the rapid antigen tests most often used at the point of care tend to have low sensitivity.[6] The resulting high rates of false negative results mean that tests performed at an urgent care facility, primary care doctor's office, or other outpatient setting often call for confirmatory testing, increasing demand on clinical labs for the patients who may be least likely to benefit. With many clinical guidelines recommending follow-up testing for negative POC results, these platforms broadly added to the clinical lab burden they were intended to ease.[6]

In addition, rapid antigen tests like the at-home flu or COVID-19 tests may be invisible to the clinical lab's information system as well as to the patient's electronic medical record (EMR). Results may not be trackable, making it more difficult for labs to evaluate epidemiological trends in their communities and hone their respiratory testing algorithms accordingly. Without a good mechanism for monitoring POC test results, these assays contribute less to the overall understanding of a healthcare system's patient population than lab-based testing would.

Consequently, much of the responsibility for respiratory testing has remained within clinical laboratories. While the results these tests produce are highly accurate, even the fastest lab-based platforms cannot match POC testing for turnaround time of reported results.

A new type of POC assay

Molecular tests are well-established for delivering excellent sensitivity and specificity; both the Infectious Diseases Society of America (IDSA) and the Association for Diagnostics and Laboratory Medicine (ADLM) recommend this method in a clinical lab.[7,8] When molecular POC systems recently became available, they lived up to their reputation for accuracy, with sensitivity and specificity as high as 100%, while offering new advantages in turnaround time and location flexibility.[9]

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Molecular POC platforms are often CLIA-waived, enabling their use outside the clinical lab; some platforms may also be authorized for patient self-testing through separate FDA pathways. They generally produce lab-grade results in less than half an hour. With this kind of speed, results can be reported back to patients during their initial visit to a doctor or urgent care clinic, a key element in ensuring that patients receive appropriate clinical recommendations for treatment, isolation, or other interventions. Rapid POC results can also reduce the likelihood that a patient is prescribed inappropriate treatment, such as antibiotics for a viral infection. Studies have shown that incorporating rapid molecular results can improve clinical outcomes and reduce unnecessary use of antibiotic or antiviral therapies.[10]

Because these platforms are based on the same underlying molecular technologies that clinical laboratory teams are already familiar with, their results may be easier to interpret and compare with laboratory-based test results. This continuity can simplify implementation decisions, support the development of testing algorithms that incorporate both POC and laboratory testing, and help ensure greater consistency in respiratory infection management across care settings. Evidence suggests that clinical laboratory teams are becoming more supportive of molecular POC tests, recognizing the value of rapid results so long as they are accurate.[11]

Key factors to consider

With a growing number of molecular POC platforms to choose from, it's important to understand how platforms differ in order to identify the ones best-suited for the needs of a specific health system. This list is not exhaustive, but it covers the primary factors to consider when selecting POC devices.

User-friendliness. Some POC instruments are designed for use by patients and others for use by hospital or office staff members; nevertheless, they must be easy to operate for people who are not highly trained clinical lab personnel. Workflows that add simple operation with room temperature storage of reagents and clear prompts from the device or instruction sheet can reduce user error and support more reliable results.

Sample type. Sample requirements influence where a platform can be deployed. Systems compatible with self-collected samples, such as nasal swabs, generally offer greater flexibility than staff-collected nasopharyngeal swabs.

Connection options. POC platforms must be connected to the laboratory information system and to the EMR system. While wired connections (such as ethernet ports) are standard, having a WiFi option can provide greater latitude to place the instrument wherever it's most needed. In addition, platforms that come with the drivers needed to connect to IT systems can reduce implementation barriers.

Turnaround time. All POC platforms are billed as delivering "rapid" results,

but the actual time between submitting a sample and having results reported can vary. For optimal utility, the turnaround time should be 20 minutes or less.

Result handling. Connectivity and result management should support both patient care and ease of access for labs. Ideally, results can flow automatically to the laboratory information system and EMRs while remaining accessible during unexpected connectivity disruptions.

Portability. Since the goal of POC platforms is to enable testing where the patient is, the instrument's footprint is an important consideration. Small, portable units that can be placed virtually anywhere provide flexibility. In peak respiratory season, these instruments may need to be moved frequently to meet testing demand. Platforms that require refrigerated reagent storage nearby are more challenging to move and less flexible to place than those that work with room-temperature reagents.

Clinical evaluation. Like any laboratory testing platform, POC systems have to go through extensive performance studies before they can be sold. However, those studies can differ in their designs, including the tests manufacturers select for comparison. Evaluating performance against an FDA-cleared comparator rather than a non-molecular test offers the clearest assessment of reliability for clinical use. Knowing how results compare to a thoroughly vetted molecular test can also help labs minimize the need for re-testing the same targets with a lab-based system if the molecular POC test results come back negative.

The hub: Laboratory testing

In the hub-and-spoke model for respiratory infection management, POC testing is just one part of the equation. There will always be a need for high-quality, laboratory-based respiratory testing as well. These two testing modalities should be complementary: POC results must be reliable enough not to need routine confirmatory testing, and lab-based tests must be flexible enough to avoid target redundancy and the associated unnecessary costs.

The ability to reflex to lab-based testing is critical for delivering comprehensive respiratory infection results. But reflexing to a standard large syndromic panel virtually guarantees that previously tested targets will be tested again. From both a diagnostic stewardship perspective and reimbursement perspective, this is a wasteful approach.

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Some laboratories have embraced a flexible testing approach that offers greater customization of molecular tests to avoid this problem. With flexible testing, clinical labs can use digital sampling to customize respiratory panels from a broad menu of available targets, selecting only the targets they want to report. This approach supports both comprehensive syndromic testing and smaller, targeted panels, while allowing labs to pay only for the targets they choose to report.[12]

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During peak respiratory season, for example, a standard POC panel might cover flu A/B, respiratory syncytial virus, and COVID-19. Patients with serious symptoms who test negative could then be reflexed to the lab for additional customized testing that excludes targets already tested at the point of care. This approach avoids redundant testing and double-billing.

Diagnostic stewardship objectives

Amid surging demand for laboratory tests to help guide clinical decision-making is the simultaneous push for diagnostic stewardship to avoid unnecessary testing and reduce healthcare costs.[13] Typically, these stewardship goals are described as getting the right test to the right patient at the right time, but real diagnostic stewardship goes beyond this simple phrase. The true goal is to ensure that all testing provided to a patient serves to further clinical care; the results of any test should be actionable, prompting clear next steps in decision-making and treatment selection.

Incorporating molecular POC testing alongside lab-based respiratory testing should align with a healthcare system's diagnostic stewardship objectives. Offering rapid, reliable results at the point of care for a single common target or for a small number of the most widely circulating targets provides immediately useful information that can help physicians recommend appropriate treatment. Testing only the most common targets at this point avoids over-testing and ensures results that are most likely to be actionable.

Pairing POC with lab-based testing also supports diagnostic stewardship efforts. Patients who are reflexed to lab tests are those who truly need more comprehensive testing, justifying the expense of additional targets or even large syndromic panels as appropriate.[14] With a flexible testing approach, the lab-based selection of targets can be informed by epidemiological patterns, patient demographics and occupation, seasonality, and other clinically relevant factors.

A hub-and-spoke respiratory testing strategy allows healthcare systems to align testing resources with patient needs. Molecular POC platforms can provide rapid answers for common

respiratory pathogens at the point of care, while centralized laboratories remain responsible for more comprehensive testing and complex cases. Together, these approaches support diagnostic stewardship by limiting unnecessary testing, improving turnaround times, and ensuring that additional laboratory resources are directed where they provide the greatest clinical value. While respiratory testing is always unpredictable, the ability to offer POC tests can help healthcare systems navigate the chaos more smoothly.

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Annanya Shetty, PhD is a translational medicine specialist with over a decade of experience in infectious diseases and diagnostics. She holds a PhD in Medicine from the National University of Singapore and has held global product leadership roles at Abbott and now **Diasorin**, where she integrates clinical research with the development of decentralized molecular diagnostics. A published scholar, Dr. Shetty is passionate about delivering impactful healthcare solutions and improving access to care.