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# Point-of-Care Testing in Microbiology



Linoj Samuel, PhD, D(ABMM)

## KEYWORDS

• Point of care • Rapid diagnostics • Microbiology

## KEY POINTS

- Point-of-care (POC) testing is a rapidly expanding area of growth for infectious diseases due to the consolidation of clinical microbiology laboratories.
- Advances in technology have increased the quality of results available in the POC setting.
- The increasing complexity of the technology involved in POC testing requires oversight by laboratory professionals.

Point-of-care (POC) testing can be defined as testing performed in close proximity to the patient with results available within a timeframe that allows for an intervention to take place while the patient is still in the care of the provider.<sup>1,2</sup> The terms POC and near patient testing may be used interchangeably because they often refer to testing performed using the same systems although the regulatory requirements may vary. The key distinction may be the level of regulatory oversight based on the complexity of testing. POC testing is often used to refer to waived testing under CLIA (Clinical Laboratory Improvement Amendments Act) but could include more complex testing nonwaived testing performed in the near patient setting. Traditional infectious disease-related POC testing typically provides results in 15 to 20 minutes but even results available in <1 hour from the time of specimen receipt are useful in patient management. There are obvious advantages to having results available immediately for patient care:

1. A timely answer can alleviate patient anxiety and improve patient satisfaction.
2. Allows the care provider to initiate appropriate therapy immediately if needed where empiric coverage is adequate, for example, streptococcal pharyngitis and sexually transmitted diseases.
3. Reduces the need for follow-up visits that add to the burden on the patient and the growing cost of health care.
4. Rapid testing results can ensure the optimal use of limited health care resources by determining which patients need to be in isolation due to potential transmissible

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pathogens and can play a significant role in interrupting community-based transmission of common pathogens, such as those causing infectious diarrhea or sexually transmitted diseases.

5. POC testing also improves the care of patients who are unlikely to return for subsequent visits. In resource-poor settings where patients have to travel long distances to obtain primary care, it is often unreasonable to expect them to return after laboratory results become available for additional care.

Clinical microbiology diagnostic testing has traditionally centered around the use of time-consuming methods such as viral and bacterial cultures. Bacterial cultures can take anywhere from 1 to 14 days depending on the suspected pathogen. Cultures for specific pathogens such as *Mycobacterium tuberculosis* require an incubation period of 6 to 8 weeks for a negative result. Viral cultures can require 1 to 21 days of incubation but have been mostly replaced by molecular-based methods. The transition from viral cultures to molecular methods has significantly improved the time to result but these assays are often batched and performed at specialized laboratories so that the results are not available in a timely manner.<sup>3</sup> Non-culture-based tests, such as stains for stool-based pathogens, require additional expertise and are not available in the POC setting.

Clinical microbiology laboratories have historically operated on a 9-to-5 schedule with limited services available outside routine working hours and on weekends, but this model has changed over time with increased focus on laboratory utilization and cost-effective strategies that facilitate timely patient care. The manual nature of microbiology testing made it less conducive to automated testing but over the years, improvements in technology have allowed for the implementation of highly automated culture-based platforms. These systems enhance the performance of clinical microbiology laboratories in terms of efficiency, speed, and culture yield.<sup>4</sup> The cost of these automated systems, shortage of trained laboratory personnel, and the constant pressure to reduce health care costs have encouraged the consolidation of microbiology laboratories into core facilities to ensure optimal utilization of these systems. Automated testing still requires prolonged culture incubation, and results are not available during the course of the patient visit. The advantages of this integrated approach to testing include the ability to provide expanded testing services around the clock and improve overall laboratory performance.<sup>5</sup> However, the consolidation of laboratory services into core facilities that are geographically distant from patient care locations and community hospitals within an expanded network can introduce further delays in results due to transport time. The consolidated laboratory model could also lead to batch processing of specimens due to the transport requirements but this may be offset by the extended working hours and the access to automation, advanced expertise, and testing panels.<sup>5</sup> With advances in testing technology, the time spent in transport often represents the largest source of delay for obtaining results.<sup>6</sup>

The transition to diagnosis-based reimbursement in the 1980s was expected to negatively impact centralized laboratory testing but the implementation of the Clinical Laboratory Improvement Amendment 1988 (CLIA 88), discouraged the expansion of laboratory testing into the primary care setting.<sup>6</sup> The recent growth in POC testing coincided with the development of novel technologies and the miniaturization of existing technologies that brought improved assay performance to the near patient setting.

The merger of clinical microbiology laboratories into core facilities coupled with the advances in POC testing system development has led to renewed interest in the role of near patient testing.<sup>1</sup> Some health care institutions have implemented rapid response

laboratories with a limited test menu composed of assays that can be performed in less than 3 hours to supplement the capabilities of the core laboratories.<sup>7</sup> These rapid response laboratories provide a limited menu of tests, are typically staffed by qualified laboratory personnel, and provide actionable timely results. This model can range from the traditional concept of POC testing, which is performed by the providers in the patient care setting, to more complex molecular testing and limited processing of positive blood cultures.

The term POC encompasses tests using a broad range of technologies. These include

1. Direct detection of antigen: This relates to the capture of antigen using a specific antibody and the detection of this antigen-antibody complex typically using a lateral flow assay or a variant of this technology, for example, rapid influenza or group A streptococcal antigen testing.
2. Detection of antibody: These are fingerstick assays for the detection of antibody toward specific pathogens, for example, human immunodeficiency virus (HIV).
3. Direct detection of pathogen RNA/DNA: Current nucleic acid amplification technologies (NAAT)-based testing directly detects the presence of pathogen genomic material in the patient sample, for example, polymerase chain reaction (PCR)-based detection of influenza and group A streptococci in respiratory samples.

POC testing has traditionally operated under the premise that speed and ease of use are essential but this is often achieved at the cost of reduced sensitivity and/or specificity. The regulatory framework for POC testing is described later in this document, but for this reason, POC testing has often been limited to settings in which the impact of an errant result is limited or can be mitigated by reflex testing. Clinical microbiologists have tended to question the potential for POC testing because of the inherent performance-related issues. Until recently, a significant proportion of POC testing was limited to lateral flow assays for common respiratory pathogens, such as group A streptococci, influenza, and respiratory syncytial virus (RSV), but performance limitations meant that negative results often had to be confirmed by alternative molecular or culture-based methods. Nevertheless, POC testing can play an important role in the diagnostic algorithm.

- Rapid streptococcal antigen testing allows quick determination and treatment of a common pathogen that can have significant long-term implications for patient health. However, because the sensitivity of the streptococcal antigen tests are only approximately 86%, negative streptococcal antigen results should be confirmed by traditional culture-based or molecular testing, particularly in children.<sup>8,9</sup>
- For the detection of sexually transmitted pathogens, such as *Trichomonas*, provider-performed microscopy was the mainstay of diagnostic testing but the sensitivity of this approach was extremely limited and relied on timely specimen transport and immediate processing as well as expertise in microscopy. The development of *Trichomonas* antigen-based testing allowed for not just significantly improved sensitivity over microscopy-based methods but also reduced the labor and expertise required for testing. In spite of these improvements, POC testing for *Trichomonas* does not rule out infection and negative results need to be confirmed by molecular methods if clinical suspicion persists.<sup>10</sup>
- POC testing for *M tuberculosis* has the potential to significantly impact both patient care and appropriate utilization of institutional resources. In low tuberculosis (TB) incidence countries, 1 to 2 negative TB PCR results can be used to remove

patients from airborne isolation with significant cost savings.<sup>11</sup> In other settings, a rapid TB PCR result can be used to not just to establish a diagnosis but detect the presence of resistance markers in patients who have traveled long distances to obtain care and are unlikely to return for follow-up with traditional methods for diagnosis of *M tuberculosis*, such as culture, which can take 6 to 8 weeks to obtain a final result.<sup>12</sup> The utility of POC testing in this setting is challenged by the costs and logistical challenges of maintaining expensive PCR-based reagents and equipment in resource-poor settings. In high disease prevalence settings, it may not be cost-effective to rely on expensive molecular-based POC testing.<sup>13</sup>

- Rapid HIV testing has become the mainstay of public health efforts to combat the spread of HIV especially among populations that do not routinely access health care services; these are antibody-based tests that are useful under these circumstances but both positive and negative results should be confirmed in high-risk individuals.<sup>14</sup>

Negative POC antigen-based testing results for most pathogens have limited value in actual patient care due to inadequate sensitivity. Negative results typically represent the vast majority of results and many institutions were routinely confirming negative influenza and RSV antigen results by alternative methods.<sup>15</sup> Recently the Food and Drug Administration (FDA) acknowledged the limitations of POC antigen-based testing for influenza and raised the bar for minimum performance standards for influenza antigen testing.<sup>16</sup> This led to the development of fluorescent immunoassays that detected the antigen using automated readers and fluorescent markers that improved performance.<sup>17</sup> The sensitivity of these improved assays still fell short of being able to rule out infection and it remained common for laboratories to continue to confirm negative results using alternative methods.<sup>17</sup>

Molecular testing or NAAT for infectious disease pathogens offer the advantages of improved sensitivity and specificity over antigen testing. Until recently, technologies such as real-time PCR required the use of significant training and specialized equipment. The challenges associated with use of NAAT include the need for molecular expertise, expensive equipment/reagents, designated testing areas, and the risk of contamination. Testing is often performed in large batches to conserve reagents and reduce costs. Traditional molecular tests were typically not performed in the near patient setting and were not available within a timeframe that allowed for intervention during the patient visit.

## REGULATORY FRAMEWORK FOR POINT-OF-CARE TESTING

A number of factors are involved in determination of which tests are appropriate for use in the POC setting.

CLIA 88 governs the classification of testing based on complexity. The level of complexity is determined by the following questions<sup>18</sup>

1. How the test may be used and in which setting?
2. Who can perform the test?
3. What kind of proficiency testing and quality assurance is required?

In addition, the type of testing performed by a laboratory determines the level of regulatory oversight of the performing laboratory.

Three categories of test complexity have been established:

1. Waived
2. Moderate complexity, including provider-performed microscopy (PPM)

### 3. High complexity.

In the United States, CLIA 88 outlines the different levels of complexity for testing but it is the FDA that issues guidelines on how to interpret CLIA 88 and determines how to categorize a new test in terms of complexity.

Waived tests generally meet the following criteria:

- The technology involved must be simple enough to have an extremely low likelihood of inaccurate results
- Should not require processing of specimens before testing
- Relatively low risk of harm to patients if the test is incorrectly performed

Nonwaived testing refers to moderate or high complexity testing. Laboratories that perform nonwaived testing must hold a CLIA certificate as well as undergo routine inspections and follow a prescribed system of proficiency testing, quality assurance, and personnel requirements. Sites performing waived testing on the other hand only need a CLIA certificate and to follow manufacturer's instructions, although they may be subject to inspections. This makes the use of CLIA-waived testing an attractive prospect to sites that have limited laboratory capability, resources, or access to trained laboratory personnel, but still want to offer some onsite testing capability for patients with relatively minor health issues. As of March 2020, there were 193,474 sites with CLIA-waived registration.<sup>18</sup> POC testing may be performed under the CLIA waiver by nonlaboratory personnel or by laboratory personnel in near patient settings such as stat laboratories.

## TRENDS IN POINT-OF-CARE TESTING

There is also renewed interest in using POC testing in nontraditional settings. The entry of giants in the field of information technology, retail, and pharmacy into the health care space has accelerated the transition in the capability and accessibility of POC testing. Traditional patient care requires the patient to take time out their daily schedule to travel to a dedicated health care facility where they spend a significant amount of time working their way through often inefficient processes to receive care for what are often relatively minor issues or concerns at relatively high costs. These visits are often associated with significant costs and loss of productivity. The entities looking to disrupt this process are seeking to provide patient care outside the confines of traditional health care spaces; the goal being to provide some level of primary care with minimal disruption by bringing care to the patient while they go through their daily routine. Large corporations like Walmart already have the stated goal of bringing low-cost primary care clinics within 15 minutes of 90% of the US population.<sup>19</sup> The effectiveness of these primary care clinics, which are typically staffed by nurse practitioners, hinges on the availability of infectious and noninfectious POC testing.

By integrating care into existing retail and other nontraditional spaces, providers can offer an attractive alternative to patients and achieve efficient delivery of health care. The challenges to this model are the need for trained personnel and the need for a new approach to POC testing. For POC testing to have a meaningful impact, it is necessary for the test to be relatively easy to perform even by a nonlaboratorian and for the results to be accurate enough to be actionable for the care provider without the need for confirmation.

The volume of POC testing is expected to grow 10% to 15% annually.<sup>20</sup> According to the National Community Pharmacists Association (NCPA), "Point-of-care testing provides an excellent opportunity for community pharmacies to enhance revenue by expanding patient care services while improving health at the patient and

population levels.<sup>21</sup> According to Deloitte,<sup>22</sup> POC testing is on track to exceed immunizations as a source of revenue for the pharmaceutical retail industry. The top 4 primary opportunities for growth in POC testing as identified by the NCPA are all for infectious disease-related assays including influenza, streptococcal antigen, HIV, and hepatitis C detection assays.<sup>21</sup> The volume of POC testing is growing rapidly globally at with the market expected to be valued at \$3 billion annually by 2021.<sup>22</sup>

The provision of care has moved toward telehealth due to the pandemic, but is limited by the lack of access to laboratory test results.<sup>23</sup> The natural progression of POC testing is therefore toward its use in at-home testing. Studies have shown that when given the choice, patients prefer at-home testing.<sup>24</sup> During the SARS-COV-2 outbreak, the FDA authorized the first at-home collection kit for the detection of the virus from saliva.<sup>25</sup> Further advances in technology are required to improve the quality and performance of at-home POC testing with a focus toward reducing the likelihood of errors and automated result interpretation.

It is important to note that the waived classification does not mean that the test is error proof and not all POC testing is able to obtain the waived classification. Early POC testing was limited to lateral flow-based antigen tests with visual detection of the positive signal by the user. These assays suffered from limited performance characteristics with sensitivities ranging from 10%-80% in comparisons with viral culture or real-time PCR.<sup>26</sup> Concerns about the about the poor negative predictive value of antigen-based assays in particular for influenza prompted the FDA to reclassify rapid influenza antigen devices as class II devices with the expectation of improved performance characteristics.<sup>16</sup> These were then replaced by FIA-based antigen detection assays. The performance of these FIA assays for the detection of influenza was significantly improved over traditional antigen-based testing with sensitivity of approximately 80% in multiple studies.<sup>17,27</sup> These assays still fell short of real-time PCR in terms of being able to rule out influenza. In contrast to lateral flow devices, the throughput of these immunofluorescent-based assays was also limited by the number of instruments/readers available with each instrument able to read one patient sample at a time.

Advances in NAAT-based testing allowed for the development of the first CLIA-waived NAAT test for influenza (Abbott ID Now, initially developed as the Alere I).<sup>27</sup> The use of isothermal amplification-based technology eliminated the need for hardware that had the temperature cycling capabilities required for real-time PCR. This development was a revolutionary step forward in being the first time that any molecular amplification-based technology was available to be performed at the level of primary care without the need to follow the CLIA requirements for moderate or high complexity testing. Subsequently additional NAAT-based platforms obtained CLIA waivers for POC testing including (among others) the Roche Liat and the Cepheid GeneXpert, both of which use real-time PCR and are capable of detecting influenza A, B, and RSV as well as group A streptococci using a variety of CLIA-waived assays. The Liat can provide results for influenza A and B as well as RSV from a respiratory sample within 22 minutes. The GeneXpert is able to provide similar results in 30 minutes with minimal sample handling requirements for both platforms. Even more revolutionary was the approval of the Biofire Filmarray Respiratory Panel EZ, which is a multiplex panel for 14 different respiratory pathogens.

## IMPACT OF POINT-OF-CARE TESTING

The ability to offer panel-based syndromic testing in the POC setting can appear to be attractive to the clinician, but it is unclear whether there is a significant benefit associated with the detection of viral pathogens in the outpatient setting, especially



when there are no interventions associated with some of the positive targets. The value of these syndromic panels has been difficult to demonstrate even in the inpatient setting and the primary care providers might also struggle to interpret panel results that detect multiple targets although in some settings.<sup>28–30</sup> The ResPOC trial evaluated the impact of syndromic panel-based testing in the POC testing and found that the results reduced length of stay (LOS) and improved influenza detection and appropriate antiviral use although it did not reduce antibiotic use.<sup>28</sup> It is possible that similar gains could be achieved using NAAT-based assays targeted at specific pathogens, such as influenza alone. Mercurio and colleagues<sup>29</sup> demonstrated that inhouse testing using syndromic respiratory panels did not have any impact on LOS, duration of therapy, or frequency of drug-related interventions. When appropriately used, NAAT-based POC testing can significantly impact patient care. POC group A streptococcal NAAT-based testing was able to significantly improve appropriate antibiotic use (97.1% vs 87.5%;  $P = .0065$ ) when compared with an antigen-based test.<sup>31</sup> Implementation of an NAAT-based rapid influenza assay reduce in appropriate antiviral use, improved appropriate antibiotic utilization, reduced LOS and also reduced the likelihood of admission when compared with antigen-based testing.<sup>32</sup>

These findings are crucial to the adoption of NAAT-based POC technology because of the significant capital and reagent costs that may be involved with NAAT tests, whereas antigen-based testing does not typically require resources beyond the testing kits and specimen collection materials. It is important for laboratories to demonstrate the direct impact and cost savings in terms of patient care that accrue from the adoption of these technologies. It is also essential to liaison with care providers to improve understanding of assay performance and interpretation of results. This is necessary to ensure that changes in testing platforms translate to changes in patient care. NAAT-based influenza and group A Streptococcal testing can offer greater than 99% sensitivity and specificity allowing the care provider to make decisions on patient care with confidence as compared with antigen tests with limited performance characteristics. There is little doubt that POC and near patient testing is an area of rapid growth. The continued consolidation of laboratories, the challenges with hiring laboratory personnel and the continued development of novel POC platforms and technologies suggests these trends will continue.

## OVERSIGHT AND PERFORMANCE OF POINT-OF-CARE TESTING

The performance of NAAT-based platforms represented a significant improvement over the previous iterations of antigen-based tests, both lateral flow and immunofluorescent-based assays.<sup>27</sup> However it does raise concerns about appropriate oversight of testing systems and methods that are far more complex than traditional POC-based testing. Laboratories that perform moderate and high-complexity NAAT testing are required by their accrediting bodies to adhere to rigorous standards and quality control.<sup>33</sup> This includes routine use of control material, monitoring of test statistics and assay performance and environmental sampling to detect potential contamination. The exquisite sensitivity of NAAT-based testing means that failure to adhere to these practices can result in erroneous results and patient harm.<sup>34</sup> Although NAAT-based testing in the POC setting has the potential to significantly impact patient care, there are significant concerns that in the absence of adequate laboratory-based oversight, problems could develop and continue undetected for significant periods of time. In an ideal world, POC testing would be performed by appropriately trained and qualified laboratory personnel but the current shortage of technologists ensures that is not a realistic goal.



A number of questions need to be addressed when moving POC testing using highly complex testing out of the laboratory and into settings in which the users are health care professionals who are not familiar with the challenges of NAAT testing.<sup>35</sup> A colloquium convened by the American Academy of Microbiology recognized the need for near patient and POC infectious disease testing but also strongly recommended that oversight of the quality assurance processes associated with this testing should remain under appropriate laboratory-based personnel.<sup>36</sup>

Examples of situations that demonstrate the need for laboratory oversight of POC and near patient testing systems are not uncommon:

- Invalid results associated with influenza B–positive samples using the Roche Liat system that generated unusual PCR curves that was determined to be related issues with the system software.<sup>37</sup>
- Point mutations in the M gene of influenza that caused false negative results using the Cepheid GeneXpert.<sup>38</sup>
- Engelmann and colleagues<sup>39</sup> suggested there was a need to review PCR curves under specific circumstances when using the Cepheid GeneXpert platform.
- The Abbott ID NOW was demonstrated to have lower sensitivity than other NAAT-based platforms in direct comparison of sensitivity for the detection of influenza due to the dilution effect of transport media.<sup>27</sup>
- Random sampling of the Roche Liat instrument in a testing laboratory determined that target viral RNA could be detected on the surface of and within the instrument testing chamber. Studies eventually demonstrated that the risk of contamination was low even in the presence of environmental contamination with viral genomic material.<sup>40</sup> Nevertheless, these findings reinforce the need for rigorous adherence to protocol and regular monitoring of test results and statistics to rule out contamination.
- False positive *Campylobacter* and *Cryptosporidium* results in Biofire gastrointestinal panel testing of stool samples.<sup>41</sup>
- False positive *Streptococcus pneumoniae* results associated with use of the Biofire ME meningitis panel.<sup>42</sup>

Although the Biofire ME and gastrointestinal panels are not CLIA-waived POC tests, they are often performed in the near patient setting. These quality issues were not limited to NAAT-based testing; false positive results were identified in comparison studies of the Quidel Quickvue Influenza A + B antigen test with NAAT-based testing during the 2009 H1N1 Influenza outbreak.<sup>43</sup>

## POINT-OF-CARE TESTING IN THE CORONAVIRUS DISEASE 2019 ERA

During the course of the Coronavirus Disease 2019 (COVID-19) pandemic, the shortage of testing resources and the need for near patient testing became severe enough that the FDA relented and relaxed the rules governing the Emergency Use Authorization (EUA) process to allow for expedited approval of testing platforms.<sup>44</sup> One of the first POC testing platforms to receive approval to operate under a CLIA waiver certificate was the Abbott ID NOW using isothermal amplification.<sup>45</sup> Early results were promising, but as was the case with the Abbott ID Now Influenza assay, issues that could impact the sensitivity of the assay were identified.<sup>46</sup> Subsequently, the FDA also issued a notification that negative results may require confirmation by an alternative NAAT-based assay.<sup>47</sup> Other NAAT-based platforms using real-time PCR that are capable of being used in the POC space are either now available or in development. This includes multiplex and syndromic panels that incorporate SARS-CoV-2

detection along with other respiratory viral pathogens. These combinations may prove essential during the flu season when multiple pathogens are circulating in the community and could potentially cause coinfections.<sup>48</sup>

In the antibody testing space, under the EUA authorization, numerous vendors were allowed to market POC antibody detection assays for COVID-19 with the disclaimer that these assays were not intended for diagnostic use.<sup>49</sup> Despite these restrictions, the market was flooded with numerous POC antibody assays with few data on actual performance characteristics. These assays were widely available and being used inappropriately for diagnosis despite the limitations.<sup>50</sup> Responding to the reports regarding inappropriate use and substandard performance of these POC antibody tests, the FDA requested the manufacturers to provide additional information on assay performance characteristics and eventually took action to remove those that did not comply or meet minimum standards.<sup>51</sup>

Despite the performance issues associated with early iterations of POC tests for COVID-19, the need for rapid near patient testing is essential to the management of this outbreak. The pandemic has forced health care providers to consider innovative steps to provide primary care without having potentially infectious patients congregating in close proximity with high-risk individuals. Providers are increasingly relying on telemedicine to continue to provide care to the patient remotely.<sup>52</sup> However, the extent of care is limited by the ability to obtain laboratory test results. The FDA recently approved the first at-home collection kit for testing for COVID-19 in saliva but these assays are not widely available.<sup>53</sup> Subsequent data on the performance of saliva for the detection of COVID-19 has not been consistent and it remains to be determined whether this sample type will be widely adopted. Specimen collection for COVID-19 remains challenging with collection of the preferred specimen type; nasopharyngeal swabs requiring specific training and infection control precautions to minimize risk to the individual collecting specimens. Approval of alternative specimen types such as nasal swabs, sputum, and tracheal aspirates have eased these concerns, although challenges still remain in the availability of swabs and transport media.

## SUMMARY

Technological advances have ensured that POC testing can become central to patient care and management. Further studies are necessary to determine the optimal strategies to use these platforms in a partnership between laboratories and care providers. The increasing complexity of these testing systems makes it essential that laboratory personnel are involved in the oversight of POC testing systems and platforms.

## DISCLOSURE

L. Samuel is on the Advisory Board of Qvella Diagnostics.

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