

# Point-of-Care Molecular Diagnostics: Current Evidence and Future Perspectives

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**Abstract:** *Point-of-care molecular diagnostics (POC-MDx) have transformed infectious disease diagnosis by enabling rapid, accurate pathogen detection at or near the patient care site. Unlike conventional laboratory-based molecular tests, POC molecular platforms provide clinically actionable results within minutes to hours, facilitating timely antimicrobial therapy, improving patient outcomes, and strengthening antimicrobial stewardship (AMS). Recent advances in nucleic acid amplification technologies, microfluidics, isothermal amplification, CRISPR-based diagnostics, and portable sequencing platforms have expanded the applications of POC molecular testing across emergency departments, intensive care units, outpatient clinics, and resource-limited settings. Despite these advances, challenges related to cost, quality assurance, interpretation of results, and integration into clinical workflows remain. This review summarizes the current evidence supporting POC molecular diagnostics and explores future innovations that are likely to redefine infectious disease management.*

**Keywords:** Point-of-care diagnostics, molecular diagnostics, antimicrobial stewardship, rapid diagnostics, CRISPR, infectious diseases.

## 1. Introduction

Timely diagnosis is essential for appropriate antimicrobial therapy. Conventional culture-based methods often require 24–72 hours, delaying targeted treatment and contributing to unnecessary empirical antibiotic use. Point-of-care molecular diagnostics bridge this gap by providing rapid pathogen identification directly at or near the site of patient care.<sup>1,2</sup>

The COVID-19 pandemic accelerated the adoption of portable molecular platforms, demonstrating their ability to improve clinical decision-making and outbreak control. Today, POC molecular diagnostics are increasingly used for respiratory tract infections, bloodstream infections, sexually transmitted infections (STIs), tuberculosis, gastrointestinal infections, and central nervous system infections.<sup>1,2</sup>

## 2. Current Molecular Technologies

Several molecular technologies have enabled rapid point-of-care testing.

### 1) Real-Time PCR

Portable real-time PCR systems remain the gold standard for many infectious diseases due to their high sensitivity and specificity.<sup>1</sup>

#### Applications

- SARS-CoV-2
- Influenza
- RSV
- Tuberculosis
- Group A Streptococcus

### 2) Isothermal Amplification

Techniques such as Loop-mediated Isothermal Amplification (LAMP) and Recombinase Polymerase Amplification (RPA) eliminate the need for thermal cycling, making them suitable for portable devices.<sup>1,2</sup>

#### Advantages

- Rapid (<30 minutes)
- Low power requirements
- Simple instrumentation
- Suitable for resource-limited settings

### 3) Multiplex Syndromic Panels

Commercial platforms simultaneously detect multiple pathogens and selected antimicrobial resistance genes from a single specimen.<sup>1,3,4</sup>

Examples include:

- Respiratory pathogen panels
- Gastrointestinal panels
- Meningitis/encephalitis panels
- Blood culture identification panels

These assays significantly reduce diagnostic turnaround time and support early optimization of antimicrobial therapy.<sup>1,3,4</sup>

### 4) CRISPR-Based Diagnostics

CRISPR-Cas systems (e.g., SHERLOCK and DETECTR) offer highly sensitive and specific nucleic acid detection with the potential for low-cost, portable testing. These technologies are being explored for rapid detection of viral, bacterial, and fungal pathogens, as well as antimicrobial resistance genes.<sup>1,2</sup>

## 3. Clinical Applications

### Respiratory Tract Infections

Rapid identification of influenza, SARS-CoV-2, RSV, and atypical respiratory pathogens enables:<sup>1,5</sup>

- Appropriate antiviral therapy
- Reduced unnecessary antibiotic prescriptions
- Improved patient isolation
- Better infection prevention measures

### Bloodstream Infections

Rapid molecular identification directly from positive blood cultures shortens the time to effective therapy by several

hours and facilitates early de-escalation of broad-spectrum antibiotics.<sup>2,6</sup>

### Central Nervous System Infections

Multiplex meningitis/encephalitis panels provide rapid diagnosis of bacterial, viral, and fungal pathogens within approximately one hour, enabling prompt targeted therapy while avoiding unnecessary antimicrobial exposure.<sup>1,2</sup>

### Tuberculosis

WHO-endorsed cartridge-based molecular assays have significantly improved early diagnosis of tuberculosis and rifampicin resistance, particularly in high-burden countries.<sup>1,2</sup>

### Sexually Transmitted Infections

POC molecular assays for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* enable same-day diagnosis and treatment, reducing disease transmission and improving patient compliance.<sup>1,2</sup>

### Impact on Antimicrobial Stewardship

Rapid molecular diagnostics are powerful tools for antimicrobial stewardship.

Major benefits include:

- Earlier initiation of appropriate therapy
- Reduced empirical broad-spectrum antibiotic use
- Faster de-escalation
- Shorter hospital stay
- Reduced healthcare costs
- Improved patient outcomes

Several studies have demonstrated that the greatest benefit is achieved when rapid diagnostics are integrated with an active antimicrobial stewardship program.<sup>6</sup>

### Current Challenges

Despite significant progress, several limitations remain.

- High equipment and reagent costs
- Limited pathogen panels
- Detection of nucleic acid rather than organism viability
- False-positive results from colonization
- Need for quality assurance and operator training
- Limited antimicrobial susceptibility information
- Integration with laboratory information systems

Careful interpretation of molecular results within the clinical context remains essential.<sup>1,2</sup>

## 4. Future Perspectives

The next generation of POC molecular diagnostics is expected to focus on:

### Artificial Intelligence

AI-assisted interpretation of molecular results may improve diagnostic accuracy and support individualized antimicrobial recommendations.

### CRISPR-Based Platforms

Portable CRISPR diagnostics promise rapid, highly sensitive detection with minimal instrumentation.

### Nanotechnology

Nanomaterial-based biosensors may allow ultra-rapid detection directly from clinical samples without extensive sample preparation.

### Portable Sequencing

Handheld nanopore sequencing devices have the potential to provide real-time pathogen identification, antimicrobial resistance profiling, and outbreak investigation at the point of care.

### Digital Connectivity

Integration of POC platforms with electronic medical records and antimicrobial stewardship dashboards will enable real-time clinical decision support and surveillance.<sup>1,2</sup>

## 5. Conclusion

Point-of-care molecular diagnostics have revolutionized infectious disease diagnosis by providing rapid, accurate, and actionable results close to the patient. Their integration into routine clinical practice has improved diagnostic stewardship, optimized antimicrobial therapy, and enhanced patient outcomes. Emerging technologies, including CRISPR diagnostics, artificial intelligence, portable sequencing, and digital health integration, are expected to further expand the role of point-of-care molecular testing. Continued efforts to improve affordability, quality assurance, and clinical integration will be critical for maximizing their impact in both high-resource and resource-limited healthcare settings.

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