

Molecular Based Diagnostic Testing for Urinary Tract Infections: The Results Remain Unclear

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Abstract

Introduction

Recent advances have led to a rise in metagenomic and molecular-based testing for more rapid diagnosis of urinary tract infections (UTI). We conducted a contemporary systematic review to understand how these molecular tests affect clinical outcomes.

Methods

A systematic review was conducted for articles in adults from January 2023 to October 2025 as an update to previous scoping reviews. Cochrane and PRISMA standards were utilized with the following databases: PubMed, OVID, and Embase (PROSPERO number: CRD420251070022). Data was extracted from the selected full-text papers including the type of study (microbiology versus clinical), patient demographics, key findings, and funding source. Excluded studies were abstracts, non-English manuscripts, and those involving only men or children.

Results

The search resulted in 12 full-text articles. Among those, 7 were published in clinical-based journals and 5 were in Microbiology. Two clinical studies were randomized controlled trials (RCTs) including a total of 830 patients, mostly female and above the age of 65. Compared to a standard urine culture, molecular based testing, specifically with polymerase chain reaction (PCR) testing yielded superior sensitivity despite lack of specificity and guided antibiotic therapy to reduce UTI baseline symptomatology in the short term (i.e. 28 days) in both RCTs. Of note, the RCTs and several of the prospective studies (5/10) were funded by the companies that developed the molecular tests.

Conclusions

Based on the increase in publications over the last three years, new industry-funded RCTs, and the limited clinical outcome data reported, this systematic review indicates the urgent need for prospective and multicentric studies to better understand the role of these molecular tests in UTI management.

Background

Urinary tract infections (UTIs) are among the most common bacterial infections and represent a substantial burden in women's health.[1]. As UTI symptoms are often nonspecific, accurate diagnostic methods are essential to confirm infection and guide appropriate therapy. Timely identification of causative pathogens is critical for effective treatment and antibiotic stewardship.

Standard urine culture (SUC) has long been the diagnostic gold standard for UTI. However, culture typically requires 24–72 hours for pathogen identification, and longer for susceptibility testing results [2]. Thus,

patients are often treated empirically, with therapy later adjusted if needed based on culture results. Conventional urine culture also has notable limitations, including reduced sensitivity in cases of low bacterial load, slow-growing organisms, or polymicrobial infections, which may lead to false-negative results. [3]

To address these limitations, molecular diagnostic methods have gained increasing attention. Common approaches include polymerase chain reaction (PCR), multiplex PCR (mPCR), next-generation sequencing (NGS), and loop-mediated isothermal amplification (LAMP). PCR-based methods enable targeted detection of specific pathogens, while mPCR allows simultaneous amplification of multiple targets. NGS provides broader microbial detection, encompassing both targeted sequencing (e.g., 16S rRNA) and untargeted metagenomic sequencing (mNGS). mNGS analyzes all nucleic acids within a sample without prior target selection, enabling comprehensive pathogen detection but with reduced sensitivity for individual organisms due to host DNA interference and sequencing depth constraints. In contrast, targeted NGS (tNGS) enhances sensitivity for specific microbial groups but is limited to predefined targets [1, 4]. LAMP offers another targeted approach with rapid amplification without the need for thermal cycling [5].

These molecular techniques have gained popularity due to faster turnaround times and broader pathogen detection compared to standard urine culture. Studies suggest that methods such as NGS may demonstrate higher sensitivity in detecting uropathogens [1,3]. However, increased sensitivity raises concerns about detecting commensal organisms within the urinary microbiome, potentially leading to overdiagnosis and unnecessary antibiotic use [6].

Despite these potential advantages, the impact of molecular diagnostics on clinical outcomes remains uncertain. A 2023 systematic review by Szlachta-McGinn et al. reported improved detection rates with PCR- and NGS-based testing but highlighted insufficient evidence regarding patient outcomes and antibiotic-guided cure rates [2,6]. Nevertheless, the use of these technologies continues to expand partially due to direct-to-consumer availability.

This systematic review aims to evaluate the most recent evidence on molecular-based diagnostics for UTIs, with a focus on studies published from 2023 onward, providing an updated assessment of their role in diagnosis and treatment [1].

Methods

This study was conducted as a systematic review to synthesize evidence published between January 2023 and October 2025 on the efficacy of molecular diagnostic methods for the diagnosis and management of UTIs. The review focused on diagnostic accuracy, clinical utility, and impact on patient outcomes. The protocol was registered with PROSPERO (CRD420251070022) and was exempt from institutional review board approval. The review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) guidelines. Study outcomes, eligibility criteria, and data synthesis methods were predefined and registered prior to the literature search. Eligible studies included observational studies (prospective or retrospective), cohort studies, case series, and clinical trials. Inclusion criteria were: (1) adult populations (≥ 18 years), including female participants, (2) use of molecular diagnostic methods (e.g., PCR, next-generation sequencing [NGS], metagenomic sequencing), and (3) reporting of diagnostic accuracy and/or clinical

outcomes such as antibiotic selection, treatment modification, or symptom resolution. Exclusion criteria included case reports, conference abstracts, editorials, and studies limited to pediatric or male-only populations. Only English-language studies published within the specified date range were included, consistent with the aim of updating prior reviews on this topic. A comprehensive literature search was performed in MEDLINE (via PubMed), EMBASE, and Ovid. The search strategy combined Medical Subject Headings (MeSH) and free-text terms related to “urinary tract infection,” “molecular diagnostics,” “polymerase chain reaction,” “next-generation sequencing,” and “metagenomics.” Reference lists of relevant articles were also manually screened to identify additional studies. All retrieved citations were imported into Excel for screening. One reviewer independently screened titles and abstracts, followed by full-text review of potentially eligible studies. Discrepancies were resolved through discussion with a second reviewer. Data extraction was performed by one reviewer and included study characteristics (author, year, country, design), population details (sample size, age, sex distribution), type of molecular assay, clinical outcomes, and funding sources. Any discrepancies were resolved by consensus among coauthors. Risk of bias was assessed using the Revised Cochrane Risk of Bias tool (RoB 2) for randomized controlled trials and the ROBINS-I tool for non-randomized studies (Table 2).

A qualitative synthesis of study characteristics, molecular diagnostic methods, and outcomes was performed. Due to heterogeneity in study design, populations, and outcome measures, meta-analysis was not feasible. Study limitations and potential sources of bias were considered in the interpretation of findings.

Results

The initial database search identified 1,284 unique records after removal of duplicates. Following title and abstract screening, 50 studies underwent full-text review. Ultimately, 12 studies met inclusion criteria.

Study Characteristics

Among the included studies, 2 were randomized controlled trials (RCTs), 8 were prospective studies, and 2 were retrospective studies. Five studies were microbiology-focused, while seven evaluated clinical outcomes. Studies were published between 2023 and 2025, with the majority conducted in the United States (n = 9) [8,9,10,11,12,13,14,17,18], with others performed in Asia (n = 2) [7,16] and Europe (n = 1) [15]. PCR-based methods (including mPCR) were the most commonly evaluated (n = 9) [8,9,10,11,12,13,14,17,18], followed by next-generation sequencing (NGS; n = 2) [7,16] and loop-mediated isothermal amplification (LAMP; n = 1) [15]. Among microbiology-focused studies, three assessed PCR [8,10,11], one targeted NGS (tNGS) [7], and one LAMP [15]. Funding sources were reported in 8 studies, most commonly from Pathnostics (n = 4) [9,10,11,18] and Doc Lab Inc. (n = 2) [13,14].

Risk of bias assessment showed one RCT with low risk and one with some concerns. Among non-randomized studies, three had serious risk of bias, six moderate, and one low (Table 2).

Across all studies, total sample size was 4,467 (range: 56–1,596). Mean participant age ranged from 65 to 80 years. All studies included female participants, with female representation ranging from 28% to 100%. Aggregate sample distribution by modality included PCR (n = 982), mPCR (n = 1,462), tNGS (n = 202), mNGS (n = 33), and LAMP (n = 1,596). Study characteristics are summarized in Table 1.

Diagnostic Sensitivity

Molecular diagnostics consistently demonstrated higher sensitivity compared to SUC, particularly for polymicrobial infections. Both RCTs reported higher PCR positivity rates compared to SUC, with increased detection of polymicrobial infections (43.5% vs. 32%) and higher discordance rates for PCR-positive/culture-negative samples (26% vs. 3%) [13,14]. Across multiple studies, PCR and mPCR identified substantially more pathogens than SUC. PCR positivity reached 69.8% compared to 47.9% with culture in one study, with 32.8% of PCR-positive results occurring in culture-negative samples. Polymicrobial detection was markedly higher with molecular methods (up to 72% vs. <10% with SUC). Several mPCR studies reported frequent detection of multiple pathogens per sample and high discordance rates with culture (up to 72.6%) [8-12,18]. NGS-based methods also demonstrated improved detection. One study reported pathogen identification in 87.9% of cases using mNGS versus 30.3% with SUC [7]. Targeted NGS showed higher polymicrobial detection than both mNGS and SUC [7,16]. The LAMP assay demonstrated high sensitivity (95.3%) in culture-positive samples [15].

Microbial Identification

Nine studies reported microbial profiles. While *Escherichia coli* remained the most commonly detected pathogen, molecular methods identified a broader range of organisms, including fastidious bacteria, fungi, and viruses not detected by SUC. [11, 12,15,17]. Common organisms included *Klebsiella*, *Enterococcus faecalis*, and *Streptococcus agalactiae*. Molecular testing also frequently identified polymicrobial infections and non-*E. coli* pathogens, including anaerobes and atypical organisms such as *Ureaplasma parvum* and *Mycobacterium tuberculosis*. One study reported exclusive detection of non-*E. coli* organisms and yeast in over half of patients using mPCR [16]. The LAMP study focused solely on *E. coli* detection [15].

Turnaround time

Molecular diagnostics demonstrated faster turnaround times compared to SUC. PCR results were available within approximately 48–49 hours versus up to 5 days for culture [11,14,18]. NGS methods showed even shorter detection times (12.9 hours for tNGS and 17.4 hours for mNGS). In the RCTs, PCR testing significantly reduced time to antibiotic initiation (20 hours vs. 52 hours)[13,14]. LAMP testing enabled near point-of-care results, with pathogen detection and susceptibility information available within approximately one hour [15].

Antibiotic Management

Five studies evaluated changes in antibiotic therapy following molecular test results [7,9,13,17,18]. Molecular results led to treatment modification in up to 57.3% of cases, with nearly half of these changes not supported by culture results alone [17]. PCR-guided therapy was associated with higher rates of appropriate antibiotic selection compared to empiric treatment (83.4% vs. 62.1%) [13]. mPCR-guided management was frequently used to treat polymicrobial and non-*E. coli* infections [9]. However, one study found no significant change in first-line antibiotic use with mPCR, aside from increased use of metronidazole following detection of *Gardnerella vaginalis* [18]. In an mNGS study, antibiotic regimens were modified in 25 of 33 patients [7].

Satisfaction

Two studies assessed clinician and patient satisfaction. One RCT reported significantly higher clinician satisfaction with PCR-guided care compared to SUC (mean score 23.95 vs. 20.64, $p < 0.001$). Another study found high patient satisfaction with PCR-guided empiric treatment (mean score 4.7/5). [12,14].

Symptom Outcomes

Five studies evaluated symptom improvement, all reporting reductions following molecular-guided therapy [7,8,9,13,14]. One RCT demonstrated significantly greater symptom improvement in subgroups including older adults, female patients, and those with polymicrobial infections [14]. Another RCT showed improvements in lower urinary tract symptoms and pyuria, though overall symptom resolution did not differ significantly [13]. Observational studies reported mixed results with symptom improvement with antibiotics with PCR or NGS, with the majority only reporting long term results to up to 14 days [7, 8, 9].

Symptom Recurrence

Four studies assessed recurrence or longer-term outcomes, with mixed findings [7,9,12,14]. One study reported a 70% recurrence rate following mPCR-guided treatment, with symptom return occurring at a mean of 24 days [12]. Other studies found no significant differences in microbial eradication or clinical cure rates between molecular-guided and culture-guided groups [9,14]. However, one study reported improvements in surrogate markers such as urinary white blood cell counts following mNGS-guided treatment [7].

Discussion

This systematic review synthesizes recent evidence (2023–2025) on molecular diagnostic testing for UTIs, highlighting both microbiological and clinical implications. Across studies, PCR- and NGS-based methods consistently demonstrated higher sensitivity than SUC, confirming prior literature. While *Escherichia coli* remained the most commonly identified pathogen, molecular tests more frequently detected polymicrobial infections, anaerobes, fungi, and viruses. This broader detection suggests that molecular diagnostics may address limitations of SUC, particularly in culture-negative but symptomatic patients. However, important uncertainties remain. Despite initial symptom improvement, recurrence rates were frequently high, and no included study evaluated outcomes beyond 28 days [9,12]. This limits conclusions regarding long-term effectiveness, recurrence prevention, and the potential impact on antimicrobial resistance. Additionally, it remains unclear whether increased diagnostic sensitivity leads to higher overall antibiotic prescribing, particularly in cases where molecular tests detect organisms not identified by culture. Some recurrent symptoms may reflect noninfectious lower urinary tract conditions rather than true infection, raising concerns about overdiagnosis. Notably, most studies did not include infectious disease expertise to contextualize positive molecular findings within clinical presentations. [9,12]. It is now known that urine is not inherently sterile, and thus, as mentioned above, symptoms may be noninfectious in etiology though with these ultrasensitive but not highly specific molecular testing, overdiagnosis is highly concerning [6]. If overdiagnosis is occurring, this also results in inappropriate prescribing of and exposure to antimicrobial agents, which can increase antimicrobial resistance and ultimately result in more-difficult-to-treat infections when a patient has a veritable UTI.

Most included studies evaluated PCR-based methods, with relatively limited data on NGS. Despite increasing clinical interest, only two studies assessed targeted or metagenomic NGS, underscoring a gap between technological potential and clinical evidence. While these studies demonstrated improved detection of polymicrobial and atypical pathogens, robust data on clinical outcomes remain limited. Larger, prospective, and independently funded studies are needed to better define the role of NGS in UTI management.

A notable consideration in interpreting the results of this review is the potential influence of industry sponsorship on study outcomes. Eight of the 12 included studies disclosed funding sources, with several sponsored by diagnostic companies that make these molecular tools such as Pathnostics and Doc Lab Inc. This raises the possibility of bias in study design, interpretation, and reporting, emphasizing the need for independent validation of findings. Appropriate clinical application of molecular diagnostics requires understanding their analytical differences. PCR assays offer high sensitivity with low limits of detection (often $\sim 10^2$ – 10^3 CFU/mL), enabling identification of low bacterial burdens but increasing the risk of detecting colonization or nonviable organisms. In contrast, NGS provides broader, hypothesis-free pathogen detection but with relatively higher effective detection thresholds and potential underrepresentation of low-abundance organisms. Accordingly, PCR may be best suited for targeted, high-suspicion cases requiring rapid results, whereas NGS may be more useful in complex, recurrent, or culture-negative infections where broader pathogen identification is needed. In all cases, results must be interpreted within the clinical context.

This review has several limitations. The number of included studies was relatively small, and populations such as pediatric patients, male-only cohorts, and catheter-associated UTIs were excluded. Significant heterogeneity in study design and outcome measures precluded meta-analysis. Additionally, the predominance of industry-sponsored studies introduces potential bias. Overall, these findings highlight the promise of molecular diagnostics in improving UTI detection and short-term management, while underscoring the need for larger, independent, multicenter trials with standardized methodologies and long-term clinical endpoints to better define their role in practice.

Conclusion

Molecular diagnostic testing for UTIs offers improved pathogen detection and faster turnaround times compared to standard urine culture, with emerging evidence suggesting benefits in targeted antibiotic use and short-term symptom resolution. However, variability in study design, limited long-term outcome data, the prevalence of industry-sponsored research, and potential for overdiagnosis and/or diagnosis of bacteriuria without true infection warrant cautious interpretation. Further independent studies focusing on clinical outcomes, cost-effectiveness, and real-world implementation are needed as the role of molecular diagnostics in UTI management continues to expand.

Declarations

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Tables

Table 1. Summary of Studies Included

Author	Study Type	Molecular Testing Method	n	Key Findings	Funding
Kardjadj 2025	RCT (C)	PCR	362	PCR identified polymicrobial infections in 43.52% of cases, a higher rate than that observed with urine culture. PCR-guided management associated with lower therapeutic failure rate	Doc Lab Inc
Spangler 2025	RCT (C)	PCR	468	PCR results yielded better clinical outcomes compared to conventional urine culture (UC) result-guided treatment overall (88.08 % vs. 78.11, p = 0.011)	Doc Lab Inc
Fritzenwanker 2025	Prosp (M)	LAMP	1596	The custom LAMP can provide detection, quantification and antibiotic susceptibility results for E. coli in urine samples in one hour	Open Access, Projekt DEAL
Chang 2025	Prosp Cohort (M)	tNGS and mNGS	202	tNGS showed 96.5% concordance with culture-positive samples and had superior specificity in culture-negative specimens for mNGS	None
Elia 2024	Prosp Obs (C)	PCR	96	In 31/59 (52.5%) of the cases, the PCR results modified the treatment where UC did not. One third of patients had modifications of antibiotic regimen based on the PCR test results	None
Haley 2024	Prosp Obs (C)	mPCR	385	Use of M-PCR did not significantly change proportion of first-line antibiotics used, nor overall proportion of treatment versus non-treatment compared to SUC	Pathnostics
Melnyk 2023	Prosp Cross Sectional (C)	mPCR	30	After mPCR based treatment, 70% of the patients developed recurrence of UTI symptoms with an average time to recontact of 24 days	None
Festa 2023	Prosp (M)	mPCR	200	The number of organisms identified via SUC was significantly reduced compared with M-PCR (p < 0.0001)	Pathnostics
Haley 2023	Prosp (M)	mPCR	583	>75% of M-PCR-positive/SUC-negative cases are true UTIs, evidenced by elevated levels of urinary biomarkers. <i>E.coli</i> and polymicrobial infections	Pathnostics

Korman 2023	Prosp Obs (C)	mPCR	264	mPCR based treated patients exhibited greater symptom reduction compared to untreated on day 14 for those with non- <i>E. coli</i> and polymicrobial infections	Pathnostics
Leech 2025	Retro (M)	mPCR	56	Increased detection rate of coinfections by PCR	Grants by Vikor Scientific, LLC.
Jia 2023	Retro Cohort (C)	mNGS	33	mNGS improved detection of pathogen and guide changes in treatment strategies, as a complement to urine culture	None
<i>Note: C=Clinical, M=Microbiology, RCT=Randomized Control Trial, Prosp= Prospective, Retro= Retrospective, Obs=Observational, PCR=Polymerase Chain Reaction, NGS=Next Generation Sequencing, mPCR=Multiplex PCR, tNGS= targeted NGS, mNGS= metagenomic NGS, LAMP=Loop Mediated Isothermal Application</i>					

Table 2. Risk of Bias using the ROB-2 tool for RCTs and ROBINS-V2 tool for non-RCTs

Author	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	--	Overall Rating
Kardjadj 2025	Some Concerns	Low	Some Concerns	Some Concerns	Some Concerns		Some Concerns
Spangler 2025	Low	Low	Some Concerns	Low	Low		Low
Author	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Domain 6	Overall Rating
Fritzenwanker 2025	Moderate	Moderate	Low	Low	Low	Low	Moderate
Chang 2025	Moderate	Serious	Low	Low	Moderate	Moderate	Serious
Elia 2024	Serious	Moderate	Low	Moderate	Low	Serious	Serious
Haley 2024	Moderate	Low	Low	Moderate	Moderate	Moderate	Moderate
Melnyk 2023	Serious	Moderate	Low	Moderate	Moderate	Low	Moderate
Festa 2023	Moderate	Serious	Low	Low	Low	Low	Moderate
Haley 2023	Moderate	Low	Low	Low	Low	Moderate	Low
Korman 2023	Moderate	Serious	Low	Moderate	Moderate	Moderate	Moderate
Leech 2025	Moderate	Low	Low	Moderate	Moderate.	Moderate	Moderate
Jia 2023	Serious	Moderate	Low	Moderate	Moderate	Moderate	Serious