

June 21, 2024

To: Nursing Home and Assisted Living Administrators, Skilled Nursing/ Long Term Care Staff, Nurses, Physicians, Nurse Practitioners, Physician Assistants, and anyone else involved in medical care for LTC patients

The gold standard method for diagnosing a urinary tract infection remains evaluation of clinical signs and symptoms followed by a urinalysis with culture and sensitivities, in the appropriate clinical context.

As it stands right now, the use of nucleic acid amplification testing (NAAT), Polymerase Chain Reaction (PCR), as a means of diagnosing a urinary tract infection is complicated. Use of this testing is of potential concern to the Centers for Disease Control and Prevention (CDC) given that inappropriate treatment of asymptomatic bacteriuria has been described to be common in older adults. The CMDA - The Colorado Society for Post-acute and Long-term Care Medicine has reviewed the literature and discussed this issue at great length with multiple stakeholders including the Colorado Department of Public Health and Environment.

We have concluded that the use of NAAT/PCR to identify organisms in a urine sample is not supported by the current evidence base and is not congruent with the standard of care for diagnosis of a urinary tract infection. We believe that utilizing this methodology will lead to overdiagnosis and exacerbate the already problematic overutilization of antibiotics due to the potentially high, false positive rate of this testing methodology.

We respectfully ask all medical providers to refrain from using NAAT/PCR when evaluating for urinary tract infections. We urge consideration of Loeb's criteria with urinalysis and urine culture with sensitivities when urine testing is warranted.

Endorsed by the CMDA Board of Directors on June 21, 2024 Updated with CDC reference Sept 27, 2024

Reference list

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- 13. <u>Urine polymerase chain reaction tests: stewardship helper or hinderance?</u> | Antimicrobial Stewardship & Healthcare Epidemiology | Cambridge Core. Accessed June 24, 2024. https://www.cambridge.org/core/journals/antimicrobial-stewardship-and-healthcare-epidemiology/article/urine-polymerase-chain-reaction-tests-stewardship-helper-or-hinderance/ED1BFD7ECE289D3029D79E5AAAC0E72F
- 14. <u>Urine Polymerase Chain Reaction (PCR) Based Testing Guidance Document (wa.gov)</u>. Washington State Society for Post-acute and Long-Term Care, Washing State Department of Health, Oct 2023, DOH 420-548.

Highlights from the literature:

Concordance Between Antibiotic Resistance Genes and Susceptibility in Symptomatic Urinary Tract Infections – PubMed (nih.gov)

 Conclusion: Given the 40% discordance rate, the detection of ABR genes alone may not provide reliable data to make informed clinical decisions in UTI management. However, when used in conjunction with susceptibility testing, ABR gene data can offer valuable clinical information for antibiotic stewardship.

Molecular Diagnostic Methods Versus Conventional Urine Culture for Diagnosis and Treatment of Urinary Tract Infection: A Systematic Review and Meta-analysis - PMC (nih.gov)

- Conclusion: Moderately strong evidence exists that molecular diagnostics demonstrate
 increased sensitivity in detecting urinary bacteria at the expense of poor specificity in
 controls. Additional data comparing patient symptoms and cure rates following antibiotic
 selection directed by molecular methods compared with culture are needed to elucidate
 their place in UTI care.
- Of asymptomatic healthy controls, 95% had positive molecular tests vs 23% who had positive urine cultures

Diagnosing UTIs with Urine PCR | Clinical Lab Products (clpmag.com)

- The Centers for Medicare and Medicaid Services (CMS) indicates there are currently no FDA cleared/approved7 uses for a urine PCR multiplexed panel as there is no peerreviewed published literature that demonstrates improved patient outcomes. CMS requires urine PCR testing to include parallel testing using conventional culture-based detection for correlation of results.
- LCD MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39038) (cms.gov)

Molecular Diagnostic Methods Versus Conventional Urine Culture for Diagnosis and Treatment of Urinary Tract Infection: A Systematic Review and Meta-analysis – European Urology Open Science

 Moderately strong evidence exists that molecular diagnostics demonstrate increased sensitivity in detecting urinary bacteria at the expense of poor specificity in controls.

ACTION TOOL



"Does the resident have new or worsening signs or symptoms that meet one of three criteria for suspected urinary tract infection?"

Ш	CRITERIA	 Painful 	urination	(meets	criteria	alone)	or
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- □ CRITERIA 2. Fever: any fever >100°F or repeated temperatures > 99°F or >2°F over resident's baseline plus at least one new or worsening sign or symptom, including:
 - Frequency of urination
 - Sensation of urgency to urinate
 - Incontinence
 - Bloody urine
 - Pain in the area over the urinary bladder, just above the pubic bone (no other known cause)
 - Flank pain or tenderness
- CRITERIA 3. No fever, but two or more of the signs or symptoms above.

If the resident meets one of the criteria above, ask the healthcare provider to

☐ Sending urine for urinalysis and culture and

☐ Ordering empiric antibiotics until culture results return.

If the resident does not meet the above criteria, **refer to the facility's care paths** for considering alternative diagnoses and when to contact the provider.

Healthcare providers should hold an **antibiotic time-out** to review and document patient signs and symptoms and urine culture results within 48 hours. Healthcare providers should then narrow or stop antibiotics as indicated and determine appropriate duration.

Guidance for management of urinary tract infection and asymptomatic bacteriuria can be found in the *Infectious Diseases Society of America Practice Guidelines* at www.idsociety.org.

Suspected Urinary Tract Infection (UTI) Action Tool

Purpose

Guide nursing staff in the initial evaluation of possible urinary tract infection (UTI) in residents without a urinary catheter.

Setting

Nursing homes.

Rationale

Overuse or misuse of antibiotics leads to antibiotic-resistant bacteria, possible side effects and adverse drug events, added costs and Clostridium difficile.

References: 1) Stone, N, et. al., Surveillance Definitions of Infections in Long-Term Care Facilities: Revisiting the McGeer Criteria; Infection Control and Hospital Epidemiology, Vol. 33, No. 10 (October 2012), pp. 965-977; 2) Loeb et al. Development of Minimum Criteria for the Initiation of Antibiotics in Residents of Long-Term-Care Facilities: Results of a Consensus Conference. Infect Control Hosp Epidemiol 2001; 22: 120-124.











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