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Urine Polymerase Chain Reaction-Based (PCR) Testing Guidance Document

Introduction:

- Urine polymerase chain reaction-based (PCR) laboratory testing has been promoted to clinicians as an alternative method of obtaining urine cultures.
- Due to the high prevalence and overuse of antibiotics for asymptomatic bacteriuria (ASB) in the postacute and long-term care population, guidance on the topic of PCR urine testing is provided to ensure safety.
- This document is intended to provide guidance but does not replace clinical judgement.

What is Urine Polymerase Chain Reaction (PCR) Based Testing?

- This is a multiplex testing method that uses pathogen-specific primers to detect several pathogens and some antibiotic resistance genes¹. There are two options: quantitative and qualitative. Quantitative PCR determines the quantity of pathogen present and qualitative PCR determines if a pathogen is present or absent.
- PCR-based technology has been utilized for specific disease states (e.g., COVID-19, Clostridioides difficile).

What is Urine PCR's Place in UTI Diagnosis?

- This testing method is not FDA-approved for diagnosing UTIs and lacks evidence showing improved patient outcomes^{1,4,5}.
- There are a lack of studies in which strict best practice definitions for UTI were utilized. It cannot replace standard urine culture techniques². Standard urine culture techniques remains the gold standard for urine testing when indicated by UTI symptoms².

What Is Known About Urine PCR?

• It cannot reliably discern between pathogenic and colonizing agents². Collection techniques that involve swabbing the briefs may further contaminate the sample, especially in incontinent residents.

This can lead to overtreatment of colonizing organisms and distress for the provider and the resident.

- It has a higher sensitivity rate then a standard urine culture, but is more likely to generate a positive result for organisms that are not considered clinically significant (e.g., organisms found as a part of normal skin flora)^{2,4,5}.
- It detects DNA of organisms that are no longer viable, unlike standard urine culture techniques⁴. Results from PCR are displayed as cells/mL or copies/µL, which counts all alive and dead cells in a sample. The standard colony-forming units/mL (CFUs/mL) measure takes into account only the cells that can actively divide under specified conditions.
- There is a lack of data to provide guidance on the interpretation of organism-specific cell counts⁶. The current treatment threshold for ≥ 100,000 CFUs/mL in a symptomatic resident is not equivalent to the copies/µL or cells/mL result that is reported from PCR testing.
- PCR is unable to detect which antibiotics an organism is sensitive to². It can only test for the presence of a limited number of resistance genes; however, it does not specify which organisms those genes are associated with².
- Results from PCR are faster than standard urine culture; however, the results may not accurately reflect the causative organism. It also cannot diagnose a UTI.
- Reports that are generated recommending antibiotic therapies based upon the PCR test result may encourage the clinician to select overly-broad antibiotics to cover organisms that are colonizers.

Recommendations:

- Share educational information with residents and family members about the definition of UTI and how unneccessary treatment can lead to potential harms
 - Communication training for staff:
 - <u>WA DOH's Communicating With Residents and Families About Antibiotics</u> is a free continuing education activity for nurses and medical assistants working in the post-acute and long-term care setting.
 - Handouts that can be provided to residents and families:
 - <u>CDC's Do You Need Antibiotics Brochure</u>
 - <u>Residents and Families UTI Pamphlet (English)</u>
 - <u>Residents and Families UTI Pamphlet (Spanish)</u>
- Refrain from ordering urine testing in asymptomatic residents.
- Use Loeb Criteria to determine the need to treat with antibiotics.
- Order traditional urine testing when testing is needed.
- Implement a facility-specific antibiogram for treatment guidance when empiric treatment is needed.
- Interpret any microbiology result using evidence-based guidelines and determine if proper collection techniques were followed.
- Consult local infectious diseases specialists & urologists for assistance with complicated cases.

More in-depth information can be found in the stewardship team's publication below:

Antimicrobial Stewardship & Healthcare Epidemiology: <u>Urine Polymerase Chain Reaction Tests: Stewardship</u> <u>Helper or Hinderance?</u> Published 5/8/24

Frequently Asked Questions:

1. How is a UTI diagnosed?^{7,8}

| UTI Syndrome | Clinical and Microbiological Findings |
|----------------------------------|---|
| Asymptomatic bacteruria | \geq 100,000 CFUs/mL of \geq 1 bacteria in urine culture without urinary symptoms present |
| Uncomplicated or simple cystitis | Localized symptoms such as acute dysuria, suprapubic tenderness, new/worsening incontinence, frequency, urgency, gross hematuria PLUS \geq 100,000 CFUs/mL of \geq 1 bacteria in urine culture |
| Catheter-associated UTI | Systemic symptoms such as fever, rigors, chills or localized symptoms such as those described above plus suprapubic/costovertebral tenderness or acute pain/swelling/tenderness of testes, epididymis, prostate. PLUS ≥ 100,000 CFUs/mL of ≥ 1 bacteria in urine culture |

2. What are the most common causative organisms?

a. Escherichia coli causes 75% - 95% of uncomplicated UTIs⁹. Other common pathogens include *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Staphylococcus saprophyticus*⁹. Other pathogens may cause UTI, but these are typically associated with complex cases and special circumstances. These are rarely isolated in uncomplicated UTIs⁹. Other organisms may represent colonizers or be present as the result of contamination of the lab specimen. Local infectious diseases experts can provide guidance on interpreting microbiological test results.

3. What is sensitivity and specificity?¹⁰

a.

| Sensitivity | The ability of a test to yield a positive result for a disease |
|-------------|--|
| Specificity | The ability of a test to yield a negative result for a disease |

4. What do I do with a urine test result that shows multiple organisms?

- a. Interpret all culture results using evidence based guidelines. Ensure proper collection technique was followed. Consult local infectious diseases specialists for assistance with complex results.
- 5. Where can I get guidance for UTI diagnosis and treatment?
 - a. Journal of the American Medical Director's Association: Diagnosis, Treatment, and Prevention of Urinary Tract Infections in Post-Acute and Long-Term Care Settings: A Consensus Statement From AMDA's Infection Advisory Subcommittee
 - b. <u>Infectious Diseases Society of America: Clinical Practice Guideline for the Management of</u> <u>Asymptomatic Bacteriuria</u>

- c. Infectious Diseases Society of America: Uncomplicated Cystitis and Pyelonephritis (UTI)
- d. Loeb Criteria
- e. WA DOH's Medical Provider's FAQs about UTI
- f. <u>WA DOH & WA-PALTC's Antimicrobial Stewardship of Urinary Tract Infections in the Long-Term</u> <u>Care Setting Series</u>

6. How can I get an antibiogram?

a. Reach out to your contract laboratory and request an antibiogram that is compliant with Clinical Laboratory Science Institute (CLSI) standards. This <u>sample letter created by the Minnesota Department of Health</u> can provide guidance.

Sources:

- Szlachta-McGinn A, Douglass KM, Chung UYR, Jackson NJ, Nickel JC, Ackerman AL. 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. 2022;44:113-124. doi: <u>https://doi.org/10.1016/j.euros.2022.08.009</u>
- Xu R, Deebel N, Casals R, Dutta R, Mirzazadeh M. A New Gold Rush: A Review of Current and Developing Diagnostic Tools for Urinary Tract Infections. *Diagnostics*. 2021;11(3). doi: <u>https://doi.org/10.3390/diagnostics11030479</u>
- 3. Indiana Department of Health. Testing for Urinary Tract Infections in Nursing Homes. Update for Post-Acute Care Clinicians. Published online July 2023. <u>https://secure.in.gov/health/ltc/files/July-2023-LTC-Clinician-Newsletter.pdf</u>
- Lehmann LE, Hauser S, Malinka T, et al. Rapid Qualitative Urinary Tract Infection Pathogen Identification by SeptiFast® Real-Time PCR. Bereswill S, ed. PLoS ONE. 2011;6(2):e17146. doi: <u>https://doi.org/10.1371/journal.pone.0017146</u>
- Wojno KJ, Baunoch D, Luke N, et al. Multiplex PCR Based Urinary Tract Infection (UTI) Analysis Compared to Traditional Urine Culture in Identifying Significant Pathogens in Symptomatic Patients. Urology. 2020;136:119-126. doi: <u>https://doi.org/10.1016/j.urology.2019.10.018</u>
- Price TK, Dune T, Hilt EE, et al. The Clinical Urine Culture: Enhanced Techniques Improve Detection of Clinically Relevant Microorganisms. Forbes BA, ed. Journal of Clinical Microbiology. 2016;54(5):1216-1222. doi: <u>https://doi.org/10.1128/jcm.00044-16</u>
- Ashraf MS, Gaur S, Bushen OY, et al. Diagnosis, Treatment, and Prevention of Urinary Tract Infections in Post-Acute and Long-Term Care Settings: A Consensus Statement From AMDA's Infection Advisory Subcommittee. Journal of the American Medical Directors Association. 2020;21(1):12-24.e2. doi: <u>https://doi.org/10.1016/j.jamda.2019.11.004</u>
- Biehle L. Stewardship strategies for interpretation of novel urinary diagnostics. Presented at: Colorado Department of Public Health & Environment (CDPHE); February 7, 2023. <u>http://docshepherd.com/wp-content/uploads/2023/03/CDPHE-Stewardship-Strategies-for-Interpretation-of-Novel-Urinary-Diagnostics-2.7.23.pdf</u>
- Gupta K, Hooton TM, Naber KG, et al. International Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women: A 2010 Update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases. Clinical Infectious Diseases. 2011;52(5):e103-e120. doi: <u>https://doi.org/10.1093/cid/ciq257</u>
- 10.Shreffler J, Huecker MR. Diagnostic Testing Accuracy: Sensitivity, Specificity, Predictive Values and
Likelihood Ratios. PubMed. Published March 6, 2023.
https://www.ncbi.nlm.nih.gov/books/NBK557491/





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420-548 October 2023 To request this document in another format, call 1-800-525-0127.

5 Urine Polymerase Chain Reaction (PCR) Based Testing Guidance Document Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

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