PRISMA HEALTH

Urine… Or Out? Informal Evaluation of UTI PCR Testing across Urgent Care Locations

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Disclosures

I have no disclosures or conflicts of interest at this time regarding the subject matter of this presentation

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Objectives

1. Describe diagnostic stewardship across the diagnostic pathway, including interventions at each stage

2. Identify the benefits and clinical utility of urine PCR testing based on available literature

3. Recognize opportunities to improve the use of urine PCR testing based on real-world practice data

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Importance

The problem: **Diagnostic Misuse**

- Often unintentional
- Most common type of inappropriate microbiologic testing: **Overtesting**
  - **Diagnostic errors**
    - Overdiagnosis, unnecessary antimicrobial exposure
    - Missed / delayed identification of the true diagnosis
    - Excess cost

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Importance

The problem: **Diagnostic Misuse** → The solution: **Diagnostic Stewardship**

- Often unintentional
- Most common type of inappropriate microbiologic testing: **Overtesting**
  - **Diagnostic errors**
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Diagnostic Stewardship

Process of modifying the ordering, performing, or reporting of diagnostic tests to improve the diagnosis of and treatment of infections and other conditions

Right Test

- Analytical performance characteristics
- False positive / false negative
- Diagnostic yield
- Context of local epidemiology

Right Patient

- Appropriate use criteria
- Patient population
- Pre-test probability

Right Time

- Time during which test results fit into the clinical workflow
- Will have an impact on patient care

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Right Time

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To prompt the right intervention (antibiotic stewardship)

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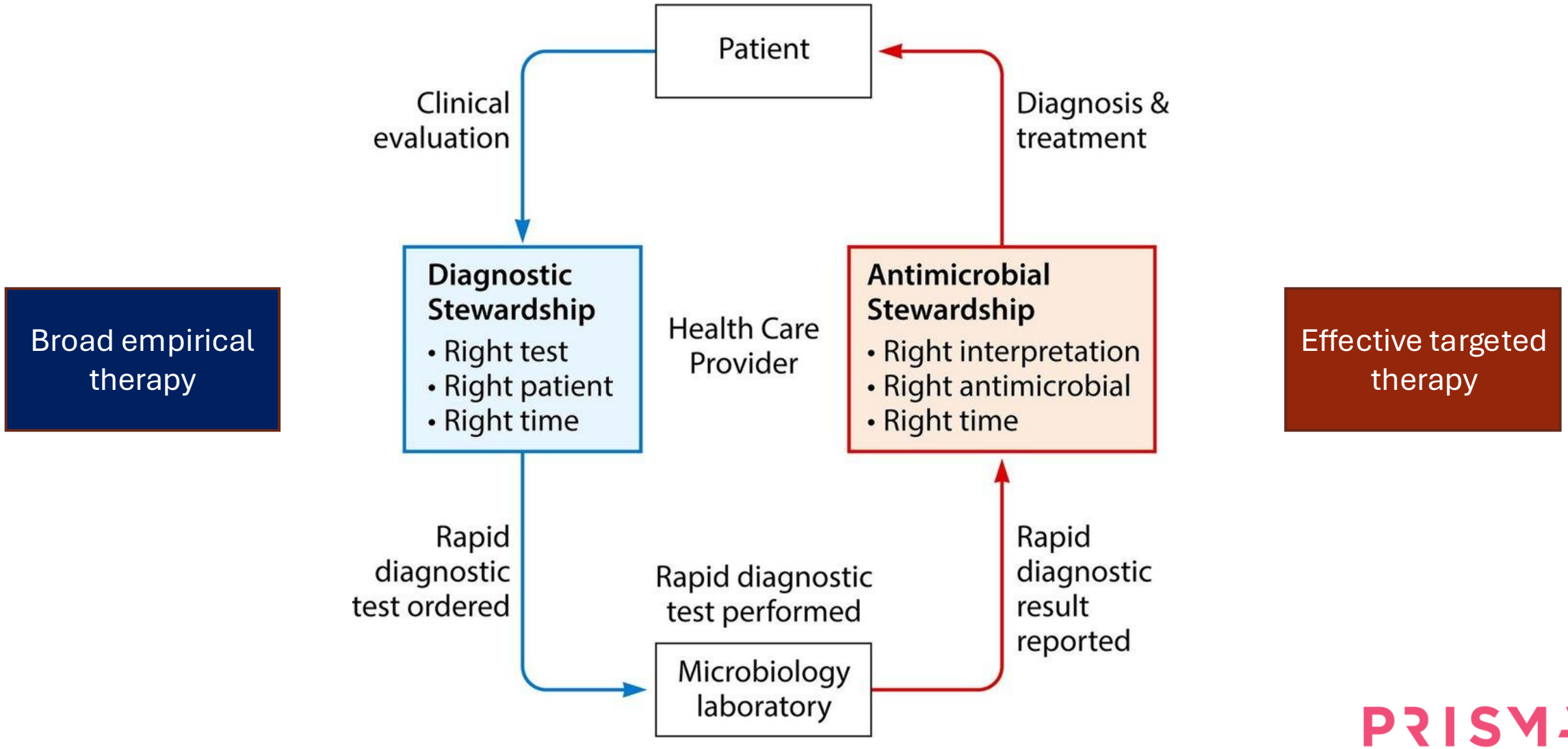
Diagnostic and Antimicrobial Stewardship



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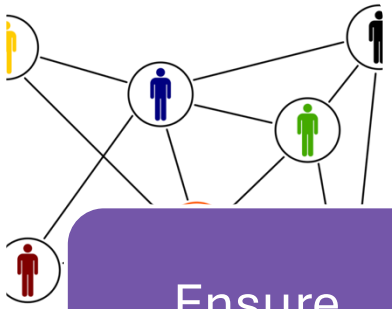
Burnham CA. *The National Academies Press*. 2023 https://doi.org/10.17226/27008

Implementing Diagnostic Stewardship

Define a clear goal



Ensure relevant stakeholders are involved

Ensure unit / hospital leadership support

Define measures to track positive or negative impact

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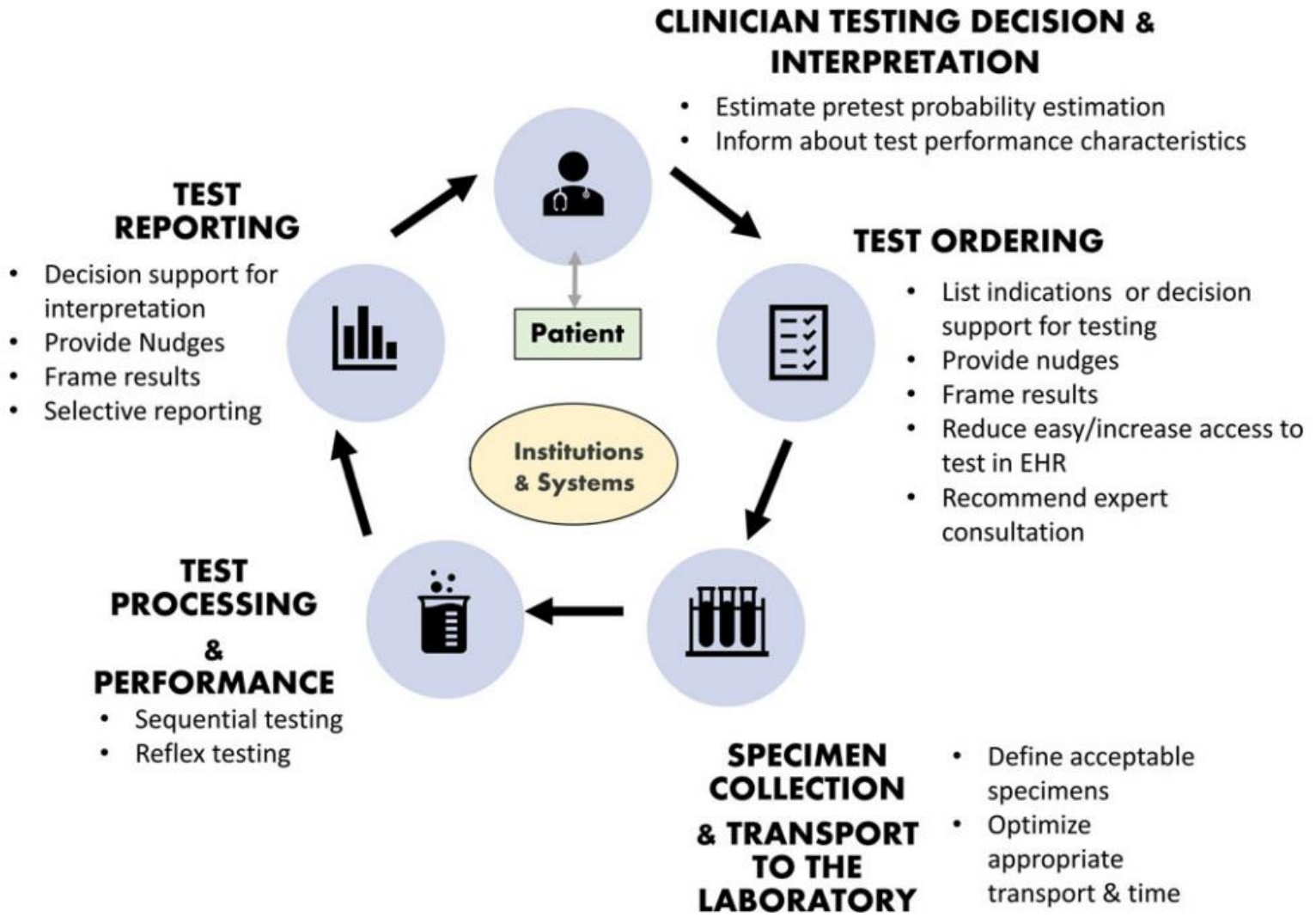
Conceptual Model of Diagnostic Stewardship



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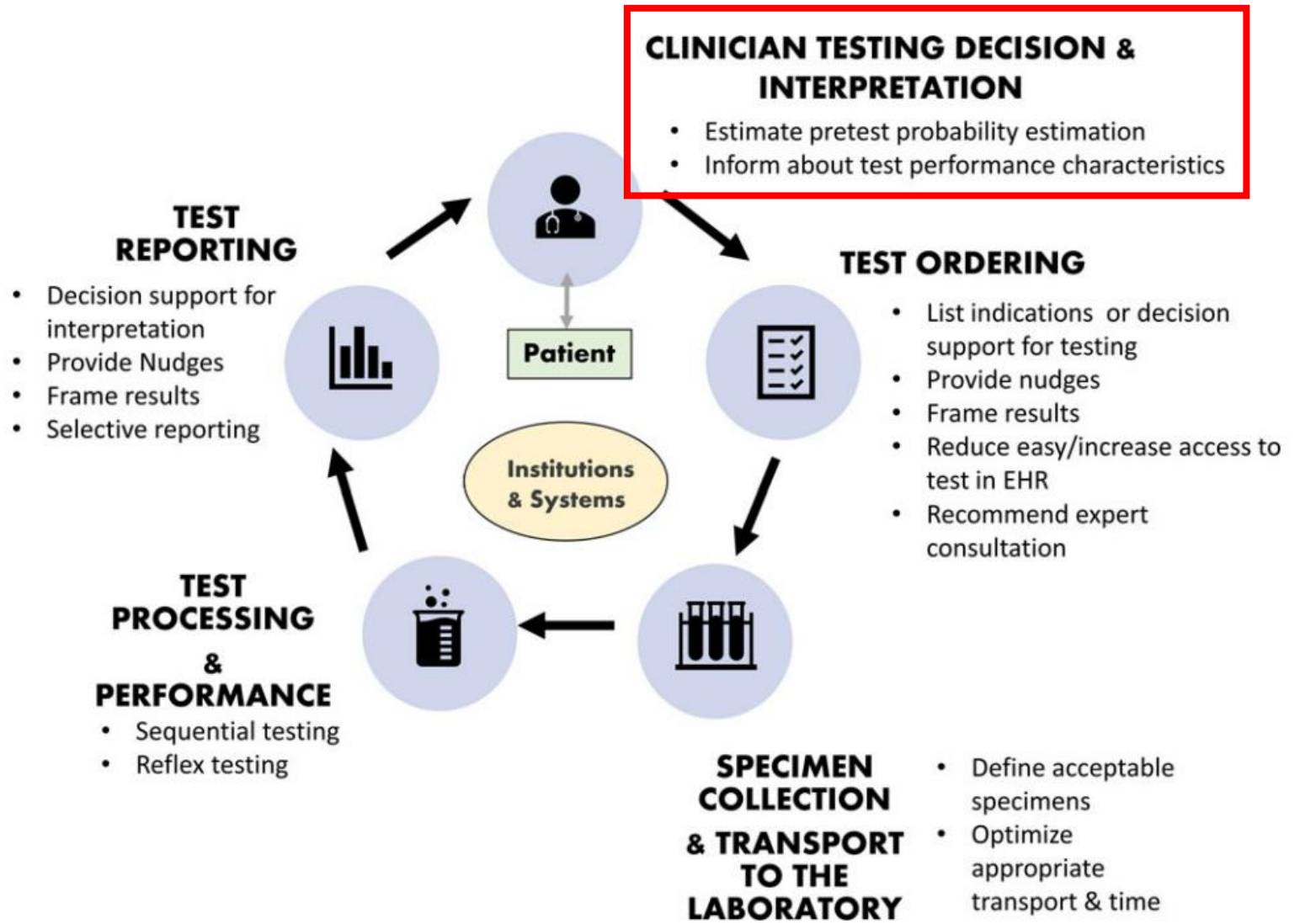
Conceptual Model of Diagnostic Stewardship



Clinician Education

- Sensitivity / specificity of test
- Pretest estimate of disease
  - Incidence of disease in specific patient populations
  - Risk factors that increase probability of disease

***Example**: Incidence of urinary tract infections in elderly women is higher than general populations*

- *As is the incidence of asymptomatic bacteriuria*

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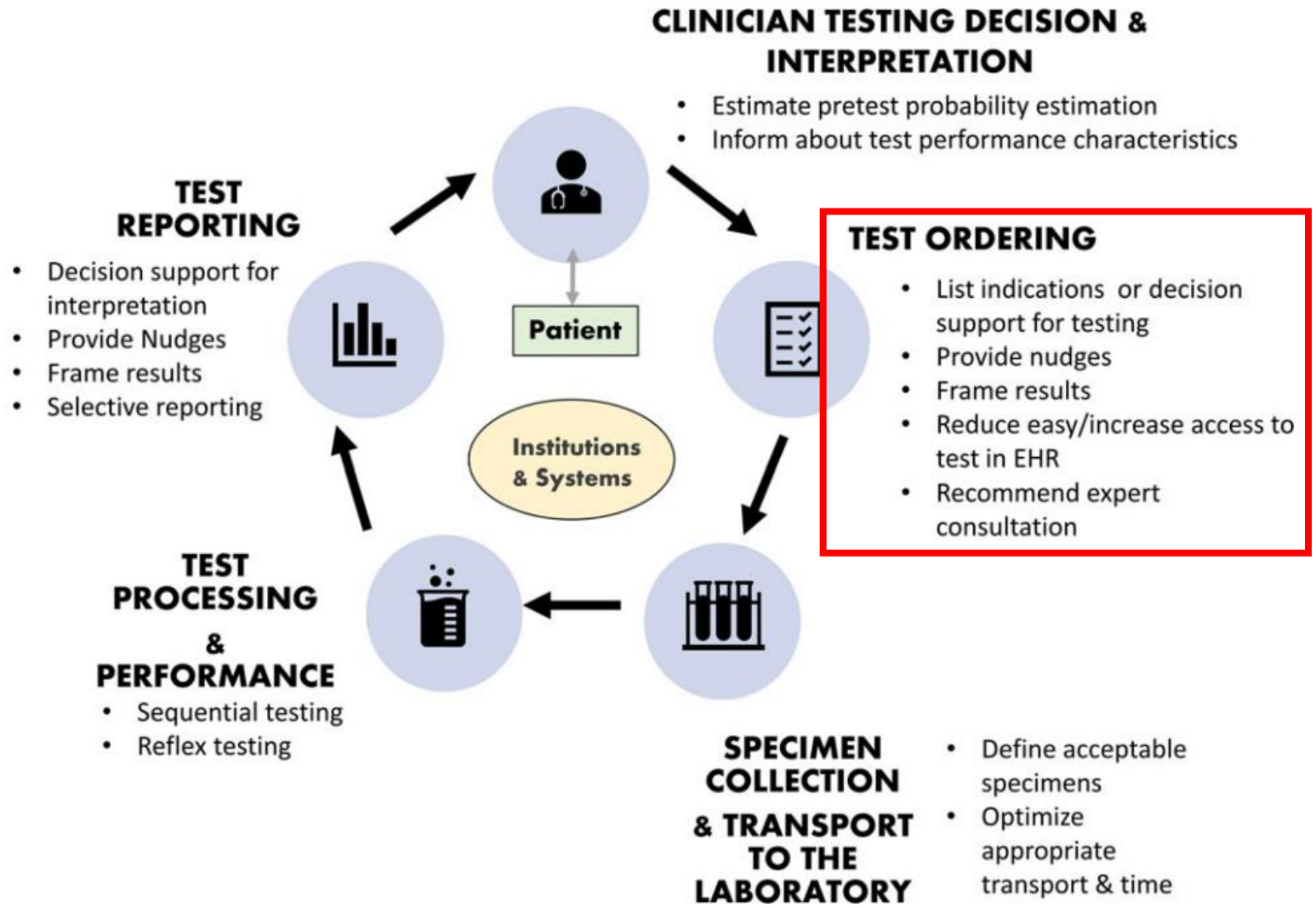
Conceptual Model of Diagnostic Stewardship



EHR Modification

- Informational alerts on utility of tests for various indications
- Requiring indication prior to ordering

***Example**: Decision support that requires documentation of symptoms prior to ordering urine culture*

- *Minimize overtreatment of asymptomatic bacteriuria (ASB)*
- *Minimize labor associated with workup of ASB*

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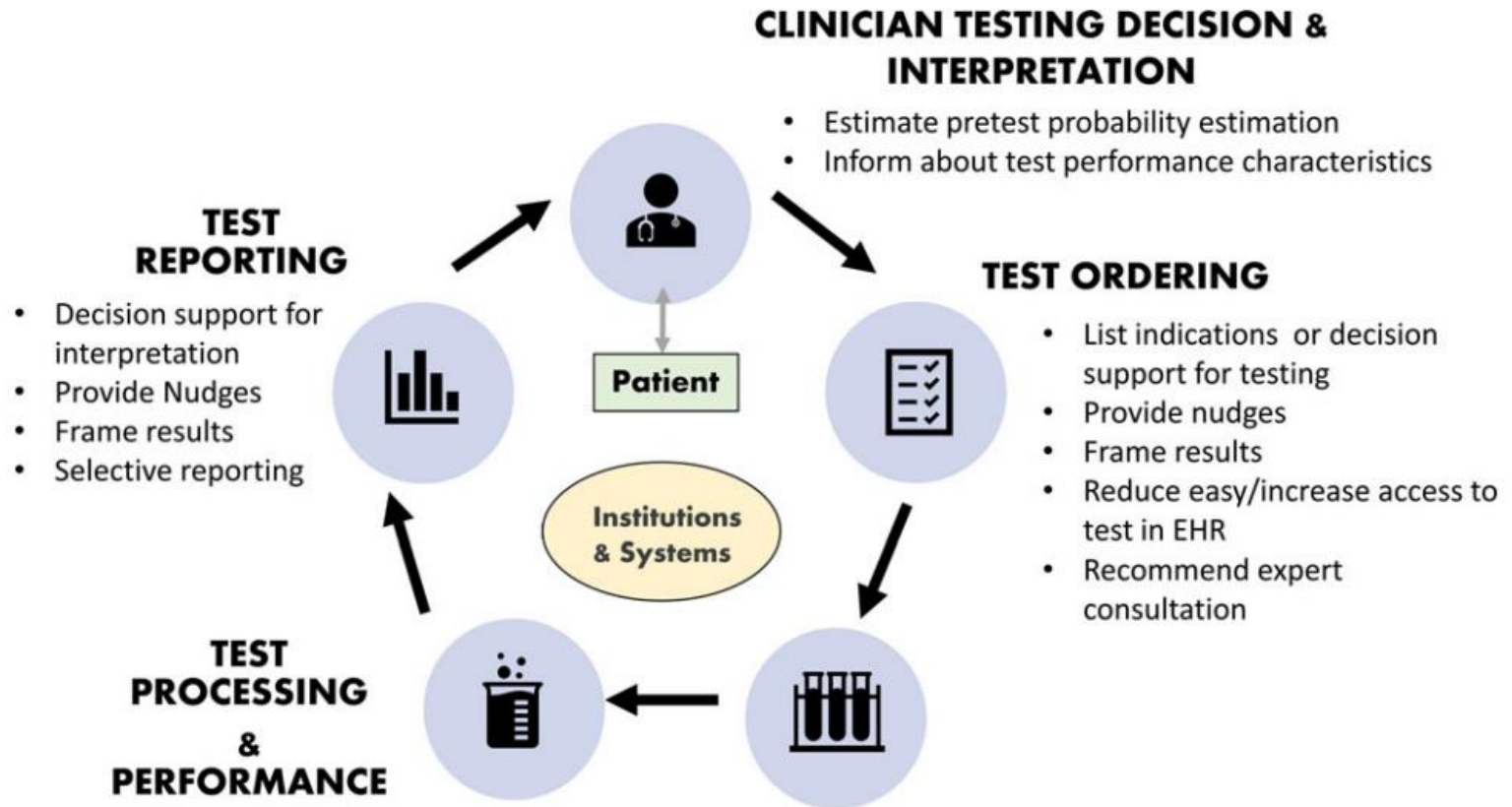
Conceptual Model of Diagnostic Stewardship



Education / Standard Procedures

- Standard operating procedures and training of staff for specimen collection
- Directions for collection and transport embedded in orderable

***Example**: Ensuring proper midstream clean-catch collection technique*

- *Reducing contamination and false-positive urine cultures*

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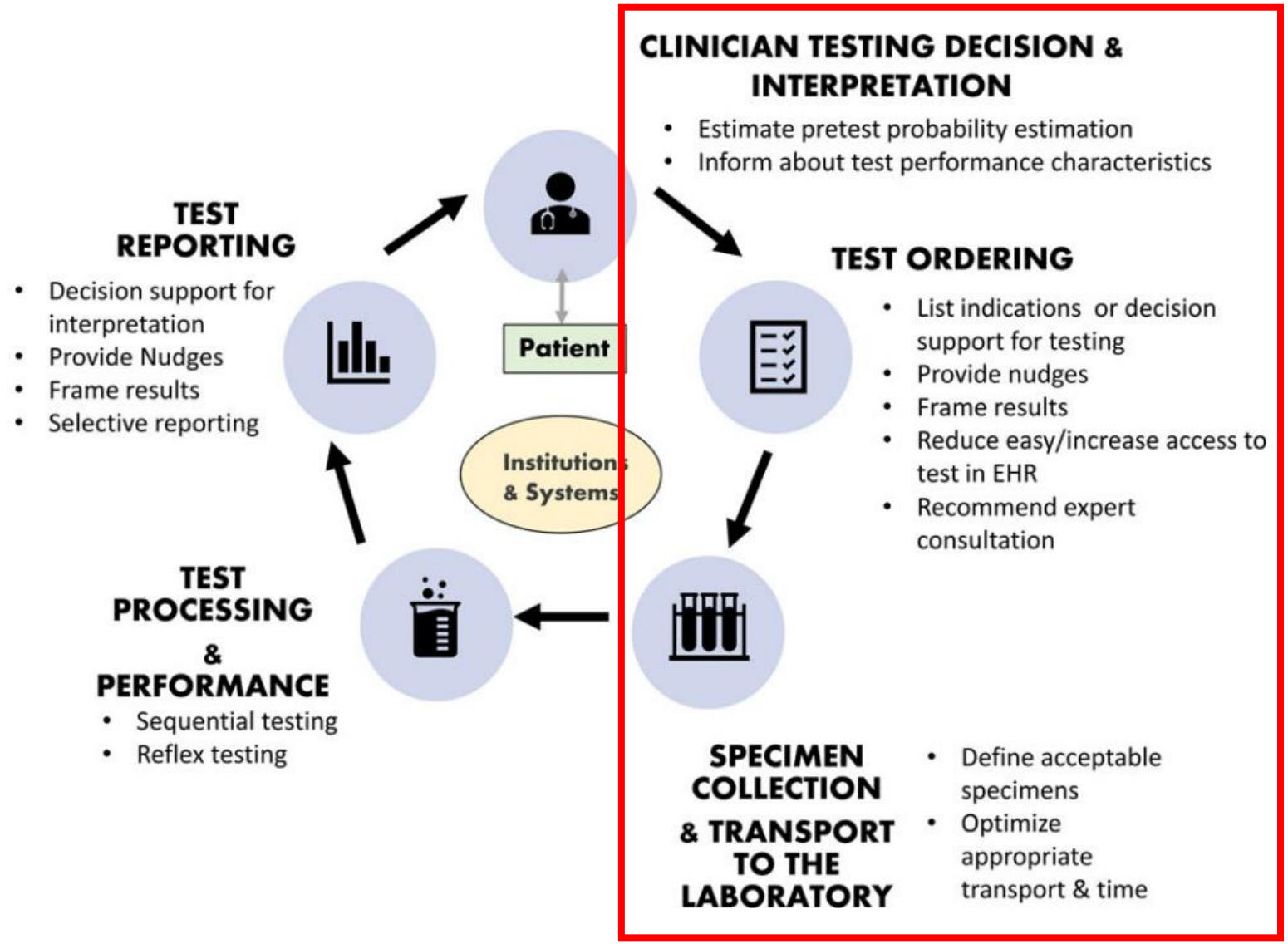
Conceptual Model of Diagnostic Stewardship



ONGOING EFFORTS

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Conceptual Model of Diagnostic Stewardship

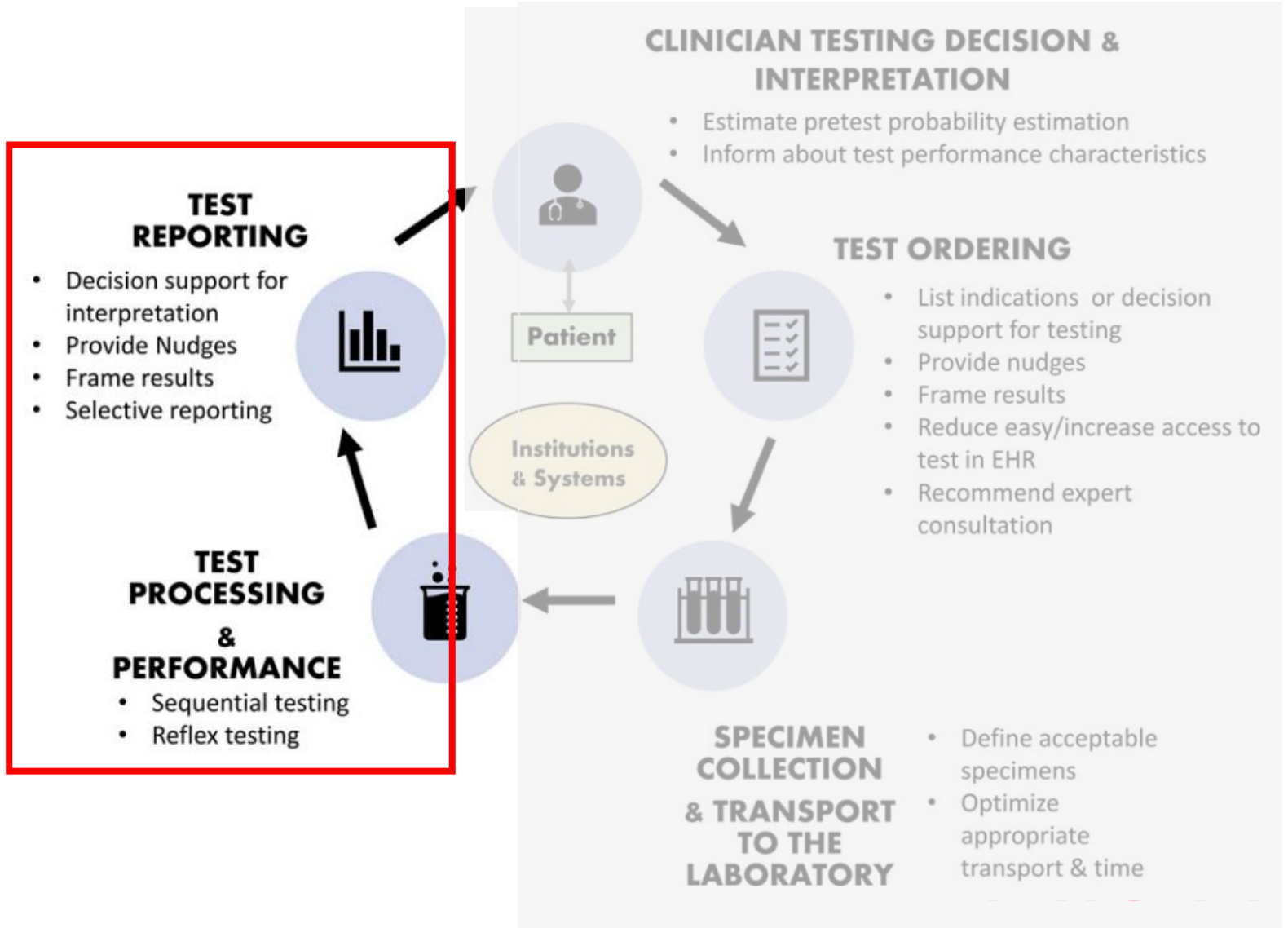
New Efforts?

Test Reporting

- Availability for comments to guide treatment decisions with urine PCR?
- *Need for tailored result reports?*

Test Processing and Performance

- Urine PCR performance characteristics in the real world?
- Ability to perform selective or reflex testing with Urine PCR?
- *Need for testing algorithm?*



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Urine PCR: The Story So Far...

Urine Polymerase Chain Reaction (PCR)

What is the Urine PCR?

- Laboratory-developed, non-FDA approved multiplex test that uses pathogen-specific primers
- Marketed to have rapid turn-around time and increased sensitivity compared to standard urine culture

What is the Associated Cost?

- Medicare analysis: Median PCR cost in 2023 was $585 (IQR $516-695) compared with $8 (IQR: $8-16) for a urine culture
  - Potential insurance caps and lower copays over time
  - Manufacturer specific
    - Some companies offering prices $100-200

What is included in urine PCR?

- Laboratory specific, tests for various organisms and resistance genes

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Zering J. *Antimicrob Steward Healthc Epidemiol*. 2024;4(1):e77
Hatfield KM. *JAMA Netw Open*. 2024;7(11):e2446842

Urine PCR Sample Reports

Vendor Sample Report

Pathogen Detected (1)

Pathogens	Relative Load
Enterobacter cloacae	HIGH

Resistance Gene Detected

Resistance Gene	Associated Resistances
Fluoroquinolones	Ciprofloxacin, Gemifloxacin, Levofloxacin, Moxifloxacin, Norfloxacin, Ofloxacin
Sulfonamides	Sulfadiazine, Sulfamethizole, Sulfamethoxazole, Sulfasalazine, Sulfisoxazole
Trimethoprim	Trimethoprim
Macrobid Comment	**Macrobid (nitrofurantoin) resistance has been seen in 30-65% of isolates based on the literature.**

Enterobacter cloacae

Antibiotic per CLSI M100	Drug Class
Amoxicillin-clavulanate	Penicillins
Ampicillin	Penicillin
Cefuroxime	Cephalosporins
Ciprofloxacin	Fluoroquinolone
Gentamicin	Aminoglycosides
Levofloxacin	Fluoroquinolone
Nitrofurantoin	Nitrofuran
Tetracycline	Tetracycline
Trimethoprim-sulfamethoxazole	Folate pathway inhibitor combination

Real Patient Data

Pathogen Detected (1)

Pathogens	Relative Load
E. coli	High

Resistance Gene Detected

Resistance Gene	Associated Resistances
Tetracycline (tetM)	Tetracyclines

E. coli

Antibiotic per CLSI M100	Drug Class
Ampicillin	Penicillin
Ampicillin-Sulbactam	Penicillin with beta-lactamase inhibitor
Cefazolin	First-generation cephalosporin
Ceftriaxone	Third-generation cephalosporin
Ciprofloxacin	Fluoroquinolone
Levofloxacin	Fluoroquinolone
Nitrofurantoin	Nitrofuran
Trimethoprim-sulfamethoxazole	Sulfonamide combination

Pathogen Detected (2)

Pathogens	Relative Load
S. agalactiae	Medium

Resistance Gene Detected

Resistance Gene	Associated Resistances
Tetracycline (tetM)	Tetracyclines

S. agalactiae

Antibiotic per CLSI M100	Drug Class
Ampicillin	Penicillin
Penicillin	Penicillin
Tetracycline	Tetracycline

Urine PCR Sample Reports

Vendor Sample Report

Pathogen Detected (1)	
Pathogens	**Relative Load**
Enterobacter cloacae	HIGH

Resistance Gene Detected	
Resistance Gene	**Associated Resistances**
Fluoroquinolones	Ciprofloxacin, Gemifloxacin, Levofloxacin, Moxifloxacin, Norfloxacin, Ofl
Sulfonamides	Sulfadiazine, Sulfa Sulfasalazine, Sulfiso
Trimethoprim	Trimethoprim
Macrobid Comment	**Macrobid (nitrofura 30-65% of isolates b**

Enterobacter cloacae	
Antibiotic per CLSI M100	**Drug Class**
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Ciprofloxacin	Fluoroquinolone
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Nitrofurantoin	Nitrofuran
Tetracycline	Tetracycline
Trimethoprim-sulfamethoxazole	Folate pathway inhibitor combination

* **Relative Load (PCR to Urine Culture CFU):**

Urine PCR Reported Result	CFU (Colony Forming Units) Equivalent
Low	1000 – 10,000
Medium	10,000 – 100,000
High	>100,000

First page(s) of report highlight direct results, including pathogen(s) identified and respective pathogen load*

Real Patient Data

Pathogen Detected (1)	
Pathogens	**Relative Load**
E. coli	High

Resistance Gene Detected	
Resistance Gene	**Associated Resistances**
Tetracycline (tetM)	Tetracyclines

E. coli	
Antibiotic per CLSI M100	**Drug Class**
	Penicillin
	Penicillin with beta-lactamase inhibitor
	First-generation cephalosporin
	Third-generation cephalosporin
	Fluoroquinolone
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Resistance Gene	**Associated Resistances**
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Urine PCR Sample Reports

Vendor Sample Report

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Tetracycline	Tetracycline
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Below, resistance genes detected for respective pathogen(s) identified. This includes any **intrinsic resistance***.

Organism	*Intrinsic Resistance Comment
K. Pneumoniae	*K. Pneumoniae* is intrinsically resistant to ampicillin
P. mirabilis	*P. Mirabilis* is intrinsically resistant to nitrofurantoin and tetracyclines

Real Patient Data

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S. agalactiae

Antibiotic per CLSI M100	Drug Class
Ampicillin	Penicillin
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Tetracycline	Tetracycline

Sample Reports

Vendor Sample Report

Lastly, antibiotic classes tested per CLSI for respective pathogen(s) identified

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Resistance Gene Detected

Resistance Gene	Associated Resistances
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Real Patient Data

Pathogen Detected (1)

	Relative Load
	High

Resistance Gene Detected

Resistance Gene	Associated Resistances
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Pathogen Detected (2)

Pathogens	Relative Load
S. agalactiae	Medium

Resistance Gene Detected

Resistance Gene	Associated Resistances
Tetracycline (tetM)	Tetracyclines

S. agalactiae

Antibiotic per CLSI M100	Drug Class
Ampicillin	Penicillin
Penicillin	Penicillin
Tetracycline	Tetracycline

Urine PCR Sample Reports

Vendor Sample Report

Test Name	Result	Relative Load	Reference Range/Cutoff
UTI53			**Run By on**
Acinetobacter baumannii	Not Detected		Not Detected
Candida albicans	Not Detected		Not Detected
Candida dubliniensis	Not Detected		Not Detected
Candida glabrata	Not Detected		Not Detected
Candida krusei	Not Detected		Not Detected
Candida parapsilosis	Not Detected		Not Detected
Candida tropicalis	Not Detected		Not Detected
Citrobacter freundii/braakii	Not Detected		Not Detected
Citrobacter koseri	Not Detected		Not Detected
Enterobacter cloacae	DETECTED	HIGH	Not Detected
Enterococcus spp.	Not Detected		Not Detected
Escherichia coli	Not Detected		Not Detected
Klebsiella aerogenes	Not Detected		Not Detected
Klebsiella oxytoca/ michiganesis	Not Detected		Not Detected
Klebsiella pneumoniae	Not Detected		Not Detected
Morganella morganii	Not Detected		Not Detected
Mycoplasma genitalium	Not Detected		Not Detected
Mycoplasma hominis	Not Detected		Not Detected
Prevotella bivia	Not Detected		Not Detected
Proteus mirabilis	Not Detected		Not Detected
Pseudomonas aeruginosa	Not Detected		Not Detected
Serratia marcescens	Not Detected		Not Detected
Staphylococcus aureus	Not Detected		Not Detected
Staphylococcus epidermidis	Not Detected		Not Detected
Staphylococcus saprophyticus	Not Detected		Not Detected
Streptococcus agalactiae (GBS)	Not Detected		Not Detected
Streptococcus pyogenes (Group A)	Not Detected		Not Detected
Ureaplasma urealyticum	Not Detected		Not Detected

Real Patient Data

Test Name	Result	Relative Load	Reference Range/Cutoff
UTI Pathogens			
E. coli	Detected	High	Not Detected
S. agalactiae	Detected	Medium	Not Detected
C. albicans	Not Detected		Not Detected
C. glabrata	Not Detected		Not Detected
C. krusei	Not Detected		Not Detected
C. parapsilosis	Not Detected		Not Detected
C. tropicalis	Not Detected		Not Detected
E. Faecium/E. Faecalis	Not Detected		Not Detected
K. pneumoniae	Not Detected		Not Detected
P. aeruginosa	Not Detected		Not Detected
P. mirabilis	Not Detected		Not Detected
S. aureus	Not Detected		Not Detected
S. saprophyticus	Not Detected		Not Detected

The following page(s) include a comprehensive list of pathogens included on PCR, with a summary of pathogen(s) detected and pathogen load

Organisms Not Included in Urgent Care PCR

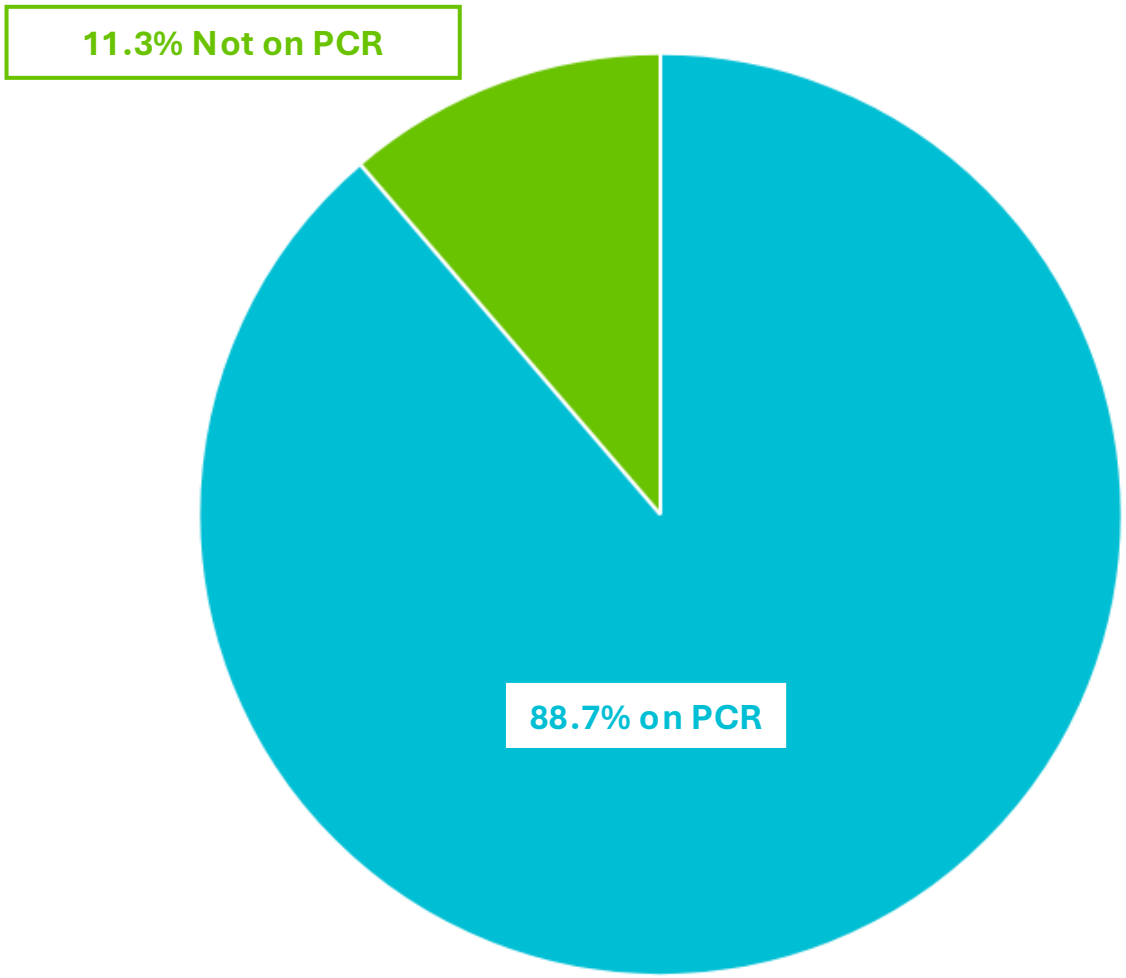
Test Name	Result	Relative Load	Reference Range/Cutoff
UTI53			Run By on
Acinetobacter baumannii	Not Detected		Not Detected
Candida albicans	Not Detected		Not Detected
Candida dubliniensis	Not Detected		Not Detected
Candida glabrata	Not Detected		Not Detected
Candida krusei	Not Detected		Not Detected
Candida parapsilosis	Not Detected		Not Detected
Candida tropicalis	Not Detected		Not Detected
Citrobacter freundii/braakii	Not Detected		Not Detected
Citrobacter koseri	Not Detected		Not Detected
Enterobacter cloacae	DETECTED	HIGH	Not Detected
Enterococcus spp.	Not Detected		Not
Escherichia coli	Not Detected		Not Detected
Klebsiella aerogenes	Not Detected		Not Detected
Klebsiella oxytoca/ michiganesis	Not Detected		Not Detected
Klebsiella pneumoniae	Not Detected		Not Detected
Morganella morganii	Not Detected		Not Detected
Mycoplasma genitalium	Not Detected		Not Detected
Mycoplasma hominis	Not Detected		Not Detected
Prevotella bivia	Not Detected		Not Detected
Proteus mirabilis	Not Detected		Not Detected
Pseudomonas aeruginosa	Not Detected		Not Detected
Serratia marcescens	Not Detected		Not Detected
Staphylococcus aureus	Not Detected		Not Detected
Staphylococcus epidermidis	Not Detected		Not Detected
Staphylococcus saprophyticus	Not Detected		Not Detected
Streptococcus agalactiae (GBS)	Not Detected		Not Detected
Streptococcus pyogenes (Group A)	Not Detected		Not Detected
Ureaplasma urealyticum	Not Detected		Not Detected

Impact of Organisms not Included in PCR?

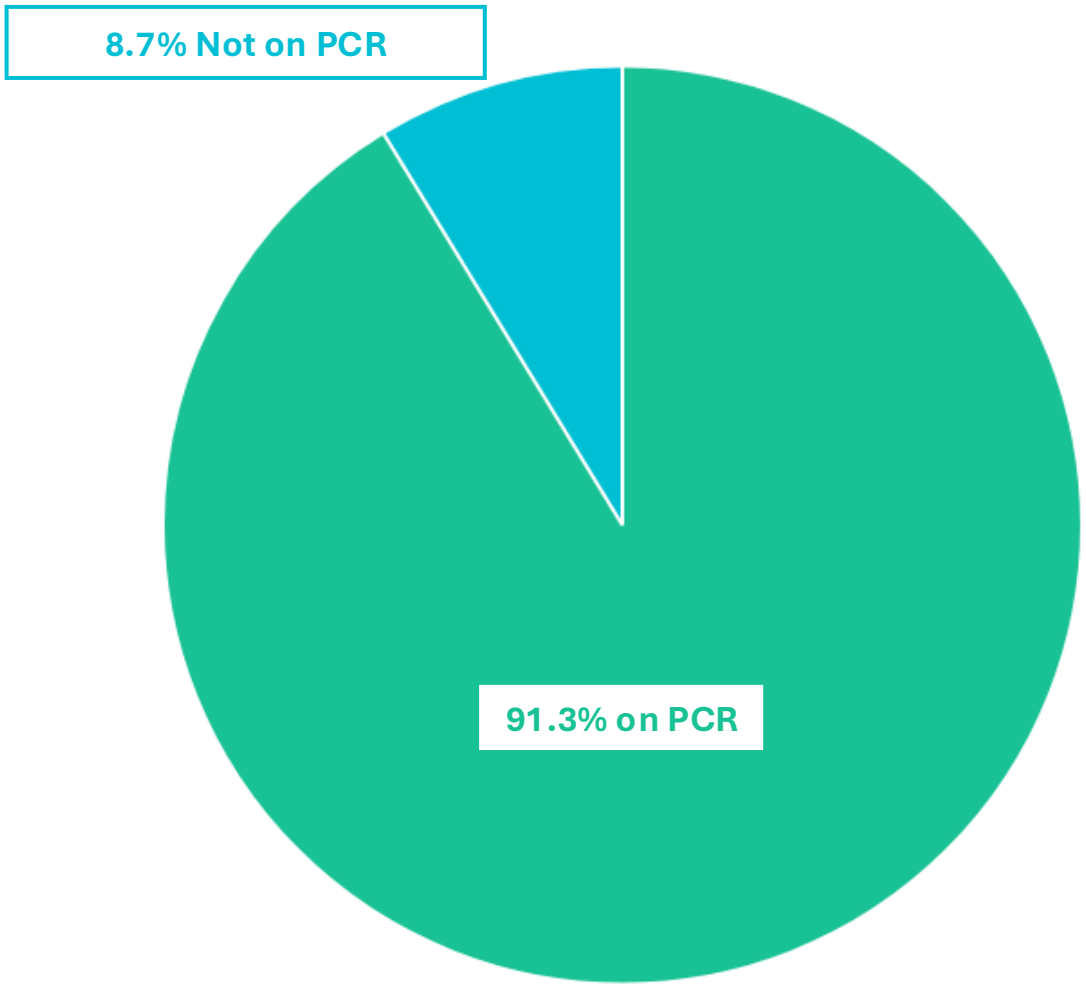
Organism, n	ED Cultures (N=67)	Total Cultures (N= 2,523)
A. baumanii	0	0
Candida spp.	0	47
C. freundii / C. braakii	1	36
C. koseri	1	17
E. cloacae	0	48
E. faecalis / E. faecium	**4**	**224**
E. coli	**49**	**1,442**
K. aerogenes	1	41
K. oxytoca / K. michiganensis	1	23
K. pneumoniae	**7**	**299**
M. morganii	1	13
P. bivia	0	0
P. mirabilis	**5**	**179**
P. aeruginosa	**2**	**92**
S. marcescens	0	24
S. aureus	1	63
S. epidermidis	3	19
S. saprophyticus	0	18
S. agalactiae	2	77
S. pyogenes	0	1

Impact of Organisms not Included in PCR?

ED Cultures by Organism



Total Cultures by Organism



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Urine PCR Sample Reports

Vendor Sample Report

Test Name	Result
Antibiotic Resistance - Enterobacter cloacae	
Class A Beta-lactamase (blaKPC)	Not Detected
Class A Beta-lactamase (CTX-M-Group 1)	Not Detected
Fluoroquinolones	DETECTED
Sulfonamides	DETECTED
Trimethoprim	DETECTED
Macrobid Comment	**Macrobid (nitrofurantoin) resistance has been seen in 30-65% of isolates based on the literature.**

The following page(s) include a comprehensive list of **resistance genes** included on PCR for each pathogen identified, with a summary of resistance genes detected for respective pathogen

Real Patient Data

Test Name	Result
Antibiotic Resistance - E. coli	
Class A Beta-lactamase (blaKPC)	Not Detected
Class A Beta-lactamase (blaSHV)	Not Detected
Class A Beta-lactamase (CTX-M-Group-1)	Not Detected
Class A Beta-lactamase (CTX-M-Group-9)	Not Detected
Class A Beta-lactamase (VEB)	Not Detected
Class B metallo-Beta-lactamase (blaNDM)	Not Detected
Class D Beta-lactamase (OXA-48)	Not Detected
Fluoroquinolones	Not Detected
Sulfonamides	Not Detected
Tetracycline (tetM)	Detected
Trimethoprim	Not Detected
Macrobid Comment	**Macrobid (nitrofurantoin) resistance not predicted.**

Test Name	Result
Antibiotic Resistance - S. agalactiae	
Tetracycline (tetM)	Detected

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Urine PCR Sample Report: Disclaimer

Real Patient Data

Test results must be evaluated with clinical symptoms to diagnose disease.

Antibiotic resistance marker testing is presented to illustrate which detected organisms could carry the genes detected per the Comprehensive Antibiotic Resistance Database as of May 2025. Due to the nature of the testing, it is not confirmed that these markers are carried by the representative organisms in the sample. In the event of a polymicrobial infection where multiple organisms could carry the same marker, it will be presented in the data for both organisms.

Associated Resistances listed on the report are antibiotics that the presence of detected resistance genes can confer resistance to. The antibiotics have not been tested for susceptibility or resistance against any detected organism.

Antibiotic tables provided are antibiotics standardly presented and tested in a culture and sensitivity report and are not actively tested for sensitivity against any detected organism in this test. Reported organism intrinsic resistance comments and the antibiotic tables are generated from CLSI M100 ED35:2025. Nitrofurantoin (Macrobid) sensitivity or resistance and its correlation with certain gene targets is pulled from the literature and does not guarantee sensitivity or resistance to the antibiotic. References are available upon request.

All tests established and validated by Laboratory and not FDA approved unless otherwise indicated. Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%. Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive. In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

End Of Report

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Urine PCR Supporting Data

Two-part analysis of the clinical utility of urine PCR testing compared with conventional culture and sensitivity in **complicated UTI (cUTI)**

Study Population Eligibility Criteria

- Adults presenting with **cUTI signs / symptoms** at initial visit
- Urine specimen with evidence of pyuria
- Having cUTI requiring microbiological diagnosis and treatment as suspected by investigator
- Symptomatic patients presenting with pyuria and identified as **high-risk patient population**

At least two:

- Fever, hypothermia, rigors, or chills
- Dysuria, urinary frequency, urgency, or hematuria
- Suprapubic pain or pelvic pain
- Costovertebral angle (CVA) tenderness
- Nausea / vomiting
- Radiographic evidence of pyelonephritis
- Leukocytosis

Higher risk of UTI complications:

- ≥ 65 years of age
- Male
- Pregnant
- ≥ 3 UTI episodes in past 12 months
- Underlying comorbidities (i.e., DM, CKD)
- Functional / anatomic abnormalities of urinary tract
- Persistent infection after primary therapy

Spangler FL. *Diagn Microbiol Infec Dis*. 2025;111(1):116601
Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(3):116646.
Kardjadj M. *Microorganisms*. 2025;13(4):949

Urine PCR Supporting Data

Two-part analysis of the clinical utility of urine PCR testing compared with conventional culture and sensitivity in **complicated UTI (cUTI)**

Part 1: Assessment of clinical outcomes, investigator satisfaction scores, and turnaround times

Part 2: Evaluation of diagnostic concordance, discordant results, and antimicrobial selection efficacy

Ad Hoc Analysis completed with focus on impact of PCR on pathogen detection, polymicrobial case identification, antibiotic resistance profiling, treatment decisions, and clinical outcomes

PRISMA

Spangler FL. *Diagn Microbiol Infec Dis*. 2025;111(1):116601
Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(3):116646.
Kardjadj M. *Microorganisms*. 2025;13(4):949

Urine PCR Supporting Data: Phase 1

Population	• **Adults meeting eligibility criteria who presented to urology clinics** *Modified ITT at EOS* • *Both PCR and C&S with positive results* • *Completed follow up with test of cure*

PRISMA

Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(1):116601

Urine PCR Supporting Data: Phase 1

Population	• **Adults meeting eligibility criteria who presented to urology clinics** *Modified ITT at EOS* • *Both PCR and C&S with positive results* • *Completed follow up with test of cure*
Intervention	• Culture and susceptibility (standard of care) • Polymerase chain reaction (intervention) • Includes targets for 28 pathogens and 16 resistance genes ***C&S and PCR were performed for all patients, and investigators were blinded to comparator test results throughout trial*

PRISMA

Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(1):116601

Urine PCR Supporting Data: Phase 1

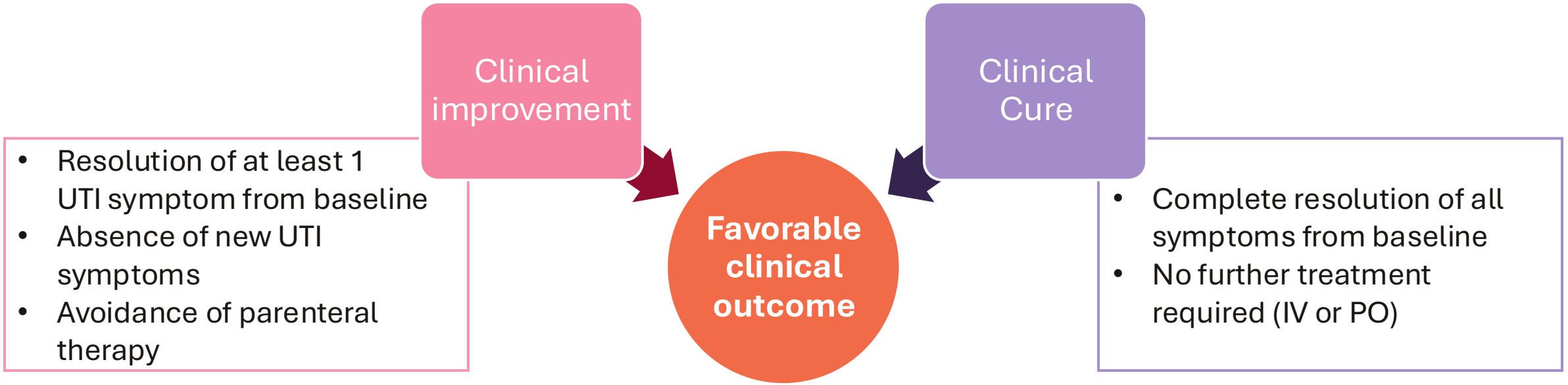
Population	• **Adults meeting eligibility criteria who presented to urology clinics** *Modified ITT at EOS* • *Both PCR and C&S with positive results* • *Completed follow up with test of cure*
Intervention	• Culture and susceptibility (standard of care) • Polymerase chain reaction (intervention) • Includes targets for 28 pathogens and 16 resistance genes ***C&S and PCR were performed for all patients, and investigators were blinded to comparator test results throughout trial*
End Points	**Primary** • Favorable clinical outcomes (FCl) at EOS **Secondary** • Microbiologic eradication at EOS, investigator satisfaction score at EOS, comparison of turnaround time between molecular and conventional diagnostic tools

PRISMA

Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(1):116601

Urine PCR Supporting Data: Phase 1

End Points	**Primary** • **Favorable clinical outcomes (FCI)** at EOS **Secondary** • Microbiologic eradication at EOS, investigator satisfaction score at EOS, comparison of turnaround time between molecular and conventional diagnostic tools



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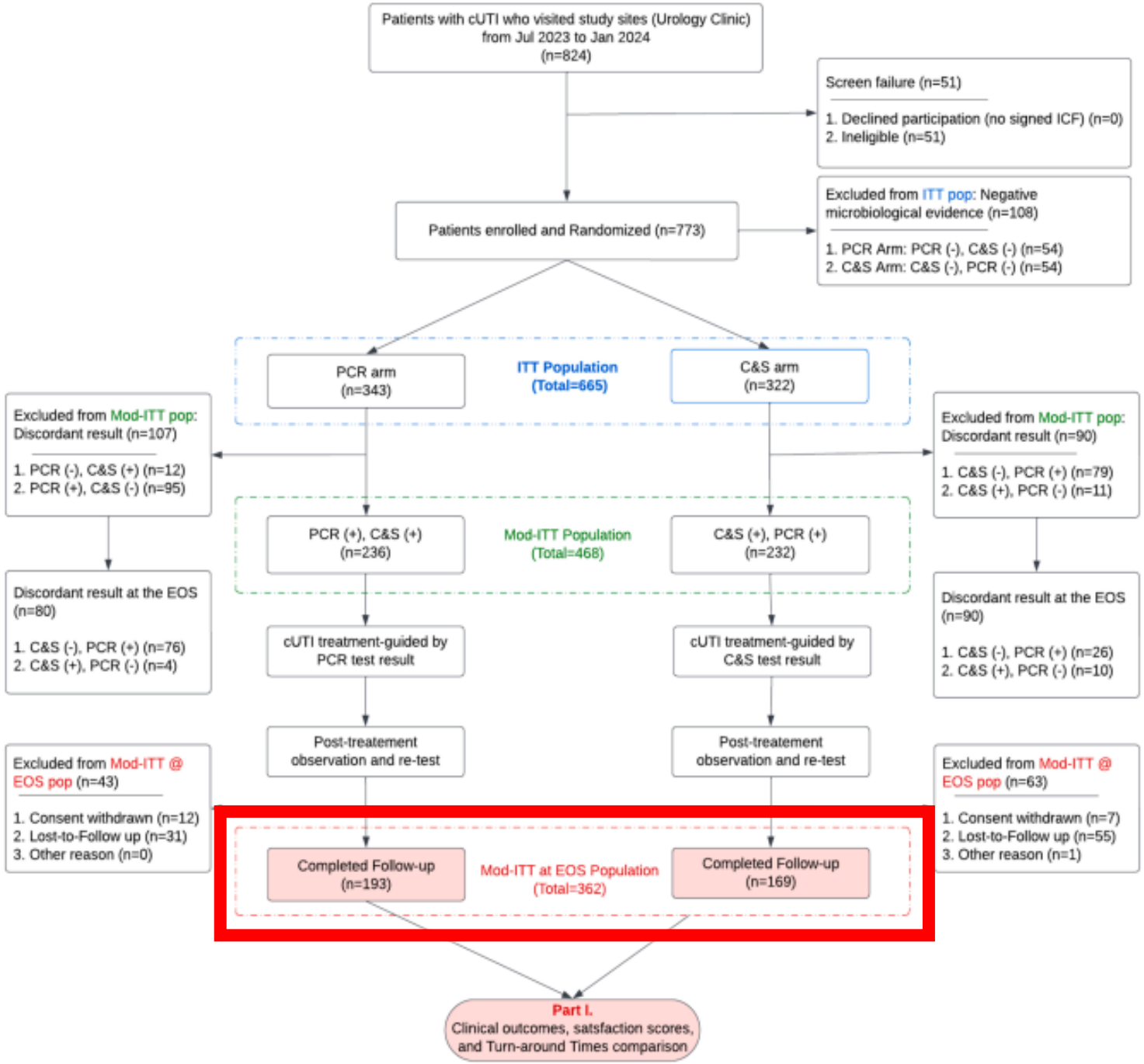
Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(1):116601

Urine PCR Phase 1



Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(1):116601

Urine PCR Supporting Data: Phase 1

Primary Outcome	PCR (n=193)	C&S (n=169)	P value
FCI, n (%)	**170 (88.08)**	**132 (78.11)**	**0.011**

Secondary Outcome	PCR (n=193)	C&S (n=169)	P value
Microbiological eradication, n (%)	120 (62.18)	95 (56.21)	0.24
Investigator satisfaction score, Total Score / 25, mean ± SD	23.95 ± 1.96	20.64 ± 4.12	**< 0.001**
Turnaround time, h, mean	49.25	105.6	**< 0.001**

PRISMA

Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(1):116601

Urine PCR Supporting Data: Phase 2

Population	• Two groups from Phase 1
	  • Patients with discordant results at EOS
	  • Modified ITT at EOS population
	• Sub-study population
	  • Patients who visited urology clinics without signs / symptoms of UTI

PRISMA

Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(3):116646

Urine PCR Supporting Data: Phase 2

Population	• Two groups from Phase 1
	  • Patients with discordant results at EOS
	  • Modified ITT at EOS population
	• Sub-study population
	  • Patients who visited urology clinics without signs / symptoms of UTI

Intervention	• Culture and susceptibility (standard of care) • Polymerase chain reaction (intervention) • Includes targets for 28 pathogens and 16 resistance genes ***C&S and PCR were performed for all patients, and investigators were blinded to comparator test results throughout trial*

PRISMA

Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(3):116646

Urine PCR Supporting Data: Phase 2

Population	• Two groups from Phase 1
	  • Patients with discordant results at EOS
	  • Modified ITT at EOS population
	• Sub-study population
	  • Patients who visited urology clinics without signs / symptoms of UTI

Intervention	• Culture and susceptibility (standard of care) • Polymerase chain reaction (intervention) • Includes targets for 28 pathogens and 16 resistance genes ***C&S and PCR were performed for all patients, and investigators were blinded to comparator test results throughout trial*
End Points	• Overall agreement between PCR and C&S results • Positive percent agreement **(PPA)** and negative percent agreement **(NPA)** • Frequency of **clinically significant infections in patients with discordant results**

PRISMA

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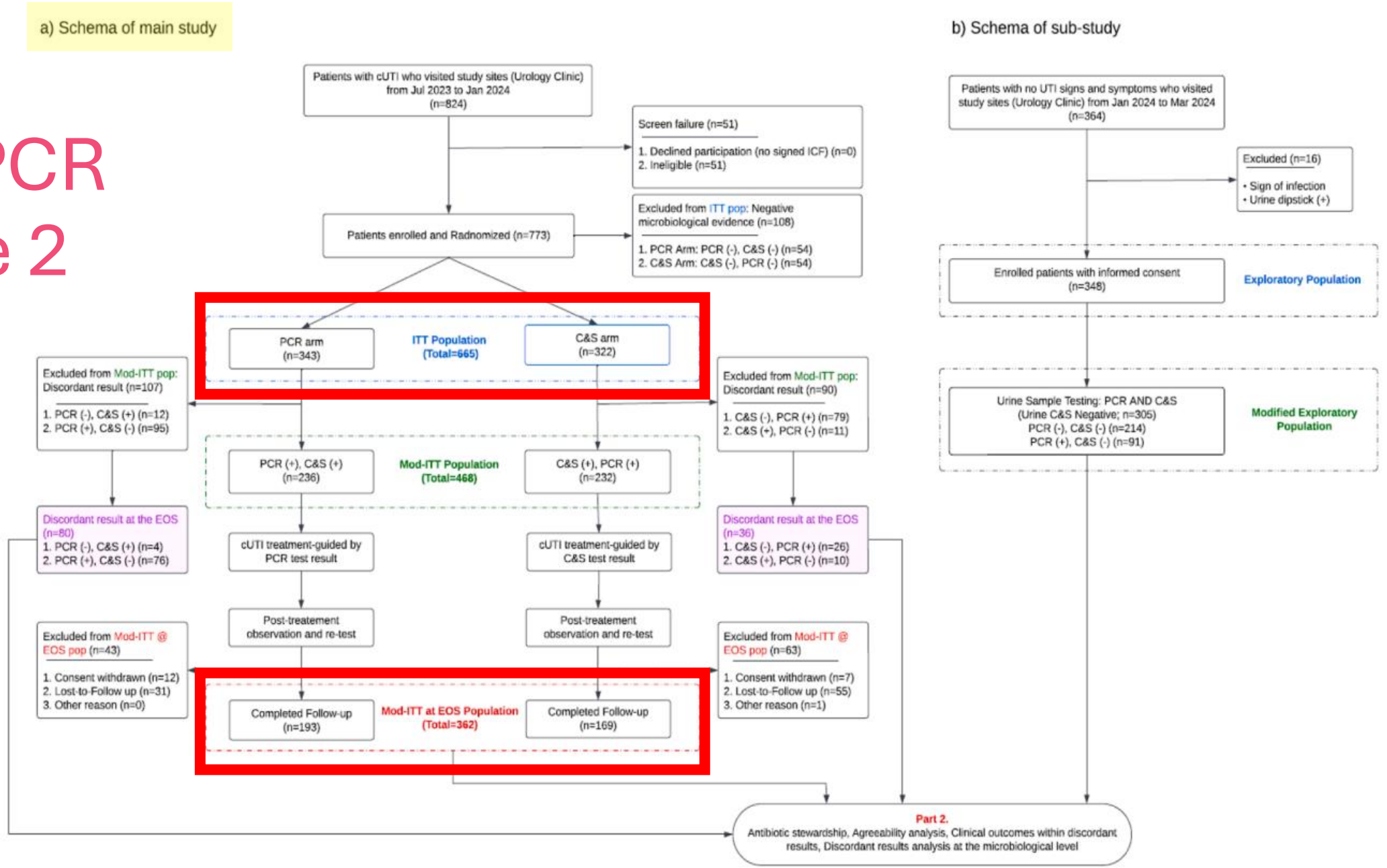
Urine PCR Phase 2



Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(3):116646

Urine PCR Supporting Data: Phase 2

Overall agreeability in ITT population (Visit 1)

PCR	C&S		Total
	Positive	Negative	
Positive	468	174	642
Negative	23	108	131
Total	491	282	773

Positive percent agreement: 95.32%

Negative percent agreement: 38.30%

Overall agreeability in Mod-ITT at EOS population (Visit 3)

PCR	C&S		Total
	Positive	Negative	
Positive	177	122	299
Negative	24	207	231
Total	201	329	530

Positive percent agreement: 88.06%

Negative percent agreement: 62.91%

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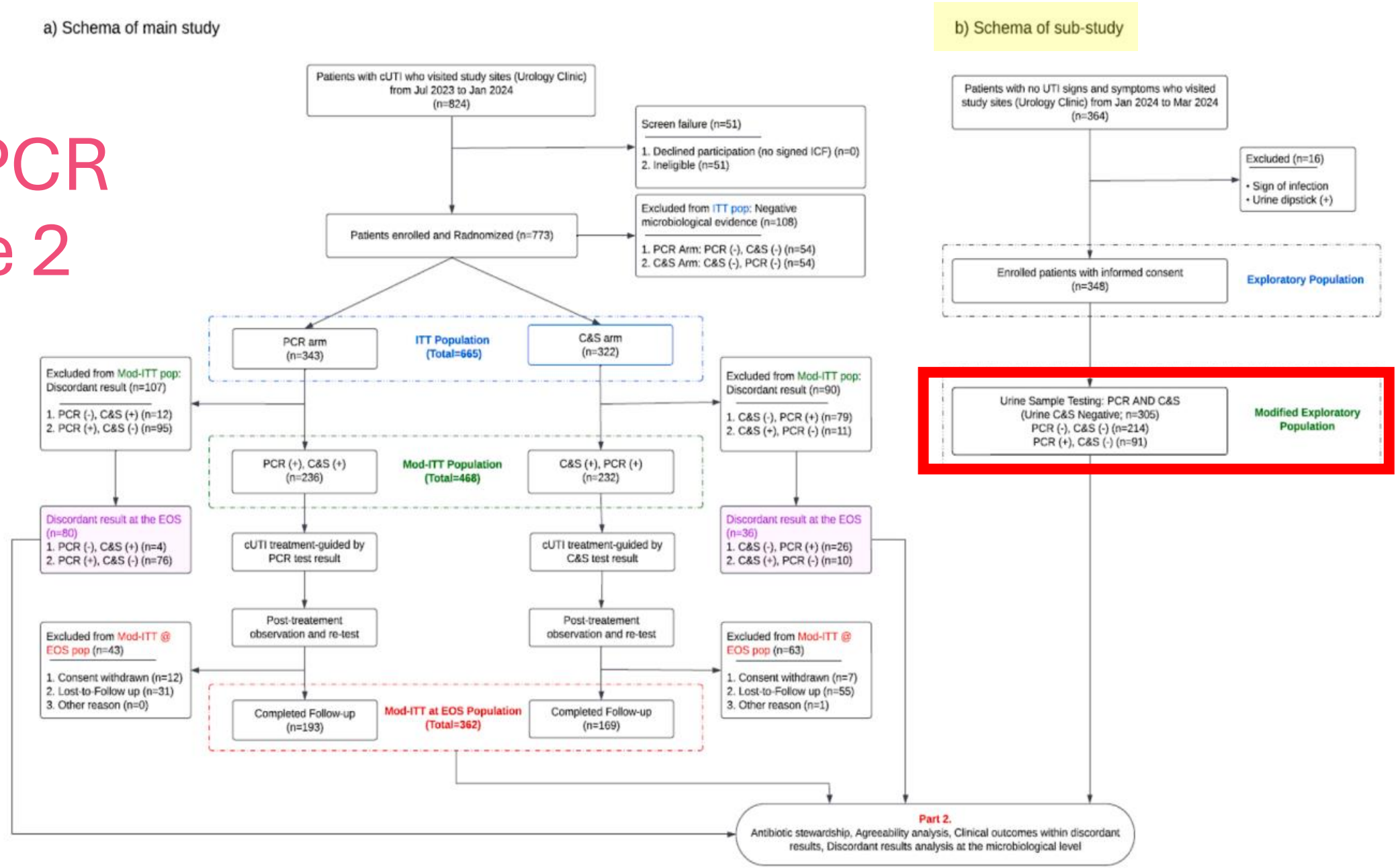
Urine PCR Phase 2



Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(3):116646

Urine PCR Supporting Data: Phase 2

Overall agreeability in Sub-Study Population *(Healthy)*

C&S	PCR		Total
	Positive	Negative	
Negative	91	**214**	305

Negative percent agreement: 70.16%

PRISMA

Spangler FL. *Diagn Microbiol Infect Dis*. 2025;111(3):116646

Urine PCR Supporting Data: Ad Hoc Analysis

Population	• **Enrolled population**
	  • All enrolled and randomized patients with available results
		• **EOS Population**
		  • All enrolled patients who completed the study procedures

PRISMA

Kardjadj M. *Microorganisms*. 2025;13(4):949

Urine PCR Supporting Data: Ad Hoc Analysis

Population	• **Enrolled population**
	  • All enrolled and randomized patients with available results
		• **EOS Population**
		  • All enrolled patients who completed the study procedures

Intervention	• Culture and susceptibility (standard of care) • Polymerase chain reaction (intervention) • Includes targets for 28 pathogens and 16 resistance genes ***C&S and PCR were performed for all patients, and investigators were blinded to comparator test results throughout trial*	

PRISMA

Kardjadj M. *Microorganisms*. 2025;13(4):949

Urine PCR Supporting Data: Ad Hoc Analysis

Population	• **Enrolled population**
	  • All enrolled and randomized patients with available results
		• **EOS Population**
		  • All enrolled patients who completed the study procedures

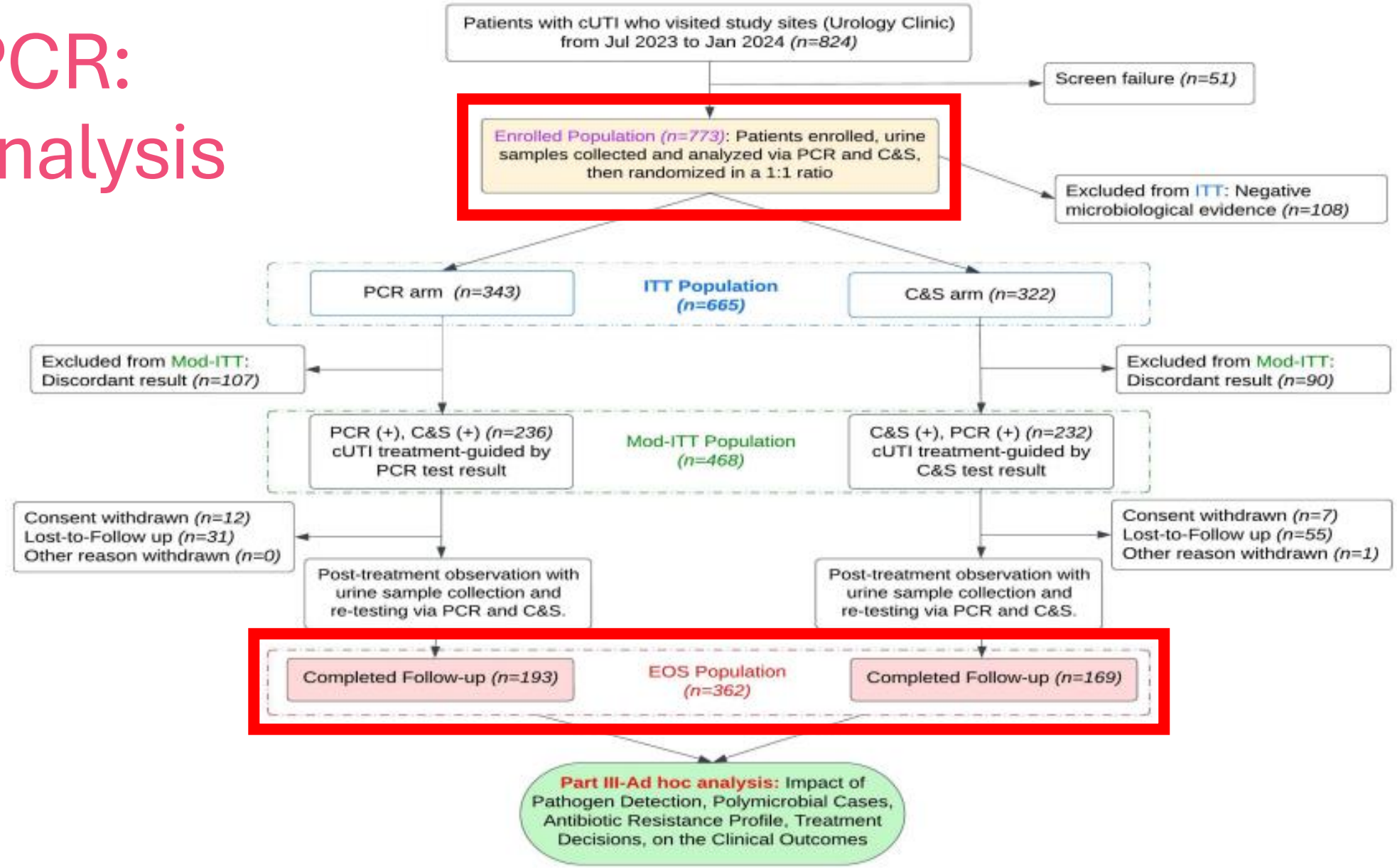
Intervention	• Culture and susceptibility (standard of care) • Polymerase chain reaction (intervention) • Includes targets for 28 pathogens and 16 resistance genes ***C&S and PCR were performed for all patients, and investigators were blinded to comparator test results throughout trial*	

End Points	• **PCR performance** at the start of the study
	  • **Sensitivity and specificity**
		• **PCR performance at EOS**
		• **Impact of PCR** on
		  • Polymicrobial case identification
		  • Pathogen detection
		  • Antibiotic resistance detection

PRISMA

Kardjadj M. *Microorganisms*. 2025;13(4):949

Urine PCR: Ad-Hoc Analysis



Kardjadj M. *Microorganisms*. 2025;13(4):949

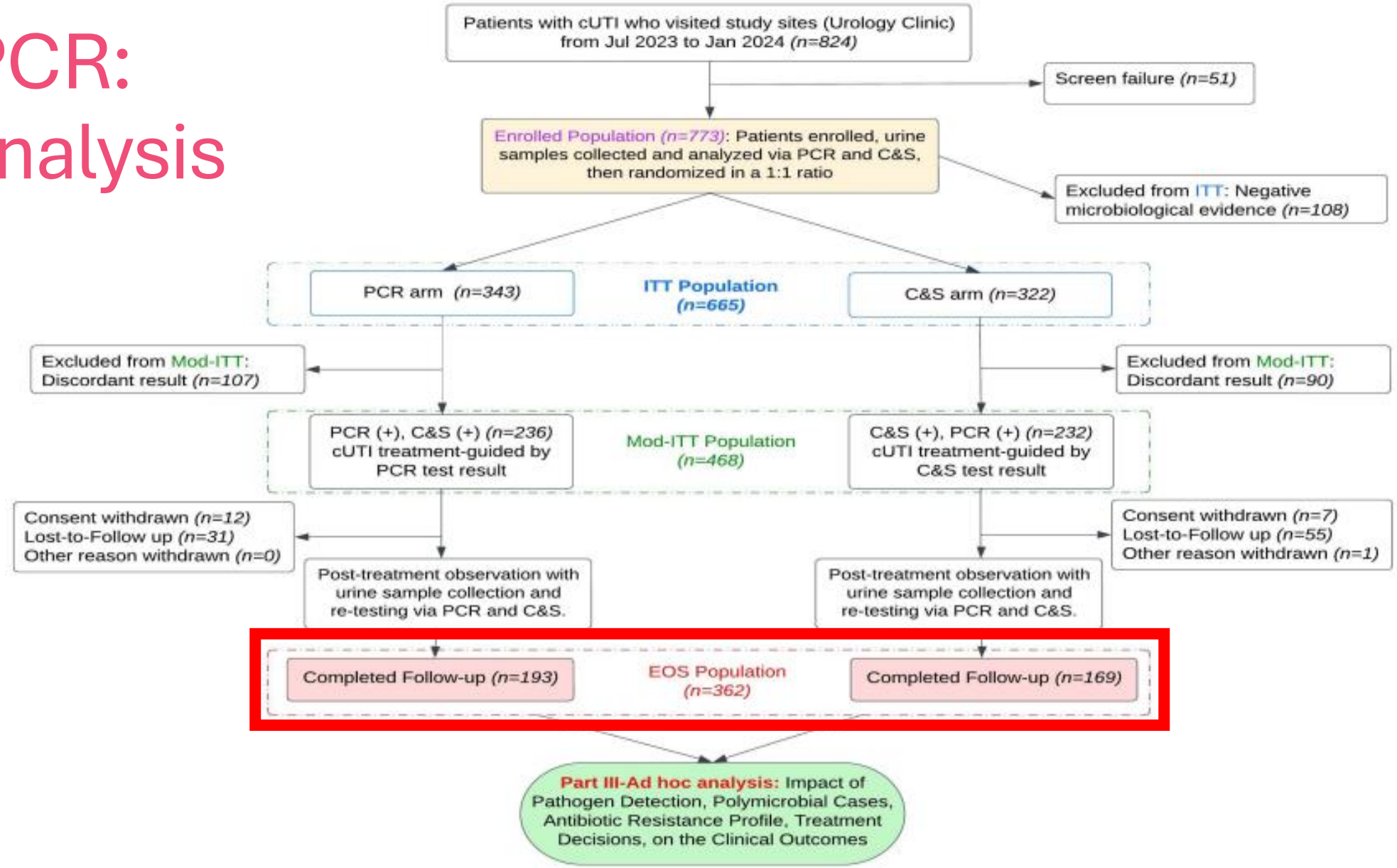
Urine PCR Supporting Data: Ad Hoc Analysis

Population	Enrolled Population (n=773)		EOS Population (n=362)	
	Sensitivity	Specificity	Sensitivity	Specificity
Overall	**95.32%**	**38.30%**	**88.06%**	**62.91%**
Monomicrobial Infection	95.12%	38.56%	88.23%	62.55%
Polymicrobial Infection	96.66%	37.89%	87.57%	63.89%
Elderly (≥ 65 yrs)	94.47%	38.35%	85.12%	62.45%
Non-Elderly (< 65 yrs)	96.32%	39.12%	88.74%	63.88%
Male	95.71%	37.23%	86.72%	61.58%
Female	95.42%	39.47%	84.71%	64.25%

PRISMA

Kardjadj M. *Microorganisms*. 2025;13(4):949

Urine PCR: Ad-Hoc Analysis



Kardjadj M. *Microorganisms*. 2025;13(4):949

Urine PCR Supporting Data: Ad Hoc Analysis

	Monomicrobial		Polymicrobial	
	Detection	FCI	Detection	FCI
C&S Arm	115 (68.05%)	90 (78.26%)	54 (31.95%)	42 (77.78%)
PCR Arm	109 (56.48%)	93 (85.32%)	84 (43.52%)	77 (91.67%)

RR for clinical failure in C&S arm was 1.83 (p=0.035)

	CF in Cases with Missed Pathogen Identification	CF in Cases with Concordant Pathogen Identification
C&S Arm	26 / 92 (28.26%)	11 / 77 (14.29%)
PCR Arm	7 / 84 (8.34%)	16 / 109 (14.68%)

RR for clinical failure in C&S arm was 2.16 (p=0.010)

	CF for Cases with Undetected Phenotypic Resistance	CF in Cases with Concordant Resistance Detected
C&S Arm	16 / 42 (50%)	21 / 121 (13.22%)
PCR Arm	6 / 48 (12.5%)	17 / 155 (10.98%)

RR for clinical failure in C&S arm was 2.31 (p=0.014)

PRISMA

Kardjadj M. *Microorganisms*. 2025;13(4):949

Urine PCR Supporting Data: Ad Hoc Analysis

	Monomicrobial		Polymicrobial	
	Detection	FCI	Detection	FCI
C&S Arm	115 (68.05%)	90 (78.26%)	54 (31.95%)	42 (77.78%)
PCR Arm	109 (56.48%)	93 (85.32%)	84 (43.52%)	77 (91.67%)

RR for clinical failure in C&S arm was 1.83 (p=0.035)

Common pathogens missed:
E. faecium / E. faecalis, G. vaginalis, C. freundii, Candida spp., *Staphylococcus* spp.

RR for clinical failure in C&S arm was 2.16 (p=0.010)

N=16 cases where C&S failed to detect key resistance mechanisms. **N=8 due to a missed pathogen on C&S**

RR for clinical failure in C&S arm was 2.31 (p=0.014)

PRISMA

Kardjadj M. *Microorganisms*. 2025;13(4):949

Urine PCR Literature Summary

- Urine PCR testing has exhibited higher favorable outcomes and more rapid turnaround times compared with standard C&S
- Urine PCR testing exhibits high PPA with C&S but low NPA, and demonstrates high sensitivity
- Despite a limited panel, urine PCR testing has been associated with identifying more pathogens, including polymicrobial results and reducing the risk of clinical failure attributed to missed phenotypic resistance

Spangler FL. *Diagn Microbiol Infec Dis*. 2025;111(1):116601
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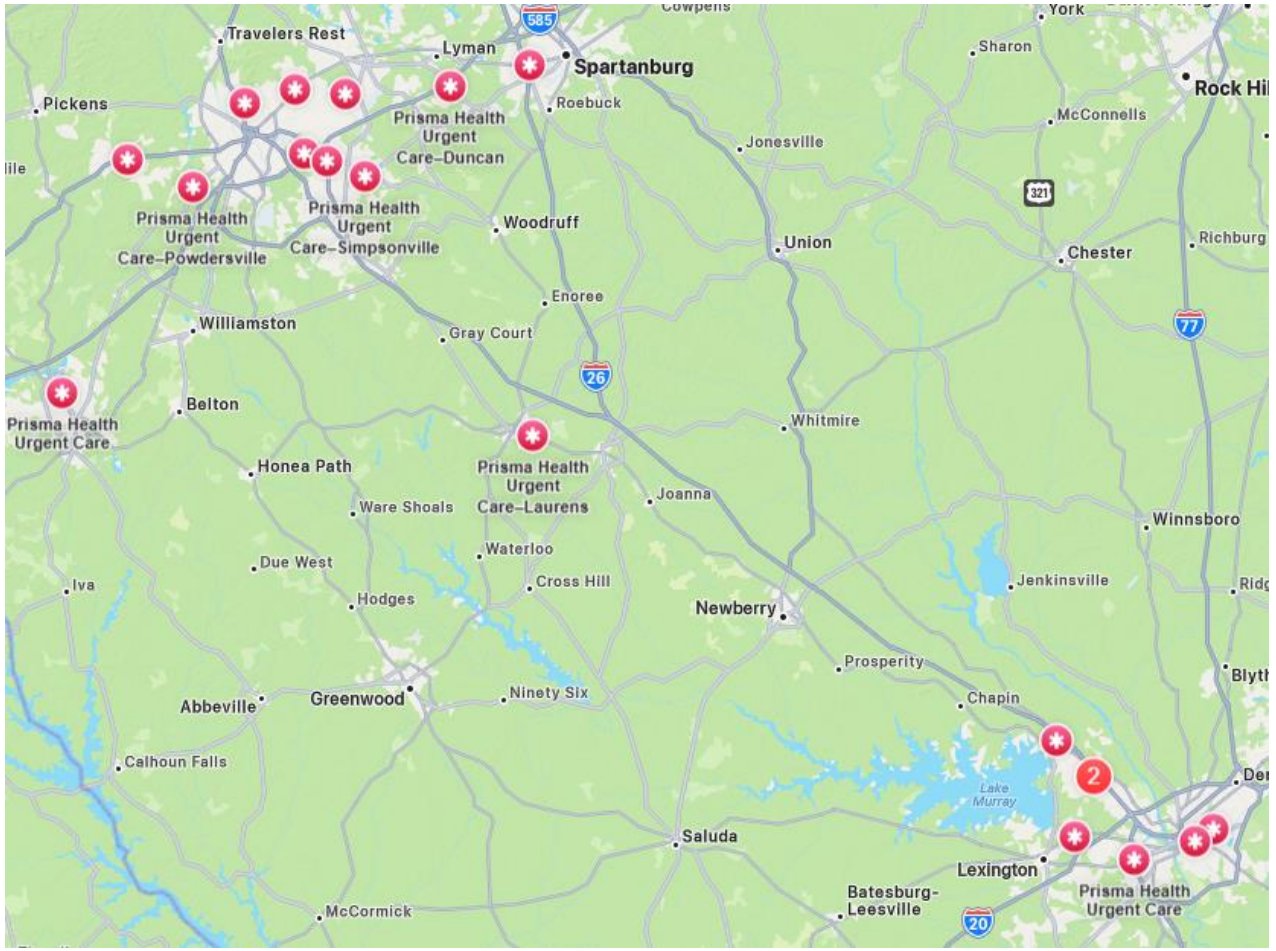
PRISMA

Objective: Evaluate limitations and potential areas for improvement in processing and reporting of urine PCR tests

Background

- Prisma Health Urgent Cares
  - Open 8am – 8pm 7 days / week
  - 27 clinics (and growing!)
  - Walk-in, appointment, virtual visits
- Woodruff location – Physician operated laboratory
  - Urine Polymerase Chain Reaction Testing center



Urine PCR Evaluation: Objectives

- Evaluate percent positivity of urine PCR and impact on prescribing before / after results
- Observe reporting of PCR results to determine potential areas for improvement
- Convenience sample: Evaluate appropriateness of ordering and prescribing based on patient presentation and PCR results

PRISMA

Urine PCR Evaluation: Methods

- Report from SlicerDicer of patients with urine PCR ordered at all Prisma Health Urgent Cares
- Data Collection:

Total Population (All patients March 1 – March 23, 2026)

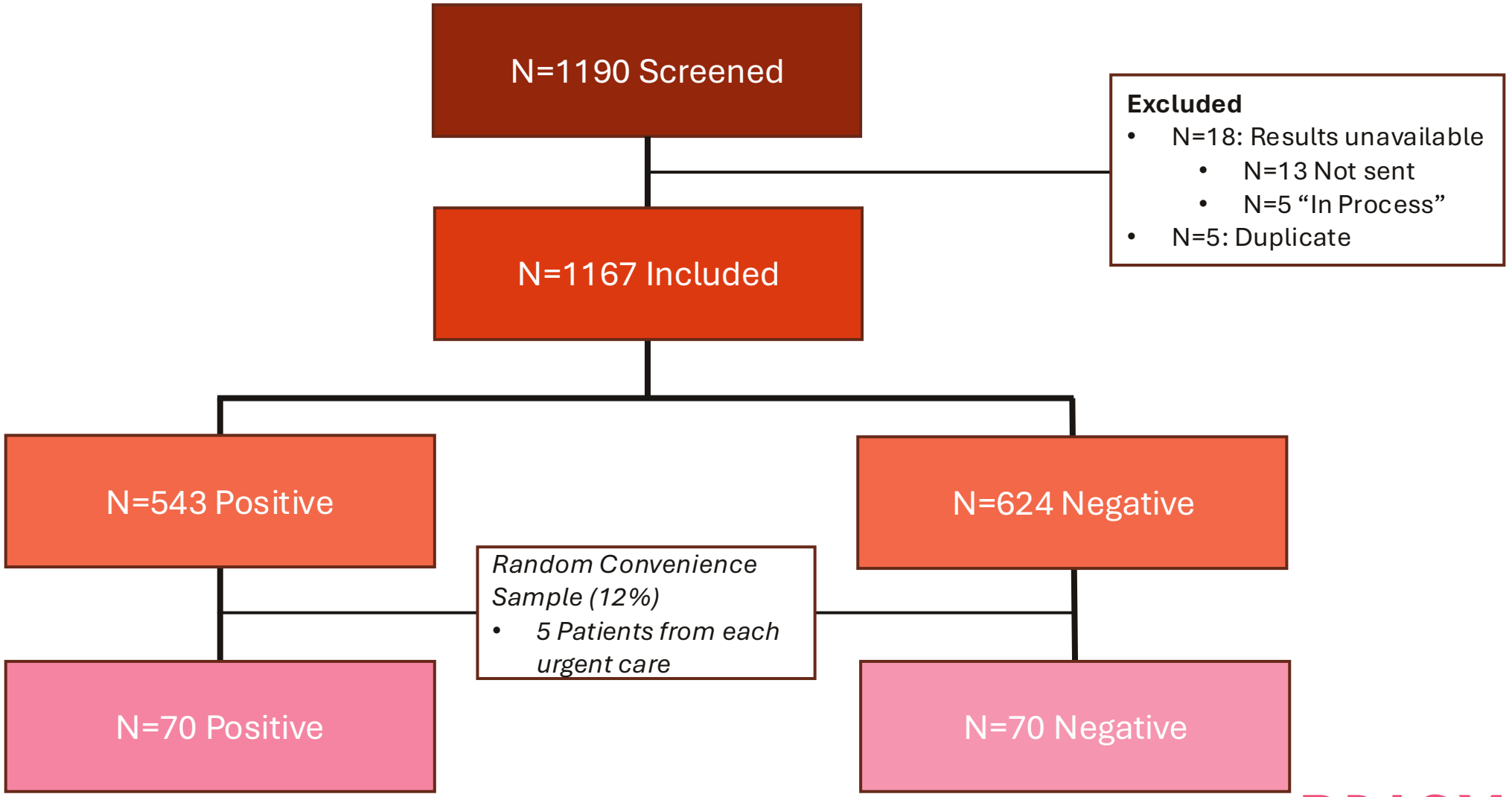
- Age, Sex, Turnaround Time, Result (positive/negative, organism(s), level of growth, resistance genes), Antibiotics prior to result, Change in antibiotics based on result

Convenience Sample (~ 12%)

- Total Population data points + Baseline urologic abnormalities, Pregnancy, LUTS, UA abnormal, Other micro tests ordered, Primary diagnosis, Other antimicrobials prescribed before / after results
- Appropriateness of ordering and antibiotics prior to and after results

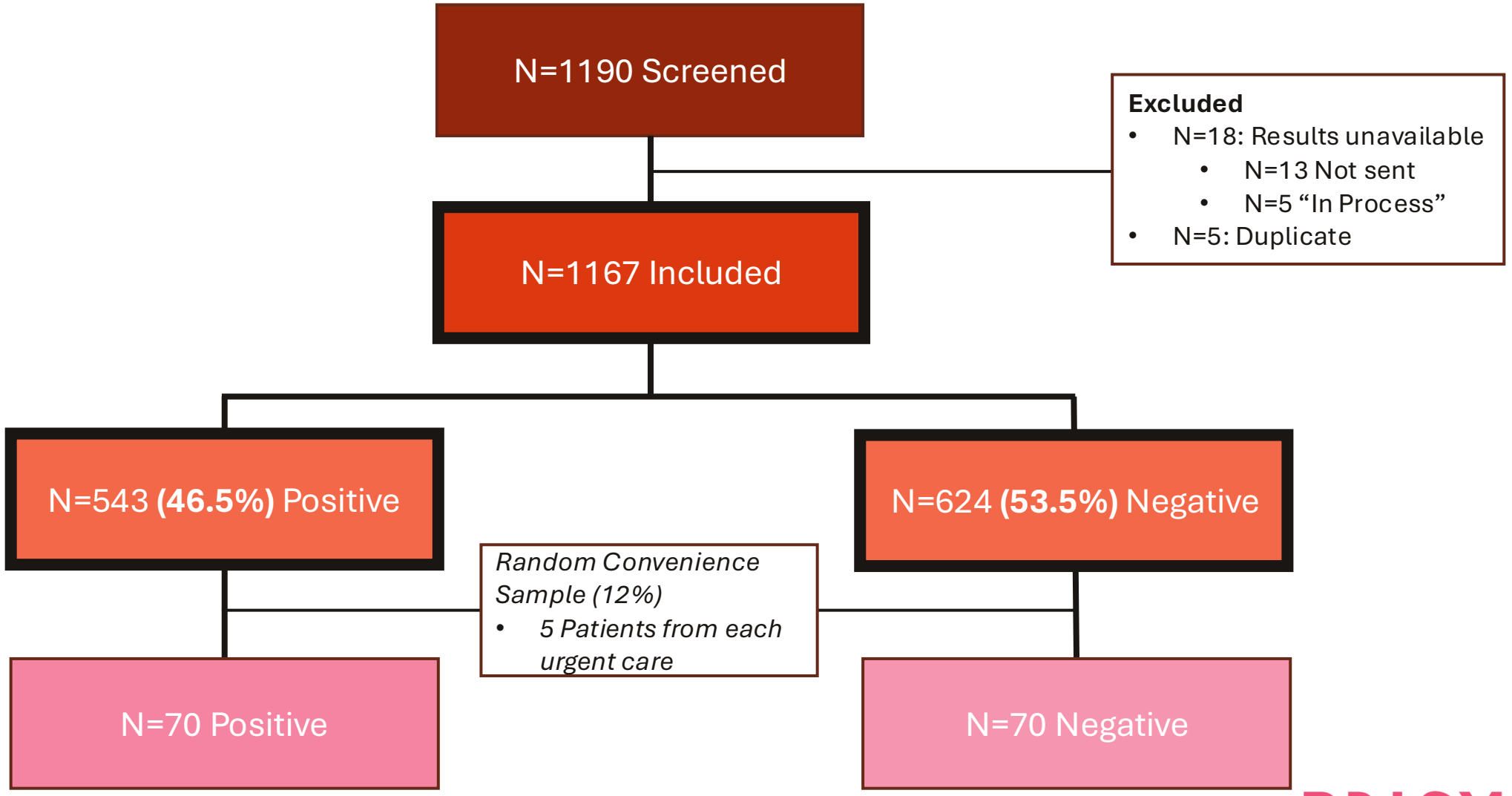
PRISMA

Urine PCR Evaluation: Results



PRISMA

Urine PCR Evaluation: Results



PRISMA

Urine PCR Evaluation: Results *(Total Population)*

Characteristic	Positive (n=543)	Negative (n=624)	Total (n=1167)
Age, y, mean ± SD	49.4 ± 22.2	43.8 ± 22	46.4 ± 22.2
Age < 18, n (%)	18 (3.3)	36 (5.8)	54 (4.6)
Sex, Female; n (%)	488 (89.9)	495 (79.3)	983 (84.2)
Turnaround Time, mean (SD)	27.5 ± 5.3	27.0 ± 6.0	27.2 ± 5.6

Urgent Care	Pos (n=543)	Neg (n=624)	All (n=1167)
Upstate	**360 (66.3)**	**393 (63)**	**753 (64.5)**
Anderson	18 (3.3)	23 (3.7)	41 (3.5)
Boiling Springs	25 (4.6)	31 (5.0)	56 (4.8)
Cherrydale	20 (3.7)	22 (3.5)	42 (3.6)
Clemson	20 (3.7)	18 (2.9)	38 (3.3)
Duncan	24 (4.4)	24 (3.8)	48 (4.1)
Easley	25 (4.6)	31 (5.0)	56 (4.8)
Greer	14 (2.6)	16 (2.6)	30 (2.6)
Laurens	16 (2.9)	12 (1.9)	28 (2.4)
Mauldin	24 (4.4)	35 (5.6)	59 (5.1)
Powdersville	26 (4.8)	28 (4.5)	54 (4.6)
Scuffletown	16 (2.9)	16 (2.6)	32 (2.7)
Seneca	26 (4.8)	19 (3.0)	45 (3.9)
Simpsonville	16 (2.9)	24 (3.8)	40 (3.6)
Spartanburg	10 (1.8)	10 (1.6)	20 (1.7)
Taylors	17 (3.1)	31 (5.0)	48 (4.1)
Travelers Rest	31 (5.7)	20 (3.2)	51 (4.4)
Verdae	20 (3.7)	19 (3.0)	39 (3.3)
Woodruff	14 (2.6)	12 (1.9)	26 (2.2)
Midlands	**178 (32.8)**	**223 (35.7)**	**401 (34.4)**
Ballentine	16 (2.9)	28 (4.5)	44 (3.8)
Five Points	24 (4.4)	43 (6.9)	67 (5.7)
Forest Acres	45 (8.3)	48 (7.7)	93 (8.0)
Garners Ferry	16 (2.9)	16 (2.6)	32 (2.7)
Harbison	14 (2.6)	15 (2.4)	29 (2.5)
Lexington Sunset	22 (4.1)	20 (3.2)	42 (3.6)
Lexington Red Bank	23 (4.2)	26 (4.2)	49 (4.2)
Parkridge	12 (2.2)	15 (2.4)	27 (2.3)
West Columbia	6 (1.1)	12 (1.9)	18 (1.5)
Virtual	**5 (0.9)**	**8 (1.3)**	**13 (1.1)**

Urine PCR Evaluation: Results *(Total Population)*

Characteristic	Positive (n=543)
Level of Growth, n (%)	
Low	105 (19.3)
Medium	248 (45.7)
High	232 (42.7)
Organism, n (%)	
E. coli	399 (73.5)
K. pneumoniae	56 (10.3)
S. agalactiae	46 (8.5)
P. mirabilis	28 (5.2)
E. faecalis / E. faecium	26 (4.8)
P. aeruginosa	16 (2.9)
S. saprophyticus	10 (1.8)
S. aureus	9 (1.7)
C. albicans	5 (0.9)
C. glabrata	5 (0.9)
C. tropicalis	1 (0.2)
Polymicrobial, n (%)	55 (10.1)

Characteristic	Positive (n=543)
Resistance Genes, n (%)	
TetM	367 (67.6)
Sulfa	90 (16.6)
Trimethoprim	54 (9.9)
blaSHV	51 (9.4)
Fluroquinolones	27 (5.0)
CTX-M Group 1	18 (3.3)
CTX-M Group 9	12 (2.2)
MecA	7 (1.3)
VanA	2 (0.4)
Predicted NTF Resistance, n (%)	53 (9.8)
No Resistance, n (%)	118 (21.7)

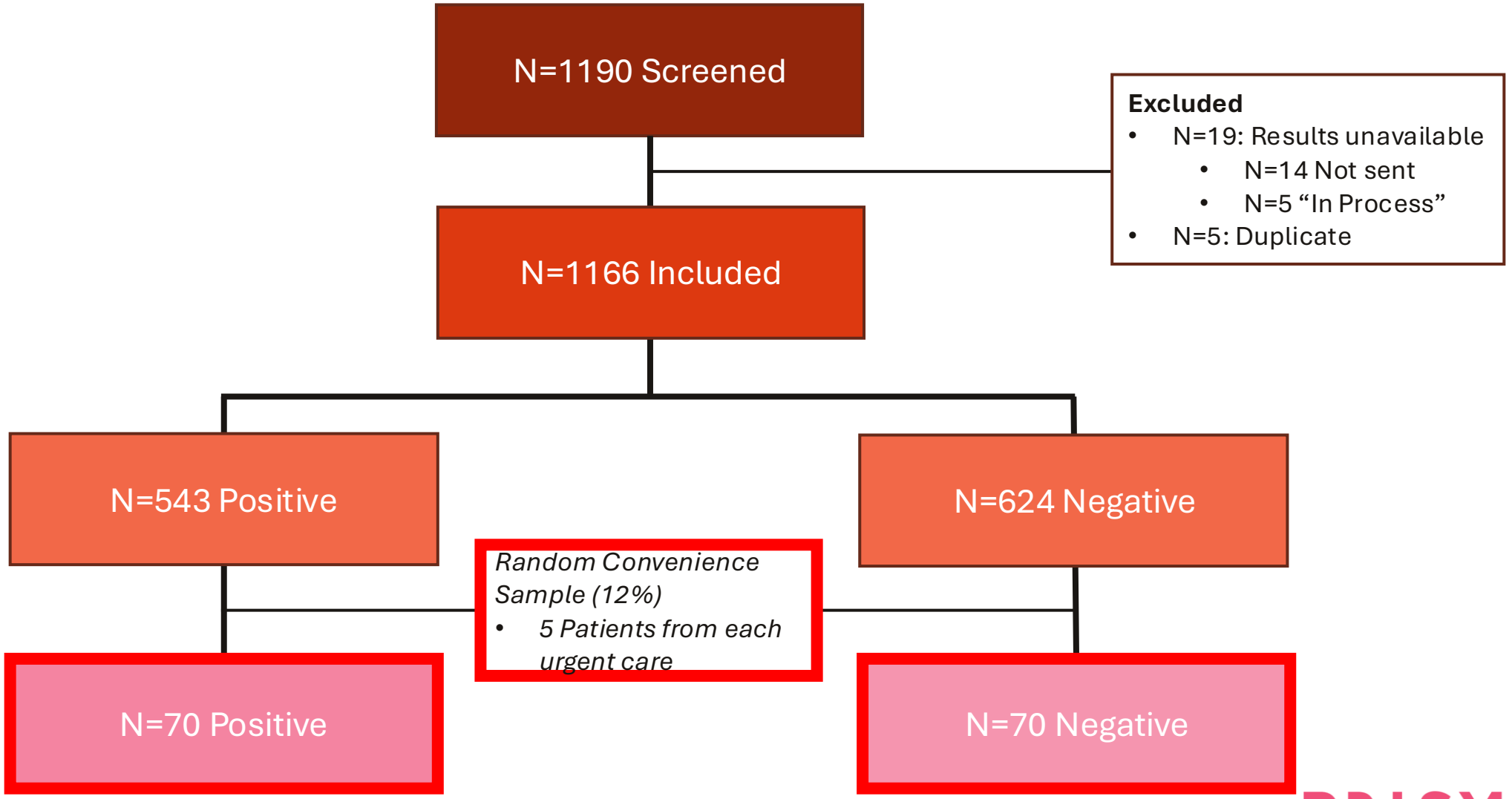
PRISMA

Urine PCR Evaluation: Results *(Total Population)*

Characteristic	Positive (n=543)	Negative (n=624)	Total (n=1167)
Empiric Antibiotics Prescribed, n (%)	**467 (86.0)**	**356 (57.1)**	**823 (70.5)**
Amoxicillin	5 (0.9)	6 (1.0)	11 (0.9)
Amoxicillin / Clavulanate	21 (3.9)	25 (4.0)	46 (3.9)
Cefadroxil	1 (0.2)	2 (0.3)	3 (0.3)
Cefdinir	4 (0.7)	3 (0.5)	7 (0.6)
Cefixime	1 (0.2)	0 (0)	1 (0.1)
Cefpodoxime	17 (3.1)	18 (2.9)	35 (3.0)
Cefuroxime	5 (0.9)	3 (0.5)	8 (0.7)
Cephalexin	149 (27.4)	99 (15.9)	248 (21.3)
Ciprofloxacin	32 (5.9)	19 (3.0)	51 (4.4)
Doxycycline	1 (0.2)	5 (0.8)	6 (0.5)
Fosfomycin	1 (0.2)	1 (0.2)	2 (0.2)
Levofloxacin	2 (0.4)	5 (0.8)	7 (0.6)
Nitrofurantoin	190 (35.0)	131 (21.0)	321 (27.5)
Sulfamethoxazole / Trimethoprim	38 (7.0)	41 (6.6)	79 (6.8)
No Empiric Antibiotics Prescribed, n (%)	76 (14.0)	268 (42.9)	344 (29.5)
Antibiotic Change Due to Result, n (%)	116 (21.4)	10 (1.6)	126 (10.8)

PRISMA

Urine PCR Evaluation: Results



PRISMA

Urine PCR Evaluation: Results *(Convenience Sample)*

Characteristic	Positive (n=70)	Negative (n=70)	Total (n=140)
Age, y, mean ± SD	51.1 ± 22.6	43.7 ± 22.4	47.4 ± 22.7
Age < 18, n (%)	2 (2.9)	7 (10)	9 (6.4)
Sex, Female; n (%)	62 (88.6)	58 (82.9)	120 (85.7)
Turnaround Time, h, mean (SD)	27.6 ± 5.2	27.3 ± 6.1	27.5 ± 5.6
Urologic Abnormalities, n (%)	4 (5.7)	5 (7.1)	9 (6.4)
Pregnant, n (%)	1 (1.4)	1 (1.4)	2 (1.4)
Abnormal Urinalysis, n (%)	55 (78.6)	34 (48.6)	89 (63.6)
Lower Urinary Tract Symptoms, n (%)	58 (82.9)	40 (57.1)	98 (70)
Other Diagnostic Tests Ordered, n (%)	10 (14.3)	22 (31.4)	32 (22.9)
Bacterial Vaginosis	6 (8.6)	6 (8.6)	12 (8.6)
Chlamydia / Gonorrhea / Trichomoniasis	3 (4.3)	6 (8.6)	9 (6.4)
Herpes Simplex Virus	0 (0)	1 (1.4)	1 (0.7)
Vaginitis PCR	2 (2.9)	5 (7.1)	7 (5)
Respiratory PCR	3 (4.3)	5 (7.1)	8 (5.7)
Sore Throat PCR	2 (2.9)	5 (7.1)	7 (10)
GAS PCR	0 (0)	2 (2.9)	2 (1.4)
Other Diagnostic Tests Positive, n (%)	1 (1.4)	8 (11.4)	9 (6.4)

Urine PCR Evaluation: Results *(Convenience Sample)*

Characteristic	Organisms (n=78)
Level of Growth, n (%)	
Low	19 (24.4)
Medium	29 (37.2)
High	30 (38.5)
Organism, n (%)	
E. coli	58 (74.4)
K. pneumoniae	5 (6.4)
S. agalactiae	5 (6.4)
P. mirabilis	4 (5.1)
E. faecalis / E. faecium	2 (2.6)
P. aeruginosa	2 (2.6)
S. saprophyticus	1 (1.3)
C. albicans	1 (1.3)
Polymicrobial, n (%) [**N=70**]	7 (10)

Characteristic	Organisms (n=78)
Resistance Genes, n (%)	
TetM	53 (67.9)
Sulfa	15 (19.2)
Trimethoprim	5 (6.4)
blaSHV	5 (6.4)
CTX-M Group 1	3 (3.8)
Fluroquinolones	2 (2.6)
Predicted NTF Resistance, n (%)	4 (5.1)
No Resistance, n (%)	19 (24.4)

PRISMA

Urine PCR Evaluation: Results *(Convenience Sample)*

Characteristic	Positive (n=70)	Negative (n=70)	Total (n=140)
Empiric Antibiotics Prescribed, n (%)			
Amoxicillin/Clavulanate	2 (2.9)	2 (2.9)	4 (2.9)
Amoxicillin	2 (2.9)	1 (1.4)	3 (2.1)
Cefadroxil	1 (1.4)	1 (1.4)	2 (1.4)
Cefdinir	0 (0)	1 (1.4)	1 (0.7)
Cefpodoxime	2 (2.9)	2 (2.9)	4 (2.9)
Cefuroxime	1 (1.4)	0 (0)	1 (0.7)
Cephalexin	17 (24.3)	12 (17.1)	29 (20.7)
Ciprofloxacin	7 (10)	4 (5.7)	11 (7.9)
Levofloxacin	1 (1.4)	0 (0)	1 (0.7)
Nitrofurantoin	24 (34.3)	17 (24.3)	41 (29.3)
Trimethoprim/Sulfamethoxazole	4 (5.7)	4 (5.7)	8 (5.7)
No Empiric Antibiotics Prescribed, n (%)	9 (12.9)	26 (37.1)	35 (25)
Other Empiric Antimicrobials Prescribed, n (%)	5 (7.1)	12 (17.1)	17 (12.1)
Fluconazole	4 (5.7)	11 (15.7)	15 (10.7)
Metronidazole	1 (1.4)	1 (1.4)	2 (1.4)

PRISMA

Urine PCR Evaluation: Results *(Convenience Sample)*

Characteristic	Positive (n=70)	Negative (n=70)	Total (n=140)
Diagnosis, n (%) UTI / Cystitis / Urinary S/Sx Other	 51 (72.9) 19 (27.1)	 36 (51.4) 34 (48.6)	 87 (62.1) 53 (37.9)
Antibiotic Changes After Result, n (%) Antibiotics 'Stopped' Antibiotic Switch Antibiotics Initiated	12 (17.1) 0 (0) 7 (10) 5 (7.1)	3 (4.3) 2 (2.9) 0 (0) 1 (1.4)	15 (10.7) 2 (1.4) 7 (5) 6 (4.3)
Antibiotic Change Appropriate*, n/N (%)	**10/12 (83.3)**	**1/3 (33.3)**	**11/15 (73.3)**
No Antibiotic Change Appropriate*, n/N (%)	**52/55 (94.5)**	**44/45 (97.8)**	**96/100 (96)**
Ordering Appropriate, n (%)	**58 (82.9)**	**42 (60)**	**100 (71.4)**

Appropriateness of remaining on empiric antibiotics or switching antibiotics based on coverage of growth on urine PCR only;* ***Does not include patients who were never initiated on antibiotics after positive culture growth (N=25)*

PRISMA

Discussion

Strengths

- Despite high sensitivity, over 50% of urine PCRs resulted negative
- In cases where results were negative, nearly 50% of patients did not receive empiric antibiotics
- **Identified areas for improvement that align with diagnostic stewardship principles**

Limitations

- Informal, retrospective analysis with related biases
- Inability to directly compare PCR results with standard C&S
- Over 50% negative results could correlate with inappropriate ordering (i.e., ASB)
- Potentially under-calling fluoroquinolone resistance

PRISMA

Diagnostic Stewardship Opportunities for Urine PCR

Clinician Testing Decision & Interpretation	Test Ordering	Specimen Collection & Transport to Lab
PCR = higher sensitivity	**Orderable unrestricted**	**Concerns for contamination**
Provider education (ASB, polymicrobial results)	Justification / Indication selection	Reinforce clean-catch technique
Avoid “test of cure”	Duplicate test restrictions	Avoid batching delays

PRISMA

Fabre V. *Infect Control Hosp Epidemiol*. 2023;44(2):178-185

Diagnostic Stewardship Opportunities for Urine PCR

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ONGOING EFFORTS

PRISMA

Fabre V. *Infect Control Hosp Epidemiol*. 2023;44(2):178-185

Diagnostic Stewardship Opportunities for Urine PCR

	Test Processing and Performance	Test Reporting
Observations with PCR Versus C&S	• Rapid turnaround times with PCR • Higher sensitivity with PCR • Genotypic versus phenotypic resistance	• PCR results report not embedded into EHR • PCR results report lengthier than C&S report • Genotypic versus phenotypic resistance

Limitations of PCR	• **Overuse** in patients with non-specific symptoms due to rapid results available
	• Identification of **less clinically significant pathogens**
	• **Missed organisms** due to limited library
	• **Under-calling** antimicrobial **resistance**
	• **Inability to develop antibiograms**
		• Results report may be **confusing** for providers
		  • **Resistance genes** reported (i.e., *blaSHV*)
		  • "Associated resistances" list **broad classes** (i.e., penicillin) for some genes
		  • ***TetM*** gene reported, **tetracyclines not recommended** for UTI
		• Limitations for **conducting research, antibiogram development**

Diagnostic Stewardship Intervention Opportunities	• Policies for reflex pyuria screening • Expand library to include more relevant gram-negative organisms • Consider culture with PCR testing (*cost impact may outweigh benefit*) • Periodically reassess impact	• Results embedded into EHR • Provide links to institutional guidance or algorithms within reports • Consider selective / cascade reporting • Further interpretation for resistance genes • Remove extemporaneous information

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Key Takeaways

- Diagnostic stewardship involves the **right test for the right patient at the right time**, and interventions require multidisciplinary involvement
- Based on available literature, urine PCR provides rapid turnaround of clinically relevant results compared with standard C&S, but results should be taken in clinical context due to increased sensitivity
- Urine PCR processing and reporting within urgent cares presents a ripe area for diagnostic stewardship intervention, and continued analysis is warranted for assessing the yield of future efforts

PRISMA

Self-Assessment Questions

Assessment Question 1

PRISMA

Which of the following is an example of a diagnostic stewardship intervention?

A) Limiting duplicate urine PCR or urine culture orders within 48 hours
B) De-escalating from piperacillin-tazobactam to ceftriaxone based on culture results
C) Initiating empiric nitrofurantoin for suspected uncomplicated pyelonephritis
D) Automatically adding urine PCR testing for all patients with hematuria

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PRISMA

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Assessment Question 2

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Based on historical data, what is the primary advantage of implementing urine PCRs into clinical practice?

A) Urine PCR provides lower sensitivity, but higher specificity than culture and susceptibility testing

B) Urine PCR provides more rapid turn around times compared to culture and susceptibility testing

C) Urine PCR identifies a broader range of organisms than culture and susceptibility testing

D) All of the above

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Assessment Question 3

PRISMA

From the informal review presented, which of the following are potential strategies to improve implementation and use of the urine PCR in practice?

A) Removing extemporaneous reporting from the results view, such as the ‘TetM’ gene, because tetracyclines aren’t routinely used for urinary tract infections

B) Providing more education surrounding ordering of urinary tract infection diagnostic tests

C) Both A & B

D) Neither A or B

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PRISMA

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PRISMA HEALTH

Urine… Or Out? Informal Evaluation of UTI PCR Testing across Urgent Care Locations

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ASC-SC Statewide Meeting
May 4, 2026