

Urinary Tract Infection and Antibiotic Resistant Markers by PCR, Molecular

Test Name:	UTI/AMR Testing by Real-Time PCR
Method Name:	Real Time – Polymerase Chain Reaction (PCR) for detection of urinary tract infections (UTI) and antibiotic markers of resistance (AMR)
Results:	Detected, Not Detected, Inconclusive
Reference Ranges:	Not Detected for all targets on panel
Clinical Significance:	Urinary tract infections (UTI) are one of the most common bacterial infections. The incidence of UTIs are greater in women than in men. Clinical presentation is often associated with a burning sensation when urinating, passing frequent, small amounts of urine, urine which may appear cloudy, and/or urine that appears red, bright pink or cola-colored.
Submission Criteria:	<p>Urine specimens should be collected as soon as possible during illness and before antimicrobial therapy begins, preferably within 72 hours or symptom onset.</p> <p>Acceptable specimen types include: Fresh-catch urine collected in unpreserved sterile containers, or Fresh-catch urine collected/transferred in sterile containers containing boric acid preservative.</p> <p>Refer to “Specimen Collection, Storage, and Shipping Instructions” for specific testing requirements.</p>
Rejection Criteria:	<p>Rejection criteria include but are not limited to those with:</p> <ol style="list-style-type: none">1. Mismatched requisitions2. Specimens without patient identifiers3. Specimens stored or shipped incorrectly4. Specimens collected using expired reagents5. Specimens collected and submitted outside of allowable timeframe and/or collection vessel.6. Specimens submitted without approval
Authorization:	Diagnostic testing can only be performed with approval from an authorized provider/agency.
Turn Around Time:	3 Days

Instructions for Urine Sample Submission

General Information

The clean-catch method is used to prevent microbes inhabiting the urethra from contaminating the urine sample. If possible, collect the sample when urine has been in the bladder for 2 to 3 hours. A special cup (which includes a lid and wipes) is used to collect the urine.

Timing: Urine specimens should be collected as soon as possible during the illness and before antimicrobial therapy begins, if possible. The likelihood of recovering most of the bacteria diminishes markedly >72 hours after symptom onset and after the initiation of appropriate antimicrobial therapy. If possible, urine specimens should be collected within 72 hours of symptom onset and no later than 7 days after onset.

Containers: Use sterile urine containers and urine vacutainer tube containing a preservative (Vacurette urine tube CCM containing boric acid preservative). The Vacurette urine tube CCM with preservative stabilizes the bacterial count.

If requesting urine culture, specimens MUST be received at Reditus Laboratories:

- Within 2 hours of collection when using sterile containers without preservative.
- Within 48 hours of collection when using sterile containers containing boric acid preservative.

Specimen Collection, Storage, and Shipping Instructions

1. Male Patients

- 1.1. Wash hands with warm water and soap. Thoroughly rinse and dry.
- 1.2. Using the wipe provided in the collection kit, clean the head of the penis. If not circumcised, retract the foreskin with one hand the clean the head of the penis. Keep the foreskin pulled back during urination.
- 1.3. Urinate a small amount into the toilet, then stop the flow of urine.
- 1.4. Hold the urine container a few centimeters from the head of the penis and continue urinating until the cup is around half-full.
- 1.5. Secure the lid to the sterile collection container.
- 1.6. Finish urinating into the toilet.

2. Female Patients

- 2.1. Wash hands with warm water and soap. Thoroughly rinse and dry.
- 2.2. Sit on the toilet with legs spread apart and use two fingers to open the labia.
- 2.3. Use the wipe provided in the collection kit to clean the inner folds of the labia. Wipe from the front to the back.
- 2.4. Use a second wipe to clean the opening of the urethra.
- 2.5. Urinate a small amount into the toilet, then stop the flow of urine.
- 2.6. Hold the urine container a few centimeters from the urethra and continue urinating until the cup is about half-full.
- 2.7. Secure the lid the sterile collection container.
- 2.8. Finish urinating into the toilet.

3. Do not use expired collection materials.

4. Obtain specimens early in the acute phase of illness.

5. Ensure that the patient's name, date-of-birth, and time/date of collection are recorded on the specimen along with the name or initials of the individual collecting the sample.

6. Complete all the demographic information on a sample requisition form or through the approved electronic submission process

7. **If requesting testing by PCR only:**

7.1. Following collection, the specimen may be stored between 2-8°C (36-46°F) but must be **received** at the laboratory within 7 Days of collection. The specimen must be shipped on cold packs.

7.2. Following collection, the specimen may be stored at $\leq -70^{\circ}\text{C}$ but must be **received** at the laboratory within 14 Days of collection. The specimen must be shipped on dry-ice.

8. **If requesting testing by PCR with Microbiology co-culture:**

8.1. Fresh-catch urine specimens collected in unpreserved sterile containers and maintained at room temperature must be **received** at the laboratory within 2-Hours from the time of collection.

8.2. Fresh-catch urine specimens collected in unpreserved sterile containers and stored between 2-8°C (36-40°F) must be received at the laboratory within 24-Hours from the time of collection. Specimens must be shipped on cold packs.

8.3. Specimens collected in sterile containers containing boric acid preservative may be stored at room- or refrigerated-temperature but must be received at the laboratory within 48-Hours from the time of collection. Specimens may be shipped ambiently.

9. **Avoid shipping specimens over weekends or holidays** as they may not be received at the laboratory and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.

10. Ensure that specimens shipped by commercial carrier are shipped with **overnight delivery**. If shipping on a Friday for Saturday delivery, ***you must include Saturday Delivery*** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive refrigerated (2-8°C) specimens *within* 24 hours of shipment will result in specimens being rejected from testing.

11. For any questions pertaining to sample collection, storage, or shipping, please contact Reditus Laboratories using the below contact information.

Instructions for Specimen Transport

12. **Messenger/Courier by ground transport.** Place specimen(s) into a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed biohazard bag and test requisition(s) inside the shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. The shipping container must be rigid, such as a Styrofoam cooler, and labeled with the UN 3373 Biological Substance Category B marking. Close securely.

13. **Commercial carrier by ground/air transport.** Place the specimen(s) inside a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed bag and completed test requisitions(s) inside the outer shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. Label the outer shipping container with Reditus Laboratories address listed below. Complete the return address section to include the name of the person shipping the package, business name and address, and a business phone number. The shipping container must include the UN3373 Biological Substance Category B marking.

14. *Ship specimens by overnight delivery* to the attention of Molecular Diagnostics at Reditus laboratories. This can be accomplished by use of local courier, shipping corporations or U.S. Postal Service.

14.1. **If specimens are shipped on a Friday for Saturday delivery, you must include/indicate Saturday delivery** during shipment or the specimens will not be received until the following non-holiday business day. Failure to receive refrigerated (2-8°C) specimens within 24 hours of shipment will result in specimens being rejected from testing.

15. Refrigerated (2-8°C) specimen(s) must be received at the laboratory **no later than** 24 hours from

the time of shipment. Do not ship specimens over weekends or holidays as they will not be received, and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.

NOTE: Testing may be delayed, or specimens may be considered UNSATISFACTORY if the above instructions are not followed or the requisition form is not filled out completely. If there are any questions about specimen collection, handling, or shipping please contact Reditus Laboratories to speak with laboratory personnel.

Ship specimens by a local courier or overnight by commercial carrier to the designated laboratories indicated below.

Send to: Reditus Laboratories
200 Enterprise Drive
Pekin, IL 61554

Phone: (469) 498-0222

Website: <https://www.redituslabs.com/>