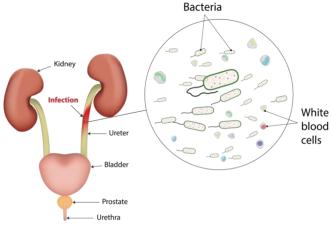




TRUPCR® UTI AST Panel Kit

NEED

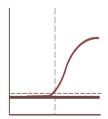
Urinary Tract Infection (UTI) is an infection in any part of urinary system-kidneys, ureters, bladder and urethra. UTI is the second most common infection after respiratory infections, affecting 150 million people each year worldwide and largely affect women. UTIs are a significant cause of morbidity in infant boys, older men and females of all ages. Approximately 11% of women suffer from UTI, 60% of women will have at least one UTI during their lifetime. 25% of UTIs will recur within six months of the initial infection. Effective treatment of UTI depends on the accurate identification of the uropathogen(s). When treated promptly and properly, lower UTI rarely lead to complications. But left untreated, UTI can have serious consequences including recurrent infections, permanent kidney damage and/or pre-term birth.



SOLUTION BY TRUPCR®

TRUPCR® UTI AST Panel Kit is a multiplexed Real Time PCR kit which is intended for detection of antimicrobial sensitivity of uropathogen(s) directly from human urine of UTI suspected individuals. It includes five tubes targeting fourteen AMR genes representing different antibiotic classes for antimicrobial susceptibility testing to accurately diagnose and report a definitive treatment recommendation for each patient. Endogenous internal control is included in each tube. This assay is based on TaqMan hydrolysis probe which allows higher specificity and sensitivity. The targets are detected with the help of four different dyes (FAM/Green, HEX/Yellow, Texas Red/Orange and Cy5/Red).

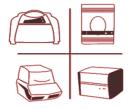
KEY FEATURES



Endogenous Internal Control incorporated within the kit to ensure reliable results



Complete workflow solution available from Extraction of sample to Post-PCR analysis



Platform agnostic as compatible with various platforms



Rapid and reliable results within 60 minutes after PCR Start





TARGET ANTIBIOTIC RESISTANCE GENE

Primer Probe Mix 1 Primer Probe Mix 2 FAM TEX RED HEX **FAM TEX RED** HEX Cy5 Cy5 **ESBL ESBL ESBL** SXT SXT SXT Endogenous Endogenous (bla_{TEM}) (bla_{CTX-M gr1}) (blashy) IC (sul2) (dfrA1) (dfrA5) IC **Primer Probe Mix 3 Primer Probe Mix 4 TEX RED FAM TEX RED** Cy5 HEX **FAM HEX** Endogenous Carbapenems Carbapenems Endogenous Carbapenems Carbapenems Carbapenems (bla_{KPC}) (blandm) IC (blaimp) IC (bla_{VIM}) (bla_{OXA-48}) **Primer Probe Mix 5 FAM TEX RED** Cy5 **HEX** Methicillin Vancomycin Vancomycin Endogenous (vanA) (vanB) IC (mecA)

TECHNICAL SPECIFICATIONS

- Sample Type Urine Specimen / Cultured Isolates
- AST profiling targeting 14 genes with 5 different classes of antibiotics
- Clinical Validation Validated on more than 500 clinical samples
- Target Regions Pathogen specific conserved regions
- LoD Data = 10 Copies/reaction
- Room temperature reaction setup
- UNG is included in the master mix to avoid carry over contamination
- Reaction Volume 20μl in each tube
- o Compatible Instruments Applied Biosystems™ 7500 series, Applied Biosystems™ QuantStudio® series, Bio-Rad CFX96, MIC PCR

CLINICAL DATA

| | | Reference Method | | |
|---------------|----------|------------------|----------|-------|
| | | Positive | Negative | Total |
| TRUPCR Method | Positive | 82 | 0 | 82 |
| | Negative | 1 | 62 | 63 |
| | Total | 83 | 62 | 145 |

| Parameters | Estimate |
|---------------------------|----------|
| Sensitivity | 98.80% |
| Specificity | 100.00% |
| Positive Predictive Value | 100.00% |
| Negative Predictive Value | 98.41% |

ORDERING INFORMATION

| Cat. No. | Description | Size |
|----------|---------------------------|--------------|
| 3B343 | TRUPCR® UTI AST Panel Kit | 48 Reactions |
| 3B344 | TRUPCR® UTLAST Panel Kit | 96 Reactions |



