

Scienetix UTI 4-Plex PCR Assay for Clinical Application

About the Kit

The Scienetix UTI 4-Plex PCR Assay is a multiplexed molecular diagnostic solution designed for clinical labs as a Laboratory Developed Test (LDT). Validated at Advanta Genetics, this comprehensive panel rapidly detects and identifies key bacterial and fungal pathogens associated with UTIs, as well as crucial antimicrobial resistance (AMR) genes—all in a single, highly efficient assay.

Key Highlights for Scienetix UTI 4-Plex PCR Assay:

• Broad Pathogen Coverage:

- o Detects 30+ bacterial and fungal targets across 8 panels, including common culprits like *E. coli*, *K. pneumoniae*, *P. aeruginosa*, and *C. albicans*.
- Simultaneously screens for critical AMR markers such as VanA, VanB, MecA, NDM, OXA-48, and CTX-M-GRP1.

• High Specificity and Sensitivity

- No cross-reactivity with normal flora or targets evaluated by the assay ensures confidence in results.
- \circ Reliable detection down to 10 copies/ μ L, enabling early and accurate pathogen identification.

• Robust Linearity:

 $^{\circ}$ R² > 0.98 across a wide dynamic range (100,000 copies/μL down to 1 copy/μL) for semi-quant applications.

• Flexible Sample Types:

 Validated for urethral and vaginal swabs in BD E-Swab Liquid, as well as urine samples using Scienetix D2P preparation or urine derived from diapers when processed with conventional nucleic acid extraction.

Stable Sample Handling:

o Maintains sample integrity for up to 7 days at refrigerated (-20°C to 8°C) conditions and up to 2 days at room or elevated temperatures.

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UTI 4-Plex PCR Assay Panel

Panel	MM#	FAM	SUN	TXRed	CY5
UTI4	1	Proteus mirabilis	Escherichia coli	Klebsiella pneumoniae	Prevotella bivia
UTI4	2	Streptococcus agalactiae	Streptococcus pyogenes	Enterobacter cloacae	Acinetobacter baumannii
UTI4	3	Enterococcus faecalis	Enterococcus faecium	Candida tropicalis	Candida parapsilosis
UTI4	4	Pseudomonas aeruginosa	Candida glabrata	Staphylococcus aureus	RNAseP
UTI4	5	Candida albicans	Trichophyton rubrum	Candida auris	Epidermophyton floccosum
UTI4	6	Citrobacter Species	Bacteroides fragilis	Proteus vulgaris	Actinotignum schaalii
UTI4	7	Serratia marcescens	Klebsiella oxytoca	Morganella morganii	Staphylococcus saprophyticus
UTI4	8	Staphylococcus haemolyticus	Extraction Control	Klebsiella aerogenes	Aerococcus urinae
AMR	1	VanB	DfrA1	VanM	MecA
AMR	2	qnrAS	gyrA	SHV	CTX-M-Grp1
AMR	3	TEM	NDM	VanA	RNAseP
AMR	4	TetB	Sul1	OXA-48	TetM