

Ezplex[®] STD 13 PCR Kit

MFDS* approved for *in vitro* diagnostic use.

Comprehensive Panel

Identifies 13 bacteria and viruses that cause sexually transmitted infections in a single kit.

Specificity

Specific for targeted bacteria and viruses without the risk of cross reactivity with other microorganisms.

Sensitivity

Detection of all targeted bacteria and viruses with high sensitivity.

Stability

Shelf life of up to 12 months.

The Ezplex[®] STD 13 PCR Kit detects 13 types of pathogens, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma genitalium*, *Mycoplasma hominis*, *Ureaplasma urealyticum*, *Trichomonas vaginalis*, *Ureaplasma parvum*, *Candida albicans*, *Treponema pallidum*, Herpes simplex virus 1, Herpes simplex virus 2, *Garnerella vaginalis*, and *Haemophilus ducreyi* that cause sexually transmitted infections using Real-time PCR.

Testing can be quickly and accurately completed in approximately 4.5 hours post extraction.

*Ministry of Food and Drug Safety of South Korea

Compatible Devices and Extraction Methods

Veriti 96-Well Thermal Cycler [ThermoFisher Scientific]
QIAamp[®] DSP DNA Mini Kit [Qiagen]

Analytical Sensitivity

Repeated tests with serial dilutions of reference materials for each of the 13 STD types showed high analytical sensitivity for the Ezplex STD 13 PCR Kit (LoD range of 0.021-50.104 copies/ μ L).



Analytical Specificity

Testing of 31 species of microorganisms with the Ezplex® STD 13 PCR Kit showed no cross reactivity.

Microorganisms
<i>Candida glabrata, Candida tropicalis, Clostridium difficile, Corynebacterium amycolatum, Corynebacterium diphtheriae, Corynebacterium glutamicum, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae subsp pneumoniae, Lactobacillus crispatus, Lactobacillus gallinarum, Lactobacillus vaginalis, Nocardia sp., Peptostreptococcus anaerobius, Prevotella bivia, Prevotella disiens, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus anginosus subsp anginosus, Streptococcus constellatus subsp constellatus, Streptococcus gordonii, Streptococcus mutans, Streptococcus oralis, Streptococcus parasanguinis, Streptococcus salivarius, Streptococcus sanguinis, Veillonella parvula</i>

Reproducibility and Repeatability

Reference materials for STD pathogens were diluted into middle concentrations (100x LoD) and low concentrations (10x LoD). Two investigators tested these samples in duplicate using 1 lot twice daily for 5 days with no difference in results between investigators. Also 1 investigator using 3 different lots tested 20 times repeatedly, 4 times a day for 5 days with no difference within a test, between tests and between lots.

Clinical Performance

Results from testing left-over vaginal swabs and urine specimens that had been previously tested with another approved product showed sensitivity of 99.01 - 100% and specificity of 100%

Stability

Shelf life of up to 12 months at -20°C (-4°F).

Ordering information

100 Tests. Catalog Number: GNT-1004-1

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