

NamuPlex™ STD 12 Real-time PCR Kit

MFDS* approved for in vitro diagnostic use

*Ministry of Food and Drug Safety of South Korea



Comprehensive Panel

Identifies 12 bacteria and viruses that cause sexually transmitted infections in a single kit

Convenience

Genetree Viewer analysis software available for users to conveniently produce test results.

Sensitivity

Detection of all targeted bacteria and viruses with high sensitivity.

Specificity

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

Precision

CV of Ct value is less than 5%

Stability

Shelf life of up to 12 months.

Intended use

The NamuPlex™ STD 12 Real-time PCR Kit detects 12 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* and *Garnerella vaginalis*, that cause sexually transmitted infections using Real-time PCR.

Testing can be quickly and accurately completed in less than 2 hours post extraction and results produced using Genetree Viewer analysis software.

Compatible Devices and Extraction Methods

CFX96 Dx Real-time PCR Instrument
QIAamp® DSP DNA Mini Kit

Limit of Detection

Repeated tests with serial dilutions of reference materials for each of the 12 STD types showed high analytical sensitivity for the NamuPlex™ STD 12 Real-time PCR Kit (LoD range of 0.081-12.719 copies/μL).



Analytical Specificity

Testing of 31 species of microorganisms with the Namuplex™ STD 12 Real-time PCR Kit showed no cross reactivity.

Microorganisms

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

Reproducibility and Repeatability

Reference materials for STD pathogens were diluted into middle concentrations (100 copies/uL) and low concentrations (10 copies/uL). Two investigators, two institutes, using one Lot, tested 2 times for 5 days (total 20 times), CV were <5% and no difference between investigators, days, locations. Also 1 investigator using 3 different lots tested 20 times repeatedly, 4 times a day for 5 days. CV were < 5%, with no difference within tests, between tests, between Lots, between days between tests and between lots.

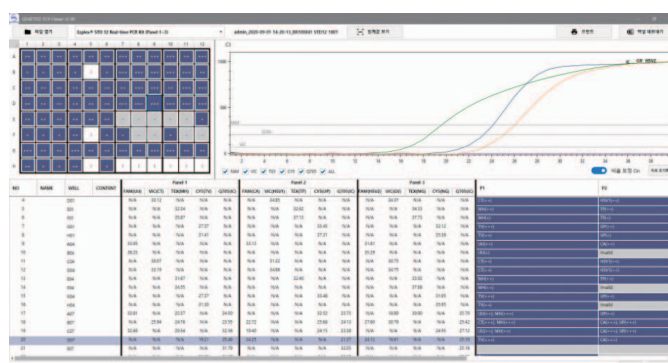
Clinical Performance

Results from testing left-over, archived nasopharyngeal swab specimens that had been previously tested with another approved product showed that positive agreement was 95.8 to 100% and negative agreement was 100%.

Genetree Viewer Analysis Software

Results of the Real-time PCR conducted by using each of the positive and negative specimens are as follows.

Example Software Analysis Result



Stability

Shelf life of 12 months at -20°C (-4°F) unopened and 6 months after opening.

Ordering information

100 Tests. Catalog Number: GNT-2005-1

Genetree Viewer Software. Catalog Number: GNT-2005-3

Korea Head Office

14F, Tera Tower B Building, 167, Songpa-daero, Songpa-gu, Seoul, South Korea
 TEL. +82-2-2057-7900 FAX. +82-70-7425-3950

SML Genetree Co. Ltd

13F, Tera Tower B Building, 167, Songpa-daero, Songpa-gu, Seoul, South Korea

United States Office

10080 N Wolfe Road Suite SW3-200 Cupertino, CA 95014