

# **Ezplex<sup>®</sup> STD 13 PCR Kit**

## **Instructions for Use (IFU)**



**Approved by MFDS (Ministry of Food and Drug Safety of South Korea)**

**100 Tests**

**Manufacturer:**

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## I. Intended Use

The Ezplex® STD 13 PCR Kit is a multiplex PCR *in-vitro* diagnostic test for the qualitative detection and differentiation of *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*, *Gardnerella vaginalis* and *Haemophilus ducreyi* by extracting deoxyribonucleic acid (DNA) in vaginal swabs from female patients and in urine samples from female and male patients with signs and symptoms of sexually transmitted disease.

The Ezplex® STD 13 PCR Kit is intended for use by qualified clinical laboratory personnel, specifically instructed and trained in the techniques of PCR and in vitro diagnostic procedures.

This product is approved for use only by the Ministry of Food and Drug Safety of South Korea (MFDS).

## II. Summary and Explanation

Sexually transmitted diseases (STDs), also known as sexually transmitted infections or STIs, are very common. More than 1 million sexually transmitted infections (STIs) are acquired every day worldwide<sup>1,2</sup>. Each year, there are an estimated 376 million new infections worldwide with 1 of 4 STIs: chlamydia, gonorrhea, syphilis and trichomoniasis<sup>1,2</sup>. More than 500 million people worldwide are estimated to have genital infections with herpes simplex virus (HSV)<sup>3</sup>. The U.S. Centers for Disease Control and Prevention (CDC) estimates about 20 percent of the U.S. population – approximately one in five people in the U.S. had an STI on any given day in 2018, and STIs acquired that year cost the American healthcare system nearly \$16 billion in healthcare costs alone.<sup>4</sup>

STDs are passed from one person to another through sexual activity including vaginal, oral, and anal sex. STDs don't always cause symptoms or may only cause mild symptoms, so it is possible to have an infection and not know it. All STDs can be treated with medications and some can be cured entirely. However, if not properly treated, STDs cause pelvic infections/pelvic inflammatory disease, and infertility.<sup>5</sup>

It is known that about 30 different microorganisms can cause STDs<sup>6</sup>. Most bacteria and other microorganisms cannot survive long in transport mediums and sometimes many other microorganisms can reproduce and overgrow, making it difficult to separate pure isolates of interest and be detectable by conventional culture methods. Existing methods of diagnosing vaginitis using Amsel's criteria or Nugent's score do not allow diagnosis in 30 % of women with symptoms, with sensitivity and specificity reported at 92 % and 77 %, respectively.<sup>5</sup> Proficiency in microscopic analysis techniques is also required, and the ambiguity of the terms used has raised questions about the accuracy of the diagnosis using these methods. With the recent development of molecular techniques, there are now more effective ways to determine the causative

microorganisms of multiple sexually transmitted diseases at once. The CDC recommends Nucleic Acid Amplification Tests (NAATs) as the method of choice for detecting *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.<sup>5</sup>

In particular, multiplex PCR methods are useful for diagnosing diseases that require rapid identification of various microorganisms by allowing simultaneous detection. As a result, a product that can accurately detect multiple microorganisms has been developed using PCR.

### III. Principles of the Procedure

The Ezplex® STD 13 PCR Kit is a polymerase chain reaction test. The primers are designed to detect nucleic acids (DNA) from *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*, *Gardnerella vaginalis*, and *Haemophilus ducreyi*

The Ezplex® STD 13 PCR Kit consists of 2 panels of primer mixtures as shown in the table below.

Panel	Target	Size (bp)	Panel	Target	Size (bp)
Mix I	<i>Chlamydia trachomatis</i> (CT)	117	Mix II	<i>Ureaplasma parvum</i> (UP)	119
	<i>Neisseria gonorrhoeae</i> (NG)	175		<i>Candida albicans</i> (CA)	187
	<i>Mycoplasma genitalium</i> (MG)	248		<i>Treponema pallidum</i> (TP)	252
	<i>Mycoplasma hominis</i> (MH)	335		Herpes simplex virus 1 (HSV1)	330
	<i>Ureaplasma urealyticum</i> (UU)	431		<i>Gardnerella vaginalis</i> (GV)	407
	<i>Trichomonas vaginalis</i> (TV)	690		Herpes simplex virus 2 (HSV2)	570
Internal control		820		<i>Haemophilus ducreyi</i> (HD)	670

The negative control included in the kit serves as a general control for exogenous nucleic acid contamination and is used to monitor cross-contamination during DNA extraction and PCR reaction setup steps. It should be run with each batch of tests.

The positive controls included in the kit consist of synthesized plasmid DNA for each gene target and are used to monitor for the presence of inhibitors and the efficiency of the polymerase chain reaction. They should be run with each batch of tests.

The internal control are utilized to ensure that clinical specimens are successfully amplified and detected. For this product, internal controls use a house keeping gene. These controls can be added to each clinical sample during extraction preparation or into the reaction master mixture during PCR preparation procedure.

## IV. Kit Components and Packaging Specifications

Catalog Number: GNT-1004-1 100 Tests/Kit

No.	Component Name	Volume	Main Ingredients
1	STD Mixture	2 vials, 800uL	DNA Taq polymerase, dNTPs with dUTP, Magnesium Chloride, Potassium, Uracil N-glycosylase
2	STD Mix I Primer	1 vial, 200uL	Tris-HCl, EDTA, oligonucleotide primers specific for pathogens
3	STD Mix II Primer	1 vial, 200uL	Tris-HCl, EDTA, oligonucleotide primers specific for pathogens
4	Internal control Primer	2 vials, 200uL	Tris-HCl, EDTA, oligonucleotide primers specific for pathogens
5	STD Mix I Positive control	1 vial, 60uL	Tris-HCl, EDTA, synthesized DNA control specific for pathogens
6	STD Mix II Positive control	1 vial, 70uL	Tris-HCl, EDTA, synthesized DNA control specific for pathogens
7	Negative control	1 vial, 100uL	Double Distilled Water

## V. Materials Required But Not Provided

No.	Name	CAT No.	Manufacturer
1	Any applicable 96-well PCR plate plastics for ThermoFisher Veriti 96-well Thermal Cycler	-	-
2	Any applicable PCR plate sealing film for ThermoFisher Veriti 96-well Thermal Cycler	-	-
3	Qiagen QIAamp <sup>®</sup> DSP DNA Mini kit	61304	Qiagen
4	Any applicable barrier tips appropriate for molecular testing	-	-
5	Any applicable pipettes with several volumes appropriate for molecular testing	-	-
6	Any applicable 1.5mL or higher distilled vials	-	-
7	Materials and equipment for agarose gel electrophoresis	-	-

## VI. Instruments

PCR Instruments validated for use with the Ezplex<sup>®</sup> STD13 PCR Kit:

- Veriti 96-well Thermal Cycler (ThermoFisher Scientific)

## VII. Storage and Handling Conditions

- All kit materials should be stored at  $-20\text{ }^{\circ}\text{C} \pm 2$  opened and unopened.
- Use the reagents before the expiration date shown on the labeling.
- The product is valid only if it is not more than 6 months from date of opening the lid.
- Completely thaw the reagents before use.
- Repeated thawing and freezing should be avoided.

## VIII. Warning and Precautions

- For *in vitro* diagnostic use—should only be used by clinical experts such as clinical pathologists and medical technologists.
- This product is intended only for the detection of nucleic acid from *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, *Gardnerella vaginalis* and *Haemophilus ducreyi* not for any other bacteria or pathogens.
- Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines.<sup>7</sup>
- Specimens may be infectious. Use Universal Precautions when performing this assay. Proper handling and disposal methods should be established by the laboratory director. Only personnel adequately trained in handling infectious materials should be permitted to perform this diagnostic procedure.
- Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with any STD pathogens.
- Wear disposable, powderless gloves, protective eyewear, and laboratory coats when handling specimens and reagents. Wash hands thoroughly after handling specimens and reagents.
- Dispose of all material that has come into contact with specimens and reagents by applicable national, international, and regional regulations.
- Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
- Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of bacteria, viruses or other organisms. Ensure that specimen containers do not come in contact with one another, and discard used materials without passing them over any open containers. Change gloves if they come in contact with specimens. It is recommended to use sterile disposable filter-tips to aspirate reagents and specimens.
- Do not use the reagents and controls after the expiration date.
- Do not mix reagents from different lots.
- Since the plasmid DNA in the positive control can degrade, it is recommended that the reagents shall be divided into amounts required for 1-2 tests and stored in a freezer.
- Qiagen QIAamp® DSP DNA Mini Kit can be used with the Ezplex® STD 13 PCR Kit for nucleic acid extraction.

- ThermoFisher Veriti 96-well Thermal Cycler can be used with the Ezplex<sup>®</sup> STD 13 PCR Kit. The PCR instruments should be calibrated regularly according to the instrument's instructions to eliminate cross-talks between channels.
- The Ezplex<sup>®</sup> STD 13 PCR Kit uses PCR-based technology and testing should be conducted in three separate areas: reagent preparation area, specimen preparation area, and amplification area. Protective equipment accessories (goggles, work clothes, hats, shoes, gloves, etc.) should be worn during operation and protective equipment accessories should be changed when entering and leaving different work areas. Protective equipment accessories in each work area are not interchangeable.
- Store assay components at the recommended storage condition.
- Quality control requirements must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.
- Each test should include positive control and negative control, and this should be taken into account when interpreting the results.
- IC may not amplify when the target nucleic acid is high in concentration or inhibitory substances are present. In this case, retest by diluting the nucleic acid appropriately.

## IX. Collection, Storage and Shipment of Specimens

### A. Specimen Collection

Vaginal swab specimens: Vaginal swab specimens should be collected and sealed in a dedicated transport container. Urine specimens: Collect more than 15mL (at least 10 mL) of urine in a sterilized container.

### B. Specimen Storage

A sample collection and transport device are not a part of the assay kit. Patient samples must be collected according to appropriate laboratory guidelines. Vaginal swabs should be stored at 2 to 8 °C for up to 10 days if the extracted DNA cannot be used immediately. Urine swabs should be stored at 2 to 8 °C for up to 7 days, if the extracted DNA cannot be used immediately.

### C. Shipping

Specimens should be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation External Icon. Store specimens at 2-8°C and ship overnight to the lab on the ice pack.

## D. Specimen Preparation

- It is recommended that nucleic acid should be isolated and purified from vaginal swabs and urine using the QIAamp® DSP DNA Mini Kit.
- Ensure homogeneous mixing of prepared specimens.
- Vaginal swabs:
  - Vortex for 15 seconds at room temperature and mix.
  - Vortexing for as long as possible, add 200 µL of suspension to a 1.5mL tube or extraction-only tube except for unremoved mucus and perform extraction according to the QIAamp DSP DNA Mini Kit instructions for use.
- Urine:
  - Centrifuge 5-10 mL of urine at 3000 rpm for 15 minutes at room temperature.
  - After centrifugation, place 200µl including the part with the cell pellet below into a 1.5mL tube or tube for extraction and proceed with extraction according to the QIAamp DSP DNA Mini Kit instructions for use.

## X. Test Procedure

### A. Nucleic Acid Extraction

It is recommended that the Qiagen QIAamp® DSP DNA Mini Kit (Qiagen GmbH) shall be used for nucleic acid extraction and users shall follow the protocol included in the Kit user manual. After extraction, nucleic acid shall be divided into amounts required for 1-2 tests and should be stored at  $-20 \pm 2 \text{ }^{\circ}\text{C}$  in a freezer since DNA can degrade.

### B. Real-time PCR Amplification

#### 1. Reagent Master Mix Solution Preparation

a. Refer to the table below and prepare each of the two PCR master mix solutions according to the number of samples /controls to be tested.

**Table 1. PCR Master Mixture Solution (unit: µL)**

Component	Volume (µL) per Specimen/Control
STD Mixture	8
STD Mix I Primer and STD Mix II Primer	2
Internal Control Primer	2
Total	12

- b. Pipette 12µL of each of the 2 PCR master mix solutions into each PCR tube. Add 4µL of the extracted DNA specimen into each PCR tube.
- c. Also, add 4µL of each of the positive controls and negative control into each PCR tube.
- d. Cap the top of the PCR tube thoroughly to prevent the liquid from spilling or leaking.
- e. Centrifuge each PCR tube to make sure that all liquids are placed at the bottom.
- f. Each batch of samples tested should include the following controls: 2 positive controls and negative control.

## 2. PCR Instrument Set Up

a. Set up the PCR Instrument according to its Instrument Reference Guide/Manual using the cycling specifications below.

Step	No.	Temperature / Time	Cycle
Hold	1	50 °C / 2 min	1 Cycle
	2	94 °C / 10 min	
Cycle	3	94 °C / 20 sec	40 Cycles
	4	62°C / 1min 20 sec	
	5	72°C / 1min	
Hold	6	72°C / 5min	1 Cycle
	7	4°C / ∞	

b. Add the prepared PCR tubes to the PCR Instrument and run according to its Instrument Guide/Manual.

## 3. Agarose Gel Electrophoresis of PCR Products

a. Measure 2.2 g of agarose. Simply adjust the mass of agarose in a given volume to make gels of other agarose concentrations (e.g., 2.2 g of agarose in 100 mL of TAE will make a 2.2% gel).

b. Mix agarose powder with 100 mL 1xTAE in a microwavable flask.

c. Microwave for 1-3 min until the agarose is completely dissolved (but do not overboil the solution, as some of the buffer will evaporate and thus alter the final percentage of agarose in the gel)

d. Let agarose solution cool down to about 50 °C (about when you can comfortably keep your hand on the flask), about 5 mins.

e. (Optional) Add ethidium bromide (EtBr) to a final concentration of approximately 0.2-0.5 µg/mL (usually about 2-3 µl of lab stock solution per 100 mL gel). EtBr binds to the DNA and allows you to visualize the DNA under ultraviolet (UV) light.

f. Pour the agarose into a gel tray with the well comb in place.

g. Place newly poured gel at 4 °C for 10-15 mins OR let sit at room temperature for 20-30 mins, until it has completely solidified.

h. Perform agarose gel electrophoresis on the PCR products to determine the presence and size of bands.

## XI. Quality Control

Positive Controls and Negative Control are provided with the Kit and should be run with each batch of specimens. The internal control provided with the kit is used as a housekeeping and is utilized to ensure that each clinical specimen is successfully amplified and detected.

## XII. Interpretation of Results

Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

Please check band presence and size on the agarose gel (2.2%) as follows.

Panel	Target	Required Size (bp) to Determine Detection
<b>Mix I Primer</b>	<i>Chlamydia trachomatis (CT)</i>	117
	<i>Neisseria gonorrhoeae (NG)</i>	175
	<i>Mycoplasma genitalium (MG)</i>	248
	<i>Mycoplasma hominis (MH)</i>	335
	<i>Ureaplasma urealyticum (UU)</i>	431
	<i>Trichomonas vaginalis (TV)</i>	690
<b>Mix II Primer</b>	<i>Ureaplasma parvum (UP)</i>	119
	<i>Candida albicans (CA)</i>	187
	<i>Treponema pallidum (TP)</i>	252
	Herpes simplex virus 1 (HSV1)	330
	<i>Gardnerella vaginalis (GV)</i>	407
	Herpes simplex virus 2 (HSV2)	570
	<i>Haemophilus ducreyi (HD)</i>	670
Internal control (IC)	820	

## XIII. Limitations

- The Ezplex® STD 13 PCR Kit has been validated for use with vaginal swabs and urine run on the ThermoFisher Veriti 96-well Thermal Cycler and utilizing the Qiagen QiaAMP® DSP DNA Mini Kit.
- The procedures in this handbook must be followed, as described. Any deviations may result in assay failure or may cause erroneous results.
- Use of this assay is limited to personnel who are trained in the procedure. Failure to follow these instructions may result in erroneous results.
- Reliable results are dependent on adequate specimen collection, transport, storage, and processing.
- Good laboratory practices are required to ensure the performance of the kit, with the care required to prevent contamination of the kit components. Components should be monitored for contamination and any components thought to have become contaminated should be discarded as standard laboratory waste in a sealed pouch or zip-lock plastic bag.
- All specimens should be handled as if they are infectious following proper biosafety precautions.
- False negative results may be caused by:
  - Unsuitable collection, handling and/or storage of specimens
  - Specimen outside of viremic phase

- o Failure to follow procedures in this handbook
- o Use of unauthorized extraction kit or PCR platforms
- False positive results may be caused by:
  - o Unsuitable handling of samples containing high concentrations of pathogenic nucleic acid (DNA) or positive control template.
  - o Unsuitable handling of amplified product
- All results should be interpreted by a health care professional in the context of the patient medical history and clinical symptoms.
- This test cannot rule out diseases caused by other pathogens.
- A negative result for any PCR test does not conclusively rule out the possibility of infection and should not be used as the sole basis for treatment or other management decisions.
- A positive result indicates the detection of nucleic acid from the relevant virus. Nucleic acid may persist even after the virus is no longer viable.
- Interpretation of results must account for the possibility of false negative and false positive results.

## XIV. Performance Evaluation

### A. Analytical Sensitivity

#### 1. Limit of Detection

Standard materials of each of the 13 STD types were serially diluted into 4 concentrations and tested in replicates of 24 for each pathogen. The limit of detection is calculated as below using probit analysis of 95% positive rate.

Target	Limit of Detection (LoD) (Copies/uL)
<i>Chlamydia trachomatis</i>	1.212
<i>Neisseria gonorrhoeae</i>	1.708
<i>Mycoplasma genitalium</i>	4.3
<i>Mycoplasma hominis</i>	2.636
<i>Ureaplasma urealyticum</i>	33.577
<i>Trichomonas vaginalis</i>	0.021
<i>Ureaplasma parvum</i>	3.071
<i>Candida albicans</i>	4.918
<i>Treponema pallidum</i>	2.636
<i>Herpes simplex virus 1</i>	17.077
<i>Herpes simplex virus 2</i>	16.231
<i>Gardnerella vaginalis</i>	4.918
<i>Haemophilus ducreyi</i>	50.104

## 2. Carry-over

The positive control and negative control were tested alternately for a total of 20 times in duplicate twice a day for 5 days to test whether the positive control showed positive results and the negative control showed negative results. As a result of the testing, all of the positive controls were positive, and all of the negative controls were negative, confirming that there was no cross-contamination.

## B. Analytical Specificity (Inclusivity)

### 1. Cross-Reactivity

Nucleic acid from 31 species of microorganisms, which could potentially cause cross-reactivity was tested in triplicate. No cross-reactivity was observed.

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

### 2. Interference

The effect of interfering substances: Albumin, Hemoglobin, Bilirubin, EDTA, Urea, and Feminine Wash on assay performance was evaluated using DNA at a concentration near the Limit of Detection. Samples containing these substances were tested in triplicate and No interference was observed as all positive samples showed positive results.

## C. Analytical Precision

### 1. Reproducibility

Reference materials for STD pathogens were diluted into middle concentrations (1000 X LoD) and low concentrations (10 X LoD). These were tested together with negative samples (D.D.W) using 1 Lot by 2 investigators. Each investigator tested twice daily for 5 days as a duplicate at two places including the manufacturer. The detection results were the same both between days and between investigators.

### 2. Repeatability

Reference materials for STD pathogens were diluted into middle (1000 X LoD) and low concentrations (10 X LoD). These were tested together with negative samples (D.D.W) using 3 Lots by 1 investigator with the investigator testing 20 times repeatedly. All Positive samples showed positive results and Negative samples showed negative results and the detection results were the same within a test, between tests, and between lots.

### D. Clinical Evaluation

Clinical performance was evaluated by a clinical laboratory in the Republic of South Korea using the left-over vaginal swabs and urine specimens that positive and negative were previously determined by MFDS (Ministry of Food and Drug Safety of South Korea) approved products with the results shown as below.










As a result, clinical sensitivity was 100% and clinical specificity was 99.01-100%.

Target	Vaginal Swab	Urine	Vaginal Swab	Urine
	Sensitivity(95% CI)	Specificity(95% CI)	Sensitivity(95% CI)	Specificity(95% CI)
<i>Chlamydia trachomatis</i>	100% (95.1 ~ 100%)	100% (99.3 ~ 100%)	100% (94.7 ~ 100%)	100% (99.3 ~ 100%)
<i>Neisseria gonorrhoeae</i>	100% (94.4 ~ 100%)	100% (99.4 ~ 100%)	100% (94.5 ~ 100%)	100% (99.3 ~ 100%)
<i>Mycoplasma genitalium</i>	100% (94.7 ~ 100%)	99.8 % (99.0 – 100%)	100 % (94.7 – 100 %)	100 % (99.3 – 100%)
<i>Mycoplasma hominis</i>	100% (97.7 ~ 100%)	100% (99.2 ~ 100%)	100% (94.3 ~ 100%)	100% (99.3 ~ 100%)
<i>Ureaplasma urealyticum</i>	100% (96.7 ~ 100%)	100% (99.3 ~ 100%)	100% (95.1 ~ 100%)	100% (99.3 ~ 100%)
<i>Trichomonas vaginalis</i>	100% (94.2 ~ 100%)	100% (99.4 ~ 100%)	100% (93.0 ~ 100%)	100% (99.3 ~ 100%)
<i>Ureaplasma parvum</i>	100% (98.6 ~ 100%)	99.01% (99.0 ~ 100%)	100% (95.7 ~ 100%)	100% (98.3 ~ 100%)
<i>Candida albicans</i>	100% (96.6 ~ 100%)	100% (99.3 ~ 100%)	100% (94.5 ~ 100%)	100% (99.3 ~ 100%)
<i>Treponema pallidum</i>	100% (93.0 ~ 100%)	100% (99.4 ~ 100%)	100% (93.0 ~ 100%)	100% (99.3 ~ 100%)
Herpes simplex virus 1	100% (94.3 ~ 100%)	100% (99.4 ~ 100%)	100% (93.2 ~ 100%)	100% (99.3 ~ 100%)
Herpes simplex virus 2	100% (94.2 ~ 100%)	100% (99.4 ~ 100%)	100% (94.4 ~ 100%)	100% (99.3 ~ 100%)
<i>Gardnerella vaginalis</i>	100% (98.8 ~ 100%)	100% (99.0 ~ 100%)	100% (96.1 ~ 100%)	100% (96.3 ~ 100%)
<i>Haemophilus ducreyi</i>	100 % (93.0 – 100 %)	100 % (99.4 – 100 %)	100 % (93.0 – 100 %)	100 % (99,3 – 100 %)

## XV. References

1. Rowley J, Vander Hoorn S, Korenromp E, Low N, Unemo M, Abu-Raddad LJ, et al. Global and Regional Estimates of the Prevalence and Incidence of Four Curable Sexually Transmitted Infections in 2016. *WHO Bulletin*. June 2019. <https://www.who.int/bulletin/volumes/97/8/18-228486.pdf>
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6. [https://www.cdc.gov/std/healthcomm/fact\\_sheets.htm](https://www.cdc.gov/std/healthcomm/fact_sheets.htm); accessed September 2021.
7. WHO, Laboratory Biorisk Management Strategic Framework for Action 2012-2016, World Health Organization, 2012.

## XVI. Symbols and Information

Symbol	Meaning	Symbol	Meaning
	Storage Temperature		In-Vitro Diagnostic Medical Devices
	Expiration date		Product User Manual
	Catalog Number		Manufacturer
	Lot Number		Keep away from sunlight (P+P)
	Contents sufficient for <n> tests		

## XVII. Technical Support

For Technical Support, please contact our Genetree Technical Support team. Before contacting Genetree Technical Support collect the following information

- Product name
- Lot number
- Software version
  
- o Email for Technical Support: [technicalsupport@smlgenetree.com](mailto:technicalsupport@smlgenetree.com)
- o Email for Customer Support: [customersupport@smlgenetree.com](mailto:customersupport@smlgenetree.com)
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