STANDARD M10 STI Panel

STANDARD™ M10 STI Panel

REF M10-STI-01

INSTRUCTIONS FOR USE

For use with STANDARD™ M10 system

www.sdbiosensor.com

SD BIOSENSOR

Contents

1. Intended Purpose

STANDARD M10 STI Panel test is a multiplex real-time PCR test intended for use with STANDARD M10 system to qualitatively detection of sexually transmitted infection (STI) pathogens: *Chlamydia trachomatis, Neisseria gonorrhoeae,* Human herpesvirus 1, Human herpesvirus 2*, Mycoplasma genitalium, Mycoplasma hominis, Trichomonas vaginalis,* and *Ureaplasma urealyticum* in urine specimens collected from asymptomatic and symptomatic individuals suspected of having STI.

It is intended as an aid to diagnose a patient's infection status. Determining a patient's infection status requires clinical correlation with the patient's medical history and other diagnostic information. Positive results do not rule out co-infection with other pathogens. Negative results do not preclude sexually transmitted infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. This test is intended to be performed by trained users in both laboratory and hospital setting

2. Summary and Explanation

Sexually transmitted infections (STIs) are caused by more than 30 different bacteria, viruses, and parasites that are known to be transmitted through sexual contact, including vaginal, anal, and oral sex. Common symptoms of STIs include vaginal discharge, urethral discharge in men, genital ulcers, and abdominal pain.

Chlamydia trachomatis

Chlamydiae are Gram-negative, obligate intracellular pathogens. It can cause cervicitis, urethritis, and proctitis in women. Strains of *C. trachomatis* are divided into three biovars. The trachoma biovar (serovars A–C) is the leading cause of non-congenital blindness in developing nations, whereas the genital tract biovar (serovars D–K) is the most prevalent sexually transmitted bacterium. In women, the lymphogranuloma venereum (LGV) biovar (serovars L1–L3) causes invasive urogenital or anorectal infection.

Neisseria gonorrhoeae

Neisseria gonorrhoeae is Gram-negative diplococcic bacteria. It causes infections in the genitourinary, genitals, rectum, and throat. It is very common, especially among young people ages 15-24 years. This Infection may experience dysuria with penile discharge, and women may have mild vaginal mucopurulent discharge, severe pelvic pain, or no symptoms. Untreated infection may lead to serious complications, including pelvic inflammatory disease, ectopic pregnancy, and infertility.

Human herpesvirus 1/2

Infection with herpes simplex virus (HSV), known as herpes, and caused by 2 types: HSV-1 and HSV-2. HSV-1 often causes oral herpes, which can result in cold sores or fever blisters on or around the mouth. However, most people with oral herpes do not have any symptoms. Most people with oral herpes get it during childhood or young adulthood from non-sexual contact with saliva. HSV-2 is a sexually transmitted infection that causes genital herpes. Most HSV infections are asymptomatic. Both oral and genital herpes are mostly asymptomatic or unrecognized but can cause painful blisters or ulcers at the site of infection, ranging from mild to severe. Infection is lifelong, and symptoms can recur over many years. Some medications are available to reduce the severity and frequency of symptoms, but they cannot cure the infection.

Mycoplasma genitalium / hominis / Ureaplasma urealyticum

Mycoplasma species are small pleomorphic bacteria that typically lack a cell wall and are bound by a cell membrane. The family Mycoplasmataceae is composed of two genera responsible for human infection: Mycoplasma and Ureaplasma. Of those, *Mycoplasma hominis*, *Mycoplasma genitalium*, and *Ureaplasma* spp., which include *Ureaplasma urealyticum* (biovar 2) Genital mycoplasmas are often associated with sexually transmitted infections such as cervicitis and nongonococcal urethritis (NGU) or with puerperal infections such as endometritis. *M. hominis* and *Ureaplasma* spp. commonly colonize the female genital tract and can cause chorioamnionitis.

Trichomonas vaginalis,

Trichomonas vaginalis is an anaerobic, flagellated protozoan parasite and the causative agent of trichomoniasis. *Trichomonas vaginalis* is the most common curable sexually transmitted infection (STI) worldwide. Symptomatic trichomoniasis presents with vaginal or urethral discharge, pelvic pain, dysuria (painful urination), and itching of the genitals. Trichomoniasis infection in pregnant women can cause adverse pregnancy outcomes, particularly premature rupture of membranes, pre-term delivery, and low birth weight.

STANDARD M10 STI Panel is a molecular *in vitro* diagnostic test that aids in the detection and identification of STI panthogens and is based on widely used nucleic acid amplification technology. STANDARD M10 STI Panel test contains primers and probes and internal control (IC) used in Real-time PCR for the *in vitro* qualitative detection of STI pathogen DNA in urine specimens.

[Cartridge Description]

STANDARD M10 STI Panel is a molecular *in vitro* diagnostic assay that aids in the simultaneous detection and differentiation of *Chlamydia trachomatis*(CT), *Neisseria gonorrhoeae*(NG), Human herpesvirus 1(HSV1), Human herpesvirus 2(HSV2), *Mycoplasma genitalium*(MG), *Mycoplasma hominis*(MH), *Trichomonas vaginalis*(TV), *Ureaplasma urealyticum*(UU) DNA based on nucleic acid amplification technology, real-time PCR. STANDARD M10 STI Panel cartridge contains nucleic acid extraction buffers and real-time PCR reagents for the *in vitro* qualitative detection of CT, NG, HSV1, HSV2, MG, MH, TV, and UU DNA in urine specimens.

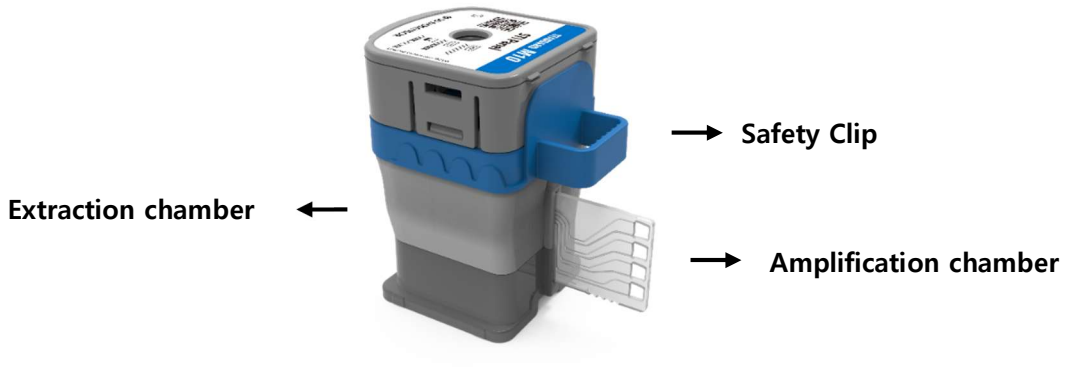

Figure 1. Layout of STANDARD M10 STI Panel cartridge

3. Principle of the Procedure

STANDARD M10 STI Panel test is an automated *in vitro* diagnostic test for the qualitative detection of nucleic acid from STIs organism. STANDARD M10 STI Panel test is performed on the STANDARD M10 system.

STANDARD M10 system automates and integrates specimen preparation, nucleic acid extraction, amplification, and detection of the target sequences in various specimens using molecular diagnostic assays. The system consists of STANDARD M10 Module and STANDARD M10 Console with preloaded software for conducting tests and analyzing the results. The system requires the use of single-use disposable cartridges that hold the real-time PCR reagents and host the real-time PCR process. Because the cartridges are self-contained, cross-contamination between specimens is minimized. For a full description of the systems, see STANDARD M10 System User Manual.

STANDARD M10 STI Panel test includes reagents for the detection of STI pathogen DNA in urine specimens. The cartridge is present to control for adequate processing of the sample and real-time PCR reaction.

The table below indicates which target is designed to be detected by which channel.

Table 1. Fluorescent channel of each target gene

Target	Channel
Chlamydia trachomatis (CT)	FAM
Neisseria gonorrhoeae (NG)	FAM
Human herpesvirus 1 (HSV1)	HEX

Human herpesvirus 2 (HSV2)	HEX
Mycoplasma genitalium (MG)	FAM
Mycoplasma hominis (MH)	HEX
Trichomonas vaginalis (TV)	FAM
Ureaplasma urealyticum (UU)	HEX
Internal control (IC)	Cy5

4. Materials Provided

STANDARD M10 STI Panel contains sufficient reagents to process 10 specimens or quality control samples.

Table 2. Contents of STANDARD M10 STI Panel kit

	Contents	Quantity	Usage in each reaction
1	Cartridge	10	1ea
2	Quick Reference Instructions	1	-

5. Storage and Handling

Store STANDARD M10 STI Panel at 2 ~ 28℃ (36 ~ 82℉). If the cartridge has been refrigerated, perform the test after stabilizing it for 30 minutes at 20 ~ 28℃(68 ~ 82℉). Do not remove the Safety Clip of the cartridge and do not press the cartridge until actual use. Do not use a cartridge that has leaked or is wet. Under these conditions, cartridges can be stored until the expiration date printed on the packaging.

6. Materials Required but Not Provided

- STANDARD M10 system with User Manual
  At least one STANDARD M10 Console (Cat. No. 11M1011) and one STANDARD M10 Module (Cat. No. 11M1012)
- Sample transfer pipettes
  - STANDARD™ Disposable dropper (1㎖) (Cat No. 90DR40)
  - Micropipette with filter tips
- Urine collection container
- PPE (Personal Protective Equipment)

7. Warnings and Precautions

1) This kit is only for *in vitro diagnosis*.
2) For professionals only.
3) Please read the Instructions for Use carefully before testing.
4) Improper specimen collection, transfer, storage, and processing may cause erroneous test results.
5) Do not remove the Safety Clip of the cartridge before use.
6) Do not press the cartridge until actual use.
7) Do not use a cartridge that has leaked or is wet.
8) Keep the cartridge away from UV/sunlight and keep dry.
9) Do not use the kit after its expiration date.
10) Do not shake, tilt, or invert the cartridge, especially after pressing the cartridge to punch the seal. It may yield invalid or false test results.
11) Do not use a cartridge with a damaged barcode label.
12) Do not reuse processed cartridges.
13) All patient specimens should be handled as if these specimens are infectious.
14) All materials should be considered potentially infectious and should be handled with precautions.

15) As this test involves the extraction of bacterial, viral, parasitic DNA and PCR amplification, care should be taken to avoid contamination. Regular monitoring of laboratory contamination is recommended.
16) Clinical laboratories should be equipped with equipment and operators in strict accordance with the "Code of Practice for Clinical Gene Amplification Laboratories."
17) When using this kit, it should be operated strictly in accordance with the instructions; the specimen processing and specimen addition steps must be performed following the technical requirements of the clinical gene amplification laboratory.
18) Follow your institution's environmental waste procedures for proper disposal of used cartridges.

8. Specimen Collection and Storage

Proper specimen collection, transportation, and storage and critical to the performance of the test. Improper specimen collection, inappropriate specimen handling, and/or transportation can lead to false results.

8.1. Specimen Collection

Collect the urine specimen into plastic urine collection cups.

8.2. Specimen Storage and Transport

The urine specimens can be stored and transported in a refrigerator at 2 ~ 8℃ (36 ~ 46℉) for up to 2 days for testing. For prolonged storage, specimens should be frozen at -70℃(-94℉).

9. Procedure

Starting STANDARD M10 system

Note	For the detailed instructions, refer to STANDARD M10 system User Manual. If you have scanned the cartridge barcode in STANDARD M10 and the software version is not compatible, a 'Not Supported Device' error message appears. Update the software before proceeding with the test.

1) Turn on the STANDARD M10 system.
2) Check if the STANDARD M10 Console and STANDARD M10 Module are connected and functional.

Figure 2. Power connection

3) Enter the User ID and Password on the Log In screen of the STANDARD M10 Console and click the Log In button.
4) Touch STANDARD M10 Module to run on the Home screen. (The door of the selected STANDARD M10 Module will automatically open for cartridge loading.)

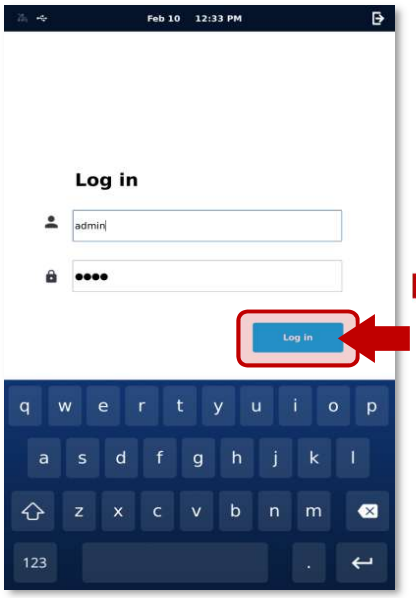

Figure 3. Log In screen

Figure 4. Home screen, Status of M10 module

5) Enter a Patient ID by scanning the barcode or using virtual keyboard on the M10 Console screen (Patient ID is optional. You can turn off the Patient ID option from the 'Settings').
6) Enter a Sample ID by scanning the barcode of the specimen or using virtual keyboard on the M10 Console screen. Make sure that the specimen tube cap is firmly closed when scan the ID barcode printed on the specimen tube (For quality control test, tick the QC check box).

Figure 5. Entering Sample ID

Figure 6. Scanning a cartridge

7) Scan the cartridge to be used. The STANDARDM10 Console automatically recognizes the assay to be run based on the cartridge barcode.

9.2 Loading a specimen into STANDARD M10 STI Panel cartridge

Caution	For If the cartridge has been refrigerated, perform the test after stabilizing it for 30 minutes at 20 ~ 28°C (68 ~ 82°F). Start the test within 30 minutes of loading the specimen into the cartridge.
Note	False negative results may occur if insufficient specimen is added into the cartridge.

1) Remove the Safety Clip located underneath the lid of the cartridge.
2) Pierce the sealed cartridge by pressing down the lid until fully engaged into the cartridge groove.
3) Open the lid and check that the seal is completely punctured before loading a specimen.
4) Mix specimen by rapidly inverting the specimen or external control tube 5 times. Carefully open the cap of the specimen tube or external control.
5) Dispense 1,000µl of the specimen into the hole in the lower right corner of the cartridge using 1,000µl of Disposable dropper or a pipette with a filter tip.
6) After a few seconds, Sample Guide screen will automatically change to the Insert Cartridge screen. Touch the Sample Guide screen if you want to skip the guide.
7) Close the lid.

Figure 7. Loading a specimen

Figure 8. Sample Guide screen

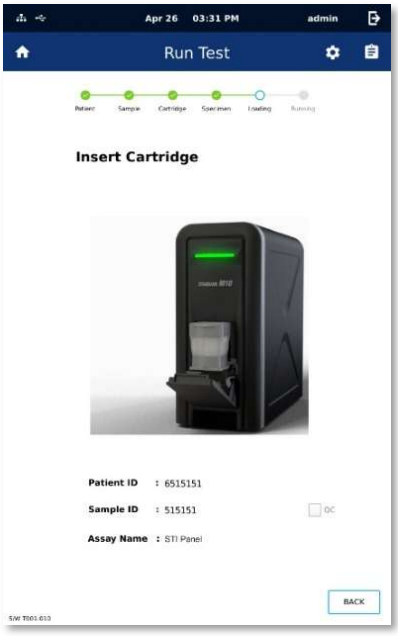

Figure 9. Insert cartridge screen

9.3 Running a test

1) Load the cartridge on the selected STANDARD M10 Module with the Amplification chamber facing the inside of the module. (The status indicator of the selected module will blink green.)
2) Close the door completely.
3) After confirming the specimen and cartridge information, touch the OK button on the screen (Touch the Reset button to re-input the information.)
4) Assay starts automatically, and remaining time will appear on the screen.

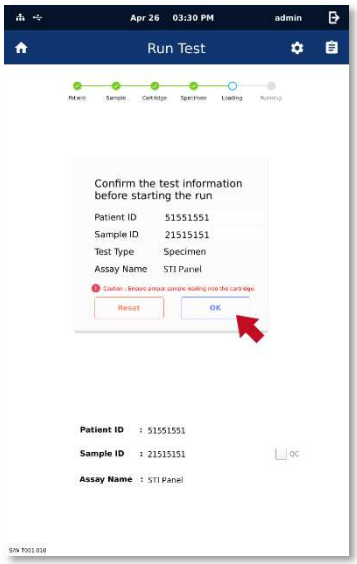

Figure 10. Confirm the test screen

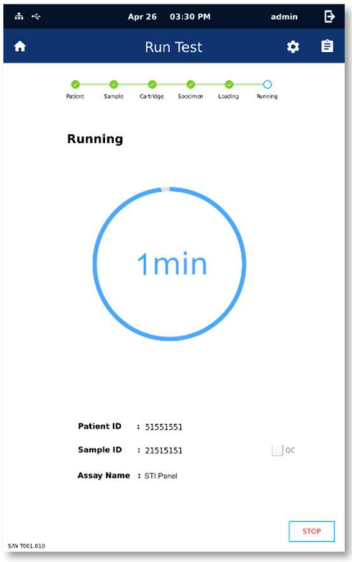

Figure 11. Running screen

5) When the run is finished, it switches to the Review screen and the result is displayed.
6) Dispose the used cartridges in the appropriate biohazard waste containers according to your institution's standard practices.
7) To run another test, touch the Home icon and repeat the process.(If another STANDARD M10 Module connected to STANDARD M10 Console is available, you can start a new test while running another test.)

10. Interpretation of Results

The results are interpreted automatically by STANDARD M10 Console and are clearly shown in the Review screen. STANDARD M10 STI Panel provides test results based on the detection of targets according to the algorithms shown in Table 3, 4.

Table 3. Description of target results

Outcome (Home screen)	Result (Review screen)	Description
Positive		At least one pathogen/target gene is positive.
Negative		No pathogen was detected.
Invalid		IC signal does not have a Ct within the valid range.
Error		The test failed because either an error occurred or the test was canceled by the user.

Table 4. Description of IC results

Outcome (Summary screen)	Result (Summary screen)	Description
IC Valid		IC has a Ct within the valid range. The test was completed. Report positive/negative results of pathogens according to the interpretation shown in table 5.
IC Invalid		IC signal does not have a Ct value within the valid range.
Error		The test failed because either an error occurred or the test was canceled by the user. Repeat the test.

Table 5. Interpretation of results

Result	Interpretation
CT Positive	The CT target DNA is detected. • The CT signal has a Ct within the valid range. • IC: Valid; IC has a Ct within the valid range.
NG Positive	The NG target DNA is detected. • The NG signal has a Ct within the valid range. • IC: Valid; IC has a Ct within the valid range.
HSV1 Positive	The HSV1 target DNA is detected. • The HSV1 signal has a Ct within the valid range. • IC: Valid; IC has a Ct within the valid range.
HSV2 Positive	The HSV2 target DNA is detected. • The HSV2 signal has a Ct within the valid range. • IC: Valid; IC has a Ct within the valid range.
MG Positive	The MG target DNA is detected. • The MG signal has a Ct within the valid range. • IC: Valid; IC has a Ct within the valid range.
MH Positive	The MH target DNA is detected. • The MH signal has a Ct within the valid range. • IC: Valid; IC has a Ct within the valid range.
TV Positive	The TV target DNA is detected. • The TV signal has a Ct within the valid range. • IC: Valid; IC has a Ct within the valid range.
UU Positive	The UU target DNA is detected. • The UU signal has a Ct within the valid range. • IC: Valid; IC has a Ct within the valid range.
CT Positive NG Positive HSV1 Positive HSV2 Positive MG Positive MH Positive TV Positive UU Positive	The CT, NG, HSV1, HSV2, MG, MH, TV, and UU target DNAs are detected. • IC: Valid; IC has a Ct within the valid range.
CT Negative, NG Negative, HSV1 Negative, HSV2 Negative MG Negative MH Negative TV Negative UU Negative	• CT, NG, HSV1, HSV2, MG, MH, TV, and UU target DNAs are not detected. • IC: Valid; IC has a Ct within the valid range.
Invalid	IC does not meet acceptance criteria. Repeat test. • IC: Invalid; IC signal does not exhibit a Ct value within the valid range
Error	The test failed because either an error occurred or the test was canceled by the user. The presence or absence of target nucleic acids cannot be determined. Repeat the test.

Note	- Co-infection can occur with these targets: CT, NG, HSV1, HSV2, MG, MH, TV, UU. - When the result of IC shows Invalid, it means that the cartridge was not properly processed. Repeat the test.

11. Quality Control

STANDARD Quality Control procedures are intended to monitor cartridge and assay performance. If the controls are not valid, the patient results cannot be interpreted.

Internal control (IC): Ensures that the processes within the cartridge are functioning properly, that there are no other interfering factors in the sample, and that the procedure has been carried out correctly. If the IC signal does not exhibit a Ct within the valid range, the result is considered invalid.

External controls should be used in accordance with local, state, and federal accrediting organizations as applicable. For external controls, it is recommended to use the list below. Please comply with the information stated on the user manual.

- NATtrol™ CT/NG/TV Negative Control(NATCTNGTV-NEG, Zeptometrix) as negative control
- NATtrol™ CT/NG/TV Positive Control(NATCTNGTV-POS, Zeptometrix) as positive control
- Mycoplasma genitalium External Run Control(NATMGN-ERC, Zeptometrix) as positive control
- MYCOPLASAMA HOMINIS TOTAL CONTROL(MC074,Vircell) as positive control
- UREAPLASMA UREALYTICUM TOTAL CONTROL(MC033) as positive control
- Herpes Simplex Virus Type 1 Strain: MacIntyre(NATHSV1-0005, Zeptometrix) as positive control
- Herpes Simplex Virus Type 2 Strain: MS(NATHSV2-0005, Zeptometrix) as positive control

Products other than the mentioned substance can be used after being evaluated and validated for efficacy by each country or hospital independently.

12. Performance

12.1. Limit of Detection Test

The analytical sensitivity of the STANDARD M10 STI Panel test was assessed with two lots of cartridges using positive reference materials. The positive reference were diluted into negative clinical urine specimen, respectively. The LoD for STIs was estimated by running at least 5 serially diluted concentrations with 20 replicates for each concentration. The LoD was determined through probit analysis based on the test results. The claimed LoD values are summarized in Table 6.

Table 6. Summary of the LoD test results

Target	LoD* 95% CI
Chlamydia trachomatis	3.8 IFU/mL (95% CI 3.79~5.53 IFU/mL)
Neisseria gonorrhoeae	1.3 CFU/mL (95% CI 1.05 ~1.76 CFU/mL)
Human herpesvirus 1	7 $TCID_{50}$/mL (95% CI 5.38~12.15 $TCID_{50}$/mL)
Human herpesvirus 2	148 PFU/mL (118~215.3 PFU/mL)
Mycoplasma genitalium	0.02 bacterial/mL (95% CI 0.019~0.036 bacterial/mL)
Mycoplasma hominis	0.06 CFU/mL (95% CI 0.043~0.13 CFU/mL)
Trichomonas vaginalis	6 trophozoites/mL (95% 4.37~13.5 trophozoites/mL)
Ureaplasma urealyticum	0.5 CCU/mL (95% CI 0.42~0.82 CCU/mL)

12.2. Cross-reactivity

The following 37 cross-reacting organisms, including sexually transmitted infections and reproductive tract infections that can be detected in urine specimens, were tested with STANDARD M10 STI Panel. In addition, the test evaluates 8 STI targets*: CT, NG, HSV1, HSV2, MG, MH, TV, and UU, which are the targets of STANDARD M10 STI Panel. As a result, no cross-reactivity was observed with 37 organisms. For the remaining 8 organisms, detection was confirmed for each target.

The organisms and test concentrations are listed in Table 7.

Table 7. Organisms and test concentration for cross-reactivity test

No.	Organism	Test concentration	Result
1	*Acinetobacter calcoaceticus*	$1x10^6$ CFU/mL	No cross-reactivity
2	*Acinetobacter schindleri*	$1x10^6$ CFU/mL	No cross-reactivity
3	*Acinetobacter ursingii*	$1x10^6$ CFU/mL	No cross-reactivity
4	*Corynebacterium diphtheriae*	$1x10^6$ CFU/mL	No cross-reactivity
5	*Edwardsiella tarda*	$1x10^6$ CFU/mL	No cross-reactivity
6	*Enterococcus faecalis*	$1x10^6$ CFU/mL	No cross-reactivity
7	*Escherichia coli*	$1x10^6$ CFU/mL	No cross-reactivity
8	*Klebsiella aerogenes*	$1x10^6$ CFU/mL	No cross-reactivity
9	*Klebsiella pneumoniae*	$1x10^6$ CFU/mL	No cross-reactivity
10	*Listeria monocytogenes*	$1x10^6$ CFU/mL	No cross-reactivity
11	*Pseudomonas aeruginosa*	$1x10^6$ CFU/mL	No cross-reactivity
12	*Salmonella enterica*	$1x10^6$ CFU/mL	No cross-reactivity
13	*Shigella boydii*	$1x10^6$ CFU/mL	No cross-reactivity
14	*Staphylococcus delphini*	$1x10^6$ CFU/mL	No cross-reactivity
15	*Staphylococcus gallinarum*	$1x10^6$ CFU/mL	No cross-reactivity
16	*Vibrio cholerae*	$1x10^6$ CFU/mL	No cross-reactivity
17	*Yersinia enterocolitica*	$1x10^6$ CFU/mL	No cross-reactivity
18	*Bifidobacterium adolescentis*	$1x10^6$ CFU/mL	No cross-reactivity
19	*Chlamydophila pneumoniae*	$1x10^6$ CFU/mL	No cross-reactivity
20	*Clostridium butyricum*	$1x10^6$ CFU/mL	No cross-reactivity
21	*Clostridium novyi*	$1x10^6$ CFU/mL	No cross-reactivity

22	*Fusobacterium necrophorum*	$1x10^6$ CFU/mL	No cross-reactivity
23	*Lactobacillus lactis*	$1x10^6$ CFU/mL	No cross-reactivity
24	*Neisseria flavescens*	$1x10^6$ CFU/mL	No cross-reactivity
25	*Prevotella melaninogenica*	$1x10^6$ CFU/mL	No cross-reactivity
26	*Providencia stuartii*	$1x10^6$ CFU/mL	No cross-reactivity
27	*Saccharomyces cerevisiae*	$1x10^6$ CFU/mL	No cross-reactivity
28	*Serratia liquefaciens*	$1x10^6$ CFU/mL	No cross-reactivity
29	*Shigella flexneri*	$1x10^6$ CFU/mL	No cross-reactivity
30	*Streptococcus agalactiae*	$1x10^6$ CFU/mL	No cross-reactivity
31	*Streptococcus sanguinis*	$1x10^6$ CFU/mL	No cross-reactivity
32	*Ureaplasma parvum*	$1x10^6$ CCU/mL	No cross-reactivity
33	**Trichomonas vaginalis*	$1x10^6$ trophozoites/mL	Only TV detected
34	*Human herpesvirus 2	$1x10^5$ PFU/mL	Only HSV2 detected
35	**Chlamydia trachomatis*	$1x10^6$ IFU/mL	Only CT detected
36	**Mycoplasma hominis*	$1x10^6$ CCU/mL	Only MH detected
37	**Mycoplasma genitalium*	$1x10^6$ bacterial/mL	Only MG detected
38	**Ureaplasma urealyticum*	$1x10^6$ CCU/mL	Only UU detected
39	**Neisseria gonorrhoeae*	$1x10^6$ CFU/mL	Only NG detected
40	*Herpes Simplex Type 1	$1x10^5$ $TCID_{50}$/mL	Only HSV1 detected
41	*Neisseria meningitidis*(A)	$1x10^6$ CFU/mL	No cross-reactivity
42	*Neisseria meningitidis*(B)	$1x10^6$ CFU/mL	No cross-reactivity
43	*Neisseria meningitidis*(C)	$1x10^6$ CFU/mL	No cross-reactivity
44	*Neisseria meningitidis*(D)	$1x10^6$ CFU/mL	No cross-reactivity
45	*Neisseria meningitidis*(Y)	$1x10^6$ CFU/mL	No cross-reactivity

12.3. Interfering Substance

A total of 17 endogenous and exogenous interfering substances, which may potentially be present in the specimen, were tested. These substances were diluted to the test concentration using negative urine specimens and evaluated under conditions with and without the addition of interfering substances in both negative and 2X LoD concentration samples. The results confirmed that there was no interference up to the specified test concentrations for the 17 substances listed below.

Table 8. Interfering substances tested in Interfering Substance test

No.	Factor	Interfering Substances	Test Conc.
1	Blood	Blood	1% w/v
2	Hormone	Progesterone	20 ng/mL
3	Hormone	β-Estradiol	1.36 ng/mL
4	Acidic urine	Acidic urine	PH 4
5	Alkaline urine	Alkaline Urine	PH 9
6	Mucus	Simulated Vaginal fluid	5% v/v
7	Protein	bilirubin	84.3 ug/mL
8	Protein	albumin	0.5 mg/mL
9	White blood cell	Leukocytes	$1x10^6$ cells/mL
10	Semen	Semen	5% v/v
11	Mucus	Mucin	25 mg/mL
12	Glucose	Glucose	0.06 mmol/mL
13	Deodorant	Norforms Feminine Deodorant Suppositories	0.25% w/v
14	Painkiller	Aspirin	900.8 ug/mL
15	Painkiller	Acetaminophen	7.6 mg/mL
16	Antibiotics	Azithromycin	39.2 ug/mL

17	Antibiotics	Doxycycline	48.1ug/mL

12.4 Precision (Repeatability & Reproducibility)

12.4.1 Precision (Repeatability)

The repeatability of the STANDARD M10 STI Panel was assessed by testing each positive reference material at three different concentrations (Negative, 1xLoD and 3xLoD). The test was conducted twice a day for 20 days in one lot, and each concentration was repeated twice during the test. Based on the test results, the SD value was derived from within-run, between-run, between-day, and within-laboratory to assess repeatability, and the SD < 2.0 Ct met the acceptance criteria, confirming the repeatability.

12.4.2 Precision (Reproducibility)

The reproducibility of the STANDARD M10 STI Panel was assessed with each of the positive reference materials being tested at three different concentrations (Negative, 1xLoD and 3xLoD). As a result, the SD value was derived from Between-Instruments, Between-Operator, Between-Lots, and Between-Site tests. Based on the test results, the SD and CV (%) values were analyzed, confirming the reproducibility of the product with an SD < 2.0 Ct and CV < 5%.

12.5 Clinical Performance Study

The clinical performance of the STANDARD™ M10 STI Panel was evaluated using archived human urine specimens. A total of 615 urine specimens were tested with the STANDARD™ M10 STI Panel and compared with CE-marked RT-PCR comparator assays.

The study demonstrated that the STANDARD™ M10 STI Panel meets the performance criteria, achieving a sensitivity of at least 91.9% and a specificity of at least 95.4% across all targets, in accordance with the acceptance criteria set for this clinical performance study (sensitivity ≥90% and specificity ≥95%).

Table 9. Summary of the clinical sensitivity and specificity test results

Chlamydia trachomatis		Compared Device		
		Positive	**Negative**	**Total**
STANDARD™ M10 STI Panel	**Positive**	68	0	68
	Negative	2	221	223
	Total	70	221	291

Diagnostic Sensitivity = 97.1% (95% CI : 90.2%- 99.2%)
Diagnostic Specificity = 100.0% (95% CI: 98.3% - 100.0%)

Neisseria gonorrhoeae		Compared Device		
		Positive	**Negative**	**Total**
STANDARD™ M10 STI Panel	**Positive**	59	0	59
	Negative	4	228	232
	Total	63	228	291

Diagnostic Sensitivity = 93.7% (95% CI : 84.8%- 97.5%)
Diagnostic Specificity = 100.0% (95% CI: 98.3% - 100.0%)

Human herpesvirus 1		Compared Device		
		Positive	**Negative**	**Total**
STANDARD™ M10 STI Panel	**Positive**	58	1	59
	Negative	4	108	112
	Total	62	109	171

Diagnostic Sensitivity = 93.5% (95% CI : 84.6%- 97.5%)
Diagnostic Specificity = 99.1% (95% CI: 95.0% - 99.8%)

Human herpesvirus 2		Compared Device		
		Positive	**Negative**	**Total**
STANDARD™ M10 STI Panel	**Positive**	62	5	67
	Negative	0	104	104

	Total	62	109	171

Diagnostic Sensitivity = 100.0% (95% CI : 94.2%- 100.0%)
Diagnostic Specificity = 95.4% (95% CI: 89.7% - 98.0%)

Mycoplasma genitalium		**Compared Device**		
		Positive	**Negative**	**Total**
STANDARD™ M10 STI Panel	**Positive**	57	0	57
	Negative	5	229	234
	Total	62	229	291

Diagnostic Sensitivity = 91.9% (95% CI : 82.5%- 96.5%)
Diagnostic Specificity = 100.0% (95% CI: 98.4% - 100.0%)

Mycoplasma hominis		**Compared Device**		
		Positive	**Negative**	**Total**
STANDARD™ M10 STI Panel	**Positive**	60	0	60
	Negative	2	91	93
	Total	62	91	153

Diagnostic Sensitivity = 96.8% (95% CI : 89.0%- 99.1%)
Diagnostic Specificity = 100.0% (95% CI: 95.9% - 100.0%)

Trichomonas vaginalis		**Compared Device**		
		Positive	**Negative**	**Total**
STANDARD™ M10 STI Panel	**Positive**	58	0	58
	Negative	4	229	233
	Total	62	229	291

Diagnostic Sensitivity = 93.5% (95% CI : 84.6%- 97.5%)
Diagnostic Specificity = 100.0% (95% CI: 98.4% - 100.0%)

Ureaplasma urealyticum		**Compared Device**		
		Positive	**Negative**	**Total**
STANDARD™ M10 STI Panel	**Positive**	61	0	61
	Negative	1	91	92
	Total	62	91	153

Diagnostic Sensitivity = 98.4% (95% CI : 91.4%- 99.7%)
Diagnostic Specificity = 100.0% (95% CI: 95.9% - 100.0%)

A total of 28 discrepant results were identified during the study, consisting of 6 false positives (FP) and 22 false negatives (FN). Upon retesting, 2 of the initially reported FP cases were resolved as negative, and 3 of the initially reported FN cases were confirmed as positive. In addition, 3 invalid results were identified during testing, all of which were successfully resolved through retesting, resulting in valid outcomes. Following the discrepancy analysis and additional testing, the overall performance of the assay improved. These discrepant results did not affect the final clinical performance assessment, as the accuracy and reliability of the assay were confirmed through repeat testing and further analysis.

For the discrepancy analysis, a total of 28 discrepant results were identified during the study.

13. Limitations

1) Performance characteristics of this test have been established with the specimen types listed in the Intended Purpose Section only. The performance of this assay with other specimen types or specimens has not been evaluated.
2) A false negative result may occur if :
   - ✓ Specimen concentrations are near or below the limit of detection of the test
   - ✓ A specimen is improperly collected, transported, or handled
   - ✓ Inadequate numbers of organisms are present in the specimen
   - ✓ Cartridges are exposed to improper environmental factors (temperature / humidity)
3) False positive results may happen from cross-contamination between patient specimens, specimen mix-up, and/or DNA contamination during product handling.
4) Qualitative detection of positive results in this kit does not indicate the presence of live bacteria or viruses. It is recommended to use other methods for confirmation at the same time.
5) This kit only detects and identifies 8 STI pathogens test results for clinical reference only. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests, and treatment responses considering.
6) Potential mutations within the target regions covered by the primer and/or probes of the test may result in failure to detect the presence of the pathogen.

14. References

1) Technical Specifications Series for submission to WHO Prequalification –Diagnostic Assessment
2) Clinical and Laboratory Standards Institute. 2008. Verification and Validation of Multiplex Nucleic Acid Assays: Approved Guideline. MM17-A. Clinical and Laboratory Standards Institute, Wayne PA.
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4) KARL E. MILLER, M.D (2006). Diagnosis and Treatment of Neisseria gonorrhoeae Infections
5) WHO guidelines for the treatment of Neisseria gonorrhoeae. 1 January 2016
6) "Genital Herpes – CDC Fact Sheet". cdc.gov. December 8, 2014. Archived from the original on 31 December 2014. Retrieved 31 December 2014.
7) Looker, K., Magaret, A., Turner, K., Vickerman, P., Gottlieb, S., & Newman, L. (2015). P234 Global estimates of prevalent and incident herpes simplex virus type 2 infections in 2012. Sexually Transmitted Infections, 91(Suppl 1), A93.1–A93
8) Ona, S., Molina, R. L., & Diouf, K. (2016). Mycoplasma genitalium: An Overlooked Sexually Transmitted Pathogen in Women? Infectious Diseases in Obstetrics and Gynecology, 2016, 1–9.
9) Genital Mycoplasmas (Mycoplasma hominis, Mycoplasma genitalium, and Ureaplasma urealyticum) Robert M. Kliegman MD, in Nelson Textbook of Pediatrics, 2020.
10) Genital Mycoplasmas. David H. Martin, in Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases (Eighth Edition), 2015.

15. Symbols

REF	Reference number	LOT	Batch code
	Consult Instructions for Use		Manufacturer
	Contains Sufficient for <n> Tests		Date of manufacture
	Caution		Keep dry
	Use-by date		Keep away from sunlight
	Do not re-use.		Do not use if the packaging is damaged
	Temperature limit	IVD	*In vitro* diagnostics medical device
UK REP	*Indicates the UK Responsible Person*	UK CA	*This product fulfills the requirements of UK MDR 2002*

For further information on

STANDARD M10
STI Panel

Please contact your
SD BIOSENSOR representative

Manufacturer
SD Biosensor, Inc.
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Manufacturing site : 14, Jeungpyeongsandan-ro, Jeungpyeong-eup, Jeungpyeong-gun, Chungcheongbuk-do, 27915, REPUBLIC OF KOREA

UK REP **MT Promedt Consulting Ltd.**
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IVD **For *In Vitro* Diagnostic Use Only**

Any inquiries regarding instructions provided should be addressed to: ts@sdbiosensor.com
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