

WizDx™ STI-12 qPCR Kit

1-tube Real-time PCR kit for 12 major STI diseases using FMCA technology



Sexually transmitted diseases (STDs) are caused by sexually transmitted infections (STIs). They are spread mainly by sexual contact. Bacteria, viruses, or parasites cause STIs. A sexually transmitted infection may pass from person to person in blood, semen, or vaginal and other bodily fluids. STIs don't always cause symptoms. A person can get sexually transmitted infections from another person who seems healthy and may not even know they have an infection. The development of fast laboratory diagnostic screening methods for STDs is an imperative tool to reduce transmission of STDs worldwide.

Key Features

- 12 types of STDs detected in 1-tube using probe-based fluorescence melting curve analysis technology
- Superior clinical sensitivity and specificity
- Easy procedures for user convenience
- 2.5 hours of test time after nucleic acid extraction
- Automatic analysis with WizDx™ Viewer
- Whole process monitoring with internal control
- UDG carry-over contamination prevention system
- Sensitivity: 5~50 copies/rxn

Sample

- Urine
- Vaginal swabs

Compatible devices

- CFX96™ Dx System (Bio-Rad)
- CLEO™ AP16 or AP48 Nucleic acid extractor



12 target pathogens

- Mycoplasma hominis (MH)
- Chlamydia trachomatis (CT)
- Neisseria gonorrhoeae (NG)
- Mycoplasma genitalium (MG)
- Candida Albicans (CA)
- Gardnerella Vaginalis (GV)
- Ureaplasma parvum (UP)
- Trichomonas vaginalis (TV)
- Ureaplasma urealyticum (UU)
- Treponema pallidum (TP)
- Human herpesvirus 1
- Human herpesvirus 2

Fluorescence probe settings

Melting curve analysis for three diseases per fluorescence channel is possible using FMCA (Probe-based fluorescence melting curve analysis) technology.

Tm Fluorescence	50-59	60-69	50-59
FAM	MH	CT	NG
HEX	MG	CA	GV
CalRed610		IC	
Cy5	UP	TV	HSV1
Cy5.5	UU	TP	HSV2

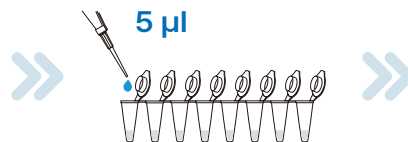
Kit Contents

Component	Amount
2X RT-PCR Master mix	1 mL
STI-12 Primer Mix	100 µL
STI-12 Probe Mix	100 µL
STI-12 Positive Control	30 µL
Deionized sterile water	1 mL

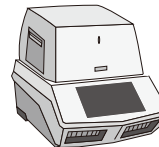
Easy and quick to use



Nucleic acid extraction



PCR mix set-up



PCR run (2.5hr)

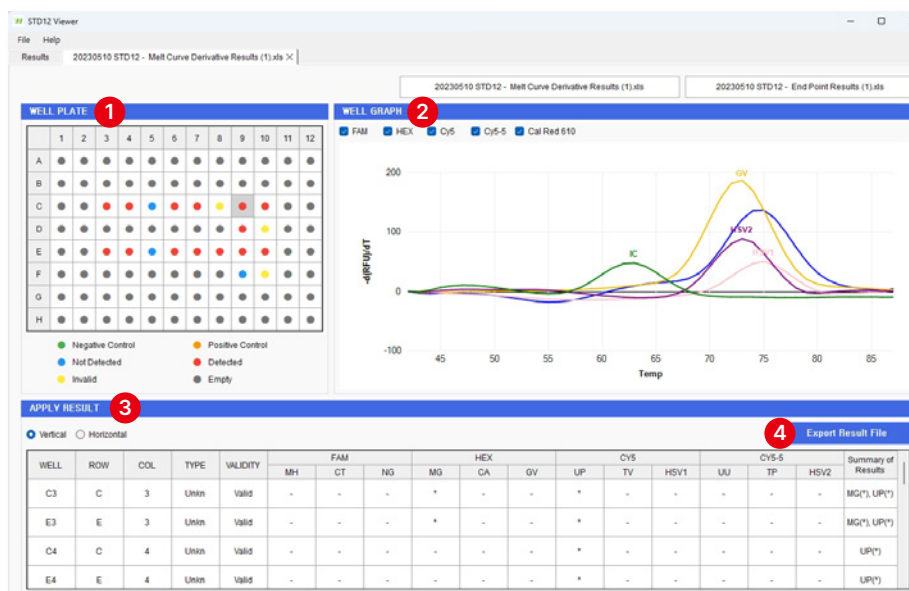


Data analysis

Easy result analysis with analysis program (STD12 Viewer)

STD12 Viewer is a program that automatically analyzes the results of the WizDx™ STI-12 qPCR Kit.

- Automatically analyzes melting curves data
- Easily check raw data analysis
- Quickly check positive and negative results
- Quickly print and save results



1 WELL PLATE

Summarize and display results for each well plate

2 WELL GRAPHIC

Check melting peak of designated well

3 APPLY RESULT

Automatically determines whether each well is infected

4 EXPORT RESULT FILE

Save results as Excel file

Limit of Detection (LoD)

The 12 standard substances containing the genes of pathogens causing sexually transmitted infections were diluted in 6 concentrations in a negative matrix, and the test was repeated 20 times with 3 lots of products. Based on the detection results, 95% probit analysis was analyzed, and the minimum detection limit concentration was confirmed as shown in the table below.

NO.	Target	LoD (copies/rxn)	95% Confidence interval
1	<i>Mycoplasma hominis</i>	5.04 X 10 ¹	4.13 X 10 ¹ ~ 6.78 X 10 ¹
2	<i>Chlamydia trachomatis</i>	6.93 X 10 ¹	5.52 X 10 ~ 9.85 X 10 ¹
3	<i>Neisseria gonorrhoea</i>	4.11 X 10 ¹	3.37 X 10 ~ 5.60 X 10 ¹
4	<i>Mycoplasma genitalium</i>	4.20 X 10 ¹	3.42 X 10 ~ 5.78 X 10 ¹
5	<i>Candida Albicans</i>	2.47 X 10 ¹	1.87 X 10 ~ 4.23 X 10 ¹
6	<i>Gardnerella Vaginalis</i>	4.78 X 10 ¹	3.79 X 10 ~ 6.89 X 10 ¹
7	<i>Ureaplasma parvum</i>	2.57 X 10 ¹	2.12 X 10 ~ 2.99 X 10 ¹
8	<i>Trichomonas vaginalis</i>	5.59 X 10 ¹	4.51 X 10 ~ 7.76 X 10 ¹
9	Herpes simplex virus 1	2.32 X 10 ¹	1.90 X 10 ~ 3.22 X 10 ¹
10	<i>Ureaplasma urealyticum</i>	2.30 X 10 ¹	1.89 X 10 ~ 3.15 X 10 ¹
11	<i>Treponema pallidum</i>	4.01 X 10 ¹	3.26 X 10 ~ 5.56 X 10 ¹
12	Herpes simplex virus 2	3.16 X 10 ¹	2.58 X 10 ~ 3.74 X 10 ¹
13	Human internal control	1.98 X 10 ¹	1.49 X 10 ~ 3.46 X 10 ¹

Clinical sensitivity and specificity

A clinical trial was conducted on a total of 1,090 samples, including 542 urine samples and 548 vaginal swab samples from men and women.

NO.	Target	Sensitivity	Specificity	95% CI (Sensitivity / Specificity)
1	<i>Mycoplasma hominis</i>	100 %	100 %	98.04% - 100% / 99.59% - 100%
2	<i>Chlamydia trachomatis</i>	99.25 %	100 %	95.91% - 99.98% / 99.61% - 100%
3	<i>Neisseria gonorrhoea</i>	100 %	100 %	97.28% - 100% / 99.61% - 100%
4	<i>Mycoplasma genitalium</i>	100 %	100 %	97.38% - 100% / 99.61% - 100%
5	<i>Candida Albicans</i>	100 %	100 %	97.66% - 100% / 99.60% - 100%
6	<i>Gardnerella Vaginalis</i>	100 %	99.25 %	99.10% - 100% / 98.27% - 99.76%
7	<i>Ureaplasma parvum</i>	100 %	100 %	97.82% - 100% / 99.60% - 100%
8	<i>Trichomonas vaginalis</i>	100 %	100 %	95.70% - 100% / 99.63% - 100%
9	Herpes simplex virus 1	100 %	100 %	96.38% - 100% / 99.62% - 100%
10	<i>Ureaplasma urealyticum</i>	100 %	100 %	98.18% - 100% / 99.58% - 100%
11	<i>Treponema pallidum</i>	100 %	100 %	88.78% - 100% / 99.65% - 100%
12	Herpes simplex virus 2	100 %	100 %	97.28% - 100% / 99.61% - 100%

Order Information

Product	Cat No.	Package Size
WizDx™ STI-12 qPCR Kit	DX1248	100 T
CLEO™ AP16 Nucleic acid extractor	CL2016	1 system
CLEO™ AP48 Nucleic acid extractor	CL2048	1 system
WizMag™ Viral DNA/RNA kit	W7020	64 prep
	W7021	192 prep



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