

TrueMark STI and Vaginal Health Research Testing Solutions

Optimize your STI and vaginal health research testing with a portfolio of reliable, accurate, and sensitive real-time PCR molecular solutions

The global prevalence of sexually transmitted infections (STIs) is measured at more than 1 million new cases every day, most of which are asymptomatic. Accordingly, there are approximately 374 million new infections each year, which include three of the most common curable STIs: chlamydia, gonorrhea, and trichomoniasis [1]. These three STIs, as well as the bacterium *Mycoplasma genitalium*, can lead to complications including cervicitis, urethritis, preterm labor, and pelvic inflammatory disease (PID). They can also increase the risk of contracting HIV.

Research to better characterize and identify vaginal microbiota is also important for the health of women, their fetuses, and newborns. Globally, there are approximately 1 billion women affected each year by urogenital infections, including vaginitis.

Bacterial vaginosis alone affects 21.2 million women annually, and is the most common vaginal condition affecting women ages 15–44 [2]. This makes the detection of common prevalent STIs and vaginal pathogens important for clinical researchers to understand outbreaks and disease etiology.

Thermo Fisher Scientific offers a full portfolio of real-time PCR (qPCR) panels for sexually transmitted infections and vaginal microbiota to provide research testing menu expansion and flexibility to fit your laboratory needs and address the growing rates of these infectious diseases.

Benefits of buying from Thermo Fisher Scientific



Complete end-to-end solution

Optimized for use on Applied Biosystems™ QuantStudio™ Real-Time PCR Systems with a verified sample-to-answer research workflow



Expertise in assay design

Select from a menu of real-time PCR panels covering STI and vaginal pathogens



Exceptional service and support

Analytical verification consultation services available to help implement solutions for research with ease

Benefits of molecular testing



Increased sensitivity

Molecular tests are more reliable, accurate, and sensitive compared to traditional culture and microscopy methods



Timely results

Real-time PCR can provide results in as little as 4–6 hours, whereas manual methods, such as culture, can take 3 days or longer [3,4]

Increased productivity, analytical sensitivity, and specificity with qPCR technology

Implementing genetic analysis systems and solutions in the laboratory has been directly linked to improved efficiencies, cost savings, and faster time-to-results. qPCR can detect slow-growing, difficult-to-cultivate microorganisms, making it ideal for when culture methods are inadequate, ambiguous, time-consuming, difficult, or costly [5].

Portfolio: TrueMark STI and Vaginal Health Research Testing Solutions

Applied Biosystems™ TrueMark™ STI and Vaginal Microbiota Panels achieve molecular detection through qPCR technology, offering an end-to-end research workflow for many common STIs and vaginal pathogens, by utilizing the power of QuantStudio Real-Time PCR Systems.* The combination of a TrueMark panel and a QuantStudio Real-Time PCR System enables rapid, accurate detection and analysis of microorganisms that cause

different STIs and vaginal infections for any level of throughput to meet your laboratory needs. This combination also increases the number of options available for running antibiotic resistance tests, when creating a custom panel on an Applied Biosystems™ TaqMan™ Array Plate, Array Card, or OpenArray™ Plate.

Compatible with QuantStudio Real-Time PCR Systems



Applied Biosystems™ QuantStudio™ 5 instrument

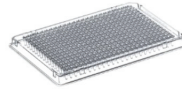


Applied Biosystems™ QuantStudio™ 7 Flex instrument



Applied Biosystems™ QuantStudio™ 12K Flex instrument

TrueMark STI and Vaginal Health Research Solutions: portfolio, options, and product details



	Applied Biosystems™ TrueMark™ STI Select Panel	Applied Biosystems™ TrueMark™ STI and Vaginal Panels, 96-well plates**	Applied Biosystems™ TrueMark™ STI and Vaginal Panels, 384-well plates**	Applied Biosystems™ TrueMark™ STI and Vaginal Panels, Array Cards**	Applied Biosystems™ TrueMark™ STI and Vaginal Panels, OpenArray plates**
Format	Single-tube multiplex (targets and internal control) Applied Biosystems™ TaqMan™ Assays	Duplex (target and internal control) TaqMan Assays, prespotted		Singleplex TaqMan Assays, prespotted	
Number of assays	4	4 or 8	12 or 24	24 or 48	34
Number of samples	1–384	12–24	16–32	1–8	24
Reaction volume	10 µL, 20 µL	10 µL, 20 µL	10 µL	1 µL	33 nL
Sample types	Urine†, vaginal‡, or genital swab				
Internal control	RNase P				
Positive controls	Applied Biosystems™ TrueMark™ STI Amplification Control§	Applied Biosystems™ TrueMark™ Amplification Control§		Applied Biosystems™ TrueMark™ Vaginal Microbiota Amplification Control§	
Instruments	<ul style="list-style-type: none"> QuantStudio 5 Dx Real-Time PCR System (96-well, 0.2 mL)* QuantStudio 7 Pro Real-Time PCR System QuantStudio 7 Pro Dx Real-Time PCR System* QuantStudio 7 Flex Real-Time PCR System QuantStudio 12K Flex Real-Time PCR System 			<ul style="list-style-type: none"> QuantStudio 7 Pro Real-Time PCR System QuantStudio 12K Flex Real-Time PCR System 	<ul style="list-style-type: none"> QuantStudio 12K Flex Real-Time PCR System
Turnaround time	<4 hours				<5 hours
Software	Applied Biosystems™ QuantStudio™ Design and Analysis Software v2.6 or later				QuantStudio 12K Flex Software
Benefit	Flexibility in sample throughput; load wells only as needed	Panels with multiple targets offer an intermediate approach to testing		Fast, easy setup	Lowest cost per pathogen for broad pathogen detection studies
Predefined	✓	✓	✗	✗	✓
Custom	✗	✓	✓	✓	✓

Workflow for TrueMark STI and Vaginal Microbiota Panels

Utilize an end-to-end workflow to expand your STI and vaginal infectious disease research menu

All TrueMark STI and Vaginal Microbiota Panels utilize the same workflow, with multiple options to fit your laboratory's needs, and are optimized for use on QuantStudio Real-Time Systems.*

Go from sample to result in approximately 4 hours.



TrueMark STI Select Panel

The TrueMark STI Select Panel includes multiplexed assays in a single-tube format for the research and detection of the following STI pathogens: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma genitalium*, and *Trichomonas vaginalis*, as well as an internal process control, all in the same reaction. QuantStudio real-time PCR systems enable rapid, accurate detection and categorization of microorganisms that cause these four common STIs. The panel is sold as a combo kit, which includes the TrueMark STI Select Panel assay and master mix.

Features of the TrueMark STI Select Panel



Single-tube multiplexed assay

It's easy to identify pathogens associated with STIs confidently, with four pathogen targets and an RNase P human internal process control all in a single well



Controls included

Included RNase P and positive controls offer reliable runs time after time



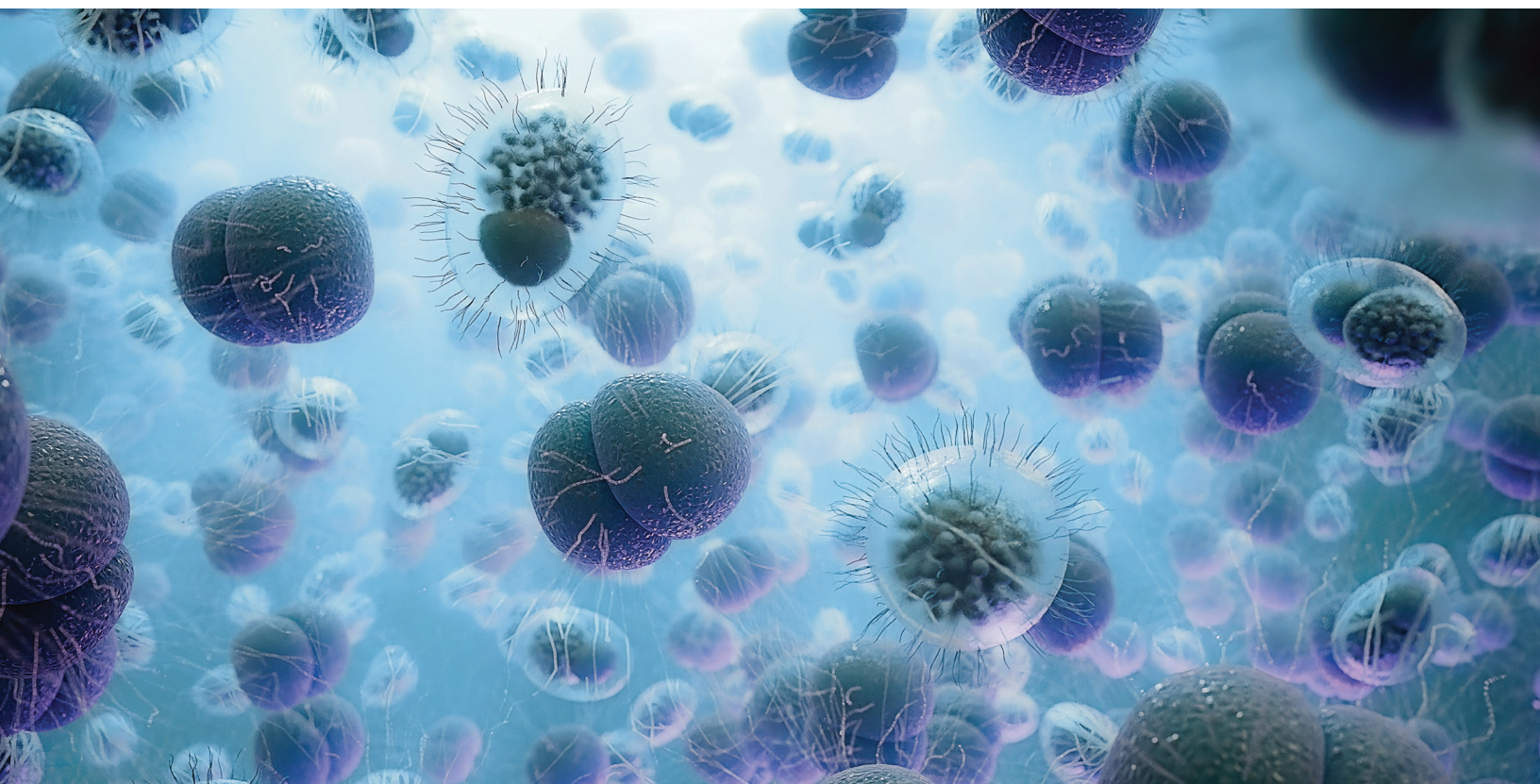
Ease of use

Easily implement the panel with an end-to-end workflow—from sample preparation to software-generated results in about 4 hours



Flexible throughput

Scalable to fit your needs, allowing you to test from 1 to 96 samples per run



TrueMark STI and Vaginal Microbiota Predefined Panels

The TrueMark STI and Vaginal Plus Panels include four different predefined options to choose from, with targets for research focused on sexually transmitted, vaginal, lesion, and genital pathogens. These duplexed reactions come in an 8-target design, dried-down on TaqMan Array Plates, and include RNase P as an internal process control in every well. The predefined panels are sold as a combo kit, which includes five plates and master mix.

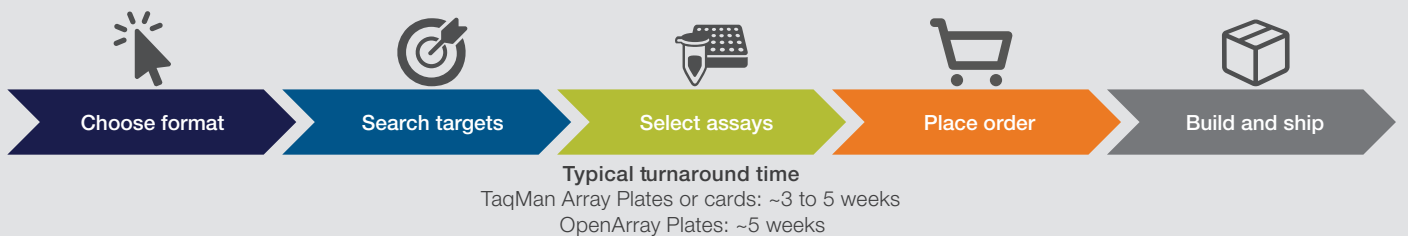
The TrueMark Vaginal and STI Expanded Panel is a more broad panel, covering 34 bacterial, viral, fungal, and parasitic assays, that enable research of organisms that cause vaginal and STI infections. This panel consists of a singleplex reaction, prespotted on an OpenArray Plate, and includes an internal control for added accuracy.

Easy-to-build custom STI and Vaginal Health Research Panels**

There is also the option to easily select and build custom STI and vaginal health research panels, from 4 to 48 targets, in various preferred research formats. This provides complete flexibility to meet the needs of each laboratory.

Custom options are available on 96-well or 384-well plates, TaqMan Array Cards, or OpenArray Plates.

How to build a custom panel



The process is efficient and involves choosing the format, identifying the targets of interest, selecting from a library of predesigned assays, and placing the order.

Features of the TrueMark STI and Vaginal Microbiota Panels, predefined and custom



Customizable

Choose from a selection of predefined panels covering 8 to 34 pathogens per panel, or customer-defined panels with targets of your choosing



Easy to use

Convenient, prespotted, and dried-down TaqMan Array assays on plates or cards, designed for easy setup and increased accuracy



Internal process controls

Panels offer internal process controls for added confidence and accuracy



Flexible throughput

Scalable to fit your needs, allowing you to test 1 to 96 samples per run

Analytical validation consultation services for research products

When adopting a new testing method for your research needs, we can assist in enabling the verification of the workflow to help ensure a successful launch. Our analytical validation (AV) consulting services can speed up the launch process by up to 75% and cut costs by up to half. Our expert team will consult to help develop and optimize your research workflow, while providing data analysis support and template documentation to fully maximize your instrument and reagent investment.*

* Consulting services offered for enabling the analytical validation cannot be used to validate a clinical diagnostic workflow and can only be used to support ongoing true research efforts.

TrueMark STI and Vaginal Microbiota Predefined Panels, options

Targeted STI and Vaginal Microbiota Panels

Applied Biosystems™ TrueMark™ STI Plus Panel

Bacterial	<i>Chlamydia trachomatis</i> (CT)	<i>Mycoplasma genitalium</i> (MG)	<i>Ureaplasma parvum</i> (UP)
	<i>Neisseria gonorrhoeae</i> (NG)	<i>Mycoplasma hominis</i> (MH)	<i>Ureaplasma urealyticum</i> (UU)
Viral	<i>Herpes simplex virus type 1 and 2</i> (HSV1 and HSV2)		
Parasitic	<i>Trichomonas vaginalis</i> (TV)		
Internal controls	RNase P		

Applied Biosystems™ TrueMark™ Vaginal Plus Panel

Bacterial	<i>Gardnerella vaginalis</i> (GV)	<i>Prevotella bivia</i>	<i>Mobiluncus curtisii</i> (MC)	<i>Lactobacillus</i> (pan)
	<i>Atopobium vaginae</i> (AV)	<i>Megasphaera Type 1</i> (Mega 1)	<i>Bacteroides fragilis</i>	<i>Bacterial vaginosis–associated bacteria 2</i> (BVAB2)
Internal controls	RNase P			

Applied Biosystems™ TrueMark™ Lesion Plus Panel

Bacterial	<i>Haemophilus ducreyi</i>	<i>Treponema pallidum</i>	<i>Lymphogranuloma venereum</i>
Viral	<i>Herpes simplex virus type 1</i> (HSV1)	<i>Cytomegalovirus</i> (CMV)	
	<i>Herpes simplex virus type 2</i> (HSV2)	<i>Varicella zoster virus</i> (VZV)	
Fungal	<i>Candida</i> (pan)		
Internal controls	RNase P		

Applied Biosystems™ TrueMark™ Genital Plus Panel

Bacterial	<i>Gardnerella vaginalis</i> (GV)					
Fungal	<i>Candida albicans</i>	<i>Candida krusei</i>	<i>Candida glabrata</i>	<i>Candida dubliniensis</i>	<i>Candida tropicalis</i>	<i>Candida parapsilosis</i>
Parasitic	<i>Trichomonas vaginalis</i> (TV)					
Internal controls	RNase P					

Syndromic STI and Vaginal Microbiota Panels

Applied Biosystems™ TrueMark™ Vaginal and STI Expanded Panel, OpenArray™ Plate

Bacterial	<i>Atopobium vaginae</i> (AV)	<i>Enterococcus faecalis</i>	<i>Lactobacillus crispatus</i>	<i>Mobiluncus curtisii</i> (MC)	<i>Neisseria gonorrhoeae</i> (NG)	<i>Treponema pallidum</i>
	<i>Bacterial vaginosis–associated bacteria 2</i> (BVAB2)	<i>Escherichia coli</i> O18	<i>Lactobacillus gasseri</i>	<i>Mobiluncus mulieris</i>	<i>Prevotella bivia</i>	Uncultured <i>Megasphaera</i> 1
	<i>Bacteroides fragilis</i>	<i>Gardnerella vaginalis</i> (GV)	<i>Lactobacillus iners</i>	<i>Mycoplasma genitalium</i> (MG)	<i>Staphylococcus aureus</i>	Uncultured <i>Megasphaera</i> 2
	<i>Chlamydia trachomatis</i> (CT)	<i>Haemophilus ducreyi</i>	<i>Lactobacillus jensenii</i>	<i>Mycoplasma hominis</i> (MH)	<i>Streptococcus agalactiae</i> (group B)	<i>Ureaplasma urealyticum</i>
Viral	<i>Herpes simplex virus type 1</i> (HSV1)		<i>Herpes simplex virus type 2</i> (HSV2)			
Fungal	<i>Candida albicans</i>		<i>Candida krusei</i>		<i>Candida tropicalis</i>	
	<i>Candida dubliniensis</i>		<i>Candida lusitanae</i>			
	<i>Candida glabrata</i>		<i>Candida parapsilosis</i>			
Parasitic	<i>Trichomonas vaginalis</i> (TV)					
Controls	16S rRNA, Human RNase P (RPPH1) gene					

Ordering information

TrueMark STI Select Panel

Description	Component	Quantity	Cat. No.
Combo kit components			
TrueMark STI Select Panel Combo Kit, 200 reactions	TrueMark STI Select Panel	1 tube x 250 µL	A57083
	TrueMark Infectious Disease 1-Step Multiplex Master Mix (No ROX)	1 tube x 1.5 mL	
Additional components required, sold separately			
TrueMark STI Amplification Control (1 x 10 ⁵ copies/µL)		1 tube x 25 µL	A57009

TrueMark STI and Vaginal Microbiota Panels, predefined and custom

Description	Quantity	Cat. No.
TrueMark Vaginal and STI Microbiota Predefined Panel, OpenArray Plate		
TrueMark Vaginal and STI Expanded Panel, OpenArray Plate	1 plate	A39899
STI and Vaginal Microbiota Predefined Panels, 96-well plate, combo kit components^{††}		
TrueMark STI Plus Panel, Combo Kit	5 plates	A56291C
TrueMark Vaginal Plus Panel, Combo Kit	5 plates	A56292C
TrueMark Lesion Plus Panel, Combo Kit	5 plates	A56293C
TrueMark Genital Plus Panel, Combo Kit	5 plates	A56294C
TrueMark Infectious Disease 1-Step Multiplex Master Mix (No ROX)	3 x 1 mL	Included with Combo Kit
TrueMark STI and Vaginal Microbiota Custom Panels, options^{**}		
TrueMark STI and Vaginal Custom Panels	Varies	Contact sales representative or customer service
TrueMark Antibiotic Resistance Custom Panels	Varies	Contact sales representative or customer service
Additional components required, sold separately		
TaqPath 1-Step Multiplex Master Mix (No ROX)	1 x 10 mL	A28523
TaqMan Universal PCR Master Mix	1 x 5 mL	4304437
TrueMark Amplification Control (1 x 10 ⁵ copies/µL)	1,000 µL	A55699
TrueMark Amplification Control (5 x 10 ⁷ copies/µL)	50 µL	A55698
TaqMan Vaginal Microbiota Amplification Control (10 ⁵ copies/µL)	20 µL	A32040
	250 µL	A32913

Recommended sample preparation components for TrueMark STI and Vaginal Health Portfolio, sold separately

Description	Quantity	Cat. No.
KingFisher Apex Purification System	1 unit	5400910
KingFisher Flex Purification System	1 unit	A32681
QuantStudio 12K Flex Accufill System	1 unit	4471021
MagMAX Viral/Pathogen Ultra Nucleic Acid Isolation Kit	Up to 100 reactions	A42356
MagMAX Viral/Pathogen Nucleic Acid Isolation Kit	Up to 200 reactions	A42352
MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit	Up to 1,000 reactions	A48383R

References

1. World Health Organization. (2022) Sexually transmitted infections (STIs) Available at [https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-\(stis\)](https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis)) Accessed December 16, 2022.
2. <http://www.cdc.gov/std/bv/stats.htm>
3. Finegold, David N. Genetic Diagnostic Technologies - Fundamentals. Merck Manuals Consumer Version, Merck Manuals, accessed 21 Feb 2023, <https://www.merckmanuals.com/home/fundamentals/genetics/genetic-diagnostic-technologies>.
4. Vazquez-Pertejo, Maria T. Diagnosis of Infectious Disease - Infections. Merck Manuals Consumer Version, Merck Manuals, accessed 21 Feb 2023, <https://www.merckmanuals.com/home/infections/diagnosis-of-infectious-disease/diagnosis-of-infectious-disease>.
5. Davenport M et al. (2017) New and developing diagnostic technologies for urinary tract infections. *Nat Rev Urol* 14:296–310.
6. Thermo Fisher Scientific. (2022) Analytical validation consulting services. thermofisher.com/av

* Applied Biosystems™ QuantStudio™ 5 Dx and 7 Pro Dx systems are For *In Vitro* Diagnostic Use. Test development mode is for Research Use Only. Not for use in diagnostic procedures.

** For specific custom options available, contact your sales representative or customer service.

† Internally tested sample type on TrueMark STI Select Panel only.

‡ Internally tested sample type.

§ TrueMark Amplification Control is required for each panel. Sold separately.

†† TrueMark STI and Vaginal Plus Panel combo kits include five Applied Biosystems™ TaqMan™ array plates and 3 x 1 mL tubes of TrueMark Infectious Disease Multiplex Master Mix (No ROX).

 Learn more at
thermofisher.com/stiandvaginalhealthproducts

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