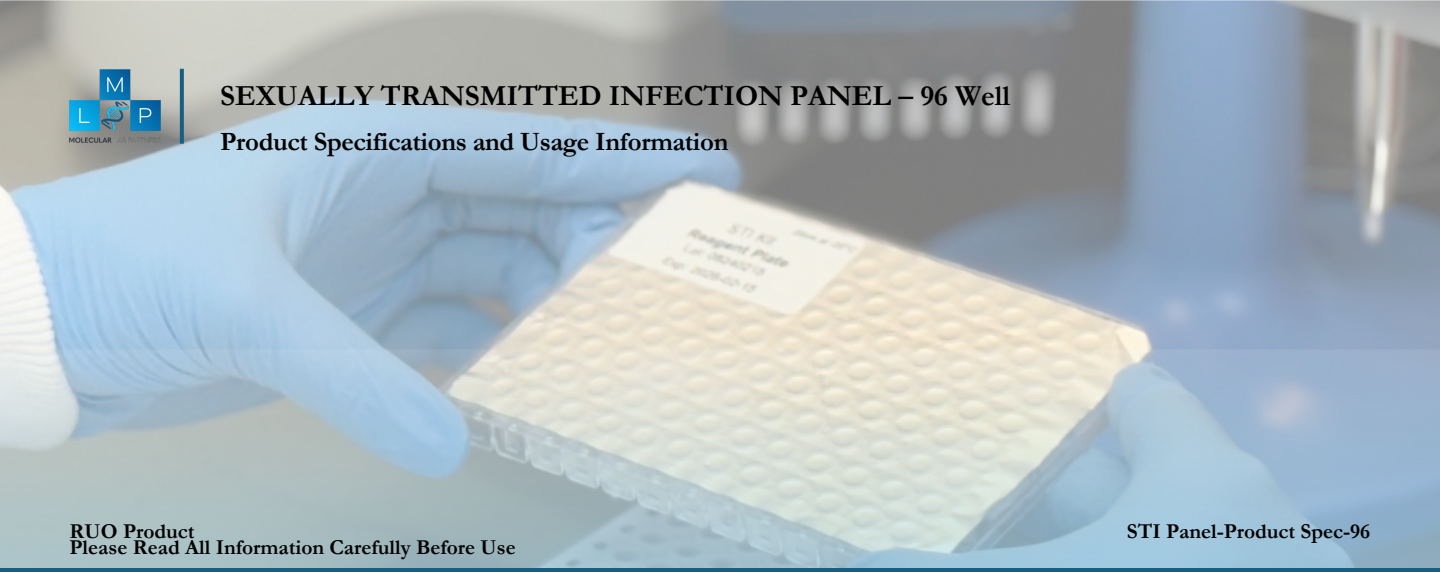

SEXUALLY TRANSMITTED INFECTION PANEL – 96 Well

Product Specifications and Usage Information

RUO Product
Please Read All Information Carefully Before Use

Product Description:

The Sexually Transmitted Infection Panel (STI Panel) is a multiplex real-time Reverse Transcription Polymerase Chain Reaction (RT-PCR) panel that contains primer/probe sets that target nucleic acid from *Chlamydia trachomatis* (*C. trachomatis*), *Haemophilus ducreyi* (*H. ducreyi*), *Neisseria gonorrhoeae* (*N. gonorrhoeae*), *Mycoplasma genitalium* (*M. genitalium*), *Treponema pallidum* (*T. pallidum*), *Trichomonas vaginalis* (*T. vaginalis*), *Ureaplasma urealyticum* (*U. urealyticum*), Human Herpesvirus-1 (HHV-1), Human Herpesvirus-2 (HHV-2), Human papillomavirus 16 (HPV-16), Human papillomavirus 18 (HPV-18), and Human papillomavirus 45 (HPV-45). The assay also contains primers and probes that detect the human Ribonuclease P gene. This gene is used as multipurpose Endogenous Control (EC). The EC control is an extraction control, a positive reverse transcriptase control, and a positive reagent control. An additional Pathogen-Positive Control (PC) is included with our STI panel.

The STI Panel is for research use only (RUO). The STI Panel has not been FDA-cleared or approved.

UNG Contamination Control:

PCR product (amplicon) carryover contamination in research laboratories that routinely run PCR is a major concern and is often the source of false positive results. To combat carryover contamination, uracil N-glycosylase (UNG) and deoxyuridine triphosphate (dUTP) are included in the reaction master mix. Replacing deoxythymidine triphosphate (dTTP) with dUTP with the addition of UNG enzymatic treatment before PCR amplification eliminates previously amplified PCR products prior to the amplification of new PCR products. This methodology helps eliminate PCR product carryover contamination and potential false positive results. All the assay components are premixed and run in a single PCR well.

This Panel Detects the Following Targets:

- *Chlamydia trachomatis* (FAM)
- *Haemophilus ducreyi* (VIC)
- *Neisseria gonorrhoeae* (FAM)
- *Mycoplasma genitalium* (FAM)
- *Treponema pallidum* (FAM)
- *Trichomonas vaginalis* (ROX)
- *Ureaplasma urealyticum* (FAM)
- Herpes simplex virus-1 (VIC)
- Herpes simplex virus-2 (ROX)
- Human papillomavirus 16 (FAM)
- Human papillomavirus 18 (VIC)
- Human papillomavirus 45 (ROX)
- Ribonuclease P (Cy5)
- Negative Control (Cy5)

Product Information:

Panel Name:	STI, 0.1 mL (96-Well Plate)
Catalog #:	STI-96-01
Reactions/Plate:	12
Storage Temp:	-15 °C to -30 °C
Positive Control:	Pathogen-Positive Control
Quality Control (QC)	RT-qPCR Cycle Threshold; Coefficient of Variation (CV)
Specification:	≤ 2.5

Disclaimer – Use of PCR :

This product is for basic PCR and has not been FDA-cleared or approved.

Limitation of Use:

This product is for research use only and is not intended for use in diagnostic procedures.

Product Guarantee:

This product should be free from defects in material and workmanship and capable of functioning to its specification. If you are not completely satisfied, please contact our team for assistance. We will work to resolve your concern and replace products as needed.

Health and Safety Information

Hazard Statements

- Causes skin irritation
- Causes serious eye irritation

Precautionary Statements

- ON CONTACT: Immediately remove all contaminated clothing. Thoroughly rinse the exposed area with cold water.
- IF INHALED: If breathing is difficult, go to a well-ventilated area and seek medical attention.
- IF IN EYES: Rinse cautiously with cold water for 15 minutes. Remove contact lenses if present and continue rinsing for at least 15 minutes with cold water. Seek medical attention if irritation persists.
- Call POISON CONTROL or doctor/physician if you feel unwell.

Warnings and Precautions

- For Research Use Only. Not for use in diagnostic procedures.
- Always use good laboratory practice and the appropriate personal protective equipment (PPE) when working in a laboratory. Follow necessary precautions when handling Potentially Infectious Material (PIM).
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where reagents and samples are handled.
- Always use universal precautions when working with samples and reagents.
- Never reuse one-time-use consumables materials.
- Dispose of kit reagents and samples according to local, state, and federal regulations.

Note: PCR amplification technology is extremely sensitive and prone to accidental contamination. Appropriate (QC) procedures/methodology should be in place to monitor for accidental contamination of reagents and samples. Workflow in the laboratory should always proceed in a unidirectional manner to minimize potential contamination events.

Reagent Storage and Use Guidelines

Reagents should be stored in a freezer at -15 °C to -30 °C and protected from light. All components of our kits are stable until the expiration date listed on the item/component. The reagent components should not undergo excessive freeze/thaw cycles, as this may reduce the accuracy and integrity of the analysis (do not freeze-thaw reagents more than 3 times). After thawing reagents, keep them in a cold block or 4 °C or laboratory refrigerator until used.

Kit Includes the Following:

- 96-well PCR plate (pre-loaded with all assay targets and master mix; the PC master mix and Pathogen-Positive target are added by the operator during assay plating)
- Assay Pathogen-Positive Control (PC) and Master Mix

General Equipment and Consumables Required but Not Provided

- Compatible nucleic acid extraction platform with compatible extraction reagents (contact our team for compatible methods/reagents)
- Micropipettes P20 (2-20 µL) , P100 (10-100 µL), and P1000 (100-1000 µL)
- Multichannel micropipettes (5-50 µL)
- Sterile aerosol barrier (filtered) pipette tips
- Disposable powder-free gloves, masks, and surgical gowns
- Ice buckets or cold blocks for 96-well PCR plates
- Plate centrifuge
- Vortex mixer
- Laboratory freezers (-15 °C to -30 °C)
- Biological Safety Cabinet, Class II, Type A2, or equivalent
- Microcentrifuge tubes
- Microcentrifuge

Reaction Plate Setup

1. Remove a reaction plate, PC, and PC master mix from the -20 °C manual defrost freezer.
2. If not running a full 96-well plate, break away the desired number of assays away from the rest of the plate. To do this, use a lab utility knife to score the foil seal on the PCR breakaway plates. After cutting the foil seal, fold the plate back and forth to break away the appropriate number of assays/panels. The plates are designed to break between columns when folded back and forth. Ensure the excess unused assays/panels are properly labeled and promptly placed back in the -20 °C freezer.
3. Use the plates within 1 hour of thawing; keep the plate sealed and stored at 4 °C if not used immediately.
4. Spin down the plate for 30 seconds in a plate centrifuge.
5. Carefully remove the foil seal from the plate.
6. Add 10.0 µL of the sample to a well. If testing more than one sample, repeat this process until all samples have been plated.
7. Add 10.0 µL of Negative Control (NC) to the NC wells on the plate. The NC should be a blank/unused swab that is processed alongside samples. Add 10 µL of PC master mix to an empty well on the plate; add 10 µL of the PC to the same well. The NC should not amplify. The EC should amplify in every well containing a sample. The PC should amplify in the plated PC reaction.
8. Seal the PCR plate using optical qPCR film.
9. Spin down the plate for 30 seconds in a plate centrifuge.

Real-Time PCR Detection System qPCR Run Setup

1. Open the specified run template and fill in the sample name fields with unique sample IDs corresponding to the samples being processed.
   a) NOTE: This step can also be done prior to reaction plate setup if sample IDs have already been specified. Laboratory barcodes and scanners can also be used to track specimens through the workflow.
2. Place the reaction plate into the instrument in the appropriate orientation (A1 in the upper left corner).
   a) NOTE: When running a partial plate, a balance is required on the other side of the instrument to ensure the lid is sealed properly and doesn't break the instrument.

Thermocycling Protocol

1. UNG Treatment
   a) 2 minutes at 50 °C
2. Denaturation
   a) 5 minutes at 95 °C
3. Annealing and Extension 40 cycles consisting of:
   a) 15 seconds at 95 °C
   b) 1 minute at 56 °C, with fluorescence acquisition during this step

STI Panel – 96 Well

Validation Kit Contents

Kit Component	Description & Quantity	Format	Volume	Qty
Linearity Testing Kit	STI Panel Linearity Kit 1 STI Panel Linearity Kit 2	96-Well Plates	Reagent Plate: 13 µL Each Well Plasmid Plate: 10 µL Each Well	4
STI LoD Study Sample & Stability Study Sample	LoD Study Plasmid in Specimen Matrix (2000 cpts/mL) LoD Study Plasmid in Specimen Matrix (1000 cpts/mL)	5 mL Tube 5 mL Tube	3.5 mL 3.5 mL	2 2
	LoD Dilution Buffer (Specimen Matrix)	5 mL Tube	3.5 mL	2
	Clinical Specimen Stability Study	5 mL Tube	3 mL	1
Comparative and Interfering Substances Test Samples	Comparative Clinical and Interfering Substances Test Specimens	96 Deep-Well Plate	8 Comparative Specimens (320 µL each) 4 Interfering Substances Test Samples (320 µL each)	1
STI Validation Reagent	Reagent Plates for LoD, Stability, Comparative Specimen Analysis and Interfering Substances Test	96-Well PCR Plates (0.1 mL)	10 µL Each Well	6
Specimens for Interfering Substances Study	Clinical Specimen with Aliquoted Interfering Substance	Individual PCR Tubes	100 µL	3
PC **(Channels FAM, VIC and ROX are positive)**	Positive Control Master Mix	1.5 mL Amber Tube	60 µL	1
	Positive Control	1.5 mL Tube	60 µL	

SEXUALLY TRANSMITTED INFECTION PANEL – 96 Well
Plate Map

	1	2	3	4	5	6	7	8	9	10	11	12
A	NC (Cy5)	NC (Cy5)	NC (Cy5)	NC (Cy5)	NC (Cy5)	NC (Cy5)	NC (Cy5)	NC (Cy5)	NC (Cy5)	NC (Cy5)	NC (Cy5)	NC (Cy5)
B	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)	C. trachomatis (FAM) HHV-2 (ROX) HHV-1 (VIC)
C	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)	N. gonorrhoeae (FAM)
D	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)	M. genitalium (FAM) T. vaginalis (ROX)
E	T. pallidum (FAM)	T. pallidum (FAM)	T. pallidum (FAM)	T. pallidum (FAM)	T. pallidum (FAM)	T. pallidum (FAM)	T. pallidum (FAM)	T. pallidum (FAM)	T. pallidum (FAM)	T. pallidum (FAM)	T. pallidum (FAM)	T. pallidum (FAM)
F	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)	HPV 16 (FAM) HPV 45 (ROX) HPV 18 (VIC) EC (Cy5)
G	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)	H. ducreyi (FAM) U. urealyticum (VIC)
H												