REF	**Sexually Transmitted Infection (STI) Panel Instruction**	
Σ	**STI - Sexually Transmitted Infection PCR Kit**	
IFU	**Information For Use**	
LDT	**Lab Development Test**	
RUO	**For Research Use Only**	
REV #	**DATE:**	**REVISION DESCRIPTION:**
REV:01	2/16/2023	EDITION: V1.0
REV:02	8/31/2025	2ND Release

Manufacturer
Bioteke Corporation (Wuxi) Co., Ltd.
Zone A, Floor 4, No. 1719-5, Huishan Avenue,
Huishan Economic Development Zone, Wuxi, Jiangsu, 214174, China
Web: www.bioteke.cn | Email: info@bioteke.cn

Authorized Distributor (U.S.)
Med X Diagnostics LLC.
1800 West Hawthorne Lane – STE P
West Chicago, IL 60185, USA

Definitions & Abbreviations

Abbreviation	Definition
Ct	Cycle Threshold; the PCR cycle at which fluorescence exceeds baseline.
IC	Internal Control: non-target DNA (Human RNaseP) added to monitor extraction and amplification.
PC	Positive Control; plasmid containing assay target sequences.
NC	Negative Control; reagent blank or plasmid containing IC only.
LoD	Limit of Detection; lowest concentration of target reliably detected.
QC	Quality Control; procedures ensuring run validity.
RUO	Research Use Only; not for use in diagnostic procedures (per 21 CFR 809.10(c)(2)(i)).
GLP	Good Laboratory Practice.
PPE	Personal Protective Equipment.
qPCR	Quantitative Polymerase Chain Reaction (real-time PCR).
UDG	Uracil-DNA Glycosylase; enzyme used to prevent carryover contamination.
dUTP	Deoxy Uridine Triphosphate; used with UDG to eliminate amplicon contamination.
FAM / VIC / ROX / CY5	Fluorescence channels are used for multiplex detection.

Pathogen & Resistances Target Symbols							
🦠	Bacteria	🧪	Virus	🍄	Fungi	💉	Resistance

List of Contents

1 Product Name.

STI – Sexually Transmitted Infection Multiplex PCR Panel (viral, bacterial, fungal, and parasitic pathogens).

2 Specification.

A. Product Name: ReagenX™ STI-X Multiplex PCR Kit

B. Catalog Number: RX-STI-001

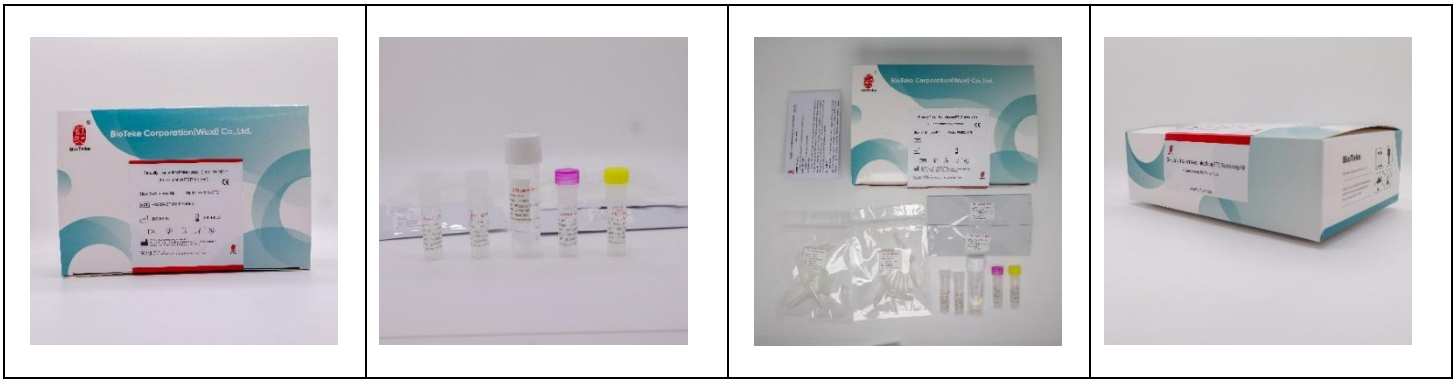
C. Kit Sizes: 8 tests / 24 tests

D. Format: Lyophilized PCR reagents in 4 well strip tubes.

3 Intended Use.

A. The **ReagenX™ STI-X Multiplex PCR Kit** is intended for the qualitative detection of nucleic acids from 14 pathogens associated with sexually transmitted infections, including Trichomonas vaginalis, Neisseria gonorrhoeae, Chlamydia trachomatis, Gardnerella vaginalis, Haemophilus ducreyi, Candida albicans, Streptococcus agalactiae, Ureaplasma urealyticum, Ureaplasma parvum, Mycoplasma hominis, Mycoplasma genitalium, Treponema pallidum, Herpes simplex virus type 1, and Herpes simplex virus type 2 in vaginal swab and urine specimens, using multiplex real-time fluorescent PCR.

B. B. For Research Use Only (RUO). Not for use in diagnostic procedures. This product is not cleared or approved by the U.S. Food and Drug Administration (FDA) for diagnostic use. Performance characteristics must be established by the end-user laboratory in accordance with 21 CFR 809.10(c)(2)(i).



4 Principle of the Procedure.

A. The ReagenX™ STI-X Multiplex PCR Kit is designed with specific primers and fluorescent probes for the qualitative detection of 14 common sexually transmitted pathogens, including trichomonas vaginalis, neisseria gonorrhoeae, chlamydia trachomatis, gardnerella vaginalis, haemophilus ducreyi, candida albicans, streptococcus agalactiae, ureaplasma urealyticum, ureaplasma parvum, mycoplasma hominis, mycoplasma genitalium, treponema pallidum, herpes simplex virus type 1&2.

B. An Internal Control (IC, Human RNaseP gene) is included to verify specimen quality, confirm successful nucleic acid extraction, and detect possible PCR inhibition, thereby reducing false-negative results.

C. To prevent carryover contamination, the amplification system incorporates a UDG/dUTP safeguard, which degrades any previously amplified products and minimizes false positives.

D. The kit is provided as a fully premixed, freeze-dried system. Each PCR tube contains Taq DNA polymerase, UDG enzyme, reaction buffer, and specific primers and probes lyophilized for long-term stability.

E. Detection workflow:

1. Add 15 μL Dissolving Solution.
2. Add 5 μL extracted nucleic acid.
3. Proceed directly to amplification and result analysis.

F. After rehydration with dissolving solution and addition of extracted nucleic acid, amplification is performed directly on a compatible real-time PCR instrument.

5 Pathogen Targets.

Icon	Category	Target	Example Role	Notes
	Bacteria	*Chlamydia trachomatis*	Most common bacterial STI	Intracellular
	Bacteria	*Neisseria gonorrhoeae*	Gonorrhea	AMR concern
	Bacteria	*Mycoplasma genitalium*	NGU, cervicitis, PID	Macrolide resistance
	Bacteria	*Mycoplasma hominis*	Vaginosis, infertility	Opportunistic
	Bacteria	*Ureaplasma urealyticum*	NGU, infertility	Common commensal
	Bacteria	*Treponema pallidum*	Syphilis	Not culturable
	Virus	HPV (high-risk types)	Cervical cancer	Carcinogenic
	Virus	HSV-1, HSV-2	Genital herpes	Recurrent
	Fungi	*Candida albicans*	Vaginitis	Opportunistic
	Fungi	*Candida glabrata*	Recurrent vaginitis	Azole resistance
	Protozoa	*Trichomonas vaginalis*	Trichomoniasis	Parasitic STI
	Resistance	mecA	MRSA marker	Rare but relevant
	Resistance	gyrA / parC mutations	Quinolone resistance in NG	AMR monitoring
	Resistance	23S rRNA mutations	Macrolide resistance in MG	AMR monitoring

Table 5. → Pathogen Targets

6 Warnings & Precautions.

A. ⚠ For Research Use Only (RUO). Not for use in diagnostic procedures.

B. Treat all human specimens as potentially infectious and handle them in strict accordance with the laboratory's biosafety requirements.

C. Laboratory personnel must receive professional training in:

- **Sample collection and specimen handling**
- **Reagent preparation and workflow setup**
- **PCR instrument operation**
- **Data analysis and interpretation**

Laboratory operations must comply with local, national, and international regulations governing molecular diagnostic testing.

D. The laboratory should be physically divided into separate areas to minimize contamination:

- **Reagent preparation area**
- **Sample preparation area**
- **Amplification and analysis area**

⚠ **Use dedicated equipment and consumables in each area. Cross-use of materials is strictly prohibited.**

E. E. Personal Protective Equipment (PPE) must be always worn, including:

- **Laboratory coats or gowns, Gloves (powder-free, disposable), Protective eyewear (goggles or face shield), Hair covers, Surgical masks or fit-tested N95 respirators**

Ensure full coverage of exposed skin to prevent direct contact with specimens or reagents.

F. In case of spills or leaks:

- **Immediately rinse exposed skin with copious amounts of water.**
- **If reagents contact wounds or mucous membranes, seek medical attention promptly and notify the appropriate health and safety office.**

G. Proper laboratory training in PCR workflows and contamination control is essential to ensure accuracy and safety. Always read and fully understand the Instructions for Use (IFU) before performing the assay.

H. Specimen collection and handling must strictly follow applicable regulations and guidelines. All specimen processing should be performed in a Class II biosafety cabinet to protect operators and prevent environmental contamination.

I. Always use RNase/DNase-free consumables and nuclease-free water during test procedures to prevent nucleic acid degradation or contamination.

7 Kit Components.

Component	8 samples/kit	24 samples/kit	Contents/Description
STI Lyophilized Reagent	8 × 4-strip tubes	24 × 4-strip tubes	Specific primer & probes for the detection of target pathogens, dNTP/dUTP Mix, Mg2+, Taq polymerase and UDG enzyme
STI Lysis Buffer	1 mL × 1 tube	5 mL × 1 tube	Surface active agent, balanced salt solution
One Test Glass Beads	8 tubes × 1 bag	8 tubes × 3 bags	Glass beads
STI Positive Control	400 µL × 1 tube	400 µL × 1 tube	Plasmid containing every target gene sequence
STI Negative Control	400 µL × 1 tube	400 µL × 1 tube	Plasmid containing internal control sequence
Dissolving Solution	1 mL × 1 tube	1 mL × 2 tubes	Stabilizer

Table 7. → Kit Components

Notes:

1. Do not mix components from different batches.
2. Positive/Negative Controls should be used when contamination or reagent failure is suspected.
3. **Store at –20 °C ± 5 °C; protect from light; avoid repeated freeze–thaw.**
4. Treat all **urogenital swabs and urine specimens** as potentially infectious and handle under appropriate biosafety precautions.
5. Perform sample preparation, reagent setup, and amplification in physically separated areas.
6. Use dedicated pipettes and filtered tips; change gloves often, especially after handling specimens.
7. Do not exchange reagents from different lots.
8. Protect fluorescent reagents and PCR tubes from direct light.
9. Dispose of swabs, tubes, and consumables according to biosafety waste regulations (autoclaving, incineration, or chemical disinfection).
10. This kit is RUO; not approved for diagnostic purposes. Use under GLP with trained operators.

7.1 Materials Required but Not Supplied

Equipment / Material	Description	Notes
Class II Biosafety Cabinet	For safe specimen handling and contamination control	Required for molecular diagnostics
Personal Protective Equipment (PPE)	Lab coats/gowns, gloves, protective eyewear (goggles/face shield), surgical or N95 masks	To ensure operator safety
Adjustable Micropipettes	0.5–10 µL, 10–100 µL, 100–1,000 µL ranges	Calibrated, single- or multi-channel
Aerosol-Resistant Filter Tips	RNase/DNase-free	To minimize contamination risk
1.5 mL Microcentrifuge Tubes & Racks	Sterile, RNase/DNase-free	For sample and reagent handling
Benchtop Microcentrifuge (≥12,000 rpm)	For nucleic acid extraction/release	Compatible with 1.5 mL tubes
Vortex Mixer	For specimen and reagent mixing	Power ≥40W recommended
Heating Block / Water Bath (95 °C)	For nucleic acid release	Fits 1.5 mL tubes
Centrifuge Tube Holder (for vortex)	Optional; can replace manual mixing	For consistent bead-based lysis if used
Laboratory Refrigerator (4–10 °C)	For sample and reagent storage	Continuous temperature monitoring recommended
Laboratory Freezer (–20 °C)	For sample/reagent preservation	Avoid repeated freeze–thaw cycles
Collection Swabs & Transport Medium – STI	Urogenital swabs and/or first-void urine specimens collected in UTM/ITM	FDA-cleared/CE-marked. Bioteke Disposable Virus Sampling Swab Kits are recommended.
Real-time PCR Instrument	With FAM, VIC/HEX, ROX, CY5 channels	Compatible systems: ABI 7500, Bio-Rad CFX96, QuantStudio, SLAN-96S, BTK-96

Table 7.1 → Materials Required but Not Supplied

8 Storage & Shelf Life.

A. The kit can be transported at room temperature (no more than one month).
B. It can be stored at-20℃± 5℃for one year.
C. Repeated freezing and thawing should not exceed 7 times.

9 Instruments.

A. Real-time PCR instruments such as ABI7500, Bio-Rad CFX96, SLAN-96S, QuantStudio and BTK-8

10 Specimen Collection & Handling

10.1 Specimen Types

- Vaginal swabs.
- First-void urine specimens (male or female).
- All specimens should be collected directly into **UTM/VTM/ITM sampling tubes** in accordance with standard technical specifications.
- Use of **Bioteke Disposable Virus Sampling Swab Kits** (with UTM/VTM) is recommended for optimal performance.

10.2 Collection

- Collection must be performed by trained personnel using **sterile synthetic flocked swabs** or approved urine collection devices.
- Avoid calcium alginate swabs or cotton swabs with wooden shafts, as they may inhibit PCR.

10.3 F. Storage

- **2–8 °C**: up to 7-days..
- **–20 °C**: up to 6-months.
- –Avoid repeated freeze–thaw cycles.

10.4 Transport

- Transport specimens in **sealed insulated containers with ice packs** at 2–8 °C if delivery is within 24–72 hours.
- For longer transport times, ship specimens **frozen on dry ice** (–20 °C).

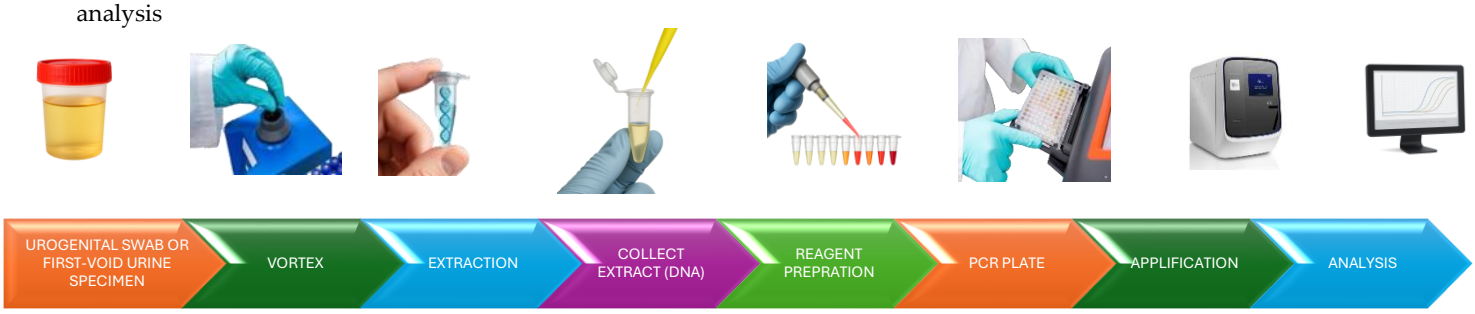
10.5 Rejection Criteria

- Specimens are not collected in VTM/UTM/ITM.
- Leaking, broken, or unlabeled tubes.
- Samples stored beyond allowable stability limits.

11 Test Procedure & Protocol

11.1 Workflow

Urogenital swab or first-void urine specimen (in UTM/ITM) → Nucleic acid extraction / release → Collect extract (RNA/DNA) → Reagent rehydration (15 μL Dissolving Solution) → PCR setup (add 5 μL extract) → Amplification (qPCR, 45 cycles) → Result analysis



According to Corresponding Requirement & Procedures

11.2 Reagent Preparation (Reagent Preparation Area)

A. Take out the **nucleic acid extraction reagent** or **Nucleic Acid Release Reagent** and the components of the kit.
B. Balance them at **room temperature**.
C. Centrifuge liquid items briefly to collect the contents, then set aside for standby use.

11.3 Specimen Processing (Specimen Processing Area)

A. **Nucleic Acid Extraction**

Specimen processing After vaginal swab-normal saline eluent/urine specimens are mixed thoroughly by vortex mixer, take 1mL liquid specimen to 1.5mL centrifuge tubes and centrifuge at 12000rpm for 10min. After centrifugation, the supernatant should be carefully discarded and ensure the precipitation remains in the tube.

a. Nucleic acid releasing

1. Add 100μL STI Lysis Buffer to the above-mentioned centrifuge tube and then take One Test Glass Beads and pour them into centrifuge tube. 2 / 6
2. Cover the tube tightly and oscillate manually for 2 minutes with vortex mixer (power≥40W) or automatically oscillate for 10 minutes on the centrifuge tube holder of vortex mixer.
3. After oscillation, place centrifuge tube in the metal bath/water bath (preheated in advance) and heat at 95℃ for 2 minutes.
4. Then centrifuge the tube at 12000rpm for 1min, and nucleic acid are in the supernatant. If the nucleic acid cannot be detected immediately, it can be stored at 2-8℃ for no more than 24 hours, and-20℃ for no more than 1 month.

B. **Amplification System Configuration**

- Take out Lyophilized reagent PCR tubes according to the number of samples.
- One strip = detection for 1 sample.
- If Negative and Positive Control tests are required, increase the number of samples by 2.

C. **Stepwise Setup:**

- Add 15 μL Dissolving Solution to each tube to dissolve the lyophilized powder.
- Add 5 μL nucleic acid of the extracted Negative Control / Sample to be tested / Positive Control.
- Total volume of each tube = 20 μL.
- Cap tubes tightly, mix gently by hand (do not vortex).
- Centrifuge briefly at low speed to collect liquid and remove bubbles.

Sample Test Well Preparation	Well 1	Well 2	Well 3	Well 4
Dissolving solution	15 µL	15 µL	15 µL	15 µL
Extracted nucleic acid of sample	5 µL	5 µL	5 µL	5 µL

Table 11.3a → Sample Well Preparation

Negative Control Test Well Preparation	Well 1	Well 2	Well 3	Well 4
Dissolving solution	15 µL	15 µL	15 µL	15 µL
Extracted nucleic acid of Negative Control	5 µL	5 µL	5 µL	5 µL

Table 11.3b: → Negative Control Well Preparation

Positive Control Test Well Preparation	Well 1	Well 2	Well 3	Well 4
Dissolving solution	15 µL	15 µL	15 µL	15 µL
Extracted nucleic acid of Positive Control	5 µL	5 µL	5 µL	5 µL

Table 11.3c → Positive Control Well Preparation

11.4 Run Setup Check List

Item	Requirement	Verified
Reagents equilibrated	All kit components at room temp; probes protected from light	☐
Strip assignment	One 4-well strip per sample; wells 1–4 assigned in order	☐
Reaction volume	15 µL Dissolving Solution + 5 µL nucleic acid = **20 µL** total	☐
Controls included	≥1 Positive Control and 1 Negative Control per run	☐
Pipetting	Always use aerosol-resistant filter tips; avoid vortex after reagent rehydration.	☐
Spin-down	Brief centrifugation to remove bubbles	☐
Instrument channels	**FAM / VIC(HEX) / CY5 /ROX** enabled.	☐
Program	50 °C 2 min → 95 °C 2 min → **45 ×** (95 °C 10 s; 60 °C 30 s)	☐
Data settings	Baseline Start 3–15; End 5–20; threshold above NC curve	☐

Table 11.4 → Run Setup Check List

11.5 Notes on Instrument Loading

- **ABI7500, CFX96, QuantStudio, SLAN-96S**:
  - The prepared 4-strip tubes can be directly transferred to the amplification detection area.
- **BTK-8**:
  - The mixture from lyophilized reagent PCR strips should be transferred into the chip wells.
  - Hold pipette at 90° vertical, use aerosol barrier tips, pipette into the center, stop at the first stop to avoid bubbles.
  - Seal wells with chip membrane before transferring to amplification area.

11.6 Storage of Remaining Tubes

A. This step is not applicable to STI Kits.

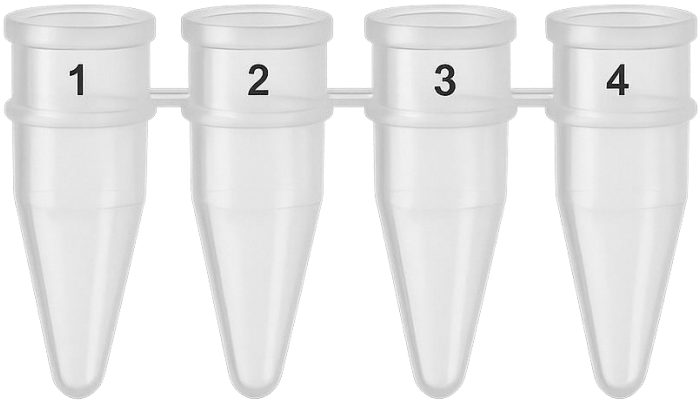
- Each UTI lyophilized strip is fully consumed by a single sample.
- No partial strip storage is required.
- Proceed directly to amplification after setting up.

11.7 PCR Amplification (Detection Area)

A. Put the reaction tubes into PCR instrument and set the names of each reaction well in the corresponding order.
B. Select fluorescence channels and targets corresponding to different tubes according to the following table:

Location	FAM	VIC/HEX	ROX	CY5
Well 1	*Trichomonas vaginalis*	*Neisseria gonorrhoeae*	*Chlamydia trachomatis*	Internal Control (Human RNaseP)
Well 2	*Gardnerella vaginalis*	*Haemophilus ducreyi*	*Candida albicans*	*Streptococcus agalactiae*
Well 3	*Ureaplasma urealyticum*	*Ureaplasma parvum*	*Mycoplasma hominis*	*Mycoplasma genitalium*
Well 4	*Treponema pallidum*	*Herpes simplex virus type 1*	*Herpes simplex virus type 2*	

Table: 11.7 → PCR Amplification (Detection Area)



11.8 PCR Cycling Program

	Steps	Temperature	Time	Cycles
1.	Pre-denaturation	95 °C	2 min	1
2	Denaturation	95 °C	10 s	45
	Annealing, extension, fluorescence acquisition	60 °C	30 s	

Table: 11.8a → Amplification Program of Common Real-Time PCR Instrument

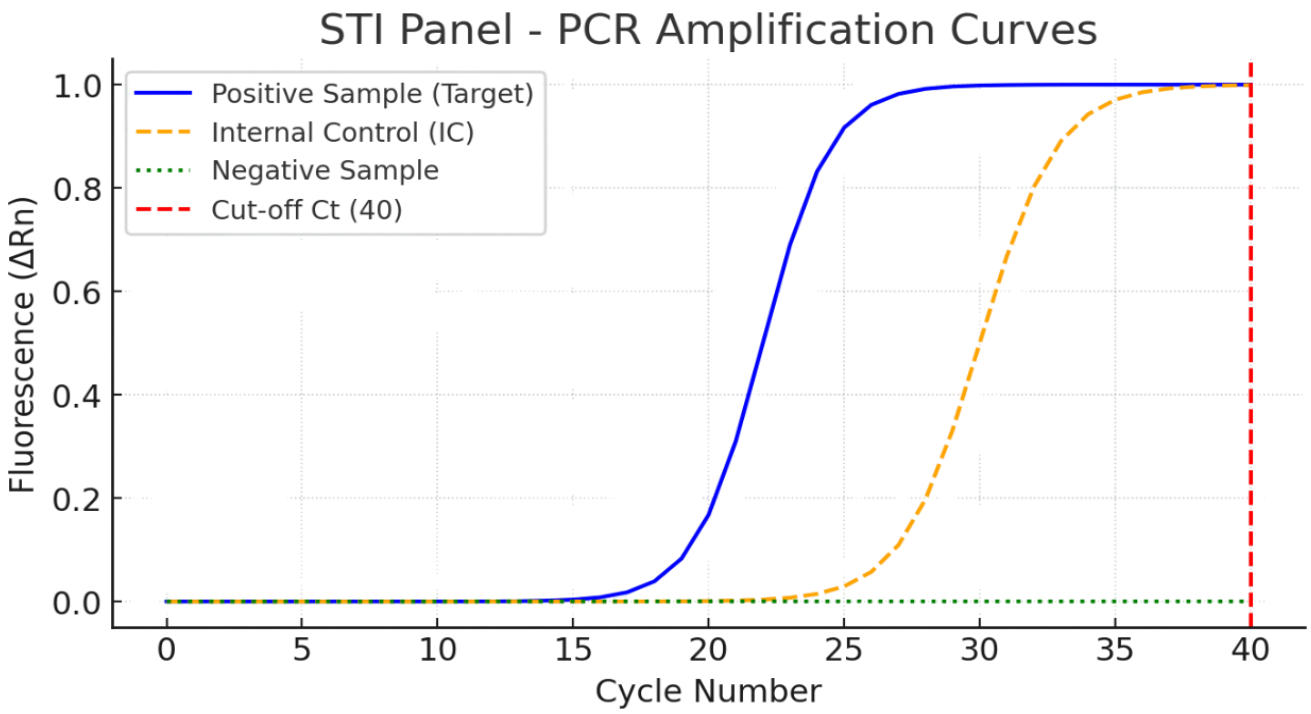
	Steps	Temperature	Time	Cycles
1.	Pre-denaturation	95 °C	2 min	1
2	Denaturation	95 °C	10 s	45
	Annealing, extension, fluorescence acquisition	60 °C	30 s	

Table: 11.8b → Amplification Program of BTK-8

11.9 Results Analysis (refer to Instrument User Manual)

After the reaction, the results will be saved automatically.

A. Common real-time PCR instruments:
- Adjust the Start value and End value of the Baseline:
  - Start value: **3–15**
  - End value: **5–20**
- The amplification curve of the Negative Control should be straight or remain below the threshold line.
- Analyze the amplification curves of different detection targets separately, using the corresponding Negative Control.
- Threshold line setting principle:
- Threshold line is recommended to be set just above the highest point of the Negative Control curve and above the fluorescence background value of the sample



B. BTK-8 instruments:
- Analysis is performed using the default program.
- Click “Analysis” to automatically obtain the results.
- Adjust parameters as needed to meet the requirements of Section 5: Quality Control.
- Review the detection results in the Report window.

11.10 Quality Control

The results of negative control and positive control in each tube and channel shall conform to the following table:

Well	Channel	Negative Control	Positive Control
Well 1	FAM (T. vaginalis)	No Ct or Ct > 40	Ct ≤ 38 with normal amplification curve
	VIC (N. gonorrhoeae)	No Ct or Ct > 40	Ct ≤ 38 with normal amplification curve
	ROX (C. trachomatis)	No Ct or Ct > 40	Ct ≤ 38 with normal amplification curve
	CY5 (IC – Human RNaseP)	Ct ≤ 38 with normal amplification curve	Ct ≤ 38 with normal amplification curve
Wells 2–4	FAM (various targets)	No Ct or Ct > 40	Ct ≤ 38 with normal amplification curve
	VIC (various targets)	No Ct or Ct > 40	Ct ≤ 38 with normal amplification curve
	ROX (various targets)	No Ct or Ct > 40	Ct ≤ 38 with normal amplification curve
	CY5 (various targets)	No Ct or Ct > 40	Ct ≤ 38 with normal amplification curve

Table 11.10 → Quality Control

12 Test Results Interpretation

12.1. Interpretation of Ct value of target gene detection:

Since Well 1 (CY5 channel) contains internal control (IC), its result must be determined before interpreting all other wells.

- If Well 1 yields a valid IC result (Ct ≤ 40 with a normal amplification curve), the test run is considered valid, and the results of Wells 2–4 may then be interpreted.
- If Well 1 does not yield a valid IC result (No Ct or Ct > 40, or abnormal curve), the entire sample test is considered invalid and must be repeated.

Well 1 Target	Channel	Negative (–)	Positive (+)	Well 1 Valid Results	Well 1 Invalid Result	Internal Control
		Well 1 Negative (-)	Trichomonas vaginalis Positive (+)	Neisseria gonorrhoeae Positive (+)	Chlamydia trachomatis Positive (+)	
Trichomonas vaginalis	FAM	No Ct or Ct > 40	Ct ≤ 40	Any results	Any results	No Ct or Ct> 40
Neisseria gonorrhoeae	VIC/HEX	No Ct or Ct > 40	Any results	Ct > 40	Any results	No Ct or Ct > 40
Chlamydia trachomatis	ROX	No Ct or Ct > 40	Any Results	Any results	Ct > 40	No Ct or Ct > 40
Internal Control (IC)	CY5	Ct ≤ 40	Any Results	Any results	Any Results	No Ct or Ct > 40

Table 12.1 → Specimen Interpretation (Well 1 IC valid vs invalid)

Target	Well	Channel	Negative (–)	Positive (+)
Gardnerella vaginalis	Well 2	FAM	No Ct or Ct > 40	Ct ≤ 40
Haemophilus ducreyi	Well 2	VIC	No Ct or Ct > 40	Ct ≤ 40
Candida albicans	Well 2	ROX	No Ct or Ct > 40	Ct ≤ 40
Streptococcus agalactiae	Well 2	CY5	No Ct or Ct > 40	Ct ≤ 40
U. urealyticum	Well 3	FAM	No Ct or Ct > 40	Ct ≤ 40
U. parvum	Well 3	VIC	No Ct or Ct > 40	Ct ≤ 40
M. hominis	Well 3	ROX	No Ct or Ct > 40	Ct ≤ 40
M. genitalium	Well 3	CY5	No Ct or Ct > 40	Ct ≤ 40
Treponema pallidum	Well 4	FAM	No Ct or Ct > 40	Ct ≤ 40
HSV-1	Well 4	VIC	No Ct or Ct > 40	Ct ≤ 40
HSV-2	Well 4	ROX	No Ct or Ct > 40	Ct ≤ 40

Table 12.2 → Interpretation of Ct value of Target Gene Detection:

Notes:

1. When an equivocal result is obtained for a single pathogen (e.g., weak amplification near the Ct 40 cutoff), the sample shall be retested. If the repeat test result remains positive for that single target, the sample is confirmed as positive for that pathogen.
2. Under the condition that the Internal Control (IC, Well 1 – CY5) is valid, the results of the other targets in Wells 1–4 shall be interpreted according to the Ct thresholds defined in Section 12.1.
3. Mixed infections may occur. Detection of more than one pathogen within the same sample should be reported as a co-infection.
4. If all target wells are negative and the IC is valid, the sample is interpreted as negative for all STI pathogens included in this assay.

12.3. Specimen Interpretation Grid – Pathogen-Specific Results

Target Gene	1	2	3	4	5	6	7	8	9
Trichomonas vaginalis	+	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+/–
Neisseria gonorrhoeae	+/–	+	+/–	+/–	+/–	+/–	+/–	+/–	+/–
Chlamydia trachomatis	+/–	+/–	+	+/–	+/–	+/–	+/–	+/–	+/–
Gardnerella vaginalis	+/–	+/–	+/–	+	+/–	+/–	+/–	+/–	+/–
Haemophilus ducreyi	+/–	+/–	+/–	+/–	+	+/–	+/–	+/–	+/–
Candida albicans	+/–	+/–	+/–	+/–	+/–	+	+/–	+/–	+/–
Streptococcus agalactiae	+/–	+/–	+/–	+/–	+/–	+/–	+	+/–	+/–
Ureaplasma urealyticum	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+	+/–
Ureaplasma parvum	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+
Mycoplasma hominis	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+
Mycoplasma genitalium	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+
Treponema pallidum	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+
HSV-1	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+
HSV-2	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+/–	+
Interpretation	*T. vaginalis Positive*	*N. gonorrhoeae Positive*	*C. trachomatis Positive*	*G. vaginalis Positive*	*H. ducreyi Positive*	*C. albicans Positive*	*S. agalactiae Positive*	*U. urealyticum Positive*	*U. parvum Positive* (etc.)

Table 12.3 → Pathogen-Specific Expanded Grid

Notes

1. When an equivocal result is obtained (e.g., amplification near Ct 40), retesting is required. If repeat is positive, the sample is confirmed positive for that pathogen.
2. If IC is valid and all targets are negative, report as Negative for all STI pathogens.
3. Multiple positives indicate a mixed infection.

13 Assay Limitations

A. The detection results of this kit are intended for clinical reference only and should not be used as the sole basis for diagnosis or treatment decisions. The clinical management of patients should always be determined in combination with clinical signs, symptoms, medical history, and other diagnostic information.

B. Test performance may be affected by factors such as specimen collection, handling, storage, and transportation.
- Improper collection may yield insufficient nucleic acids, causing false negatives.
- Cross-contamination during specimen handling may cause false positives.

C. This kit targets conserved regions of the genomes of **sexually transmitted pathogens** (*C. trachomatis, N. gonorrhoeae, T. vaginalis, M. genitalium, etc.*). Mutations or sequence variations in these regions may cause target failure, leading to potential false negatives

14 Performance Characteristics

14.1 Limit of Detection (LoD):

A. ~500 copies/mL for pathogens (*C. trachomatis, N. gonorrhoeae, M. genitalium, etc.*).

14.2 Precision:

B. CV ≤ 5% within-run and between-run.

14.3 Accuracy:

C. 95–100% agreement with sequencing/clinical PCR assays.

14.4 Specificity:

D. In-silico confirmed probes.

E. Cross-reactivity noted: Candida albicans ↔ C. dubliniensis; Ureaplasma species cross-react; Mycoplasma hominis vs. M. genitalium partial homology.

F. No cross-reactivity for HSV-1/HSV-2 with other herpesviruses.

G. Possible interference from vaginal commensals.

14.5 Inclusivity: (Pathogen Strain Coverage)

H. The assay detects the following pathogens across multiple lineages and circulating strains:

Chlamydia trachomatis *Neisseria gonorrhoeae* *Mycoplasma genitalium* *Mycoplasma hominis*	*Ureaplasma urealyticum / parvum* *Trichomonas vaginalis* *Treponema pallidum* *Haemophilus ducreyi*	*Herpes simplex virus types 1 and 2 (HSV-1/2)* *Human papillomavirus (HPV; multiple high- and low-risk genotypes)* *Cytomegalovirus (CMV)* *Candida albicans*

I. The assay also includes an internal control (RNaseP) to confirm specimen integrity, nucleic acid extraction, and amplification performance.

15 Attention

A. ⚠ For Research Use Only (RUO). Not for use in diagnostic procedures
B. Transport conditions: The kit must be transported at ≤ 37 °C. If ambient temperature exceeds 37 °C, use insulated containers with ice packs to maintain temperature.
C. Always use sterile, DNase-free and RNase-free consumables (tubes, pipette tips) during testing to prevent contamination.
D. To avoid RNase/DNase contamination, all procedures must be performed in a Class II biosafety cabinet while wearing appropriate personal protective equipment (PPE): disposable gloves, lab coats/gowns, protective eyewear, and surgical or N95 masks.
E. In case of accidental contact with skin or mucous membranes, rinse immediately with plenty of flowing water. If irritation persists, seek medical advice.
F. Before use, ensure all liquid reagents are completely thawed at room temperature, mixed thoroughly, and centrifuged briefly (≥8,000 rpm for a few seconds) to collect contents.
G. After use, all packaging, consumables, and waste liquids must be disposed of as regulated medical waste, following institutional and local biosafety regulations.
A. STI: Handle all urogenital swabs and first-void urine specimens as potentially infectious. Follow institutional biosafety guidelines for sexually transmitted infections.

16 Troubleshooting

Problem	Possible Cause	Solution
Signal in Negative Control	Contamination (amplicons, aerosols)	Clean workspace, replace reagents/consumables
No IC amplification	RNA degradation or inhibitors	Re-extract; use RNase-free conditions; dilute sample 1:5
High Ct / weak signal	Low viral load; poor swab quality	Recollect sample; ensure proper transport/storage
Positive control fails	PC degraded or program error	Use new kit; verify RT-PCR cycling (including 50 °C RT step)
Irregular fluorescence	Tube sealing or optical issues	Re-spin tubes; reseal; check instrument optics
Channel cross-talk	Spectral overlap between fluorophores	Adjust baseline/thresholds; re-run if needed
Multiple invalid samples	Workflow contamination; RNase contamination	Recheck biosafety workflow; enforce RNase-free technique

Table 16. → Troubleshooting Guide

17 References

A. Clinical management of severe acute respiratory infection when novel coronavirus (nCOV) infection is suspected-Interim guidance, 2020.
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18 Manufacturer & Distributor

Manufacturer
Bioteke Corporation (Wuxi) Co., Ltd.
Zone A, Floor 4, No. 1719-5, Huishan Avenue,
Huishan Economic Development Zone, Wuxi, Jiangsu, 214174, China
Web: www.bioteke.cn | Email: info@bioteke.cn

Authorized Distributor (U.S.)
Med X Diagnostics LLC.
1800 West Hawthorne Lane – STE P
West Chicago, IL 60185, USA

19 Regulatory Statement

This product is labeled **For Research Use Only (RUO)** in accordance with **21 CFR 809.10(c)(2)(i)**. It is not intended for use in diagnostic procedures. The end-user laboratory is responsible for establishing performance characteristics.

20 Symbols

	Refer to the Manufacturer	REF	UTO Panel PCR Kit	LDT	Lab Development Test
	Distributor Med X Reagent Solutions	IVD	Diagnostic Use	RUO	For Research Use Only
IFU	INFORMATION FOR USE	LOT	Batch code Use-by date	EX/REP	Authorized representative in the European Community
CE	CE mark of conformity				Keep away from Sunlight
	Do not use if package is Temperature limit		Use by date:		Temperature Limit Damaged
COLA	Commission On Laboratory Accreditation	CLIA Certified	Med X Diagnostics is CLIA Certified Diagnostic Lab	CMS	Center of Medicare & Medicaid
	DNA strand (molecular diagnostics		Caution (general hazard warning)	FDA REGISTERED	The Food and Drug Administration Registered
	In vitro diagnostic medical device (⚠ remove if RUO only)		Consult instructions for use		Keep dry
	Date of manufacture For In Vitro		Temperature limit (e.g., –20 °C storage)		Contains sufficient for <n> tests
EU	Authorized representative in the European Community		Keep away from sunlight		Control standard (if supplied)
+ / −	Positive control / Negative control		Keep upright		Do not use if package is damaged
	(Hourglass)		Recyclable packaging		Flammable reagent (if applicable)