Product information
STD VIRPLEX® MINILAB PANEL (ML001)

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BACKGROUND

Sexually transmitted infections (STIs) are a significant global health challenge with widespread social, economic, and public health repercussions. In 2020, an estimated 374 million new cases of four treatable STIs were reported among people aged 15–49, averaging approximately one million new infections daily. This includes *Chlamydia trachomatis* (129 million), *Neisseria gonorrhoeae* (82 million), *Trichomonas vaginalis* (156 million), and *Treponema pallidum* (8 million). Beyond these, the WHO estimates up to 500 million cases of herpes simplex virus type 2 (HSV-2). Genital mycoplasma infections, though often underdiagnosed, are also prevalent, with *Mycoplasma genitalium* affecting 1–3% of the general sexually active population, while *Mycoplasma hominis* and *Ureaplasma urealyticum* show even higher rates in asymptomatic women.

Many STIs are asymptomatic, and untreated cases can lead to severe complications, disproportionately affecting women and newborns. Congenital syphilis causes hundreds of thousands of fetal and neonatal deaths annually. Bacterial infections like *Chlamydia trachomatis* and *Neisseria gonorrhoeae* can lead to infertility, pelvic inflammatory disease, and complications in pregnancy, including ectopic pregnancies and preterm deliveries. Neonates exposed to HSV during birth may suffer fatal consequences. Misdiagnosis or delayed diagnosis exacerbates these risks, underscoring the critical need for precise and early detection.

Traditional STI diagnosis based solely on symptoms is often inadequate, as many infections present no symptoms or share overlapping signs. This can lead to misdiagnosis, resulting in either overtreatment with unnecessary antibiotics, contributing to antimicrobial resistance, or undertreatment, which increases transmission and complications. Nucleic acid amplification tests (NAATs) address these challenges by enabling simultaneous detection of multiple pathogens, allowing for accurate and differential diagnoses even in asymptomatic cases. Molecular methods represent the gold standard for STI diagnosis, enhancing surveillance, improving public health outcomes, and supporting rational antimicrobial use. These advancements are pivotal in reducing transmission, preventing complications, and improving sexual health globally.

Differential treatment for STI

The **syndromic approach to STI management ensures targeted, personalized care, reducing unnecessary treatments, medication costs, side effects, and antibiotic resistance.** It minimizes long-term complications and optimizes patient outcomes while promoting efficient healthcare resource use. This table shows the differential treatment of main STI targets:

		Recommended treatment
Bacteria	*C. trachomatis*	Azithromycin, doxycycline
	Ureaplasma spp	Azithromycin, doxycycline
	Chancroid	Azithromycin, ceftriaxone
	M. genitalium	Azithromycin, moxifloxacin if resistant
	N. gonorrhoeae	Ceftriaxone, cefixime
	Lymphogranuloma venereum	Doxycycline
	M. hominis	Doxycycline
	Syphilis	Penicillin
	Trichomonas vaginalis	Metronidazole
Virus	HSV-1/HSV-2	Acyclovir, valaciclovir, famciclovir
	Mpox virus	Tecovirimat

This summary table has been made according to WHO and CDC recommendations, and treatment may vary due to disease severity, symptoms, co-infections and other aspects.

Advantages of sample-to-result testing for STI

Improved Patient Satisfaction

- Accurate diagnosis/accurate treatment
- Less time spent on recurring visits

Improved Clinician Satisfaction

- Accurate diagnosis/accurate treatment
- Less time spent trying to contact patients for follow-up; less time spent on follow-up treatment visits
- Fewer patients lost to follow-up
- Enables "teachable moment" for the patient on the day of the visit

Improved Clinic Workflow

- Less time spent trying to contact patients for treatment
- Fewer treatment visits

When does sample-to-result STI testing have the greatest impact?

Where patients are unlikely to return for follow-up
Eliminate loss to follow-up for difficult-to-contact patients

Where same-day treatment is indicated/desired

- Symptomatic patients in vaginal discharge (WHO recommendation)
- Surgery
- Pregnant women

Where patients are likely to spread infection in the absence of same-day treatment
Patients with multiple partners or high levels of sexual activity

Sites with delayed/limited access to lab-based testing

STD VIRPLEX® MINILAB PANEL

Ideal solution for the **most comprehensive diagnosis of STIs.**

RELEVANT FEATURES	WHY?	WHEN?
• 15 targets for STD testing • Real-time **technology based** • Simplifying the workflow **in a lab (< 2 min handling)** • **Quick TAT,** results in 1h30	• **Complete diagnosis**, including **speciality testing and resistances** • Allows an **appropriate treatment from day 1** • **Mpox importance**	• Emergency samples (surgery, urgency…) • Improperly treated patients • Small laboratories • Unlikely returners • Sexual violence cases

STD VIRPLEX® MINILAB PANEL - Product information

Name / Reference / Intended Use / Test Type

Name: STD VIRPLEX® MINILAB PANEL
Reference: ML001

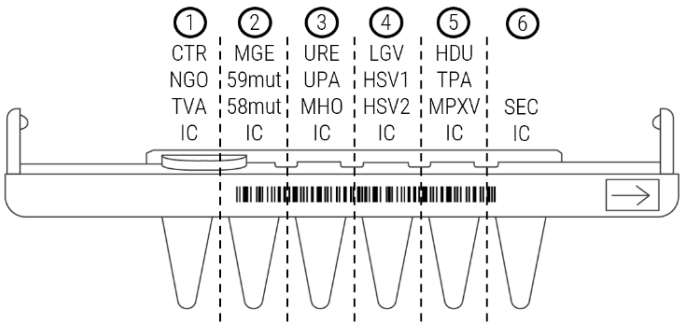
Intended Use: Nucleic acid amplification test for the simultaneous detection of nucleic acids from the following microorganisms:
Chlamydia trachomatis (CTR) and *Neisseria gonorrhoeae* (NGO) in human pharyngeal swabs, vaginal/endocervical swabs, urethral swabs, rectal swabs and urine.
Trichomonas vaginalis (TVA) in human vaginal/endocervical swabs.
Mycoplasma genitalium (MGE) and *23S rRNA* macrolide resistance-associated mutations at A2059 (59mut) and A2058 (58mut) in human vaginal/endocervical swabs, urethral swabs, rectal swabs and urine.
Ureaplasma urealyticum (URE), *Ureaplasma parvum* (UPA), *Mycoplasma hominis* (MHO) in human vaginal/endocervical swabs, urethral swabs and urine.
CTR serovar L (LGV) in human ulcer specimens and rectal swabs.
Herpes simplex virus type 1 (HSV1), Herpes simplex virus type 2 (HSV2), *Treponema pallidum* (TPA), *Haemophilus ducreyi* (HDU) and mpox virus (MPXV) in human ulcer specimens.

Regulatory status: CE_{0123} (CE-IVDR)

Test principle and kit contents

The VIRPLEX® MINILAB STD PANEL is designed to amplify specific fragments of various microorganisms, including CTR, LGV, NGO, TVA, MGE with macrolide resistance-associated mutations (A2059 and A2058), URE, UPA, MHO, HSV1, HSV2, TPA, HDU, and MPXV, using six distinct lyophilized PCR mix tubes. It includes an internal control (IC), an unrelated and non-infectious microorganism that ensures proper amplification setup and absence of carry-over inhibitors, with specific oligo pairs/probes integrated into each tube, and validates specimen processing. Additionally, VIRPLEX MINILAB EC1 is included. This sample extraction control (SEC) detects the presence of human DNA in the sample, verifying the correct collection and processing by targeting a specific fragment of the human *RNAse P* gene.

The VIRPLEX® MINILAB STD PANEL needs to be used with an automated processor (MiniLab System, Ref. VMLS) and the extraction system (GS Nucleic Acid Extraction, Ref. VXGS001).



The included targets for each microorganism are:

- **TUBE 1:**
  - *pmpH* gene and a specific region within the pCTT1 plasmid for CTR, labelled in FAM.
  - *opaI* gene for NGO, labelled in HEX.
  - *G3hp* gene for TVA, labelled in Cy5.
  - IC, labelled in ROX.
- **TUBE 2:**
  - mutations in the 23S rRNA gene at positions A2059, labelled in FAM.
  - mutations in the 23S rRNA gene at positions A2058, labelled in HEX.
  - specific fragment of the *mgpA + ITS rRNA* genes for MGE, labelled in Cy5.
  - IC, labelled in ROX.
- **TUBE 3:**
  - specific fragment of the *ureC* gene for URE, labelled in FAM.
  - specific fragment of the *ureC* gene for UPA, labelled in HEX.
  - *ftsY* gene for MHO, labelled in Cy5.
  - IC, labelled in ROX.
- **TUBE 4:**
  - specific fragment of the *pmpH* gene for LGV, labelled in FAM.
  - *GlyB* gene for HSV2, labelled in HEX.
  - *GlyG* gene for HSV1, labelled in Cy5.
  - IC, labelled in ROX.
- **TUBE 5:**
  - specific fragment of the *wecA* gene of HDU, labelled in FAM.
  - *ttp47* gene for TPA, labelled in HEX.
  - *F3L* gene for MPXV, labelled in Cy5.
  - IC, labelled in ROX.
- **TUBE 6:**
  - specific fragment of the human *RNAse P* gene. This control is defined as sample extraction control (SEC), labelled in HEX.
  - IC, labelled in ROX.

Samples validation

Our internal validation was performed with more than 1235 samples of different types: pharyngeal, endocervical, vaginal and urethral exudates, urine, and ulcers.

The following table summarizes with which kind of sample different microorganisms included in VIRPLEX MINILAB STD ASSAY KIT have been validated:

	Pharyngeal swab	Urine	Vaginal/ Endocervical swab	Urethral swab	Ulcer	Rectal swab
CTR	*	*	*	*		*
LGV/ HDU					*	*
HSV1/ HSV2					*	
MPXV					*	
MGE		*	*	*		*
MHO		*	*	*		
NGO	*	*	*	*		*
TPA					*	
TVA			*			
UPA/ URE		*	*	*		

Components and appearance. Transport and storage requirements.

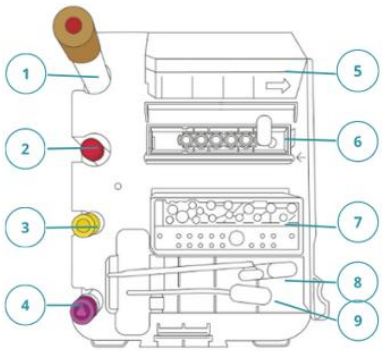
Kit appearance	Ref.	Kit contents & features	Pack size	Transport	Storage
STD VIRPLEX MINILAB PANEL  	ML0001	• 1 unit of VIRPLEX MINILAB STD ASSAY KIT (PCR reagent cassette) • 1 vial of VIRPLEX MINILAB EC1 (extraction control/IC) 	10 tests	Room temperature	2-8º
GS Nucleic Acid Extraction Kit  	VXGS001	• Cartridge lid • 40µL Proteinase K (yellow cap) • 600µL • Lysis buffer (purple cap) • Disposable quantitative dropper (400µL) • Disposable transfer pipette 	10 tests	Room temperature	4-30º
MiniLab System 	VMLS	• Microfluidic based automated nucleic acid extraction and detection device • Based on Real-time PCR technique: Qualitative results. • One test (one sample) per run. • Dimensions: 27.5 × 17.2 × 23 .5 cm. Weight: 4.5 Kg	1 unit	Room temperature	Room temperature

Assay procedure

The process is video-guided in the instrument with the steps, minimizing handling and contamination. The assay procedure is summarised in a chart flow in the Annex 1 (at the end of this document). Below is a summary of the simple procedure.

1. Device Setup

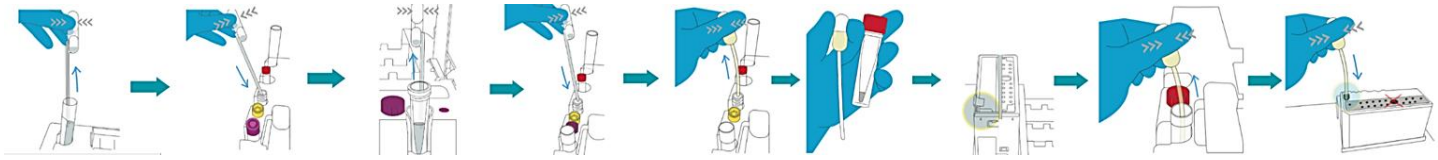
- Open the foil package containing the extraction cassette and the VIRPLEX MINILAB SET.
- Arrange all reagents and materials in the tray. These include (see the picture plotted):
    1. Sample tube
    2. VIRPLEX MINILAB EC
    3. Proteinase K (yellow cap)
    4. Lysis buffer (purple cap)
    5. Cartridge lid
    6. VIRPLEX MINILAB ASSAY KIT
    7. Extraction cartridge
    8. Quantitative dropper
    9. Transfer pipette



- Remove the cap of the VIRPLEX MINILAB ASSAY KIT and assemble the extraction cassette with the VIRPLEX MINILAB ASSAY KIT, ensuring they are properly aligned.

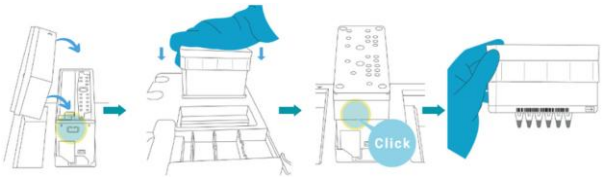
2. Sample Preparation

- Use the disposable quantitative dropper to transfer **400µl of the sample** and **400µl of lysis buffer** (purple cap) into the *Proteinase K buffer tube* (yellow cap).
- Mix the solution by transferring it into the *VIRPLEX MINILAB EC* vial using the disposable transfer pipette, then close the vial tightly and invert it three times to mix.
- Open the rubber plug on the extraction cassette, transfer the mixture into the sample chamber using the same pipette, close the plug, and attach the cassette lid securely.



3. Start the Process

- Finish the cassette assembly, place it into the instrument, and start the procedure. Results will appear automatically after 90 minutes approximately.



Interpretation of the results

The Minilab System automatically interprets the results based on the amplification of each target, the IC and SEC. The information about the sample ID, user, sample type and interpretation of the result for each target is displayed on the result screen and test report.

The different possible results interpretation for **tube 1-5** is described in the table below:

REPORT RESULT		INTERPRETATION
Target	Detected +	Presence of target DNA with valid IC
IC	Valid	
Target	Detected +	Presence of target DNA with invalid IC
IC	Invalid [1]	
Target	Not detected -	Absence of target DNA with valid IC
IC	Valid	
Target	Invalid ! [2]	Absence of target DNA with invalid IC
IC	Invalid ! [2]	

The result interpretation for **tube 6** is described in the table below:

REPORT RESULT		INTERPRETATION
SEC	Detected +	Presence of human DNA in the sample with valid IC
IC	Valid	
SEC	Detected +	Presence of human DNA in the sample with invalid IC
IC	Invalid [1]	
SEC	Not detected -	Absence of human DNA in the sample with valid IC [3]
IC	Valid	
SEC	Invalid ! [2]	Absence of human DNA in the sample with invalid IC
IC	Invalid ! [2]	

[1] In case of a high copy number of the target nucleic acid, the amplification of the IC may be affected. An invalid IC result in presence of at least one target DNA does not change the interpretation of the result

[2] An invalid IC result in absence of any target DNA in the tube, invalid just the tube with this result, but not the entire assay. In case of an invalid IC result, it is recommended to re-test the sample. Improper extraction of nucleic acids, inhibition of amplification or cartridge error could be assumed.

[3] Absence of detection of SEC does not invalid the assay.

In case of an invalid result, it is recommended to repeat the analysis. Possible reasons for an invalid run or cartridge failure are the use of difficult to pipette specimens, poor specimen quality, or failure to follow the instructions provided in Assay procedure.
If the test result remains invalid, testing a new sample is recommended. Improper collection, handling or storage of the sample and/or presence of inhibitors could be assumed.

Different examples of possible results are shown in the Annex 2 (at the end of this document).

Performance evaluation- Sensitivity and specificity

	SENSITIVITY	SPECIFICITY	NO. OF SAMPLES
CTR	99%	99.5%	799
LGV	94.6%	99.4%	405
HDU	100%	99.5%	272
HSV-1	96.3%	99.4%	211
HSV-2	98%	99.4%	216
MPXV	100%	98%	107
MGE	98.3%	99.6%	632
MHO	97.3%	98.5%	450
NGO	99.4%	99.4%	797
TPA	96%	100%	276
TVA	98.2%	100%	169
UPA	99.1%	99.1%	454
URE	99.7	94.3%	447

For more performance information, precision and cross-reactivity check the instructions for use.

Recommended external controls

Positive controls that are recommended to help monitoring any cross- contamination that occurs during the process, additionally serve as validation tools.

- AMPLIRUN® CT/NG TOTAL CONTROL (URINE). Cat. MBTC003 (Vircell).
- AMPLIRUN® CT/NG TOTAL CONTROL (EXUDATE). Cat. MBTC006 (Vircell),
- AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB). Cat. MBTC024-R (Vircell).
- AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB). Cat. MBTC029 (Vircell).
- AMPLIRUN® TOTAL MONKEYPOX VIRUS CONTROL (SWAB) Cat. MBTC032-R (Vircell).

Comparison of VIRPLEX MiniLab with open Real-time kits

(ie. VIRPLEX)

	VIRPLEX - RTPCR	VIRPLEX MINILAB - ML001
PCR method	Real-time reading of results (Ct values)	Results (Ct values) are exhibit at the end of the process
NA extraction	Compatible with different extraction methods	Integrated closed system (VXGS001 + VMLS)
Components	8-well PCR strips. Material supplied and laboratory equipment	PCR tube holder for 6 PCR tubes with lid - 1 sample. No materials other than those supplied are required.
Tubes/mixes **Reactions**	1-2 tubes Up to 96 samples/assay	Up to 6 tubes/sample 1 sample/assay
Controls	Negative (CN), positive (CP), Internal control (IC)	Exogenous extraction control to be added to the sample. IC included. Not CP/CN in the kit.
Channels	5 channels (FAM, HEX/VIC, Cy5, Texas/ROX and Q705)	4 channels (FAM, HEX, Cy5 and ROX)
Protocol	Extraction + PCR setup + PCR cycling	All steps integrated
Time to result	Extraction >15min PCR 1h 20min-2h	Full run 1h 30min
Traceability	Manual	Barcode scanning cartridge/assay kit/sample before starting test

MARKET ALTERNATIVES AND COMPETITION

As highlighted earlier in this document, the increasing number of STIs is concerning, and the situation continues to worsen each year. The WHO has set the goal of eliminating STIs as a public health threat by 2030.

Currently, several diagnostic guidelines recommend a syndromic approach, as microbiological multiplex tests are particularly effective in two key situations: when polymicrobial infections are likely and when multiple pathogens need to be ruled out as causes of symptoms.

Molecular diagnostics offer several advantages, such as higher sensitivity compared to other direct pathogen detection methods, enabling the detection of non-viable or non-cultivable organisms (e.g., *Neisseria gonorrhoeae*, *Treponema pallidum*, *Mycoplasma genitalium*), and allowing the use of less invasive samples (e.g., urine, vaginal swabs). This approach also supports self-sampling, which is an essential aspect of modern diagnostics.

The market for STI molecular diagnostics is highly competitive, with several methods available:

- **End-point PCR + Array/Strip** combines DNA amplification through PCR with the simultaneous detection of multiple genetic sequences using probe strips or arrays. This method is very useful in diagnostic tests for detecting various infections or genetic mutations, but requires quite a lot manipulation, increasing contamination risk, so it is not widely used. Some examples are the EUROArray STI (Euroimmun, detection of 11 pathogens) and the GenoFlow STD Array (DiagCor, 9 pathogens).
- **Fully automated Real-time PCR systems,** compatible with TLA platforms (cobas® from Roche, Allinity from Abbott and Panther® from Hologic), are designed for routine testing in large laboratories with high throughput. These systems typically use kits that detect a limited number of pathogens (between 2 and 4). Usually, these companies are market leaders due to the volume.
- **Open semi-automated Real-Time Multiplex PCR kits**, are well-established and have different kits that detect multiple pathogens (usually more than 4). It is designed for mid-to-large throughput, offering an efficient procedure for routine testing. Some examples are Allplex® (Seegene), Viasure (Certest), Virplex (Vircell), Bosphore (Anatolia Geneworks), Geneproof, etc.
- **Closed-system semi-automated Real-time PCR.** These systems like BDMax (BD) or InGenius (Elitech), are targeting a few specific pathogens. They might be an intermediate solution for low-to-medium volume testing.
- **Sample-to-result systems** integrate extraction and amplification in a single cartridge, targeting one pathogen or a panel. They are ideal for smaller laboratories or urgent specimens, providing quick and accurate results with minimal setup. Here we have several examples for lower-plex capacity as GeneXpert (Cepheid), Solana® (QuidelOrtho). STANDARD M (SD Biosensor) and Vivalytic (Randox/Bosch) are high-plex molecular assays that directly compete with VIRPLEX MINILAB.

In the following table we have plotted a **comparison between the high-plex sample-to-results systems for STI** that we have found in the market research:

	VIRCELL	RANDOX	SD BIOSENSOR	CEPHEID	FLASH DX
Kit	STD VIRPLEX® MINILAB PANEL	Vivalytic | Sexually Transmitted Infection Array	STANDARD M*	Xpert® CT/NG ResistancePlus® MG FleXible	sSPRT™ STI Panel
PATHOGENS	Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaginalis Mycoplasma genitalium MGE A2059 (59mut) resistance gene MGE A2058 (58mut) resistance gene Ureaplasma urealyticum Ureaplasma parvum Mycoplasma hominis Chlamydia trachomatis serovar L Herpes simplex virus type 1 Herpes simplex virus type 2 Haemophilus ducreyi Treponema pallidum Mpox virus Sample extraction control	Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaginalis Mycoplasma genitalium Ureaplasma urealyticum Mycoplasma hominis Herpes simplex virus type 1 Herpes simplex virus type 2 Haemophilus ducreyi Treponema pallidum Vivalytic | MPOX (RUO)	Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaginalis Mycoplasma genitalium Ureaplasma urealyticum Mycoplasma hominis Herpes simplex virus type 1 Herpes simplex virus type 2	Chlamydia trachomatis Neisseria gonorrhoeae Xpert® TVA Mycoplasma genitalium MGE A2059 (59mut) resistance gene MGE A2058 (58mut) resistance gene	Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaginalis Mycoplasma genitalium Ureaplasma spp Mycoplasma hominis
Sample type	Genital exudates (vaginal/endocervical/urethral/perianal), urine, ulcers and pharyngeal exudates	Swab or urine	Urine	Swab (vaginal, cervical, rectal) or urine. For CT/NG and TV tests faringeal samples have been validated too.	Vaginal and urethral swabs
Sample volume	400 µl	300 µl	-	300 µl	120 µl
Pack size	10	15	10	10	10
Detection Method	Realtime PCR (Ct values exhibited)	Randox Biochip Technology (end-point PCR)	Realtime PCR (Ct values exhibited)	Realtime PCR	semi-Solid Phase Real Time PCR (sSPRT™).
Time to result	90 min	2h20	64 minutes	1:30h/ 1h / 2h	1h
Transport	Room temperature (both, cardtridge and PCR reagents)	Room temperature	Room temperature	Frozen	Room temperature
Storage	Cartridge room temperature and PCR reagents refrigerated	Room temperature	Room temperature	Refrigerated	Refrigerated
Marking	CE IVDR	CE IVD	**Coming soon*	CE IVD	RUO

VIRPLEX® MINILAB MARKET POSITIONING

VIRPLEX Minilab stands out with its **real-time technology**, detection of a wide range of STI pathogens (the highest in the market), and **inclusion of mpox and resistance detection**. To position it effectively, we can differentiate between large laboratories with existing STI diagnostic solutions and smaller clinics that may lack one. The following table outlines the advantages for each.

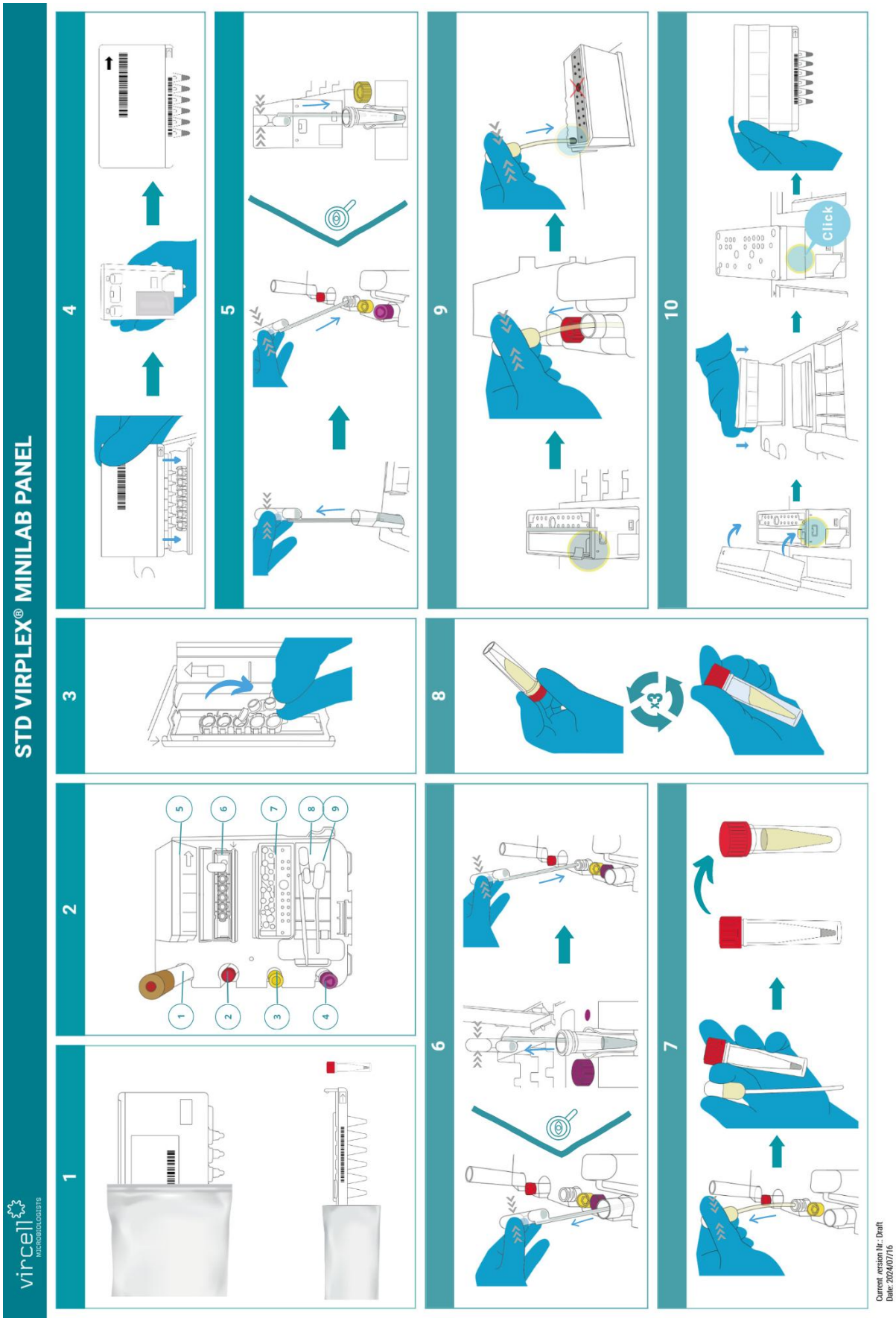
Large Laboratories	Small Laboratories /Private Clinics

• **MGE resistance detection**: Once MGE is diagnosed, it is of obligated report its macrolide resistance.
• **Mpox detection**- unique in the market in an integrated multiplex assay.
• **Sexual Violence:** Provides comprehensive results for related pathogens.
• Surgery (**Emergency**).
• Rare or invalidated specimens: confirms positive results.
• **Unlikely returners:** provides same-day results and treatment options within ~90 minutes.
• **Comprehensive diagnoses:**
  ○ Negative CT/NG results, suspicion of other STI
  ○ Genital Ulcers: detects pathogens often missing in larger platforms like Roche, Abbott, or BD.
	• Non-routine STD analysis in the laboratory: Offers an **alternative to sending samples** away.
	• **Comprehensive diagnoses.**
	• **Adapted to small sample volume**
	• **Short time response without specialised staff**

Bibliography

1. www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis)
2. www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/stis/testing-diagnostics
3. World Health Organization. *Report on Global Sexually Transmitted Infection Surveillance 2018*; World Health Organization: Geneva, Switzerland, 2018.
4. Caruso, G.; Giammanco, A.; Virruso, R.; Fasciana, T. Current and Future Trends in the Laboratory Diagnosis of Sexually Transmitted Infections. Int. J. Environ. Res. PublicHealth 2021, 18, 1038. https://doi.org/10.3390/ijerph18031038
5. Bagga, R.; Arora, P. Genital Micro-Organisms in Pregnancy. *Front. Public Health* 2020, 8.
6. Adamson PC, Loeffelholz MJ, Klausner JD. Point-of-Care Testing for Sexually Transmitted Infections: A Review of Recent Developments. Arch Pathol Lab Med. 2020 Nov 1;144(11):1344-1351. doi: 10.5858/arpa.2020-0118-RA. PMID: 32810868; PMCID: PMC7606737.
7. Cole, S. Herpes Simplex Virus: Epidemiology, Diagnosis, and Treatment. Nurs. Clin. N. Am. 2020, 55, 337–345.
8. Tsevat, D.G.; Wiesenfeld, H.C.; Parks, C.; Peipert, J.F. Sexually transmitted diseases and infertility. Am. J. Obs. Gynecol. 2017, 216, 1–9.
9. Farsimadan, M.; Motamedifar, M. Bacterial infection of the male reproductive system causing infertility. J. Reprod. Immunol. 2020, 142, 103183
10. Galvin, S.R.; Cohen, M.S. The role of sexually transmitted diseases in HIV transmission. Nat. Rev. Microbiol. 2004, 2, 33–42.
11. Elendu C, Amaechi DC, Elendu ID, Elendu TC, Amaechi EC, Usoro EU, Chima-Ogbuiyi NL, Arrey Agbor DB, Onwuegbule CJ, Afolayan EF, Balogun BB. Global perspectives on the burden of sexually transmitted diseases: A narrative review. Medicine 2024; 103:20 (e38199).

Annex 1: Workflow of STD VIRPLEX® MINILAB PANEL.



Annex 2. Examples of possible results obtained with of STD VIRPLEX® MINILAB PANEL.

Positive sample:

VIRCELL Molecular

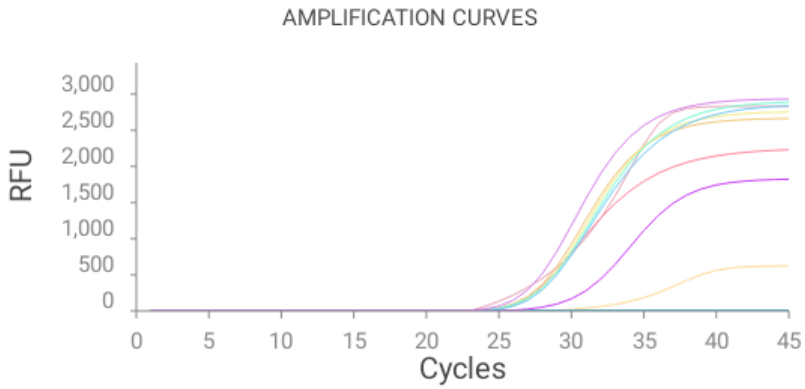
STD VIRPLEX MINILAB PANEL

Sample ID	STI I24S-03		
User Name	Admin	Test Date	2024/10/07
Doctor		Test Time	13:17
Sample Type	QCMD	Extraction	Z21240710E1
Machine Number	1C217260021	Amplification	V02240507ML001205

TEST RESULTS

Detected : Trichomonas vaginalis (TVA) + Mycoplasma genitalium (MGE) + Sample Extraction Control (SEC)

TARGET	RESULT		Cq	TUBE
Chlamydia trachomatis (CTR)	Not Detected	–	-	Tube1
Neisseria gonorrhoeae (NGO)	Not Detected	–	-	Tube1
Internal Control (IC)	Valid		26.38	Tube1
Trichomonas vaginalis (TVA)	Detected	+	27.58	Tube1
MGE A2059mut (59mut)	Not Detected	–	-	Tube2
MGE A2058mut (58mut)	Not Detected	–	-	Tube2
Internal Control (IC)	Valid		26.90	Tube2
Mycoplasma genitalium (MGE)	Detected	+	32.72	Tube2
Ureaplasma urealyticum (URE)	Not Detected	–	-	Tube3
Ureaplasma parvum (UPA)	Not Detected	–	-	Tube3
Internal Control (IC)	Valid		27.12	Tube3
Mycoplasma hominis (MHO)	Not Detected	–	-	Tube3
C.trachomatis (LGV)	Not Detected	–	-	Tube4
Herpes virus 2 (HSV2)	Not Detected	–	-	Tube4
Internal Control (IC)	Valid		27.18	Tube4
Herpes virus 1 (HSV1)	Not Detected	–	-	Tube4
Haemophilus ducreyi (HDU)	Not Detected	–	-	Tube5
Treponema pallidum (TPA)	Not Detected	–	-	Tube5
Internal Control (IC)	Valid		27.22	Tube5
Mpox virus (MPXV)	Not Detected	–	-	Tube5
Sample Extraction Control (SEC)	Detected	+	29.99	Tube6
Internal Control (IC)	Valid		26.41	Tube6



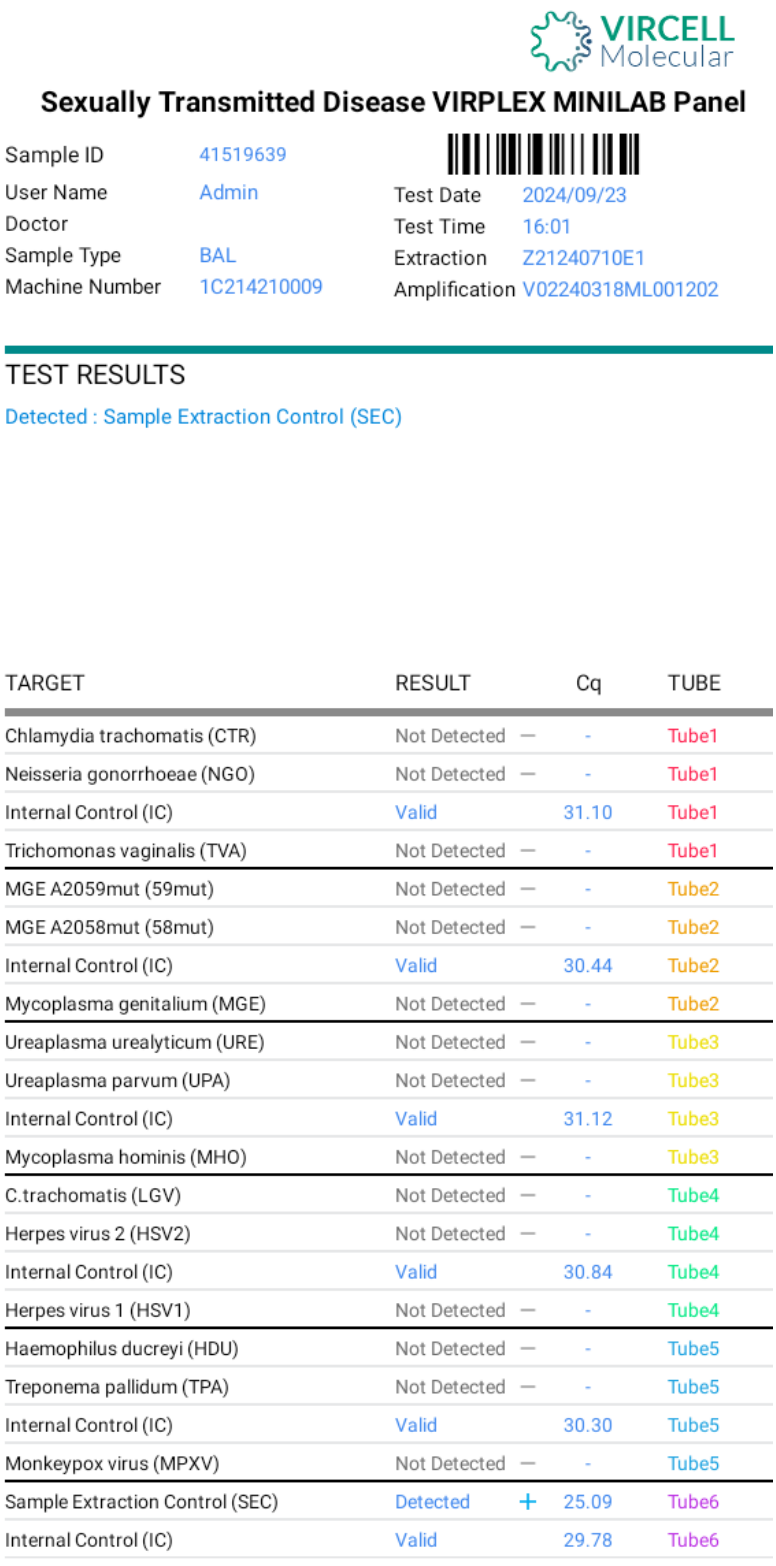
Data

FAM	CTR: N/D	59mut: N/D	URE: N/D	LGV: N/D	HDU: N/D	
HEX	NGO: N/D	58mut: N/D	UPA: N/D	HSV2: N/D	TPA: N/D	SEC: 29.99
ROX	IC: 26.38	IC: 26.90	IC: 27.12	IC: 27.18	IC: 27.22	IC: 26.41
Cy5	TVA: 27.58	MGE: 32.72	MHO: N/D	HSV1: N/D	MPXV: N/D	

Note

Signature

Negative sample with SEC detected:



VIRCELL Molecular

Sexually Transmitted Disease VIRPLEX MINILAB Panel

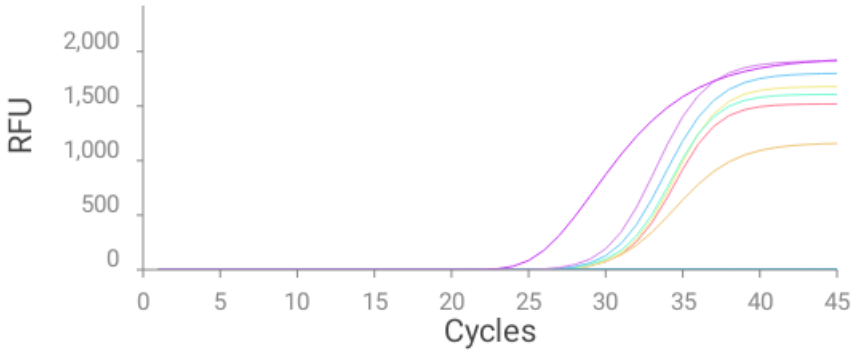
Sample ID	41519639		
User Name	Admin	Test Date	2024/09/23
Doctor		Test Time	16:01
Sample Type	BAL	Extraction	Z21240710E1
Machine Number	1C214210009	Amplification	V02240318ML001202

TEST RESULTS

Detected : Sample Extraction Control (SEC)

TARGET	RESULT		Cq	TUBE
Chlamydia trachomatis (CTR)	Not Detected	–	-	Tube1
Neisseria gonorrhoeae (NGO)	Not Detected	–	-	Tube1
Internal Control (IC)	Valid		31.10	Tube1
Trichomonas vaginalis (TVA)	Not Detected	–	-	Tube1
MGE A2059mut (59mut)	Not Detected	–	-	Tube2
MGE A2058mut (58mut)	Not Detected	–	-	Tube2
Internal Control (IC)	Valid		30.44	Tube2
Mycoplasma genitalium (MGE)	Not Detected	–	-	Tube2
Ureaplasma urealyticum (URE)	Not Detected	–	-	Tube3
Ureaplasma parvum (UPA)	Not Detected	–	-	Tube3
Internal Control (IC)	Valid		31.12	Tube3
Mycoplasma hominis (MHO)	Not Detected	–	-	Tube3
C.trachomatis (LGV)	Not Detected	–	-	Tube4
Herpes virus 2 (HSV2)	Not Detected	–	-	Tube4
Internal Control (IC)	Valid		30.84	Tube4
Herpes virus 1 (HSV1)	Not Detected	–	-	Tube4
Haemophilus ducreyi (HDU)	Not Detected	–	-	Tube5
Treponema pallidum (TPA)	Not Detected	–	-	Tube5
Internal Control (IC)	Valid		30.30	Tube5
Monkeypox virus (MPXV)	Not Detected	–	-	Tube5
Sample Extraction Control (SEC)	Detected	+	25.09	Tube6
Internal Control (IC)	Valid		29.78	Tube6

AMPLIFICATION CURVES



Data

FAM	CTR: N/D	59mut: N/D	URE: N/D	LGV: N/D	HDU: N/D	
HEX	NGO: N/D	58mut: N/D	UPA: N/D	HSV2: N/D	TPA: N/D	SEC: 25.09
ROX	IC: 31.10	IC: 30.44	IC: 31.12	IC: 30.84	IC: 30.30	IC: 29.78
Cy5	TVA: N/D	MGE: N/D	MHO: N/D	HSV1: N/D	MPXV: N/D	

Note

Signature

Negative sample without SEC detected:

VIRCELL Molecular

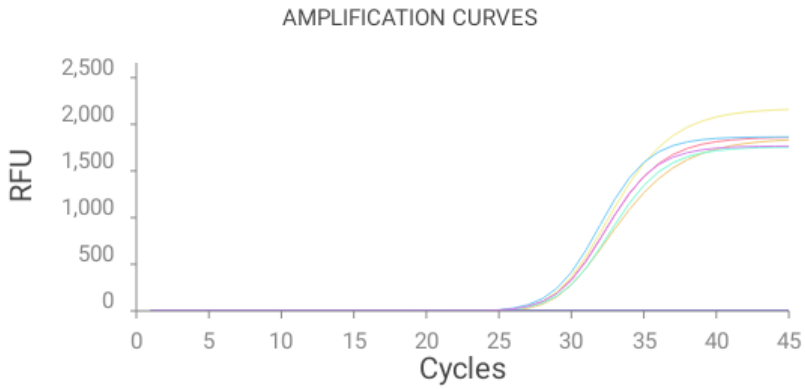
STD VIRPLEX MINILAB PANEL

Sample ID	T tenax 2		
User Name	Admin	Test Date	2024/10/17
Doctor		Test Time	11:40
Sample Type	Others	Extraction	Z21240710E1
Machine Number	1C217260030	Amplification	V02240318ML001202

TEST RESULTS

Detected : None

TARGET	RESULT	Cq	TUBE
Chlamydia trachomatis (CTR)	Not Detected	-	Tube1
Neisseria gonorrhoeae (NGO)	Not Detected	-	Tube1
Internal Control (IC)	Valid	28.52	Tube1
Trichomonas vaginalis (TVA)	Not Detected	-	Tube1
MGE A2059mut (59mut)	Not Detected	-	Tube2
MGE A2058mut (58mut)	Not Detected	-	Tube2
Internal Control (IC)	Valid	28.60	Tube2
Mycoplasma genitalium (MGE)	Not Detected	-	Tube2
Ureaplasma urealyticum (URE)	Not Detected	-	Tube3
Ureaplasma parvum (UPA)	Not Detected	-	Tube3
Internal Control (IC)	Valid	28.55	Tube3
Mycoplasma hominis (MHO)	Not Detected	-	Tube3
C.trachomatis (LGV)	Not Detected	-	Tube4
Herpes virus 2 (HSV2)	Not Detected	-	Tube4
Internal Control (IC)	Valid	28.85	Tube4
Herpes virus 1 (HSV1)	Not Detected	-	Tube4
Haemophilus ducreyi (HDU)	Not Detected	-	Tube5
Treponema pallidum (TPA)	Not Detected	-	Tube5
Internal Control (IC)	Valid	28.31	Tube5
Mpox virus (MPXV)	Not Detected	-	Tube5
Sample Extraction Control (SEC)	Not Detected	-	Tube6
Internal Control (IC)	Valid	28.65	Tube6



Data

FAM	CTR: N/D	59mut: N/D	URE: N/D	LGV: N/D	HDU: N/D	
HEX	NGO: N/D	58mut: N/D	UPA: N/D	HSV2: N/D	TPA: N/D	SEC: N/D
ROX	IC: 28.52	IC: 28.60	IC: 28.55	IC: 28.85	IC: 28.31	IC: 28.65
Cy5	TVA: N/D	MGE: N/D	MHO: N/D	HSV1: N/D	MPXV: N/D	

Note

Signature