

# Full Solution for Detecting Sexually transmitted diseases (STD) in Various Sample Types

## Background

As the most prevalent infectious disease worldwide, sexually transmitted diseases (STDs) demand heightened attention from both the public and healthcare sectors<sup>1</sup>. Achieving extensive screening on a global scale requires high-throughput, high-performance testing. Beyond general screening, **multiple pathogens** tests offer detailed insights into infections, including co-infection data, thereby reducing misdiagnosis and facilitating patient follow-up. In pursuit of comprehensive STD detection, our technical note showcases the application of an automated workflow using the GenoFlow™ STD Array Test Kit, which effectively **detects 11 STD pathogens** (see Figure 1) and demonstrates its clinical performance and informational significance.

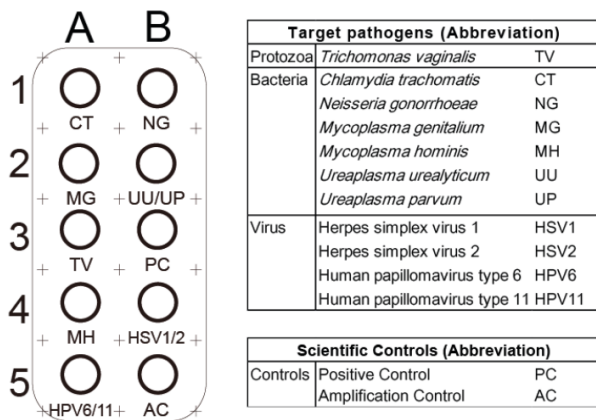


Figure 1. 11 types of STD pathogens detectable by GenoFlow™ STD Array Test Kit

## Sample Extraction and STD Detection

From a clinical study done by a medical diagnostic laboratory [4], 1,461 clinical specimens in the types of **urine, liquid based cytology** samples, and **swabs** were pre-treated and identified with GenoFlow™ STD Array Test Kit in FT<sup>PRO</sup> Flow-through System. DNA was extracted from various sample using **DiagPuro™ Nucleic Acid Extraction System**. The extracted DNA was amplified using **Genesis 96T Thermal Cycler**. The amplified products were subsequently denatured and then analyzed with **FT<sup>PRO</sup> Flow-through System**. Detection result can be drawn from the visualized colored signal generated in the **GenoFlow™ STD Array Test Kit**. Representative workflow is indicated in Figure 2. GenoFlow™ STD Array Test Kit allows simultaneous detection of 11 STD pathogens and the whole process takes about **3 hours**.

STDs often present asymptotically or with non-specific symptoms, making them prone to misdiagnosis. Physicians may request tests for incorrect pathogens due to overlapping symptoms. The paper stresses that accurate diagnosis is crucial, especially in outpatient settings where the test for less than five pathogens could lead to an oversight of other infections. The authors emphasize the importance of using comprehensive diagnostic methods and suggest that selecting broader test panels could significantly reduce misdiagnosis rates.

## Full Solution for STD Detection

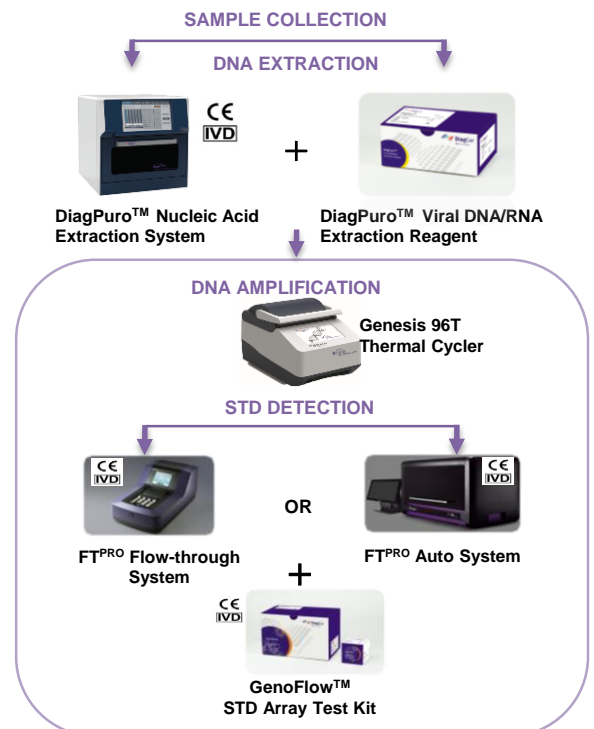



Figure 2. An overview on the full solution workflow from DNA extraction to STD signal detection in various samples types

### Trademark Information:


ThinPrep is a registered trademark of Hologic, Inc., USA.

SurePath is a registered trademark of Becton, Dickinson and Company, USA.

**DiagPuro™ Nucleic Acid Extraction System**




**DiagPuro™ Viral DNA/RNA Extraction Reagent**





**Sample types available:**


- Urine
- Liquid based cytology specimen (e.g. SurePath, ThinPrep)
- Swabs (cervix, glans, anal, throat)

## ADVANTAGES OF OUR FULL SOLUTION

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**MULTIPLEX**  
Both screening and genotyping on the single machine
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**COMPLETE**  
Covers comprehensive types of STD in high occurrence according to the clinical study.
- 

**SCALABLE**  
Scalability perfectly fit for various labs
- 





**EASY**  
Requires almost no training

### Significance of Selecting STD Test Capable in Multiple Pathogens Detection for Effective Diagnosis

The study collected samples from physicians which then underwent molecular testing according to the specific testing number and type of STD pathogen requested based on the judgement of the physicians. **For the order for single pathogenic type detection, 20.9%** of the samples fall into the inconsistent result with the actual infected type(s) while only **1.1%** was recorded from the order testing for the 7 types of the STD pathogens, **and zero misdiagnosis for the 8 types.** Among the study group, **26.9%** of the patients suffer from multiple pathogens infection which means merely test for one type of pathogens can miss out the identification of the other infected types.

Wrong judgement on choice of a particular pathogen test by the physician and the overlook of the cases of co-infection can lead to misdiagnosis and delayed treatment. The notably higher STD misdiagnosing rate in the test for single type of pathogen when comparing with the test for multiple pathogens suggests the **need of multiple pathogens detection** in correct diagnosis and hence proper treatment. The multiple detection targets of the GenoFlow™ STD Array Test Kit provides the medical diagnostic laboratory with a competitive edge in high accuracy and precision.

### Reducing misdiagnosis by selecting broader testing

-  Asymptomatic/Nonspecific Symptoms
-  Overlapping Symptoms
-  Accurate Diagnosis
-  Minimize oversight

Percentage of misdiagnosis assorted by requested test plans

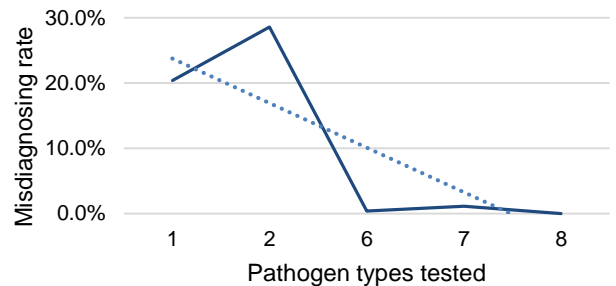


Figure 1. Misdiagnosing rate observed from different numbers of pathogen tested

### Alignment of Positive Samples with Requested Tests

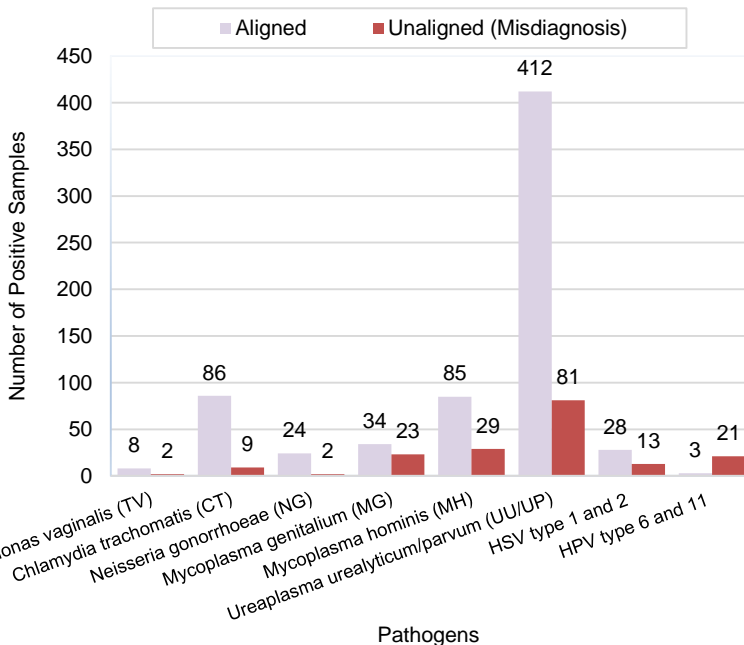


Figure 2. Number of samples with detected pathogen aligned and not aligned with requested tests

### References:

- [https://www.who.int/en/news-room/fact-sheets/detail/sexually-transmitted-infections-\(stis\)](https://www.who.int/en/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis))
- <https://www.who.int/publications/i/item/9789240053779>
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- Lau, A. and Ho, D.W.Y. Misdiagnosis of Sexually Transmitted Diseases in Hong Kong Outpatient Private Healthcare. *Open Journal of Medical Microbiology*, 2023 Feb; 13, 31-42.
- Fuchs, W. and Brockmeyer, N.H. (2014) Sexually Transmitted Infections. *JDDG*, 12, 451-464.
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- Van Gerwen, O. T., Camino, A. F., Sharma, J., Kissinger, P. J., & Muzny, C. A. (2021). *Epidemiology, Natural History, Diagnosis, and Treatment of Trichomonas vaginalis in Men.* *Clinical Infectious Diseases*, 73(7), 1119-1124.

