NUSANTICS
Product Sheet




# PathoScan hrHPV qPCR Kit

HPV DNA Detection Kit for Early and Better Screening

Ver 3.1
Updated 12-Mar-2026



# NUSANTICS

is a leading precision molecular diagnostics company in Indonesia that develops PCR-based and Next Generation Sequencing solutions to bridge diagnostic gaps and improve the quality of healthcare services.

## Our Vision

We envision a healthy world enabled by genomics, microbiomics, and precision medicine.

## Our Mission

To close the diagnostics gap and improve healthcare outcome for both humans and animals.

## Product & Solution :

causa

PathoScan

OncoScan

PathoSeq

EKOLAM

ShrimProtect

FishProtect

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# What is cervical cancer screening and why is it necessary?

In general, screening is described as administering a test to a community of people who appear healthy and asymptomatic in order to identify those who are most likely to already have or develop a specific condition. For the purpose of diagnosing women who test positive during screening, additional research is necessary. For cervical cancer screening, women within a specific age range who appear healthy are regularly examined, regardless of whether they show any symptoms. These tests are referred to as screening tests.



Cervical cancer screening is incredibly important to protect you from one of the most severe types of illness. Cervical cancer ranks as the fourth most prevalent cancer in women globally, with approximately 570,000 cases and 311,000 fatalities reported in 2018 alone. About 85% of worldwide deaths from cervical cancer occur in low and middle-income countries. It is reported that more than 36,000 new cases occur each year in Indonesia. More than 99% of cervical cancer is caused by persistent high-risk Human Papillomavirus (hrHPV) infection[1].

REFERENCES

[1] Bray, F., Ferlay, J., Soerjomataram, I., Siegel, R.L., Torre, L.A. and Jemal, A., 2018. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA: a cancer journal for clinicians, 68(6), pp.394-424.

# What is Human Papillomaviruses?

Human papillomaviruses (HPV) are small non-enveloped double-stranded DNA viruses with genomes containing 8 kb of DNA sequences. There are over 200 related HPV viruses, some of which can be transmitted through sexual contact. HPV is categorized into two groups based on its cancer-causing potential: low-risk and high-risk[1].

- **High-risk HPV types** include HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68, can lead to long-lasting infections and contribute to cancer development in various body parts, such as the cervix, oropharynx, anus, penis, vagina, and vulva. Among high-risk HPV types, HPV 16 is the most prevalent, followed by HPV 18.
- **Low-risk HPV types** include HPV 6, 11, 42, 43, and 44 are associated with benign lesions that typically form warts but are rarely involved in malignant tumors.

High-risk HPV genotypes play a crucial role in the progression of normal cells to precancerous lesions and eventually invasive lesions. This process is driven by the overexpression of viral oncoproteins, which inhibit various cellular proteins and disrupt essential biological processes like cell proliferation, cell cycle regulation, and apoptosis.



REFERENCES

[1] Balasubramaniam, S.D., Balakrishnan, V., Oon, C.E. and Kaur, G., 2019. Key molecular events in cervical cancer development. Medicina, 55(7), p.384.

# How does screening for cervical cancer reduce the disease burden?

Cervical cancer has a unique natural history that allows its prevention through screening. The cancer is caused by infection from high-risk types of human papillomavirus (HPV). About 10% of Asian women are estimated to harbour cervical HPV infection at any given time, and 65–85% of invasive cancers of cervix detected in Asian women are attributed to HPV types 16 or 18[1].

The virus infection induces a precancerous change known as cervical intraepithelial neoplasia (CIN). CIN can be detected by various screening tests and can be treated by simple techniques. Detection and treatment of the disease at the CIN stage prevents development of cervical cancer in the future. Countries that introduced national programmes to systematically screen women for cervical cancer and treat precancerous conditions, observed significant reduction in deaths from cervical cancer over a few years.

# What are the different screening tests for cervical cancer?

An ideal screening test for cervical cancer should be accurate, easy to use on a large number of women, feasible to perform in the particular setting, be able to provide results immediately (point of care), acceptable to the women, and inexpensive. There are a number of tests available for cervical cancer screening as shown in **Table 1**[2].

**Table 1.** Three Approaches to Cervical Cancer Screening and Future Tests

| Molecular | Cytologic | Visual Inspection |
|---|---|---|
| **Nucleic acid amplification tests (NAAT)**<br>• High-risk DNA HPV/NAAT<br>• mRNA | **Pap smear** | • Visual inspection with acetic acid or Lugol's iodine (VIA/VILI)<br>• Naked eye<br>• Magnified by colposcope or camera |
| DNA methylation | Liquid-based cytology | Automated visual evaluation of digital images |
| Protein biomarker | Dual staining to identify p16 and Ki-67 | |

REFERENCES

[1] World Health Organization. (2017). Trainees' handbook Cervical cancer screening and management of cervical pre-cancers.
[2] World Health Organization. (2021). WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention. (2nd ed.).

# Priority of Cervical Cancer Screening

Cervical cancer ranks as the second most frequent cancer among women in Indonesia and the second most frequent cancer among women between 15 and 44 years of age[1]. The incidence of cervical cancer in Indonesia is estimated to have 180,000 new cases per year and the death rate is thought to reach 75% in the first year. There are numerous possible combinations or algorithms for screening and treatments. In December 2019, Guideline Development Group (GDG) members were surveyed to prioritize the screening and/or triage tests and the treatments that should be evaluated[2].

**Table 2.** The Seven Algorithms Considered

| | |
|---|---|
| **Screen-and-treat approaches:** | |
| **1.** | VIA as the primary screening test, followed by treatment. |
| **2.** | HPV DNA detection (self- or clinician-collected) as the primary screening test, followed by treatment. |
| **Screen, triage, and treat approaches:** | |
| **3.** | Cytology as the primary screening test, followed by colposcopy triage, followed by treatment |
| **4.** | HPV DNA detection as the primary screening test, followed by HPV16/18 triage when already part of the HPV test), followed by treatment, and using VIA triage for those who screen negative for HPV16/18. |
| **5.** | HPV DNA detection as the primary screening test, followed by VIA triage, followed by treatment. |
| **6.** | HPV DNA detection as the primary screening test, followed by colposcopy triage, followed by treatment. |
| **7.** | HPV DNA detection as the primary screening test, followed by cytology triage, followed by colposcopy and treatment. |

**5 of 7 screening algorithms prioritize HPV DNA detection as the primary screening test.**

REFERENCES

[1] Bray, F., Ferlay, J., Soerjomataram, I., Siegel, R.L., Torre, L.A. and Jemal, A., 2018. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA: a cancer journal for clinicians, 68(6), pp.394-424.



# Embrace the Progressive Shift towards HPV DNA Testing!

Since 2021, WHO recommended the use of Human Papillomavirus (HPV) testing as the primary method for cervical cancer screening, replacing Visual Inspection with Acetic Acid (VIA) or cytology (Pap smear)[1].

This screening is now recommended to be conducted once every 5 years for women aged 30 and older.

Multiple benefits of HPV DNA testing[2]:

- **Early stage cervical abnormalities detection ability:** HPV DNA is more sensitive in discovering cervical dysplasia.
- **Highly objective and precise:** less prone to interpretation error.
- **Extended screening interval:** from 3 years to 5 years.


REFERENCES

[1] World Health Organization, 2021. WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention: web annex A: syntheses of evidence.
[2] Świderska-Kiec, J., Czajkowski, K., Zaręba-Szczudlik, J., Kacperczyk-Bartnik, J., Bartnik, P. and Romejko-Wolniewicz, E., 2020. Comparison of HPV testing and colposcopy in detecting cervical dysplasia in patients with cytological abnormalities. in vivo, 34(3), pp.1307-1315.




# Get to know PathoScan hrHPV qPCR Kit

**Test Principle:**

The PathoScan hrHPV qPCR Kit utilizes the advanced technology of quantitative Polymerase Chain Reaction (qPCR) with specific fluorescent–labeled target-specific probes to accurately identify and genotype high-risk HPV DNA in samples.

**Intended Use:**

| PathoScan hrHPV qPCR Kit | PathoScan hrHPV qPCR Kit Lite |
|---|---|
| Able to detect 14 high-risk HPV types associated with cervical cancer, including HPV16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68. Has the ability to perform genotyping for HPV16, HPV18, and HPV52. | Able to detect 14 high-risk HPV types associated with cervical cancer, including HPV16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68. Has the ability to perform genotyping for HPV16 and HPV18. |

**Storage Condition:**

- 20°C to - 25°C



# Start a Convenient and Reliable HPV DNA testing with PathoScan hrHPV qPCR Kit!

***Open-System***
Compatible with any existing qPCR machine*

**Fast**
Get your results below 45 minutes!**

**High Accuracy**
99.65% accuracy compared to FDA-approved HPV DNA test method***

**Ease of Operation**
"*Thaw, Mix, Run*" — Our ReadyMix technology provides a faster and easier sample preparation.

*Minimum requirement: Able to read FAM, HEX, Texas Red, Cy5 for PathoScan hrHPV qPCR Kit Lite and FAM, HEX, Texas Red, Cy5, and Cy5.5 for PathoScan hrHPV qPCR Kit.
**Estimated operational time for qPCR using QuantStudio 5.
***Using standard cervical swab samples.

Urine Sample

Cervical Swab

# High accuracy of PathoScan hrHPV qPCR kit in Cervical Swabs and Urine samples

| Parameter \ Sample | Cervical Swab PathoScan hrHPV qPCR Kit vs FDA-approved HPV DNA test method + NGS | Urine vs Cervical Swabs PathoScan hrHPV qPCR Kit + NGS |
|---|---|---|
| Sensitivity | 96.55% | 80.88% |
| Specificity | 99.87% | 100.00% |
| PPV | 98.25% | 100.00% |
| NPV | 99.75% | 98.38% |
| Accuracy | 99.65% | 98.48% |

| | |
|---|---|
| Sensitivity | The proportion of people who test positive among all those who actually have the disease. |
| Specificity | The proportion of people who test negative among all those who actually do not have that disease. |
| Positive Predictive Value (PPV) | The probability that following a positive test result, that individual will truly have that specific disease. |
| Negative Predictive Value (NPV) | The probability that following a negative test result, that individual will truly not have that specific disease. |
| Accuracy | Total agreement between the tested and reference methods. |
| NGS | Next Generation Sequencing |

# Easy Steps to Use the PathoScan hrHPV qPCR Kit in just 3 Steps!

**HPV DNA kit testing has never been this simple. Here's how it works:**

**1.** **Thawing**

Take out the reagents from the freezer and ensure they are completely thawed before use.

**2.** **Mixing**

Place the sample into the tube containing the HPV ReadyMix. No need to hassle with mixing multiple reagents! HPV ReadyMix is a single, ready-to-use qPCR reagent.

**3.** **Testing**

Sample testing is performed using qPCR machine in less than 45 minutes!*

*qPCR run time only. Performed in QuantStudio 5

## Fast, Easy, and Accurate!

## PathoScan hrHPV qPCR Kit Target and qPCR Channel for Detection

| Channel | PathoScan hrHPV qPCR Kit | PathoScan hrHPV qPCR Kit Lite |
|---|---|---|
| Cy5.5 | β-globin (IC) | - |
| HEX | HPV16 | |
| Texas Red | HPV18 | |
| Cy5 | HPV52 | β-globin (IC) |
| FAM | HPV31, 33, 35, 39, 45, 51, 56, 58, 59, 66, dan 68 | HPV31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, dan 68 |

## Compatible with qPCR Platforms:

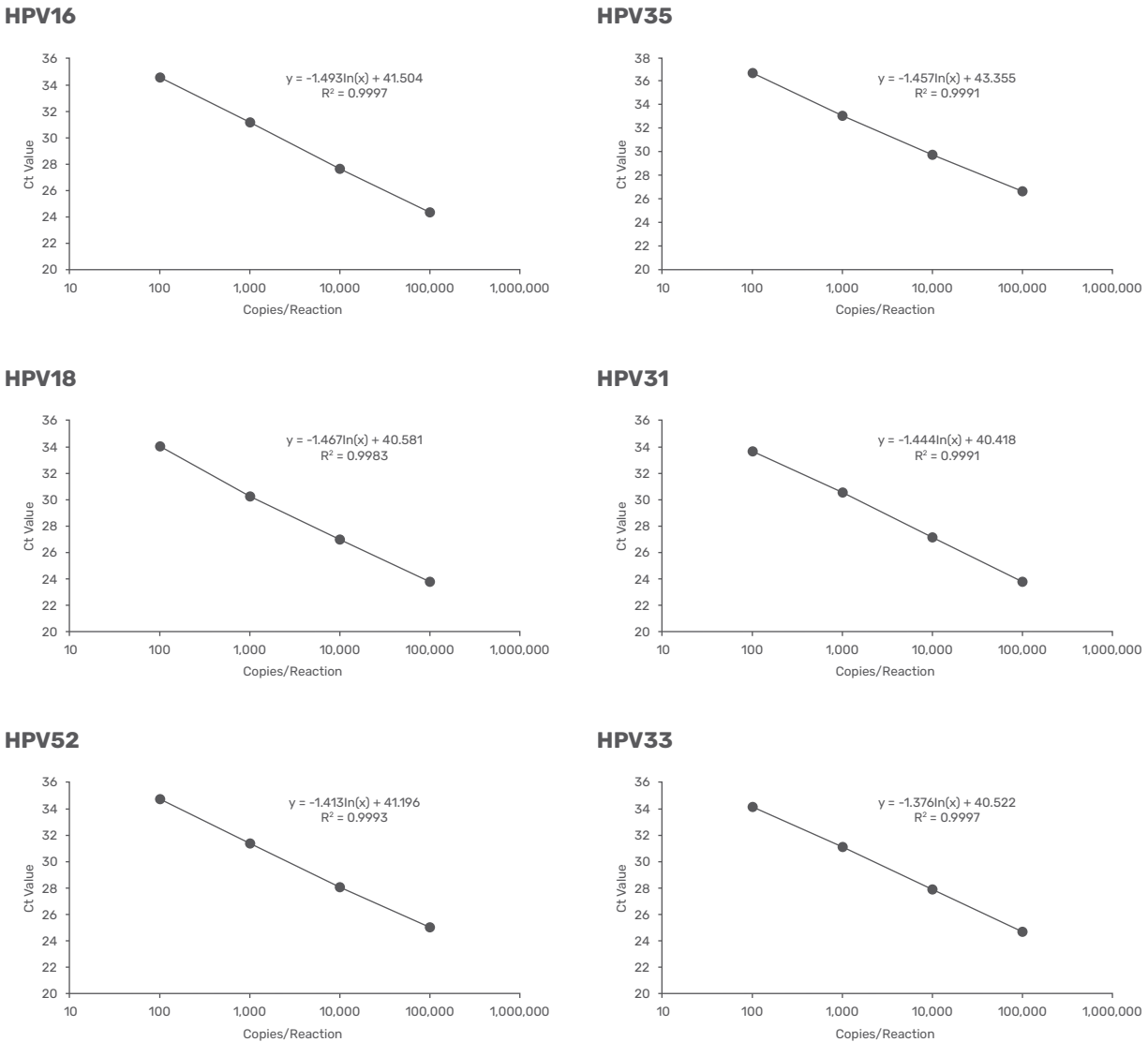
| qPCR Platforms | PathoScan hrHPV qPCR Kit | PathoScan hrHPV qPCR Kit Lite |
|---|---|---|
| BioRad CFX96/CFX96 Touch | ✓ | ✓ |
| Life Technologies Quantstudio 5 | ✓ | ✓ |
| Life Technologies Quantstudio 6 Flex | ✓ | ✓ |
| Life Technologies Quantstudio 7 Flex | ✓ | ✓ |
| Life Technologies Quantstudio 12K Flex | ✓ | ✓ |
| QIAGEN Rotor-Gene Q 5plex | ✓ | ✓ |
| QIAGEN QIAquant 96 5plex | ✓ | ✓ |
| Roche LightCycler (LC) 2.0 | ✓ | ✓ |
| Roche LightCycler (LC) Nano | ✓ | ✓ |
| Tianlong Gentier 96E Real-Time PCR System | ✓ | ✓ |
| Tianlong Gentier 96R Real-Time PCR System | ✗ | ✓ |
| Tianlong Gentier48E Real-Time PCR System | ✗ | ✓ |
| LightCycler® 96 Real-Time PCR System | ✗ | ✓ |

# PathoScan hrHPV qPCR Kit
# Performance Data

## I. Linearity

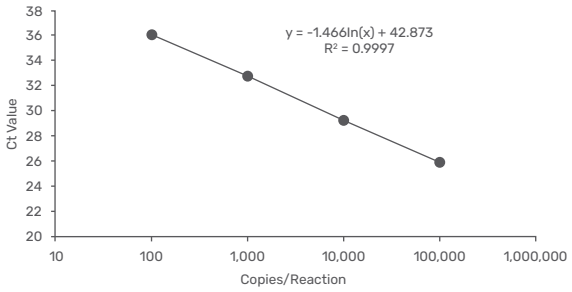
The linearity test was carried out using each HPV synthetic DNA as a template (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68). Each template was serially diluted to obtain a concentration of 100,000 copies/reaction, 10,000 copies/reaction, 1,000 copies/reaction, and 100 copies/reaction. The results of the linearity test showed that all HPV target amplification had efficiencies in the range of 90-110% with an $R^2$ of >0.99.

**Figure 1.** Linearity assay of ReadyMix in detecting 14 hrHPV types using HPV synthetic DNA as template ranging from 100 to 100,000 copies/reaction.

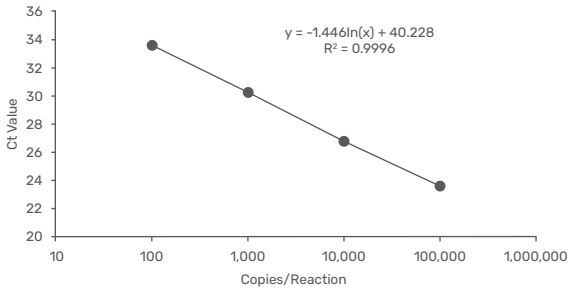


# PathoScan hrHPV qPCR Kit
# Performance Data

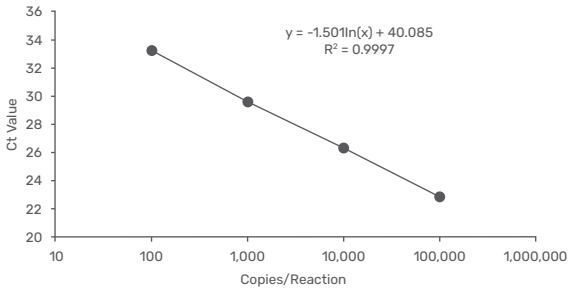
### HPV39



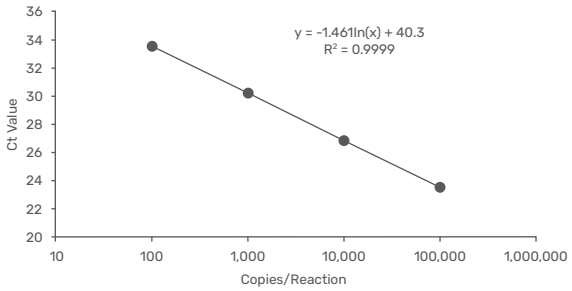

### HPV58



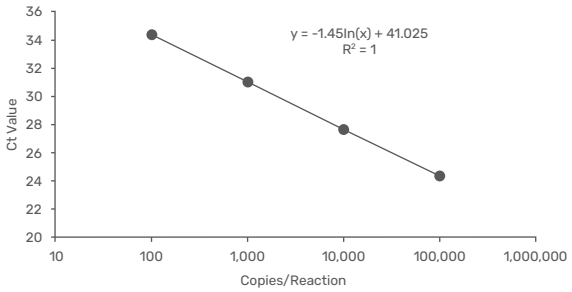

### HPV45



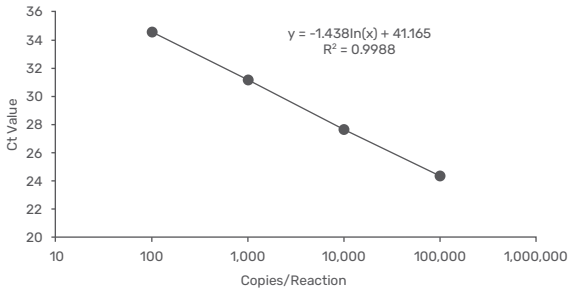

### HPV59



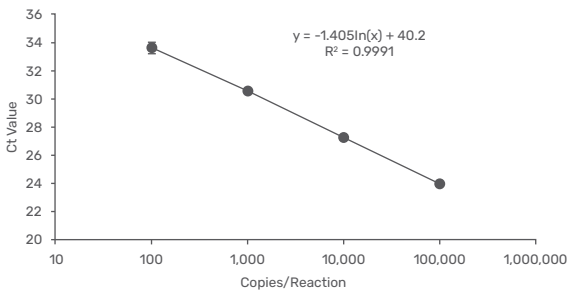

### HPV51



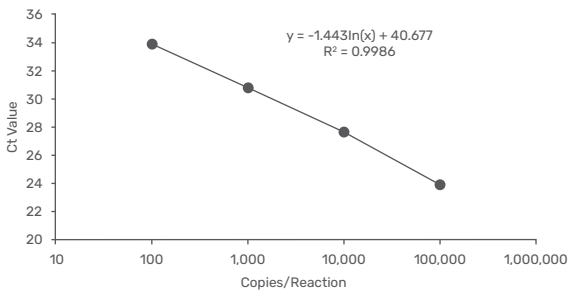

### HPV66




### HPV56




### HPV68



# PathoScan hrHPV qPCR Kit
# Performance Data

## II. Limit of Detection (LoD)

The Limit of Detection (LoD) in the molecular diagnostic kit is defined as the smallest template concentration that can still be detected at ≥95% repeats. LoD testing in this study utilized synthetic DNA as a template, approximately at concentrations of 10 copies/reaction (HPV16), 15 copies/reaction (HPV18, 31, 33, 35, 45, 51, 52, 56, 58, 59, 66, 68), and 25 copies/reaction (HPV39). The copy number approximations derived from actual Ct values obtained from 19-20 replicates are provided below. All HPV assays in this kit have an LoD ranging from 10 to 28 copies/reaction.

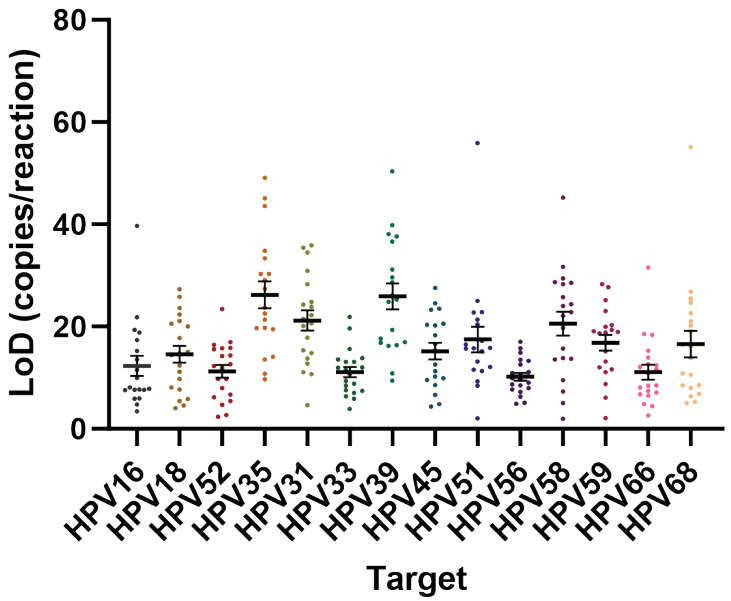



**Figure 2.** Limit of Detection (LoD) of PathoScan hrHPV qPCR Kit for each hrHPV target ranging from 10-28 copies/20 µL qPCR reaction

## PathoScan hrHPV qPCR Kit has a sensitivity of 90.48% for urine HPV detection in confirmed cervical cancer cases compared to cervical swabs

A preliminary study including 30 paired cervical swabs-urine samples from confirmed cervical cancer patients (CA st I-IV) showed a comparable HPV detection pattern in cervical swabs and urine sample, resulting in a 90.48% sensitivity.

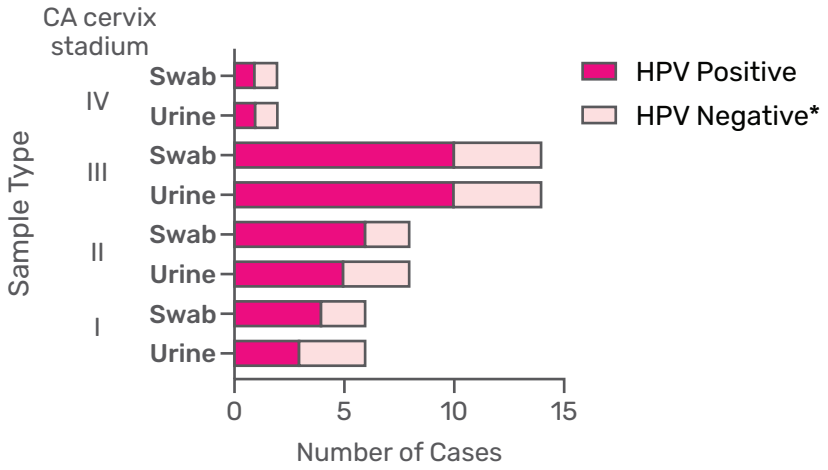
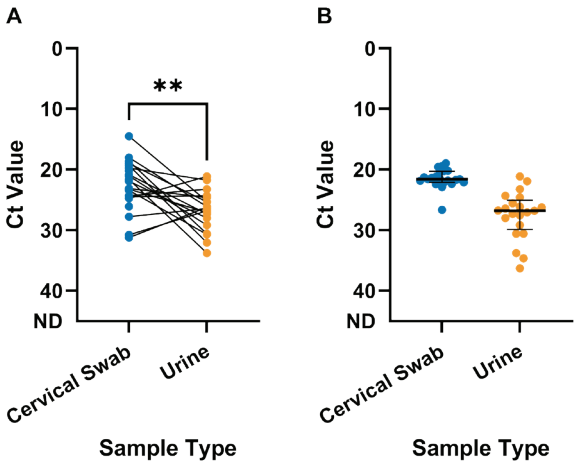



**Figure 3.** HPV detection in various stages of confirmed cervical cancer cases by cervical swabs and urine samples

Cervical swabs technically have a larger concentration of HPV DNA than urine (A), owing to the greater number of cells recovered in a swab, which is also reflected in internal control (ß-globin) detection (B).

However, the sensitivity of HPV detection in urine remains **high**.




*An HPV-negative result in cervical cancer cases is possible due to lower viral load in severely damaged cells compared to unaffected cells and DNA integration into host cells

REFERENCES

Lee, S.H., Vigliotti, J.S., Vigliotti, V.S. and Jones, W., 2014. From human papillomavirus (HPV) detection to cervical cancer prevention in clinical practice. Cancers, 6(4), pp.2072-2099.

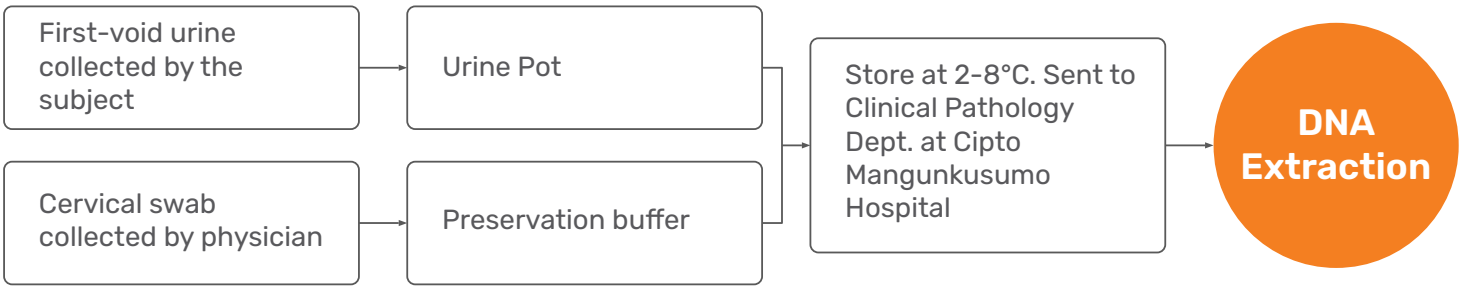
# PathoScan hrHPV qPCR Kit
# Clinical Trial Data

## I. Study Design

The study was conducted in Cipto Mangunkusumo Hospital, involving 876 women aged between 20 - 50 years old reside in Jakarta, Bandung and Semarang. The study excluded pregnant women, women who currently menstruating and individuals who had received HPV vaccination prior to the study.

This study evaluates the performance of the newly developed PathoScan hrHPV qPCR Kit for detecting hrHPV in urine samples and conducting simultaneous genotyping of HPV16, HPV18, and HPV52, the most prevalent hrHPV type in Indonesia.

## II. Sample Collection and DNA Extraction




## III. HPV DNA Detection and Genotyping

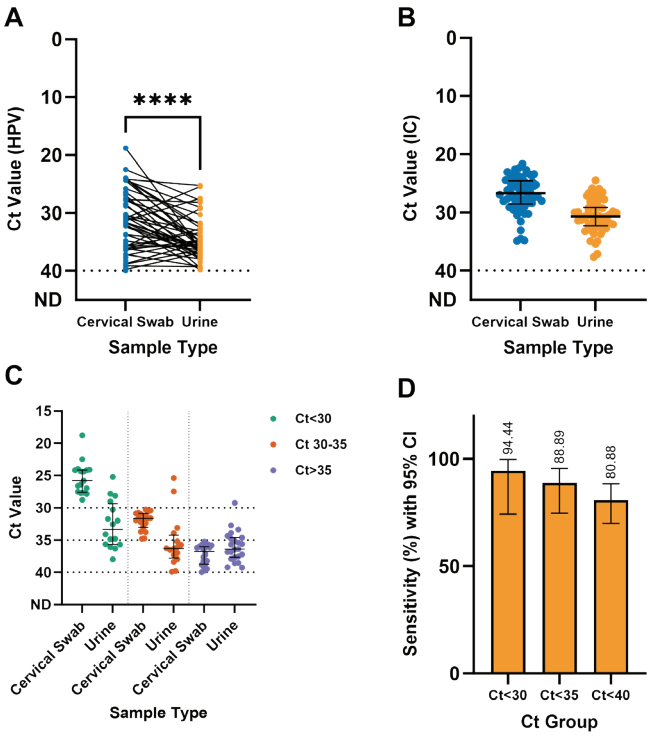
In this study, the PathoScan hrHPV qPCR Kit was ran on the CFX96TM System (Bio-Rad), while FDA-approved HPV DNA test method was operated directly within the system.

Summary of Test Participation and Validity in Study Subjects

| Results | PathoScan hrHPV qPCR Kit | | FDA-approved HPV DNA test method | |
|---|---|---|---|---|
| | Cervical Swab | Urine | Cervical Swab | Urine |
| Total Subjects | 876 | 876 | 876 | 876 |
| Subjects with Complete Test Results | 874 | 857 | 852 | 670 |
| Invalid | 2 | 19 | 24 | 206 |
| Invalid Rate | 0.23% | 2.17% | 2.74% | 23.52% |

# PathoScan hrHPV qPCR Kit
# Clinical Trial Data

## IV. Urine Samples Show a High Sensitivity Across Low, Medium, and High Ct Value Group



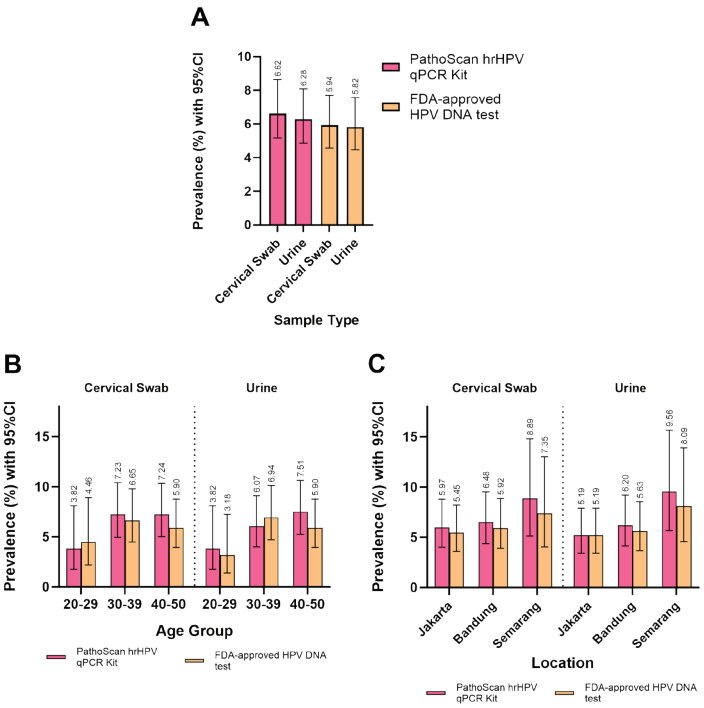

A) A significant difference between HPV Ct value of cervical swabs and urine samples (Wilcoxon matched-pairs signed rank test, p-value: <0.0001);

B) Ct values of IC detection in cervical swabs are tend to be lower than that from urine samples;

C) The gap between HPV Ct values of cervical swabs and urine samples is narrower in high Ct value group (Low: Ct<30; Medium: Ct 30-35; High: Ct>35);

D) The high sensitivity of urine samples across all Ct value groups.

## V. PathoScan hrHPV qPCR Kit and FDA-approved HPV DNA test method Produced a Comparable HPV Prevalence Pattern Across Different Age Groups and Locations



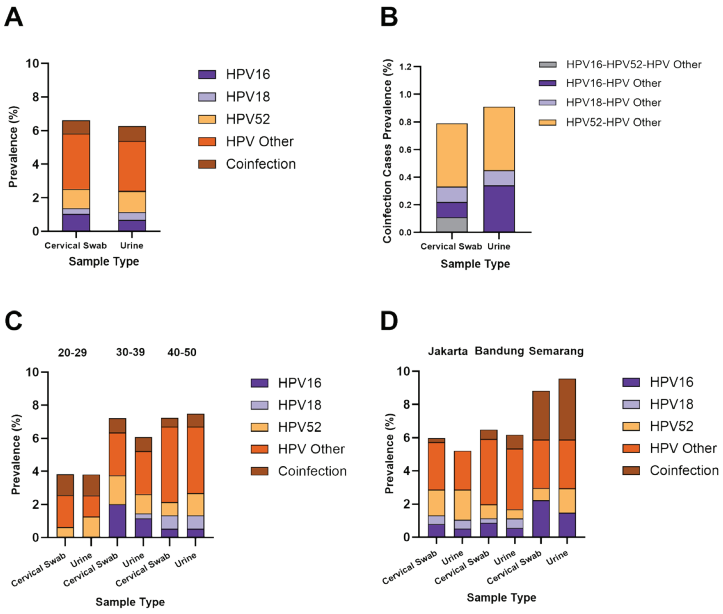

A) PathoScan typically finds more cases of HPV positivity, as supported by Next Generation Sequencing test, indicating increased sensitivity.

B) The distribution of positive cases found by PathoScan among various age groups is comparable to that found by FDA-approved HPV DNA test method.

C) The distribution of positive cases found by PathoScan among different locations is comparable to that found by FDA-approved HPV DNA test method.

# PathoScan hrHPV qPCR Kit
# Clinical Trial Data

## VI. Urine Samples Showed a Similar HPV Proportion Pattern to Cervical Swabs



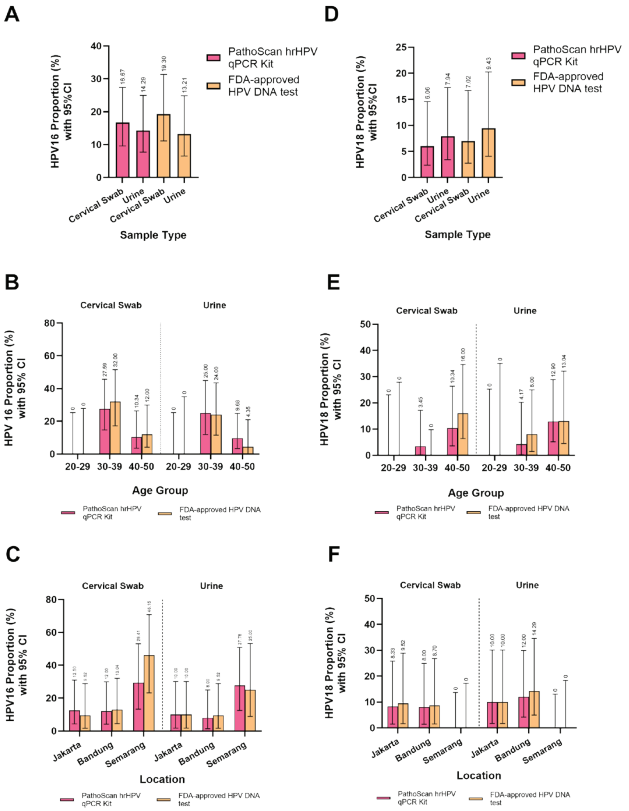

A) The proportions of each HPV type/group are comparable between urine and cervical swabs.

B) Coinfection cases are successfully detected in urine, resulting in a pattern similar to cervical swabs.

C) The distribution of HPV type/group proportions in urine samples across different age groups is comparable to cervical swabs.

D) The distribution of HPV type/group proportions in urine samples across different locations is comparable to cervical swabs.

## VII. HPV16 and HPV18 Genotyping Result by PathoScan hrHPV qPCR Kit is Proportional to FDA-approved HPV DNA test method




A) The pattern of HPV16 and HPV18 proportions among positive cases resulting from PathoScan is similar to FDA-approved HPV DNA test method, in both cervical swabs and urine samples.

B) The pattern of HPV16 and HPV18 proportions among positive cases across different age groups is similar to FDA-approved HPV DNA test method, in both cervical swabs and urine samples.

C) The pattern of HPV16 and HPV18 proportions among positive cases across different locations is similar to FDA-approved HPV DNA test method, in both cervical swabs and urine samples.

# Price and Performance

**Table 3.** Price and Performance Comparison of VIA, Pap Smear and HPV DNA by PathoScan hrHPV qPCR

| Category | Visual Inspection with Acetic Acid | Cytologic Conventional Pap Smear | HPV DNA by PathoScan hrHPV qPCR Kit |
|---|---|---|---|
| Screening Protocol | The cervix is smeared with a 3% acetic acid solution for 30-60 sec and then observed under sufficient light.<br><br>The result is positive when the whitening reaction (Aceto White) is clearly seen. | The cervical sample is collected by scraping or brushing cervix then observed for any abnormal changes.<br><br>Positive Pap smear test refers to Atypical Squamous Cells of Undetermined Significance (ASCUS) lesions and more severe lesions. | 1. Using Cervical Swab as a sample: The sample is collected by gently brushing the cervix multiple times.<br>2. Using Urine as a sample: Up to 20 mL of first-void urine is collected in a sterile pot.<br><br>Samples are processed through DNA extraction and qPCR steps. Positive HPV qPCR signal indicates the presence of HPV in the sample. |
| Performance | Sensitivity: 50-88.6%<br>Specificity : 66.7-89.7%[1] | Sensitivity: 30-87%<br>Specificity: 86-100%[2] | Using Cervical Swab Samples<br>Sensitivity: 96.55%<br>Specificity: 99.87%<br><br>Using Urine Samples<br>Sensitivity: 80.88%<br>Specificity: 100.00% |
| Monitoring Frequency | Every 3 years from age 25 to 60[3] | Every 3 years from age 21 to 65[4] | Every 5 to 10 years starting from the age of 30[5] |
| Patient Comfort | Less comfortable | Less comfortable | Using Cervical Swab:<br>Less comfortable<br><br>Using Urine:<br>Comfortable |
| Testing Price | IDR20,000 - IDR25,000 | IDR400,000 - IDR650,000 | IDR550,000 - IDR1,000,000 |

REFERENCES

[1] Poli, U. R., Bidinger, P. D., and Gowrishankar, S., 2021. Visual Inspection with Acetic Acid (VIA) Screening Program: 7 Years Experience in Early Detection of Cervical Cancer and Pre-Cancers in Rural South India, Indian J Community Med. 40(3): pp.203–207.
[2] Pankaj, S., Kumari, A., Kumari, S., Choudary, V., Kumari, J., Kumari, A., Nazneen, S., 2018. Evaluation of Sensitivity and Specificity of Pap Smear, LBC and HPV in Screening of Cervical Cancer. Indian J Gynecol Oncology 16(49).
[3] P2PTM Kemenkes RI, 2021. Skrining dan deteksi dini Kanker Leher Rahim.
[4] Division of Cancer Prevention and Control, Centers for Disease Control and Prevention, 2023. Cervical Cancer.
[5] World Health Organization, 2023. Cervical Cancer

# Price and Performance

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| Category | Visual Inspection with Acetic Acid | Cytologic Conventional Pap Smear | HPV DNA by PathoScan hrHPV qPCR Kit |
|---|---|---|---|
| Pros | Simple, cheapest compared to Pap smear and HPV DNA, immediate result. | Gold standard test, higher specificity compared to VIA. | Early detection for cervical cancer, simultaneous HPV genotyping, compatible with cervical or urine samples, fast result (1-3 days) |
| Cons | Simple, cheapest compared to Pap smear and HPV DNA, immediate result. | More expensive than VIA, causing discomfort, and requires long time to get the result (1-3 weeks) | More expensive compared to VIA and Pap smear and requires specific instrument. |

# Technology Specifications
# PathoScan hrHPV qPCR Kit

**Table 4.** Summary of PathoScan hrHPV qPCR Kit Technology Specifications

| Storage Conditions |
|---|
| -20°C to -25°C |

| 14 Types of High-Risk HPV Associated with Cervical Cancer Detected by the PathoScan hrHPV qPCR Kit | | | | | | |
|---|---|---|---|---|---|---|
| HPV 16 | HPV 18 | HPV 31 | HPV 33 | HPV 35 | HPV 39 | HPV 45 |
| HPV 51 | HPV 52 | HPV 56 | HPV 58 | HPV 59 | HPV 66 | HPV 68 |

| High Accuracy of the PathoScan hrHPV qPCR Kit in Cervical Swab and Urine Samples | | |
|---|---|---|
| Parameter/ Sample | Cervical Swab PathoScan hrHPV vs Cervical Swab FDA-approved HPV DNA test method + NGS | Urine PathoScan hrHPV vs Cervical Swab PathoScan hrHPV + NGS |
| Sensitivity | 96.55% | 80.88% |
| Specificity | 99.87% | 100.00% |
| PPV | 98.25% | 100.00% |
| NPV | 99.75% | 98.38% |
| Accuracy | 99.65% | 98.48% |

# Technology Specifications
# PathoScan hrHPV qPCR Kit

| Target PathoScan hrHPV aPCR Kit and qPCR Channel Detection | | |
|---|---|---|
| **Channel** | **PathoScan hrHPV qPCR Kit** | **PathoScan hrHPV qPCR Kit Lite** |
| Cy5.5 | β-globin (IC) | - |
| HEX | HPV16 | |
| Texas Red | HPV18 | |
| Cy5 | HPV52 | β-globin (IC) |
| FAM | HPV31, 33, 35, 39, 45, 51, 56, 58, 59, 66, dan 68 | HPV31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, dan 68 |

| LOD | Shelf Life |
|---|---|
| 10-28 copies/reaction | 18 Months |

# PathoScan hrHPV qPCR Kit




| Catalog Number | Test Kit | Unit (Test/Box) | Price |
|---|---|---|---|
| NUS-HP001.100 | PathoScan hrHPV qPCR Kit (5-Channel) | 100 tests/box | Please contact our distributor |
| NUS-HP002.100 | PathoScan hrHPV qPCR Kit Lite (4-Channel) | 100 tests/box | Please contact our distributor |

*Exclude PPN

**Product Requirement:**

- qPCR instrument with the capability of reading signals from FAM, HEX, Texas Red, Cy5, Cy5.5*
- Recommended specimen: Cervical swab and urine.
- Compatible with most of DNA extraction kit for corresponding specimen.

*Only required for PathoScan hrHPV qPCR Kit

**Product limitation: For professional use only.**

1. **Which organs can be infected by HPV?**
   HPV infection affects epithelial cells and can lead to dysplasia of the cervix, anus, oropharynx, penis, vagina, and vulva.

2. **What are the extraction methods that can be used to perform the qPCR test?**
   This qPCR Kit is compatible with various extraction methods, including commercially available spin column extraction.

3. **What qPCR channel is being used in the testing?**
   - qPCR channels used for **PathoScan hrHPV qPCR Kit** includes Cy5.5/Far Red for β-globin (internal control), HEX/Yellow for HPV16, TEX/Orange for HPV18, Cy5/Red for HPV52 and FAM/Green for HPV31, 33, 35, 39, 45, 51, 56, 58, 59, 66, 68.
   - qPCR channels used for **PathoScan hrHPV qPCR Kit Lite** includes Cy5/Red for β-globin (internal control), HEX/Yellow for HPV16, TEX/Orange for HPV18, and FAM/Green for HPV31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.

4. **Why can urine be used as an HPV DNA specimen?**
   Urine that can be used as an HPV DNA test specimen is the first void urine/first stream urine. First void urine is preferred as it contains a higher concentration of HPV DNA compared to random or midstream urine due to its ability to collect most of the cellular debris from the urogenital tract.

5. **What sets PathoScan hrHPV qPCR test apart from other tests like Pap smear? Is the obtained data more accurate?**
   PathoScan hrHPV qPCR relies on HPV DNA detection, whereas the Pap smear is based on the observation of cervical cells. Due to its focus on HPV DNA, PathoScan hrHPV qPCR Kit enhances the likelihood of early detection of cervical cancer.

6. **What is the difference between the PathoScan hrHPV qPCR Kit Lite and the PathoScan hrHPV qPCR Kit?**
   - **The PathoScan hrHPV qPCR Kit Lite** can be tested using 4 qPCR channels: HEX, TEX, FAM, and Cy5. In addition, it can perform genotyping for HPV 16, HPV 18, and others (HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68).
   - **The PathoScan hrHPV qPCR Kit** shall be tested using qPCR channels: HEX, TEX, FAM, Cy5, and Cy5.5. In addition, it can perform genotyping for HPV 52, HPV 16, HPV 18, and others (HPV 31, 33, 35, 39, 45, 51, 56, 58, 59, 66, and 68).

**Our PathoScan hrHPV qPCR Kit provides comfort away from the Pap smear. It is cost-effective in its use of existing technologies.**

**Put together, our innovative technology enables you to test for HPV in a single day pain-free.**



**Distributor Contact:**

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