ZAREPHATH HEALTH
INNOVATIVE GROWTH

IVD

Version No.: 4.0
REF HPVU01

Specimen: Urine
Format: Midstream
Size: 1 Test/kit

Human Papilloma Virus (HPV) Urine Rapid Test

Auxiliary Probe Reagent (In-Situ hybridization)

Intended use:
This reagent performs in-situ hybridization staining on the basis of conventional staining to provide auxiliary HPV diagnostic information for physicians or home healthcare.

Summary:
Human Papillomavirus (HPV) is a spherical DNA virus belonging to the genus Alpha papillomavirus of the family Papillomavirus. It can cause the proliferation of squamous epithelium in human skin and mucous membranes. HPV testing is generally conducted through staining microscopy, TCT examination, or serological tests to determine whether an individual is infected with the virus. The testing process is time-consuming, requiring 3 to 7 days to produce results. Early HPV infection can be detected through cervical cytomorphology examinations or HPV DNA testing. However, these methods involve traumatic sampling, which can easily lead to bleeding and postoperative infections. Additionally, due to the unique anatomical structure of the cervix and cervical os, smear sampling may cause discomfort or injury to patients. Moreover, sampling and testing must be performed in hospitals or other professional institutions, making the process inconvenient and lacking in privacy. This limits its applicability for large-scale self-testing among the general population. Individuals infected with HPV need not panic excessively. According to a World Health Organization report, 80% to 90% of people of appropriate age have experienced transient HPV infections at some point. However, most individuals with robust immune systems can self-resolve the infection after contracting the virus. Nevertheless, some people may experience persistent or recurrent infections due to compromised immunity. Therefore, developing simple and effective methods for HPV detection is highly necessary.

Test principle:
HPV infects cervical tissue and can spread to the adjacent urinary system through sexual contact, self-touching, or secretions. The virus produces sufficient reducing substances in the epithelial tissues of the urinary system throughout various stages from typical infection to carcinogenesis. The concentration gradient of these reducing substances in urine serves as a specific marker for cervical HPV infection, exhibiting high consistency and correlation with the patient's condition.

Materials provided:

Each foil pouch contains:
1.One test
2.Desiccant

Each box contains:
1.One foil pouch
2.Package insert
3. Urine collection container

Materials required but not provided:
Timer or watch.

Storage conditions & validity period:
1.Store at 2℃ to 25℃ in the sealed pouch up to the expiration date (24 months). Do not freeze.
2.Use immediately after opening.
3.Production date and validity period: see labelling.

Sample requirements:
1.Maintain a normal diet within 24 hours before sampling; avoid sexual activity.
2. Avoid consuming or injecting large amounts of vitamin C or vitamin C-rich foods within 10 hours before sampling.
3.Refrain from excessive water intake within 4 hours before sampling. Ideally, urine should be retained in the bladder for at least 4 hours.
4.Collect first-morning urine or fasting urine retained for over 4 hours(First-void urine), and ensure the sample is fresh (used within 2 hours). Random urine samples may have insufficient marker concentrations, affecting test accuracy.
5. Perform urine collection and testing in a hygienic environment to avoid contamination.
6.Normal urine is pale to dark yellow. Avoid testing pathological urine samples (e.g., haematuria, milky urine, haemoglobinuria, bilirubinuria).

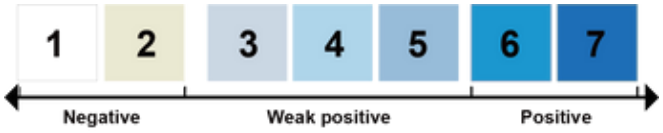
Inspection method:

Type I:
• Bring the test components to room temperature, if refrigerated or frozen.
• Remove the reagent from the package, take off the cap to expose the absorbent tip.
• Hold the handle and immerse the tip in the urine cup for at least 2 minutes, or directly apply urine to the absorbent swab for at least 5 seconds.
• Recap the pen and lay it flat on a clean surface with the window facing upward.
• Wait 10-15 minutes, then compare the test zone colour with the provided colour chart to interpret results.

Interpretation of results:

Negative: A negative result of level 1 or 2 indicates a low risk of infection. It is recommended to undergo testing every six months or annually.
Weak positive: A positive result of level 3, 4 or 5 indicates a risk of infection. Monthly testing is recommended. If continuous testing over 3–6 months shows an increasing gradient in colour intensity, further examination at a hospital is advised.
Positive: A positive result of level 6 or higher indicates a relatively high risk of infection. Further examination at a hospital is recommended.

Notes:
• Individual immune responses may vary; adjust testing frequency based on personal conditions.
• For tracking, mark results on the colour chart with dates.
• Routine HPV screening is recommended every 3 years. High-risk individuals or confirmed HPV carriers should test annually or more frequently.
• Results are invalid after 15 minutes.
• Samples with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis decision is made.



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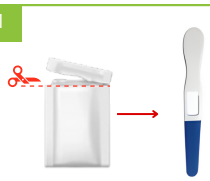
Assay procedure:

1

Take out the HPV test from foil pouch using the notch.

2

Place the HPV test on a clean, well lit flat surface

3


Label the device with specimen ID & remove the device cap

4 METHOD 1: IMMERSION

Collect a urine sample using the urine cup provided

*COLLECT MIDSTREAM URINE

5

Submerge tip in urine for at least 2 minutes, remove, re-cap, and lay the HPV device flat.

6 OR METHOD 2: STREAM


Urinate on the tip for 5-10 seconds, avoid result window.

*USE MIDSTREAM URINE

7

Remove from stream, re-cap, and lay the HPV device flat.

8


Observe results between 10-15 minutes of testing

*DO NOT INTERPRET RESULTS AFTER 15 MINUTES

Result Interpretation

Limitations:
1. **HPV is a DNA virus with over 200 subtypes.**
This reagent may detect high-risk types (e.g., 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66) and some low-risk or cutaneous types (e.g., 6, 11, 30, 39, 42, 43, 44, 54).
2. **Potential False Positives:**
-Excessive reducing substances (e.g., vitamin C ≥70 μg/mL, uric acid).
-Vaginal infections (e.g., Gardnerella, Trichomonas, Candida) producing interfering metabolites.
-Improper operation.
3. **Potential False Negatives:**
-Insufficient sample volume, non-fasting urine, or incomplete reaction.
-Immune clearance of HPV in some individuals.
-Colour blindness or improper interpretation.
-Operational errors.
4. This reagent is suitable for detecting HPV virus markers in urine, and the test results for other samples may leading incorrect results.
5. This reagent is qualitative and not for early cancer diagnosis. It does not replace cytology (Papsmear) or colposcopy.

Performance Index:
1.Appearance: Intact packaging with clear labelling (batch number, expiry date)
No leakage or damage to reagents.
2.Detection Limit:0.25% L-cys.

VANCOEIN BIOTECH®

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BeSure

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Visit our website using the QR code below for more information, test procedure videos & to learn more about Zarephath Health

Index of symbols:

	Information for Use	REF	Catalogue #		Store between
	Manufacturer	LOT	LOT number		Self-testing
	Date of manufacture	IVD	In-Vitro Diagnostics		Do not re-use
	Keep away from direct sunlight		Use by date		Warnings & Precautions