

Self-sampling HPV Test

Best choice for boosting rate of cervical cancer screening



- Accurate
- Comfortable
- Convenient
- Cost effective



Economic, cultural, and policy factors influence cervical cancer screening rates in Southeast Asian countries

Cervical cancer statics (HPV Information Center, 2022)	Taiwan	Singapore	Malaysia	Indonesia	Thailand	Philippines	World
All age							
New cases	1,436	309	1,740	36,633	9,158	7,897	604,127
Incidence per 100,000 women	7.8	6.9	10.2	24.4	16.4	15.2	13.3
Deaths	668	172	991	21,003	4,705	4,052	341,831
Mortality per 100,000 women	3.1	3.9	5.9	14.4	7.5	7.9	7.3
Rank for most common female cancer	10 th	11 th	4 th	2 nd	2 nd	2 nd	4 th
Rank for leading cause of female cancer deaths	8 th	8 th	5 th	2 nd	2 nd	4 th	4 th
Age 15-64							
Population	8,260,168	1,988,886	11,245,746	90,578,114	25,568,678	35,212,766	2,510,256,812
Rank for most common female cancer	4 th	8 th	3 th	2 nd	2 nd	2 nd	2 nd
Rank for leading cause of female cancer deaths	6 th	5 th	3 th	2 nd	3 th	2 nd	2 nd
WHO Statics							
Primary screening method	Pap Smear	HPV	Pap Smear	VIA	Pap Smear	VIA	
Screening rate (1 time in 5 years)(WHO)	63%	67%	47%	9%	67%	1%	-
Screening age	30-65	Over 25	30-65	30-50	30-60	25-55	
GDP per capita (USD) (CEIC Data, 2022)	32,756	82,794	12,472	4,783	7,498	3,623	12,648

High-risk HPV can cause cervical precancerous lesions, cervical cancer, and external genital cancer in both men and women

- Over 99% of cervical cancer cases result from persistent HPV infection.
- Certain high-risk HPV types, such as 16 and 18, are responsible for up to 70% of cases globally, increasing the risk of cervical precancerous lesions by up to 35 times.
- The human immune system often eliminates HPV without symptoms. Early identification is crucial for successful treatment of advanced cervical cancer.
- **Early diagnosis of cervical cancer leads to a high cure rate**, with over 90% of patients surviving for 5 years. However, **if detected late and in advanced stages, only 20% will live beyond 5 years.** Regular screening aids in prevention.

HPV self-sampling helped the increase of screening rate for both high and low income countries (3/4)

- Self-sampling for Human Papillomavirus Testing: Increased cervical cancer screening participation and incorporation in **international** screening programs
 - ❑ Barriers to cervical cancer screening
 - Feelings of embarrassment and shame
 - The socioeconomic and sociocultural, reluctance to having a physician see and touch their genital area, barriers prevent many women from complying with recommendations for cervical cancer screening
 - Lack of understanding about the importance of HPV or cervical cancer screening or underestimation of the risk of disease
 - Women living in small rural communities indicated that the time it would take them to drive to clinic for a Pap smear provided a significant barrier to accessing care, because of the disruption to their daily lives and the resulting difficulties with transportation or childcare services
 - ❑ Self-sampling increase cervical cancer screening participation

<https://www.frontiersin.org/articles/10.3389/fpubh.2018.00077/full>

Comfortable, safe, user friendly

High satisfaction for HygeiaTouch self sampling kit by end users survey



SECURE INSERT DEPTH CONTROL

THE PETAL STOPPER HELPS TO CONTROL THE DEPTH OF INSERTION TO MAXIMIZE THE EFFECTIVENESS OF SAMPLING



SMOOTH TOUCH

THE MATERIAL IS MADE FOR SMOOTH AND EASY INSERTION



SAFE & SECURED FOAM

SEALED AND FIXED DESIGN TO ENSURE THE FOAM IS SAFE & SECURED

Dry storage and transportation of specimen

- No leakage problem
- Same quality at varying room temperatures, up to 100 degree c
- One month storage at room temperature



Questionnaire	Not at all		Low		High		Extremely	
	N	%	N	%	N	%	N	%
1. Satisfaction level of the design of the self-sampling kit	5	(0.4)	32	(2.6)	896	(74.0)	277	(22.9)
2. User-friendly level of using the self-sampling kit	2	(0.2)	37	(3.1)	594	(49.2)	575	(47.6)
3. If the self-sampling tests are used for primary HPV screening, your willingness for testing HPV regularly will increase	14	(1.2)	99	(8.2)	579	(47.9)	518	(42.8)
4. Willingness level of using the self-sampling kit again	2	(0.2)	45	(3.7)	735	(60.8)	427	(35.3)
5. Willingness level of introducing the self-sampling kit to your relatives/friends	2	(0.2)	118	(9.8)	768	(63.5)	321	(26.6)
6. Easy-to-use level of using the self-sampling kit to collect specimens	3	(0.2)	60	(5.0)	649	(53.8)	494	(41.0)
7. Safety feeling during the self-sampling procedure	0	(0)	8	(0.7)	742	(61.4)	459	(38.0)
8. Comfort level after using the self-sampling kit	0	(0)	91	(7.5)	845	(69.9)	273	(22.6)
9. User-friendly level of the instructional manual for the self-sampling kit	2	(0.2)	36	(3.0)	703	(58.1)	469	(38.8)

Easy to Use

Preparation

After washing your hands, get undressed in a suitable, private area. Take out the foil package and collection tube from the box. Twist open the cap and place the tube with the cap facing upward.

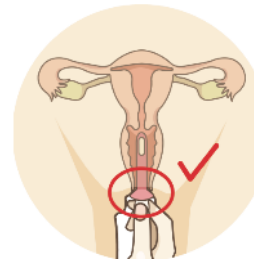
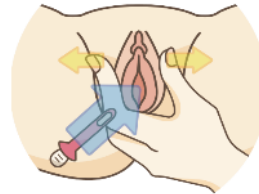


Tear open the foil package and use your thumb and index finger to grip the white handle of the sampling swab, avoiding contact with the foam at the tip of the swab.



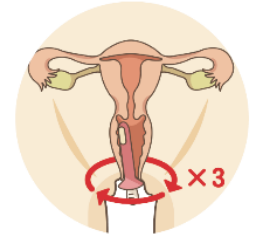
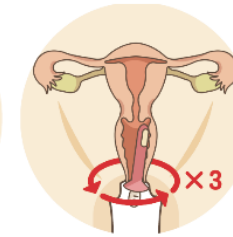
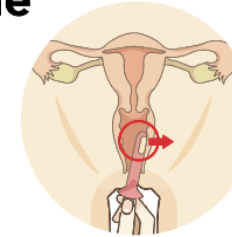
Insertion

Using the other hand to separate the labia and slowly insert the foam end of the sampling swab into the vagina until the petal stopper is in contact with the labia, then stop.



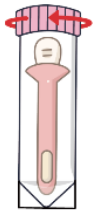
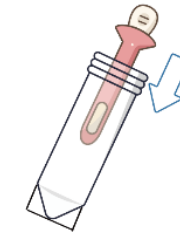
Collect Sample

Still holding the sampling swab with your thumb and index finger, press the foam against the vaginal wall. Rotate the swab by turning your wrist in a clockwise and counter-clockwise direction 3 times.

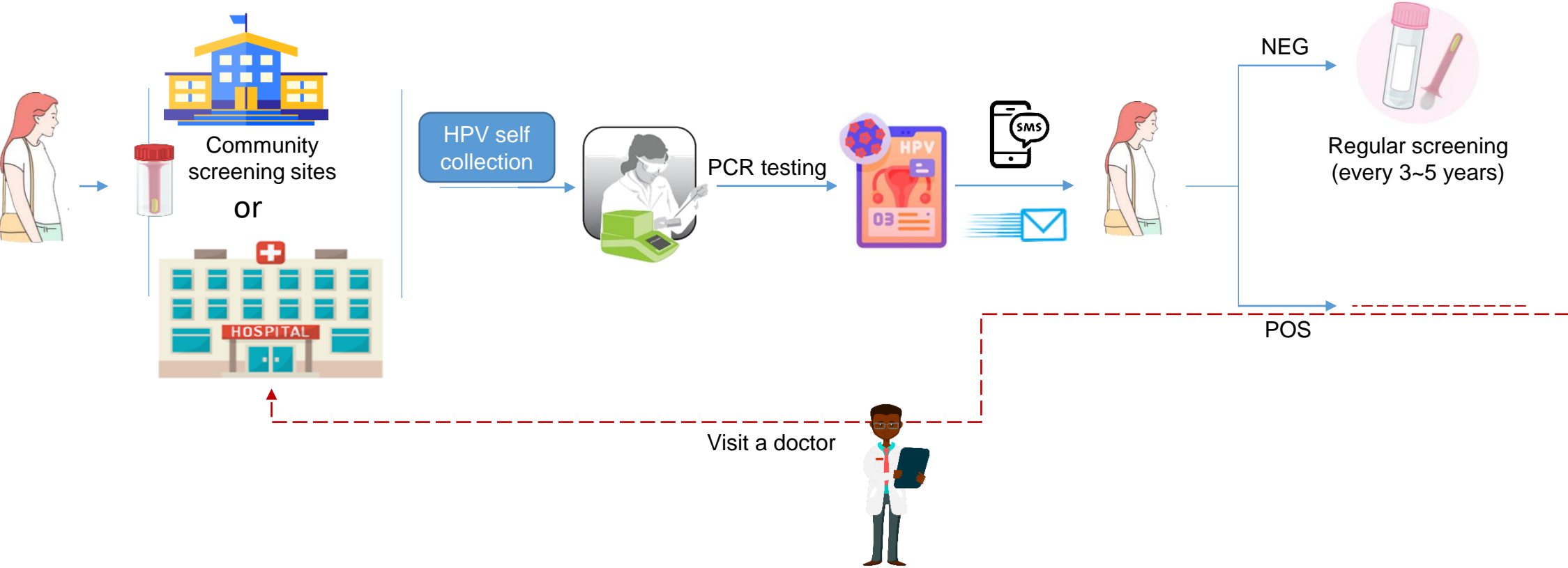


Sample Delivery

Remove the sampling swab from the vagina and immediately place it into the collection tube. Secure the cap tightly. Hand the collection tube to a healthcare personnel or send it for testing.



PROCEDURES FOR NOTIFICATION



Global strategy to accelerate the elimination of cervical cancer



**UN Joint Global Programme on Cervical
Cancer Prevention and Control**



World Health
Organization

THE ARCHITECTURE TO ELIMINATE CERVICAL CANCER:

VISION: A world without cervical cancer

THRESHOLD: All countries to reach < 4 cases 100,000 women-years

2030 CONTROL TARGETS



90%

of girls fully
vaccinated with HPV
vaccine by 15 years
of age

70%

of women screened with
an high precision test at
35 and 45 years of age

90%

of women identified
with cervical disease
receive treatment and
care

Sustainable Development Goal 2030 Target 3.4: **30% reduction in mortality from cervical cancer**

Global Clinical Trial Information

1. Our clinical trial is registered on the global clinical trials website “*ClinicalTrials.gov*” with the number NCT04472377 (<https://clinicaltrials.gov/study/NCT04472377>).
2. Two published journal papers in *Journal of Medical Virology* (Impact Factor: 12.7) and *Bioengineering & Translational Medicine* (Impact Factor: 7.4)

Received: 27 November 2023 | Accepted: 12 January 2024

DOI: 10.1002/jmv.29426

RESEARCH ARTICLE

JOURNAL OF
MEDICAL VIROLOGY WILEY

Consistency in human papillomavirus type detection between self-collected vaginal specimens and physician-sampled cervical specimens

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Received: 7 November 2023 | Revised: 9 January 2024 | Accepted: 29 January 2024

DOI: 10.1002/btm2.10653

RESEARCH ARTICLE

BIOENGINEERING &
TRANSLATIONAL MEDICINE

Evaluation of a novel vaginal cells self-sampling device for human papillomavirus testing in cervical cancer screening: A clinical trial assessing reliability and acceptability

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