Human Papilloma Virus (HPV) Antigen Rapid Test Kit

[Product Name]
Human Papilloma Virus (HPV) Antigen Rapid Test Kit

[Package Reference and Specification]

Catalog No.	Size
IS-MY-004-1	1 test/kit
IS-MY-004-5	5 tests/kit
IS-MY-004-20	20 tests/kit
IS-MY-004-50	50 tests/kit

[Intended Use]
HPV Antigen Lateral Test Kit is an in vitro, visually read test for the qualitative determination of HPV oncoproteins in female cervical swab specimens.

[Summary and Explanation of the Test]
Cervical cancer is one of the most common female cancers in the world. HPV is the etiological agent responsible for more than 99% of all cervical cancers. According to the World Health Organization (WHO), cervical cancer is the fourth largest contributor to female cancer mortality worldwide, claiming an estimated 311,000 lives annually. Human Papilloma Viruses are composed of an icosahedral viral particle (virion) containing an 8000 base pair double-stranded circular; a persistent infection of one of the fourteen sexually transmitted HPV genotypes considered high risk (genotypes 16, 18, 31,33, 35, 39,45, 51, 52, 56, 58, 59, 66, and 68) can lead to the development of cervical cancer and its precursor lesions. In particular, the risk of progression for HPV types 16 and 18 was greater (approximately 40%) than for other HPV types. Human Papilloma Virus (HPV) self-sampling test kits may increase screening for and early detection of cervical cancer and reduce its burden globally [1]. Human Papilloma Virus (HPV) Antigen Rapid Test Kit is an immunochromatographic assay, which utilizes unique antibodies to selectively identify HPV antigens in female cervical swab.

[Principle]
Human Papilloma Virus (HPV) Antigen Rapid Test Kit detects HPV 16/18 proteins through visual interpretation of color development. Anti-HPV antibodies are immobilized on the test region of the nitrocellulose membrane. Anti-HPV antibodies conjugated to colored particles are immobilized on the conjugated pad. A sample is added to the extraction buffer in the base, which is optimized to release the HPV antigens from the specimen. During testing, HPV antigens, if present in the samples, will be released into the extraction buffer individually packed in the kit. The extracted antigens will bind to anti-HPV antibodies conjugated to colored particles. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by the anti-HPV antibodies at the test region. Excess colored particles are captured at the internal control zone. The presence of a colored band in the test region indicates a positive result for the HPV antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that the proper volume of specimen has been added and membrane wicking is working.

[Materials Provided]

Components	Spec. & Qty				Content
	1 test/kit	5 tests/kit	20 tests/kit	50 tests/kit	
Test cassette	1 cassette*1	1 cassette*5	1 cassette*20	1 cassette*50	Anti-HPV antibodies conjugated to colored particles are immobilized on the conjugated pad in advance. The test line (Anti-HPV antibodies), and the control line (antibodies against mouse IgG) are pre-coated on the surface of Nitrocellulose (NC) membrane.
Extraction buffer	1 tube	5 tubes	20 tubes	50 tubes	Buffer solution containing phosphate buffer solution.
Instruction for use	1	1	1	1	

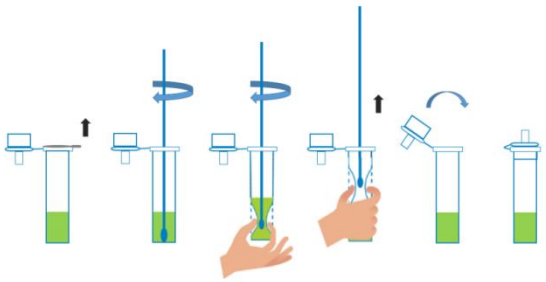
Note:
The components of different batches cannot be used interchangeably.

[Material Required but not Provided]
Timer
The disposable swab
Note:
①Products with CE marking are recommended for the above materials.
②The Disposable Swabs with CE marking are produced by another manufacturer.

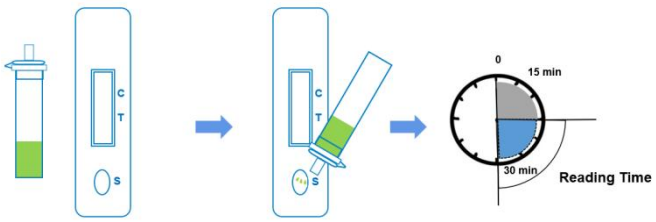
[Storage Conditions and Shelf Life]
1. The test cassettes and the extraction buffer must be stored at 2℃-30℃ until expiration date. The shelf-life is 18 months.
2. After opening the test cassette, use it within 1 hour.
3. Do not use frozen or expired devices.
4. Production date and expiry date please refer to packing label.

[Specimen Requirement]
1. Types of samples: Female cervical swab.
2. The collected sample should be used for test as soon as possible.
3. The extraction buffer provided in this kit should be used for processing as soon as possible after the swab sample is collected. If the swab sample cannot be processed in time, it can be stored for 8 hours at 2℃-8℃; If detection is delayed more than 8 hours, specimens should be stored at -20℃ or lower.
4. Female cervical swab: Before specimen collection, remove excess mucus from the endocervical area with a separate swab or cotton ball and discard. Insert the swab into the cervix until only the bottommost fibers are exposed. Firmly rotate the swab for 15-20 seconds in one direction. Pull the swab out carefully.

[Test Procedure]
PLEASE USE IN STRICT ACCORDANCE WITH THE INSTRUCTIONS FOR USE.
EQUILIBRATE ALL SPECIMENS AND THE DEVICES TO ROOM TEMPERATURE 15-30℃ (59-86 ℉) BEFORE TESTING (AT LEAST 30 MINUTES).
1. Remove the test cassette from the sealed pouch just prior to testing and lay it flat on workbench.
2. Insert the swab into the extraction tube after collecting the sample. Rotate the swab about 10 times in the solution and squeeze it repeatedly with your fingers to dissolve the sample in the solution as much as possible.
3. While firmly squeezing the sides of the tube to extract the specimen from the head of the swab, remove the swab from the extraction reagent. Ensure the swab is above liquid level before squeezing and twist as you remove the swab.



4. Press the dropper cap firmly onto the extraction buffer tube containing the sample. Mix thoroughly by swirling or flicking the bottom of the tube.
5. Add 3 drops (or 80μL) of sample to sample well by squeezing the extraction buffer tube.
6. Wait for exactly 15 minutes after adding the sample to check the result. Do not read the test after 30 minutes, as the result may no longer be accurate.



[Quality Control]
The test device has a control line and test lines on its surface of the test device. Neither the test line nor the control line is visible in the result window before applying a specimen. The control line is used for procedural

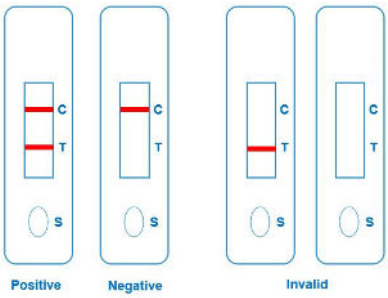
control and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

[Interpretation of Results]

Positive: Visible red bands appear both at the control line (C line) and the test line (T line) of the cassette. Any T line, even if very faint, is positive. This indicates a positive result for the HPV antigens in the specimen.

Negative: A visible red band appears only at the C line of the cassette. This indicates that the concentration of the HPV antigens are zero or below the detection limit of the test.

Invalid: A test is invalid if the C line is not present at all, whether the test line is present or not. Repeat the test with a new test cassette.



Suggestions:

1. In case of a positive test result:

- There may currently be a suspicion of HPV infection

2. In case of a negative test result:

- There is no HPV antigen detected in the sample, but the negative result cannot completely rule out the possibility of infection.

3. In case of an invalid test result:

- Possibly caused by faulty test execution.
- Repeat the test with a new test device.
- If test results remain invalid, contact your local distributor.

[Disposal of the Product]

1. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
2. The used cassette should be discarded according to federal, state, and local regulations.

[Warranty Limitations]

1. HPV Antigen Lateral Test Kit is an in vitro, visually read test for the qualitative determination of HPV oncoproteins in female cervical swab specimens. The assay can be used for clinical reference and should not be the only basis for the diagnosis and treatment. The clinical management of patients should be considered in combination with patients' symptoms and medical history, other laboratory tests, treatment response, epidemiology and other information.
2. Due to the operation and the sample collection, the result may be suspected, at this time repeated testing should be done to ensure consistent results.
3. A false negative test result may be caused by low concentration of HPV antigens in the sample so the possibility of infection of HPV 16/18 cannot be excluded. Therefore, the results obtained with the Human Papilloma Virus (HPV) Antigen Rapid Test Kit should be used in conjunction with clinical findings to make an accurate diagnosis.
4. Inadequate specimen collection or improper sample handling/transport may yield a false negative/positive result.
5. The negative results of patients with symptoms should be treated with caution and confirmed by a professional laboratory. Used for clinical management when necessary.

[Performance Characteristics]

1. Limit of Detection (LoD): 1.0×10^5 Copies/mL.
2. Precision: Repeatability and reproducibility experiments were carried out by different people, in different places and at different times with 3 batches kits, and the results met the performance requirements of the product.
3. Analytical specificity

Interference: There is no interference found when tested in the table below.

Potential cross interference	Interference
Vitamin A	No
Mucin	No
Blood sample	No
Triglyceride	No
Cholestero	No
Rheumatoid factor	No
HAMA antibody	No

Cross-reactivity Evaluation: There is no cross-reactivity found when tested in the table below.

Cross-reactant/interferant analyte	Cross-reactivity	Cross-reactant/interferant analyte	Cross-reactivity
Acinetobacter calcoaceticus	No	Proteus vulgaris	No
Salmonella typhi	No	Acinetobacter spp.	No
Staphylococcus aureus	No	Candida albicans	No
Neisseria catarrhalis	No	Neisseria gonorrhoea	No
Neisseria meningitidis	No	Neiiseria lactamica	No
Escherichia coli	No	Gardnerella vaginalis	No
Streptococcus faecalis	No	Streptococcus faecium	No
Pseudomonas aeruginosa	No	Trichomonas vaginalis	No
Ureaplasma Urealyticum	No	Mycoplasma hominis	No

4. Clinical performance

A total 320 of female cervical swab specimens were collected from clinical organization and tested with the Human Papilloma Virus (HPV) Antigen Rapid Test Kit. Comparison for all subjects is shown in the following table.

Contrast reagents			
Assessment reagents	Positive	Negative	Total
Positive	104	17	121
Negative	15	184	199
Total	119	201	320

Positive Percent Agreement (PPA) = 87.39%
Negative Percent Agreement (NPA)= 91.54%
Total percent agreement = 90.00%

[Warnings and Precautions]

1. This kit is only used for in vitro diagnosis by professionals and any form of in vivo use is prohibited.
2. This kit contains small parts. Please keep it out of the reach of children.
3. Incorrect reporting and false results may occur if the instructions for use are not followed strictly.
4. Patient samples and test cassettes should be handled as though they could transmit disease. Observe established precautions against microbial hazards.
5. Each test is single-use only.
6. The desiccant in the aluminum foil bag is not to be taken orally.
7. Do not use the kit if the aluminum foil bag is damaged.
8. Do not mix test cassettes and sample extraction buffer from different batches.
9. The extraction buffer Warning: It may cause an allergic skin reaction, causes serious eye irritation, please rinse with plenty of water if the solution contacts skin or eyes.
10. Follow your national, regional, and local ordinances accordingly for waste disposal regulations.
11. This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

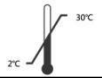
Warning
H317 May cause an allergic skin reaction
Prevention
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
Response
P321 Specific treatment (see first aid measures on this label).
P302+P352 IF ON SKIN: Wash with plenty of water/soap.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

[References]

[1] Sexually Transmitted Diseases, 4th Edition. King K. Holmes. McGraw-Hill Professional, 2007.

[Date of Issue] Version 02, 17th May, 2024

[Explanation of the Symbols Used]

	Caution
	Temperature limit at 2°C-30°C
	Batch code
	Date of manufacture
	In vitro diagnostic medical device
	Consult instructions for use
	Do not use if package is damaged
	Use-by date
	Contains sufficient for <n> tests.
	Do not re-use
	Manufacturer
	Authorised representative in the European Community
	CE marking
	Keep dry
	Keep away from sunlight
	Catalogue number
	Warning

[Basic Information]

EC REP

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