# HPV Antigen Rapid Test (Cervical Swab) For professional use

ELISURE

IVD REF SIC-RDT-HPV-202081

*A rapid test for the qualitative detection of Human Papillomavirus antigen in human cervical swab specimen.*
*For professional in vitro diagnostic use only.*

## INTENDED USE

The HPV Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Human Papillomavirus antigen in human cervical swab specimen as an aid for the screening of cervical cancer and infection of HPV-16/18.

## SUMMARY

HPVs are distinguished and typed by DNA sequence homology. At least 100 types have been identified. High-risk HPV types can initiate the development of cervical carcinoma and oropharyngeal, esophageal, penile, and anal cancers. Viral DNA is found in benign and malignant tumors, especially mucosal papillomas. Almost all cervical carcinomas contain integrated HPV DNA, with 70% from HPV-16 or HPV-18. The E5, E6, and E7 proteins of HPV-16 and HPV-18 have been identified as oncogenes.[1]

Human papillomavirus (HPV) is the most common viral infection of the reproductive tract and can cause cervical cancer in women, other types of cancer, and genital warts in both men and women. Including 5 new introductions, 116 Member States have introduced HPV vaccine by the end of 2021. Since many large countries have not yet introduced the vaccine and vaccine coverage decreased in 2021 in many countries, global coverage with the first dose of HPV among girls is now estimated at 15%. This is a proportionally large reduction from 20% in 2019.[2]

## PRINCIPLES

The HPV Antigen Rapid Test (Cervical Swab) is a qualitative, lateral flow immunoassay for the detection of *Human Papillomavirus* antigen in human cervical swab specimen. In this test, anti-HPV antibody are coated in the test line region of the test. During testing, the HPV antigen specimen reacts with anti-HPV antibody recombinant protein coated particles in the test strip, then the antibody-antigen complex will be captured with anti-HPV antibody in the membrane when migration. The presence of a colored line in the test line region indicates a positive result for HPV infection, while its absence indicates a negative result for that infection.

To serve as a procedural control, a colored line will always appear in the control line region of the strip indicating that proper volume of specimen has been added and membrane wicking has occurred.

## MATERIALS

### Materials Provided

- Test Cassettes
- Package Insert
- Sterile Cervical Swabs
- Workstation
- Specimen Collection Tubes with Extraction Buffer

### Materials Required But Not Provided

- Timer

## WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Do not exchange or mix buffer and test cassettes from kits of different lots.
8. Be sure to add sufficient extracted specimen to the cassette's specimen well. Invalid result may occur if inadequate extracted specimen is added.

## STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

## SPECIMEN COLLECTION AND PREPARATION

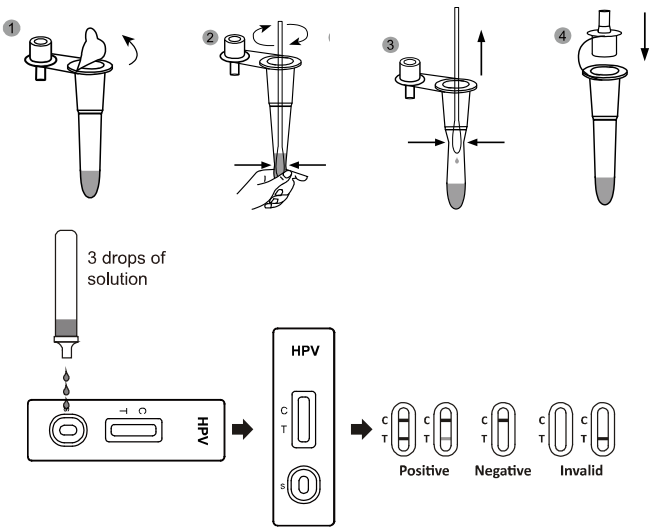
It is recommended to use the swab supplied by the kits manufacture.

- Insert the swab into the inside of the vagina, samples are taken at the cervicosquamous junction or transition zone, and rotate for 10 seconds. Pull the swab out carefully.
- Do not place the swab in any transport device containing medium since transport medium interferes with the assay and viability of the organisms is not required for the assay. Put the swab to the extraction tube, if the test is to be performed immediately. If immediate testing is not possible, the patient specimen should be placed in a dry transport tube for storage or transport. The swabs may be stored for 24 hours at room temperature (15-30 ºC) or 1 week at 2-8 ºC or no more than 6 months at -20 ºC. All specimens should be allowed to reach a room temperature of 15-30 ºC before testing.
- Do not use 0.9% sodium chloride to treat swab before collecting specimen.

## DIRECTIONS FOR USE

**Allow the test, specimen swab, buffer and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Remove the cover on the specimen collection tube.
3. Immediately add the swab into the extraction tube, agitate the swab vigorously **15 times**, Leave the swab soak in the extraction tube for 1 minute.
4. Remove the swab while squeezing the swab head against the inside of the specimen collection tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.
5. Fit the tube tip onto the extraction tube. Hold the specimen collection tube upright then unscrew the small cap of the specimen collection tube.
6. Add **3 drops of the solution** (approx.100 µL) to the sample well and then start the timer. **Read the result at 15 minutes.** Do not interpret the result after 20 minutes.




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**POSITIVE:* Two colored lines appear.** One colored line should be in the control line region (C) and another colored line should be in the test line region (T). A positive result indicates that HPV antigen was detected in the specimen.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HPV antigens present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T). A negative result indicates that HPV antigen is not present in the specimen, or is present below the detectable limit of the test.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS

1. The HPV Antigen Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of HPV *antigen* in cervical swab specimen only. Neither the quantitative value nor the rate of increase in HPV antigen concentration can be determined by this qualitative test.
2. A negative result should be confirmed by standard method. A negative result may be obtained if the concentration of the HPV antigen present is not adequate or is below the detectable limit of the test.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

## PERFORMANCE CHARACTERISTICS

### Sensitivity and Specificity

The HPV Antigen Rapid Test (Cervical Swab) was compared with PCR when test with clinical cervical swab. The results were tabulated as below.

| Method | | PCR | | Total Results |
|---|---|---|---|---|
| HPV Antigen Rapid Test | Results | Positive | Negative | |
| | Positive | 86 | 1 | 87 |
| | Negative | 4 | 134 | 138 |
| Total Results | | 90 | 135 | 225 |

Relative Sensitivity: 95.6% (95%CI*: 89.0%~98.8%)
Relative Specificity: 99.3% (95%CI*: 95.9%~100%)
Accuracy: 97.8% (95%CI*: 94.9%~99.3%) *Confidence Intervals

### Limitation of Detection

The minimum detection level is 50ng/ml for HPV-16 positive specimen and 100ng/ml for HPV-18 positive specimen.

### Precision

#### Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens: negative, low positive and middle positive. The negative and positive values were correctly identified >99% of the time.

#### Inter-Assay

Between-run precision has been determined by 10 independent assays of three specimens: negative, low positive and middle positive. Three different lots of the HPV Antigen Rapid Test (Cervical Swab) have been tested over a 3-days period using a negative, low positive and middle positive specimen. The specimens were correctly identified >99% of the time.

### Cross-reactivity

Cross reactivity with other organisms has been studied using suspensions of $10^7$ Colony Forming Units (CFU)/test. The following organisms were found negative when tested with the HPV Antigen Rapid Test (Cervical Swab).

*Acinetobactercalcoaceticus*
*Salmonella typhi*
*Staphylococcus aureus*
*Neisseria catarrhalis*
*Neisseria meningitides*
*Gardenerellavaginalis*
*Streptococcus faecium*
*Chlamydia trachomatis*
*Mycoplasma hominis*
*Proteus vulgaris*
*Trichomanasvaginalis*
*Acinetobacter spp.*
*Neisseria gonorrhea*
*Escherichla coli*
*Streptococcus faecalis*
*Pseudomonas aeruginosa*
*Ureaplasmaurealyticum*

## BIBLIOGRAPHY

1. Patrick R. Murray, Ken S. Rosenthal, Michael A. Pfaller, Medical-Microbiology-9th (USA: Elsevier Inc, 2021).
2. WHO, https://www.who.int/news-room/fact-sheets/detail/immunization-coverage.

**INDEX OF SYMBOLS**

| | | | |
|---|---|---|---|
|  | Consult instructions for use |  | Contains sufficient for <n> tests |
| IVD | *In vitro* diagnostic medical device |  | Use-by date |
|  | Temperature limit | LOT | Batch code |
|  | Do not use if package is damaged |  | Manufacturer |
| REF | Catalogue number |  | Do not re-use |

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Statement: Information about manufacturer of sterile swab is placed on the packaging.

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