



OneStep HPV Antigen RapiCard™ InstaTest (Cervical Swab)

REF 175110

PIC ID175110VV86

IVD See External Label 20 Tests

HPV Antigen RapiCard™ InstaTest (Cervical Swab)

Principle	Rapid Chromatographic Immunoassay
Detection	Qualitative
Sensitivity	95.6%
Specificity	99.3%

PRODUCT FEATURES

High Sensitivity and Specificity

Built in Internal Controls

Simplified Workflow, Non-invasive, and Safe

Rapid and Faster Results

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 OneStep HPV Antigen RapiCard™ InstaTest 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.

SIGNIFICANCE AND 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

ASSAY PRINCIPLE

The OneStep HPV Antigen RapiCard™ InstaTest (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 antibodyantigen 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.

REAGENT

The test contains anti-HPV-16 and anti-HPV-18 antibody as the capture reagent, and anti-HPV antibody as the detection reagent. A goat anti-rabbit IgG and rabbit IgG are employed in the control line system.

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.

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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 cervicousquamous 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°C) or 1 week at 2-8°C or no more than 6 months at -20°C. All specimens should be allowed to reach a room temperature of 15-30°C before testing.
- Do not use 0.9% sodium chloride to treat swab before collecting specimen.

MATERIALS AND COMPONENTS

Materials provided with the test kit

- Test Cassettes
- Extraction Tubes
- Workstation
- Package Insert
- Extraction Tube Tips
- Extraction Buffer
- Sterile Cervical Swabs

Materials required but not provided

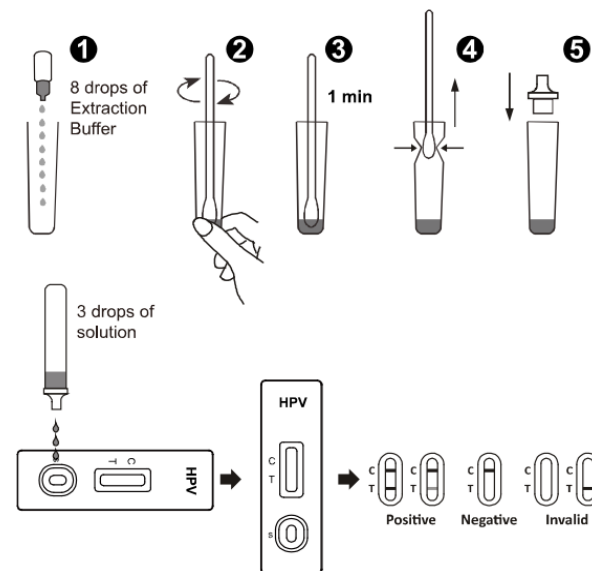
- Timer

ASSAY PROCEDURE

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. Add 8 drops (approx. 450 µL) of extraction buffer into the 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. Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. Add three drops of the solution (approx. 100 µL) to the sample well(s) and then start the timer.
6. Wait for the colored line(s) to appear. The result should be read at 15 minutes, do not interpret the results after 20 minutes.

Note: It is suggested not to use the buffer beyond 6 months after opening the vial.



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



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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 OneStep HPV Antigen RapiCard™ InstaTest 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 OneStep HPV Antigen RapiCard™ InstaTest (Cervical Swab) was compared with PCR when test with clinical cervical swab. The results were tabulated as below.

Method	PCR			Total Results
	Results	Positive	Negative	
HPV Antigen RapiCard™	Positive	86	1	87
	Negative	4	134	138
Total Results		90	135	22

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

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 RapiCard™ InstaTest (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 107 Colony Forming Units (CFU)/test. The following organisms were found negative when tested with the HPV Antigen RapiCard™ InstaTest (Cervical Swab).

<i>Acinetobacter calcoaceticus</i>	<i>Proteus vulgaris</i>
<i>Salmonella typhi</i>	<i>Trichomonas vaginalis</i>
<i>Staphylococcus aureus</i>	<i>Acinetobacter spp</i>
<i>Neisseria catarrhalis</i>	<i>Neisseria gonorrhoea</i>
<i>Neisseria meningitidis</i>	<i>Escherichia coli</i>
<i>Gardnerella vaginalis</i>	<i>Streptococcus faecalis</i>
<i>Streptococcus faecium</i>	<i>Pseudomonas aeruginosa</i>
<i>Chlamydia trachomatis</i>	<i>Ureaplasma urealyticum</i>
<i>Mycoplasma hominis</i>	

REFERENCES

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>.

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016



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