AG- HPV Ag Rapid Test Kit

INSTRUCTION FOR USE

AstraGene's HPV Ag Rapid Test Kit 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.

PRINCIPLE

In developing countries, cervical cancer is a leading cause of cancer related death of women, due to the lack of implementation of screening tests for cervical pre-cancer and cancer. A screening test for low resource settings should be simple, rapid, and cost effective. Ideally, such a test would be informative regarding Human Papillomavirus (HPV) oncogenic activity. Expression of both HPV E6 and E7 oncoproteins is essential for cervical cell transformation to occur. Some research results demonstrated a correlation of E6 &E7 oncoprotein positivity with both severity of cervical histopathology and risk for progression. Hence, E6&E7 oncoprotein promises to be an appropriate biomarker of HPV-mediated oncogenic activity.

AstraGene's HPV Ag Rapid Test Kit 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.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassettes with desiccant	10	1
Extraction tube with cap	10	1
Extraction Buffer	1×4.5mL	1×0.45mL
Sterile cervical swab	10	1
IFU	1	1

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/HPVAg/23/01	AG/RTK/HPVAg/23/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Sterile Swabs
- Clock or timer.
- Pipette
- Latex gloves

STORAGE &STABILITY

- Store as packaged in the sealed pouch at 2-30ºC. The test is stable until the expiration date marked on its sealed pouch. The test must remain in the sealed pouch until use. Do not freeze

SPECIMEN COLLECTION & 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. test.

PROCEDURE

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

- 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.
- Add 8 drops (approx. 450 µL) of extraction buffer into the tube.
- 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.
- 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.
- 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.
- 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.

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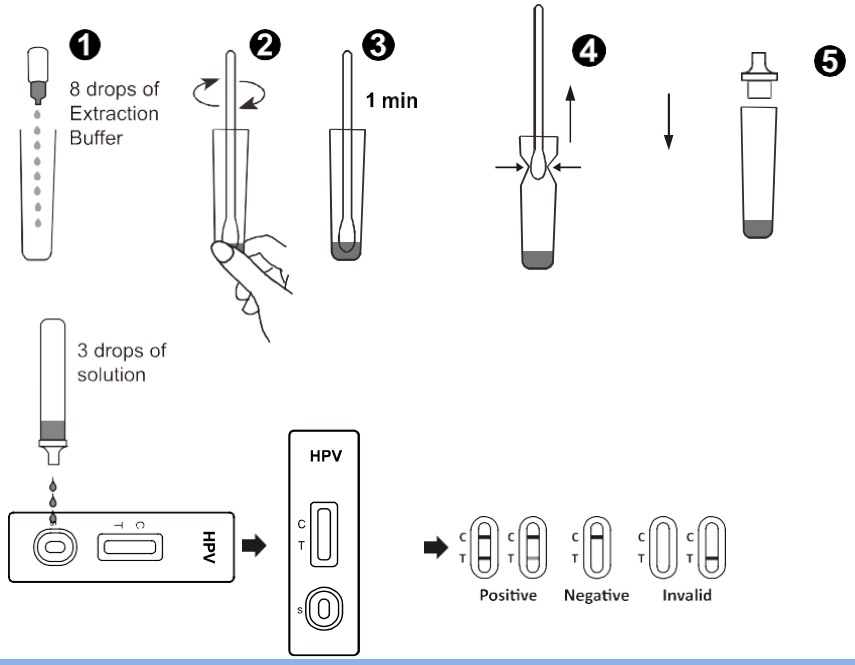

RESULT INTERPRETATIONS

Positive

A clear colored control band (C) and a detectable test band (T) appears, indicating a positive result. C and T: Positive for Human papillomavirus Antigen test

Negative:

A colored band appears only at the control region (C), indicating a negative result.

Invalid

No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number.

SENSITIVITY & SPECIFICITY

AstraGene's HPV Ag Rapid Test Kit was compared with PCR when test with clinical cervical swab

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 THE PROCEDURE

- AstraGene's HPV Ag Rapid Test Kit 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.
- 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.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

WARNING AND PRECAUTION

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Do not exchange or mix buffer and test cassettes from kits of different lots.
- Be sure to add sufficient extracted specimen to the cassette's specimen well. Invalid result may occur if inadequate extracted specimen is added.

SYMBOLS

Do not use if package is damaged | Manufacturer | LOT Batch Code

CE mark of Conformity | Refer to the instructions | ISO 13485:2016 | GMP

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