

Human Papillomavirus E7 Protein Rapid Test Cassette (Swab)

INTENDED USE

Human Papillomavirus E7 Protein Rapid Test Cassette (Swab) is a rapid lateral flow immunoassay for *in vitro* qualitative detection of E7 protein in female cervical exfoliated cells. This product is used in medical and health institutions to detect Human Papillomavirus E7 Proteins as an auxiliary diagnosis. For *in vitro* diagnostic use. For professional use only.

INTRODUCTION

High-risk human papillomavirus (HPV) is an important factor causing cervical cancer, and the oncogenes E6 and E7 derived from high-risk HPV can only express functional protein E7 after their coding sequences are integrated into the human genome. The function of E7 protein in cytoplasm plays an important role in the occurrence and development of cervical cancer. The E7 protein allows cells to proliferate indefinitely by inhibiting retinoblastin (pRb), which is expressed when the gene tissue is damaged. Detection of E7 protein in female cervical exfoliated cells can qualitatively detect cervical cancer.

PRINCIPLE

This kit uses double antibody sandwich method principle and lateral flow immunoassay technology to qualitatively detect the concentration of E7 protein in female cervical exfoliated cells.

The membrane is pre-coated with E7 Proteins on the test line and pre-coated with mouse IgG on the control line. During testing, the processed sample to be tested is dropped into the sample well. The sample migrates through the test strip and dissolves the colloidal gold conjugate on the glass fiber. If the sample contains E7 protein, the E7 protein will combine with the detection antibody-colloidal gold conjugate to form an Ag-Ab-colloidal gold conjugate. The conjugate continues to migrate through the nitrocellulose membrane and specifically assembles with the E7 protein-specific capture antibody pre-coated with the test line to form Ab-Ag-Ab-colloidal gold. It accumulates and develops into an obvious red band, the T line, which represents a positive result. If the sample does not contain E7 protein, no obvious red line will be formed at the test line, which represents a negative result.

The free detection antibody-colloidal gold continues to migrate through the test strip to the quality control region and binds to the pre-coated goat anti-mouse IgG antibody. It accumulates and develops color to form a red band, which represents the quality control line, the C line.

Regardless of whether the sample contains E7 protein, the quality control line of the test strip should appear in a valid test. The red band appearing in the quality control region (C) is the standard for determining whether there are enough samples and whether the lateral flow immunoassay process is normal. It also serves as the internal control standard for the test.

MATERIALS SUPPLIED

20 Test cassettes
20 Droppers
20 Extraction tubes with buffer
1 Tube holder
1 Package insert

NOTE: Components in different lots of kits should not be mixed.

MATERIAL REQUIRED BUT NOT PROVIDED

Clock, timer or stopwatch
Sterilized and qualified cervical swabs

STORAGE AND STABILITY

Kits should be stored at 2-30°C in a cool, dark, dry place, valid for 24 months. The test cassette 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.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use expired, damaged products.
2. The kit can only be used to detect E7 protein in female cervical exfoliated cells from cervical swabs. The operation should be strictly in accordance with the instructions.
3. Test is for single use only. Do not re-use under any circumstances.
4. The collection of exfoliated cervical cell samples must be carried out in strict accordance with the instructions.
5. Keep kits away from children and animals.
6. Please keep the cervical swab tip clean and avoid touching the cervical swab tip with your hands. Keeping the cervical swab tip clean can ensure the accuracy of the test results to a certain extent and avoid errors caused by contamination.
7. The liquid in the kit should not be swallowed. If you accidentally splash the liquid reagent into your eyes, mouth or body surface, please rinse it immediately with plenty of running water. If you still feel unwell, please seek medical help immediately.
8. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.
9. Incorrect operation may affect the accuracy of the results, such as insufficient sample mixing, incorrect sample adding amount, wet display window or inaccurate detection time, etc.
10. Please operate in accordance with the laboratory testing procedures for infectious diseases. Waste after use should be treated in accordance with infectious substances and should not be discarded at will.

SPECIMEN COLLECTION AND PREPARATION

1. This kit is only applicable to the detection of female cervical exfoliated cells from

cervical swab.

- When there is a large amount of visible mucus and bleeding in the sample, the test will be affected, resulting in false test results. It is recommended that users avoid the period of menstruation and ovulation for sampling.
- Vaginal medications (such as dakanine, clotrimazole ointment, vaginal contraceptives) and vaginal lubricants can affect the test and lead to false test results. It is required that there be no sexual intercourse and vaginal medication within the first three days of sampling.
- After first collection, if you need to collect again, please collect one week later and use a new test cassette.
- The samples should be processed as soon as possible after collection, and the processed samples should be used within 2 hours.
- Before specimen collection, remove excess mucus from the endocervical area with a cotton ball and discard.
- Do not place the cervical swabs in any transport device containing medium since transport medium interferes with the assay and viability of the organisms is not required for the assay. If immediate testing is not possible, the patient samples should be placed in a dry transport tube for storage or transport. All specimens should be allowed to reach a room temperature of 15-30°C before testing.
- Specimen Collection:
 - Immediately before performing the test, clear, clean and dry a flat surface to place the test kit on. This is to avoid contaminating the test.
 - Wash your hands thoroughly for 20 seconds, using soap and water, or hand sanitizer. This is to avoid contaminating the test. If doing more than one test, clean the surface and rewash hands between each test. keep your hands clean, and wear disposable protective gloves.
 - The swab should be inserted into the endocervical canal, past the squamocolumnar junction until most of the tip is no longer visible. This will permit acquisition of columnar or cuboidal epithelial cells, which are the main reservoir of the Chlamydia organism. Firmly rotate the swab 360° in one direction (clockwise or counterclockwise) several turns to get enough exfoliated cells and then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do not use 0.9% sodium chloride to treat swabs before collection specimens.

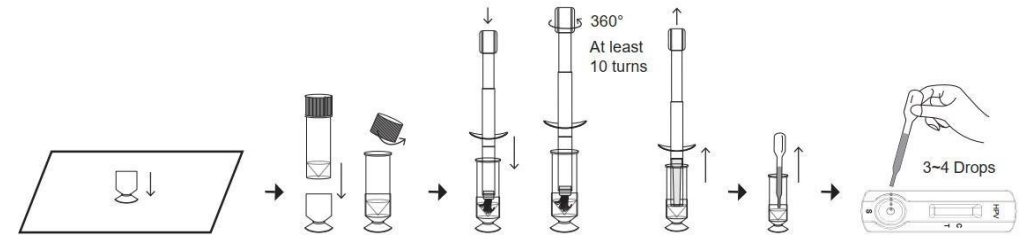
TEST PROCEDURE

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

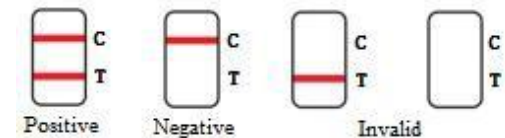
- Wash your hands thoroughly with soap or hand sanitizer, keep them clean, and wear disposable protective gloves.
- Take out the test materials from the kit and check the expiry date.
- Place the tube holder on the table and press firmly on the tube holder to attach it to the table surface.
- Insert the extraction tube with buffer into the tube holder. Unscrew the cap from the extraction tube.
- Insert the cervical swab into the extraction tube with buffer, make the swab tip contact with the bottom of the tube. Hold the cervical swab lever and Rotate it 360°

for at least 10 turns.

- Pull out the swab, and discard it as medical waste.
- Take out the test cassette from the sealed foil pouch and lay it on a clean, flat table. (Note: Do not touch the membrane in the result window with your fingers)
- Use the dropper to draw 3-4 drops (about 100uL) from the supernatant of the solution in the extraction tube and add it vertically into the sample well of the test cassette in a steady speed.
- Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS



(Please refer to the illustration above)

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T). Which indicate the patient's Human Papillomavirus E7 Proteins is detected. It is recommended to seek help from the health professionals for further diagnosis of the disease condition.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). Which indicate the patient's Human Papillomavirus E7 Proteins is not detected.

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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local supplier.

LIMITATIONS

- This kit is a qualitative *in vitro* diagnostic reagent for auxiliary diagnosis. The test results are only used for clinical diagnosis, and the clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response.
- The kit is only used for the detection of cervical exfoliated cells.
- The color depth of the positive test line is not necessarily related to the

concentration of E7 protein in the sample. Individual differences between individual subjects or differences in the recognition of the kit itself may produce false positive results.

4. A negative test result does not rule out the possibility of infection.
5. Other situations, such as 5 % doxynine, vaginal contraceptives, vaginal lubricants, hemoglobin and hemoglobin/ mucin at a concentration of 1.2 mg/ml, clotrimazole ointment at a concentration of 0.4 g/ml will cause errors in the test results of the kit. Mucin at a concentration of 5% has an inhibitory effect on the test results of this kit, leading to false negative results.

PERFORMANCE CHARACTERISTICS

Cut-off

The cut-off of this kit is 1 ng/ml for Human Papillomavirus E7 Proteins.

Analytical sensitivity

Limit of detection (LoD): The LoD enterprise references L1-L3 were taken to test once each. The L1 test result should be negative, the L2 test result can be negative or positive, and the L3 test result should be positive.

Accuracy

1. Negative references compliance rate: The enterprise negative references N1-N5 used for evaluation reagents were taken to test once each, and the test results should all be negative (the compliance rate is 5/5).
2. Positive references compliance rate: The enterprise positive references P1-P5 used for evaluation reagents were taken to test once each, and the test results should all be positive (the compliance rate is 5/5).

Repeatability

The enterprise repeatable reference J was taken to test 10 times each. The test results of J should be positive.

REFERENCE

1. Giovane C, Travé G, Briones A, et al. Targetting of the N - terminal domain of the human papillomavirus type 16 E6 oncoprotein with monomeric scFvs blocks the E6 - mediated degradation of cellular p53[J]. Journal of Molecular Recognition, 1999, 12(2): 141-152.
2. Kim J H, Cho I H, Seo S M, et al. Immuno-chromatographic analysis for HPV-16 and 18 E7 proteins as a biomarker of cervical cancer caused by human papillomavirus[J]. Bull Kor Chem Soc, 2009, 30(12): 2999-3005.
3. Sexually Transmitted Diseases, 4th Edition. King K. Holmes. McGraw-Hill Professional, 2007.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#

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REF

HPV20 T

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