

HPV Antigen Rapid Test Device Package Insert

Cat: IHV-522	Specimens: Cervical Swab
Version: 01	Effective Date: 2022-09
For professional <i>in vitro</i> diagnostic use only.	

INTENDED USE

The Human papillomavirus (HPV) 16&18 Antigen Rapid Test Device is a rapid visual immunoassay for the qualitative, presumptive detection of Human papillomavirus viral antigens type 16 and 18 from cervical Swabs specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute Human papillomavirus (HPV) 16&18 infection.

INTRODUCTION

Human papillomavirus (HPV) belongs to the genus of papilloma viruses of the Papovaviridae family and has a definitive biocycle associated with differentiation of keratinocytes. The virus infects only proliferating epithelial cells of the basal layer. Formation of viral particles occurs in the upper layers of the epithelium. Presently over 100 types of HPV are distinguished, with about 30 of them being able to infect the epithelium of a human urogenital tract.

The most frequently used test for screening of cervical cancer and precancerous changes in the epithelium is a cytological one. At the same time the diagnostic accuracy can vary depending on the specimen collection method, binding technique and smear preparation as well as a researcher's skills. It is believed that nearly one third of cervical cancer cases are diagnosed in women who were screened regularly during cytological examination and thus false negative results for these patients were obtained. Therefore, DNA diagnostics of HPV infection is currently considered the basis for cervical cancer screening and prevention.

PRINCIPLE

The Human papillomavirus (HPV) 16&18 antigen Rapid Test Device detects HPV viral antigens type 16&18 through visual interpretation of color development on the strip. Anti-HPV 16 and 18 antibodies are immobilized on the test region 16 and 18 of the membrane respectively. During testing, the extracted specimen reacts with anti- HPV 16& 18 antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient HPV 16& 18 antigens in the specimen, colored band(s) will form at the according test region of the membrane. The presence of a colored band in the 16 and/or 18 region indicates a positive result for the particular viral antigens, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Individually packed Test Devices	Each test contains colored conjugates and reactive reagents precoated at the corresponding regions
Extraction solution	For specimens extraction.
Extraction tubes	For specimen preparation
Sterile swabs	For specimen collection
Package insert	For operating instructions

MATERIALS REQUIRED BUT NOT PROVIDED

Timer	For timing use
Pipette	Capable of delivering 300 ul

PRECAUTIONS

- 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 and kits are

- handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure 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.
- Humidity and temperature can adversely affect results.
- Use only sterile swabs to obtain endocervical specimens.
- Tindazole vaginal effervescent tablets and Confort Pessaries with negative specimens may cause very weak interference effect.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

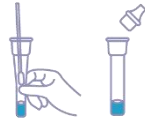
- Specimen Collection**
Use the swab in the kit if provided. Alternatively, any plastic-shaft swab may be used.
Before specimen collection, remove excess mucus from the endocervical area with a cotton ball and discard. The swab should be inserted into the endocervical canal, past the squamocolumnar junction 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), let stand for 15 seconds, then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do not use 0.9% sodium chloride to treat swabs before collecting specimens.
Put the swab into the extraction tube, if the test is to be conducted immediately.

- Specimen Transport and Storage:**
Specimens should be tested as soon as possible after collection. If transport of the samples is required, the following transport media are recommended and have been tested and shown not to interfere with the performance of the test: Hank's BalanceMKd salt solution, M5 Media, or saline. Alternatively, samples may be stored refrigerated (2-8 °C), or at room temperature(15-30°C), in a clean, dry, closed container for up to eight hours prior to testing. Nasal wash/aspirate specimens may also be stored frozen(-70°C or colder) for up to one month.

PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

- Wear the protection equipment. Remove the test from its sealed pouch, and place it on a clean, level surface. For best results, the assay should be performed within one hour.
- Place the swab specimen into the Extraction Tube. Roll the swab at least 10 times while pressing the swab against the bottom and side of the Extraction Tube. Roll the swab head against the inside of the Extraction Tube as you remove it. Try to release as much liquid as possible. Dispose of the used swab into the Disposal Bag considered as biohazard waste.



- Put on the tube tip, then add 3 drops (100ul) of extracted sample into

- the sample well (S). Do not handle or move the Test Device until the test is complete and ready for reading.
- As the test begins to work, color will migrate across the membrane. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.
 - Dispose all assayed equipment (cassette, buffer and so on) into the Disposal Bag considered as biohazard waste.

INTERPRETATION OF RESULTS

POSITIVE RESULT:



HPV 16 Positive:* A colored band appears in the control band region (C) and another colored band appears in the 16 region.



HPV 18 Positive:* A colored band appears in the control band region (C) and another colored band appears in the 18 region.



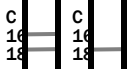
HPV 16+18 Positive:* A colored band appears in the control band region (C) and two other colored bands appear in the 16 region and 18 regions, respectively.

NEGATIVE RESULT:

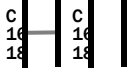


Only one colored band appears, in the control band region (C). No band appears in either test band region (A/B).

INVALID RESULT:



Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.



NOTE:

- The intensity of color in the test region (16/18) may vary depending on the concentration of analyses present in the specimen. Therefore, any shade of color in the test region (16/18) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

LIMITATIONS OF THE TEST

- The Human papillomavirus (HPV) 16&18 antigen Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of Human papillomavirus viral antigens type 16 and 18.
- The etiology of respiratory infection caused by microorganisms other than Human papillomavirus type 16 or 18 will not be established with this test. Human papillomavirus (HPV) 16&18 antigen Rapid Test Device is capable of detecting both viable and non-viable influenza particles. The performance of the Human papillomavirus (HPV) 16&18 antigen Rapid Test Device depends on antigen load and may not correlate with

- cell culture performed on the same specimen.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of HPV 16 and/or 18 viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
 - The validity of Human papillomavirus (HPV) 16&18 antigen Rapid Test Device has not been proven for identification or confirmation of cell culture isolates.
 - Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test result.
 - Positive and negative predictive values are highly dependent on prevalence. False positive test results are more likely during periods of low Human papillomavirus activity when prevalence is moderate to low.

PERFORMANCE CHARACTERISTICS

Table: HPV 16 & 18 Rapid Test vs. other commercial brand

HPV 16		HPV 16 & 18 Rapid Test		
		+	-	Total
Relative Sensitivity: 100% (99.7%~100%)	Other brand	52	0	52
Relative Specificity: 100% (99.8%~100%)				
Overall Agreement: 100% (99.8%~100%)		0	103	103
*95% Confidence Interval		52	103	155

HPV 18		HPV 16 & 18 Rapid Test		
		+	-	Total
Relative Sensitivity: 100% (99.6%~100%)	Other brand	27	0	27
Relative Specificity: 100% (99.8%~100%)				
Overall Agreement: 100% (99.8%~100%)		0	103	103
*95% Confidence Interval		27	103	130

ANALYTICAL SPECIFICITY AND CROSS-REACTIVITY

The antibody used in the Human papillomavirus (HPV) 16&18 antigen Rapid Test Device has been shown to detect Human papillomavirus type 16 and 18. Cross reactivity with other organisms has been studied using suspensions of 107 org/mL. The following organisms were found negative when tested with the Chlamydia Rapid Test Device:

Acinetobacter calcoaceticus	Candida albicans
Acinetobacter spp	Proteus vulgaris
Enterococcus faecalis	Gardnerella vaginalis
Enterococcus faecium	Proteus mirabilis
Staphylococcus aureus	Neisseria gonorrhea
Klebsiella pneumoniae	Group A/B/C/D Streptococcus
Pseudomonas aeruginosa	Hemophilus influenza
Neisseria meningitidis	Branhamella catarrhalis
Salmonella Minnesota	Chlamydia trachomatis

INTERFERING SUBSTANCES

Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the Human papillomavirus (HPV) 16&18 Test at the levels tested: whole blood (2%); three OTC mouthwashes (25%); three OTC throat drops (25%); three OTC nasal sprays (10%); 4-Acetamidophenol (10 mg/mL); Acetylsalicylic Acid (20 mg/mL); Chlorpheniramine (5 mg/mL); Dextromethorphan (10 mg/mL); Diphenhydramine (5 mg/mL); Ephedrine (20 mg/mL); Guaiacol glyceryl ether (20 mg/mL); Oxymetazoline (10 mg/mL); Phenylephrine (100 mg/mL); and Phenylpropanolamine (20 mg/mL).

LITERATURE REFERENCES

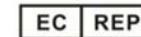
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Index of Symbols

	Consult instruction for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number	REF	Catalog #
	Do not use if package is damaged				



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