CE IVD

HPV Antigen Rapid Test Kit (Colloidal Gold)

PRODUCT NAME
HPV Ag Rapid Test

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE
The HPV Ag Rapid Test Device is a rapid visual immunoassay for the qualitative presumptive detection of used to test for HPV infection in Vaginal secretions specimens.
It is intended to be used by professionals as a test and provides a preliminary test result to aid in the diagnosis of infection with HPV .
Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this test

INTRODUCTION
HPV is a very common, mainly through sexual contact infection virus, long-term continuous HPV infection will lead to the development of genital warts and precancer lesions and even cervical cancer.Cervical cancer is a high incidence of malignant tumor harmful to women's health The rate is second only to breast cancer, accounting for all female malignancies Thirteen percent, 59% occurred in Asia.HPV viruses belong to a member of the papillomaviridae family, and the natural virus capsid presents an icosahedral structure, and is a membrane-free, double-stranded circular DNA virus.The HPV genome is surrounded by the main (L1) and secondary (L2) capsid structural proteins, and the L1 protein accounts for more than 90% of the whole protein on the virus surface, and is the main antigen that induces the body to produce antibodies and can assemble into virus-like particles (VLPs).At present, more than 100 HPV types are found, of which about 40 of them can infect human Yin and anus and cause cervical damage and cervical cancer, which are called high-risk HPV (for example, HPV-16, -18, -31, -33, and-58).Epidemiological investigations have found that persistent high-risk HPV infection is a necessary prerequisite for cervical cancer development.Numerous epidemiological adjustments High-risk human papillomavirus (HPV) persistent infection was found It may be an important cause of the occurrence and development of cervical cancer and its precancerous lesions factor.

PRINCIPLES
The HPV Ag Rapid Test Device (Vaginal secretions) is a lateral flow chromatographic immunoassay.The membrane was immobilized with anti-HPV antibodies on the test region. During the test, the specimen is allowed to react with colored anti-HPV antibodies colloidal gold conjugates colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough HPV Ag in specimens, a colored band will form at the T region of the membrane. Presence of colored band(s) indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS REQUIRED BUT NOT PROVIDED
Specimen collection container	For specimens collection use.
Timer	For timing use.
Centrifuge	For treatment of special specimens.

PRECAUTIONS
• For professional in vitro diagnostic use only.
• Do not use after expiration date indicated on the package. Do not use the test if its foilpouch is damaged. Do not reuse tests.
• This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated aspotentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
• Avoid cross-contamination of specimens by using a new specimen collection container foreach specimen obtained.
• Read the entire procedure carefully prior to performing any tests.
• 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 standardprocedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
• Buffered Saline contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of buffered saline or extractedsamples, always flush with copious quantities of water to prevent azide build up.
• Do not interchange or mix reagents from different lots.
• Humidity and temperature can adversely affect results.
• The used testing materials should be discarded in accordance with local, state and/ orfederal regulations.

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.
• Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE
• The HPV Ag Rapid Test Device (Vaginal secretions) is intended only for use with human Vaginal secretions specimens.
• Female cervical sampling:
• Viscous material in the vagina was removed with a cotton ball before specimen collection and then discard Take cotton ball.Extend the standard Polyester cotton swabs inside thevagina until most of the swabs Has been extended into it.Turn the swab for 15-20 seconds.
• If test immediately, put the swab in a test tube.

PROCEDURE
Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.
1.Remove the test from its sealed pouch, and place it on a clean, level surface.
2.Gently mix Extraction reagent solution. Add 6 drops(about 200ul) of the ExtractionSolution into the Extraction tube.
3.Place the patient swab specimen into the Extraction Tube. Roll the swab at least 10times 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 in accordance with your biohazardwaste disposal protocol.
4.Put on the tube tip, then add 3 drops (about 120ul) of extracted sample into the samplewell. Do not handle or move the Test Device until the test is complete and ready for reading.
5.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 resultafter 20 minutes.

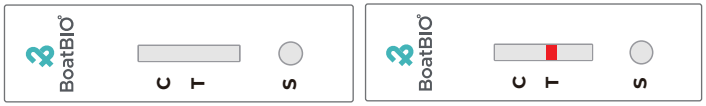
INTERPRETATION OF RESULTS
POSITIVE RESULT:
*A colored band appears in the control band region (C) andanother colored band appears in the T band region.

Postive

NEGATIVE RESULT:
One colored band appears in the control band region (C). No band appears in the test band region (T).

Negative

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 newtest. If the problem persists, discontinue using the kit immediately and contact your local distributor.



Invalid

'NOTE:
1.The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not bedetermined by this qualitative test.
2.Insufficient specimen volume, incorrect operation procedure, or performing 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. It confirms sufficient specimen volume and correct procedural technique.
External controls are not supplied with this kit. It is recommended that positive andnegative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS
1.The HPV Ag Rapid Test Device (Vaginal secretions) is for professional in vitro diagnosticuse, and should be used for the qualitative detection of HPV Ag only.
2.As with all diagnostic tests, a definitive clinical diagnosis should not be based on theresults of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
3.If the test result is negative and clinical symptoms persist, additional testing using otherclinical methods is recommended. A negative result does not at any time preclude the possibility of HPV Ag infection with low concentration of virus particles.
4.Only sample in utero using polyester cotton swabs.

PERFORMANCE CHARACTERISTICS
	HPV Ag Rapid Test		
PCR	+	-	Total
+	49	4	53
-	3	146	149
	52	150	202

Relative Sensitivity:	**92.4% (88.07%-95.27%)***
Relative Specificity:	**97.98% (94.5%-99.9%)***
Overall Agreement:	**96.53% (91.7%-98.41%)***
***95% Confidence Interval**	

Specificity:
Cross reactivity with following organisms has been studied at 1.0 x 107 organisms/ml. The following organisms were found negative when tested with the HPV Ag Rapid Test Device (Vaginal secretions).

Acinetobacter calcoaceticus	Proteus vulgaris	Klebsiella pneumoniae
Candida albicans	Proteus mirabilis	GroupC/D Streptococcuss
Acinetobacter spp	Staphylococcus aureus	Pseudomona aeruginosa
Streptococcus faecalis	Neisseria gonnorhea	Hemophilus influenza GroupA/B
Gardnerella vaginalis	Salmonella minnesota	Streptococcuss
Streptococcus faecium		

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	**Use-by date**		**Consult instructions for use**
	**Batch code**		**In vitro diagnostic medical device**
	**Temperature limit**		**Manufacturer**
	**Please don't reuse it**		**Keep away from sunlight**
	**Don't use the product when the package is damaged**		**Keep dry**
	**Date of manufacture**		**Tests per kit**
	**CE Mark**		**Biological Risks**
	**Authorized representative in the European Community**		

BASIC INFORMATION

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