GENETRACK Diagnostics

Human Papillomavirus (HPV)

WHAT IS HUMAN PAPILLOMAVIRUS (HPV)?

Human papillomavirus (HPV) is a common sexually transmitted DNA virus (1). HPV is transmitted through vaginal, anal, or oral sex. It can be spread even when an infected individual does not show any symptoms. Most women effectively clear HPV infections within 6 to 12 months (2). However, specific HPV genotypes increase the risk of cervical cancer, one of the most common cancers affecting females around the world. More than 99% of all cervical cancers are caused by HPV (1).

SYMPTOMS

Usually HPV does not cause any symptoms, and is effectively cleared without any medical interventions. However, in some cases, genital warts can occur, or cell changes that lead to cervical cancer and other cancers of the vulva, vagina, penis, anus, or throat. Generally the types of HPV that cause warts differ from those that cause cancer (3).

WHICH HPV GENOTYPES ARE HIGH RISK FOR CERVICAL CANCER?

There are more than 100 genotypes of HPV, of which 14 are considered high risk for cervical disease – genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. Individuals who have a persistent infection with one of these pathogenic genotypes have an increased risk for cervical carcinoma or severe dysplasia (4).

PREVALENCE

HPV is the most common sexually transmitted disease in the United States. An estimated 43 million Americans were infected with HPV in 2018, with many infections among people in their late teens and early 20s. Almost every non-vaccinated sexually active individual will get HPV at some time in his or her life (3).

TESTING RECOMMENDATIONS

HPV testing for the 14 high-risk HPV genotypes is recommended for screening for cervical cancer in women aged 30 years and older. Routine screening for HPV is not recommended for under 30 years of age, as HPV is very common in young people, and will often clear without intervention within one to two years. HPV testing is often conducted at the same time as a routine Pap smear. However, self-collected cervical swabs are an efficient alternative with many studies showing similar diagnostic test accuracies as clinician-sampled HPV tests (5).

DIAGNOSIS

Most HPV infections are asymptomatic and clear up without medical intervention within 6 to 12 months. Hence, most infected individuals are unaware of their diagnosis. Nucleic acid tests (such as this one) are available to accurately identify individuals who are infected with one of the 14 high-risk HPV strains. Detection of HPV nucleic acid (a positive test result) is indicative of an active HPV infection, but does not mean that cervical dysplasia or cervical cancer is present.

Follow up testing is recommended for any positive results, with protocols varying based on the results of recent pap smears. Another HPV test and/or pap smear in a shorter time period from routine testing may be all that is required. Alternatively, a colposcopy to further examine the cervix, vagina, or vulva can be used to detect abnormal cells or blood vessels. Other options include tissue biopsies, removal of abnormal cervical cells, and referral to a gynaecologist (6).

TREATMENT

There is no treatment for HPV itself; however, there are treatments for the health problems associated with HPV. Genital warts can be treated with prescription medication, and cervical precancer can be effectively treated. Any cancers that are associated with HPV are more treatable when diagnosed and treated early; hence the importance of routine screening (6).

HPV VACCINATION

HPV vaccination is safe and effective to prevent against diseases (including cancer) caused by HPV. It is recommended at age 11 or 12 years, and for everyone through to 26 years, if not vaccinated already. Vaccination for individuals older than 26 years provides less benefit, as most sexually active adults have already been exposed to HPV (3).

TEST PROCEDURE

Correct specimen collection and handling is required for optimal assay performance.

This test requires a self-collected cervical swab. All supplies for sample collection are provided in this kit. First wash and dry hands, and make sure that you are in a comfortable position with your underwear lowered. Twist the cap and remove the swab from the packaging. Ensure that you do not touch the tip of the swab that is used to collect the sample. Use your free hand to move skin folds at the entrance of your vagina. Carefully insert the swab into your vagina about 2 inches (5 cm) inside the opening of the vagina and gently rotate the swab for 10-30 seconds. This should not hurt, but may feel slightly uncomfortable. Carefully remove the swab and place back into the packaging without touching the tip of the swab that was used for sample collection. Screw the cap back on, and return sample to the laboratory in the provided prepaid return shipping envelope.

Upon receipt at the laboratory, the sample is analyzed by a fully automated nucleic acid amplification testing procedure. This assay combines the technologies of target capture, transcription-mediated amplification, and detection of amplification products by nucleic acid hybridization.

TEST INTERPRETATION

A positive result indicates that nucleic acid from one or more of the high-risk HPV genotypes is present in the specimen tested. Follow up testing is recommended for any positive results, with protocols varying based on the results of recent pap smears.

A negative result indicates that nucleic acid from the high-risk HPV genotypes was not detected in the specimen tested. Additional specimens should be collected for testing if clinical symptoms strongly suggest an HPV infection.

An indeterminate result indicates that a new specimen should be tested.

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DISCLAIMERS/LIMITATIONS

This report is not intended for use in medico-legal applications. These results are intended for screening for HPV and should be interpreted in conjunction with other laboratory and clinical information.

Correct specimen collection and handling is required for optimal assay performance.

A negative result does not exclude the possibility of HPV infection, nor does it exclude the possibility of cytologic abnormalities, or of future or underlying cervical cancer.

The use of this test has not been evaluated for the management of women with prior ablative or excisional therapy, or who are pregnant.

REFERENCES

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