HPV Genotyping qPCR Kit

GeneNav HPV Genotyping qPCR Kit

Introduction
90% of HPV positive cases clear up naturally within 2 years. Our GeneNav HPV Genotyping qPCR Kit offers simultaneous detection and genotyping of all 14 high risk HPV subtypes, enabling you to monitor your patient for any persistent infection of the same HPV subtype that could lead to cervical cancer.

Description
The GeneNav HPV Genotyping qPCR Kit is designed for continuous monitoring of individuals who have been confirmed to be HPV positive with one of the 14 High Risk human papilloma virus (HPV) subtypes. This kit allows physicians to track patients who are at a greater risk of developing cervical cancer by identifying individuals who show persistent infection with the same HPV subtype. This in vitro diagnostic kit allows for the specific detection and discrimination of all 14 High Risk HPV subtypes: HPV 31, HPV 33, HPV 35, HPV 39, HPV 45, HPV 51, HPV 52, HPV 56, HPV 58, HPV 59, HPV 66, and HPV 68. A β-Actin internal control is also used in the GeneNav HPV Genotyping qPCR Kit to assess specimen quality and ensure the reliability of the HPV detection results.

Principle of Assay
The GeneNav HPV Genotyping qPCR Kit uses probe-based qPCR technology to detect HPV with high specificity. While replicating the DNA sample, the PCR Taq Polymerase’s 5’ to 3’ exonuclease activity also hydrolyzes the probe, releasing a free-floating 5’-fluorophore that is detectable by the qPCR machine and can be translated into an amplification plot. In this HPV Genotyping qPCR kit, the 14 types of high risk HPV and a human β-Actin control are divided into 8 reaction tubes, with 2 fluorescent channels per tube: FAM and HEX. Detection of a positive signal in a particular channel can identify a specific genotype of HPV. An internal control, β-Actin, indicates the quality of extracted DNA.

Intended Use
The GeneNav HPV Genotyping qPCR Kit is a qualitative in vitro diagnostic test that detects all 14 high risk HPV subtypes: HPV 31, HPV 33, HPV 35, HPV 39, HPV 45, HPV 51, HPV 52, HPV 56, HPV 58, HPV 59, HPV 66, and HPV 68) at clinically relevant infection levels from cervical swab specimens.

Performance Characteristics
Analytical Sensitivity: 130 copies/reaction

Analytical Specificity: Cross reaction among these 14 HPV types was not observed. A panel of bacteria, fungi, and viruses commonly found in the female anogenital tract were tested with the GeneNavTM HPV Genotyping qPCR Kit to assess potential cross-reactivity. The pathogens tested include: Candida albicans, Proteus vulgaris, Corynebacterium pseudodiphtheriticum, Staphylococcus aureus, Enterococcus faecalis, Staphylococcus epidermidis, Escherichia coli, Streptococcus millis, Lactobacillus acidophilus, Streptococcus pyogenes, Herpes simplex virus, type 1 and 2 (HSV-1 and 2), Chlamydia trachomatis, Neisseria gonorrhoeae, Human Immunodeficiency Virus type 1 (HIV-1 pol and env regions), and Mycoplasma hominis. Negative results were obtained from all above-mentioned organisms.

Reproducibility: Reproducibility of the GeneNav HPV Genotyping qPCR Kit was assessed at two external sites using a panel of HPV positive and negative cultured cells and HPV positive and negative cervical specimens. DNA was extracted from sixteen samples and tested with GeneNav HPV Genotyping qPCR Kit at two sites on non-consecutive days within a two-week time period. Two lots of GeneNav HPV Genotyping qPCR kits were used across the two sites for the study. The total number of measurements for each sample was 20 (2 sites x 5 days x 2 lots x 1 run per day). The results showed that the coefficient of variation (CV) for the kit performance was less than 5% among different product lots and different operators.

Registration Status
CE-IVD
Health Canada-IVD
FDA-IVD

Rapid and precise analysis: From collected samples to results in less than 2hr.

Quality by Design: Flag samples with low cellularity through β-Actin internal control reducing false negative results.

3 Real time PCR kits for your HPV screening
- HPV One qPCR Kit
- HPV Complete qPCR Kit
- HPV Genotype qPCR Kit

Quick and Easy Set-up Procedure:
- 20min of hands on time for evaluating 96 patient samples

No Need for Purchasing Equipment:
- compatible with all current qPCR platforms (4 Fluorescent Channels)

GeneNav HPV Detection Kits

The Human Papilloma Virus, also known as HPV, is the most common sexually transmitted disorder affecting millions worldwide. In fact, at least 4 out of 5 women will have been infected with the HPV virus by age 50. There are over 120 known types of HPV; about 40 of these types infect the epithelial lining of the anogenital tract.

In the majority of individuals (90%), HPV infections are asymptomatic and usually clear up within 2 years without the need for any medical intervention. However, a infections with any of the 14 High Risk HPV Subtypes can persist and progress into cervical cancer.
Introduction
Screen your patients for HPV 16, HPV 18, and a pool of 12 other high risk HPV subtypes with our GeneNav™ HPV One qPCR Kit. This simple one-tube system is designed for quick and accurate initial screening of patients who are HPV positive from those who are HPV negative so that you may identify those who require continuous monitoring.

Rapid and precise analysis - From collected samples to results in less than 2hr
Quick and easy setup procedure - 20min of hands on time for evaluating 96 patient samples
No need for purchasing equipment - compatible with all current qPCR platforms (4 Fluorescent Channels)

Description
The GeneNav™ HPV One qPCR Kit is designed for quick initial screening of individuals for the presence of all 14 High Risk Human papilloma virus (HPV) subtypes allowing physicians to identify those at risk for cervical cancer. This in vitro diagnostic kit allows for the specific detection and discrimination between HPV 16, HPV 18, and nonspecific pooled detection of the other 12 high risk HPV subtypes (HPV 31, HPV 33, HPV 35, HPV 39, HPV 45, HPV 51, HPV 52, HPV 56, HPV 58, HPV 59, HPV 66, and HPV 68). A human β-Actin internal control is also used in the GeneNav™ HPV One qPCR Kit to assess specimen quality and ensure the reliability of the HPV detection results.

Principle of Assay
The GeneNav™ HPV One qPCR Kit uses probe-based qPCR technology to detect HPV with high specificity. Each sequence-specific probe contains a 5’ fluorophore and a 3’ quencher. While replicating the DNA sample, the PCR Taq Polymerase’s 5’ to 3’ exonuclease activity also hydrolyzes the probe, releasing a free-floating 5’ fluorophore that is detectable by the qPCR machine and can be translated into an amplification plot. This HPV One qPCR kit identifies 14 high risk HPV and a Human β-Actin control using 4 fluorescence channels in one tube: FAM, HEX, ROX and Cy5. As a result, this kit can not only detect the 14 high risk HPV types, it is capable of distinguishing HPV 16 and 18 from the other types. The internal control, Human β-Actin, indicates the quality of extracted DNA.

Intended Use
The GeneNav™ HPV One qPCR Kit is a qualitative in-vitro diagnostic test that detects HPV 16 and HPV 18 specifically, and the remaining 12 High Risk HPV subtypes non-specifically (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) at clinically relevant infection levels from cervical swab specimens.

Performance Characteristics
Analytical Sensitivity: 130 copies/reaction
Analytical Specificity: Cross reaction among these 14 HPV types was not observed. A panel of bacteria, fungi, and viruses commonly found in the female anogenital tract were tested with the GeneNavTM HPV One qPCR Kit to assess potential cross-reactivity. The pathogens tested include: Candida albicans, Proteus vulgaris, Corynebacterium pseudodiptheriticum, Staphylococcus aureus, Enterococcus faecalis, Staphylococcus epidermidis, Escherichia coli, Streptococcus mitis, Lactobacillus acidophilus, Streptococcus pyogenes, Herpes simplex virus, type 1 and 2 (HSV-1 and 2), Chlamydia trachomatis, Neisseria gonorrhoeae, Human Immunodeficiency Virus type 1 (HIV-1 pol and env regions), and Mycoplasma hominis. Negative results were obtained from all above-mentioned organisms.

Reproducibility:
Reproducibility of the GeneNav™ HPV One qPCR Kit was assessed at two external sites using a panel of HPV positive and negative cultured cells and HPV positive and negative cervical specimens. The results showed that the coefficient of variation (CV) for the kit performance was less than 5% among different product lots and different operators.

Registration Status
- CE-IVD
- Health Canada-IVD
- FDA-IVD

HPV Complete qPCR Kit

Introduction
Over 130 HPV types have been documented in literature, approximately 40 of which infect the anogenital area and are sexually transmitted. Persistent anogenital high risk HPV infection is associated with the majority of cervical cancers. Cervical cancer is highly preventable when cytological and HPV screening programs are employed to facilitate early detection and treatment of pre-cancerous lesions. Of the sexually transmitted HPV genotypes, 14 (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) are considered high risk as they lead to cervical cancer or anogenital warts. In addition, HPV types 6 and 11 are considered low risk for cervical cancer, however they are the cause of 90% of all cases of genital warts as well as respiratory papillomatosis.

Description
The GeneNav™ HPV Complete qPCR Kit is a single tube system which utilizes quantitative PCR (qPCR) technology to detect the 16 HPV types described. This kit is able to simultaneously detect the presence of HPV 16 or HPV 18, one of the other high risk HPV subtypes, and HPV 6 or 11.

Principle of Assay
The GeneNav™ HPV Complete qPCR Kit uses probe-based qPCR technology to detect HPV with high specificity. While replicating the DNA sample, the PCR Taq Polymerase’s 5’ to 3’ exonuclease activity also hydrolyzes the probe, releasing a free-floating 5’ fluorophore that is detectable by the qPCR machine and can be translated into an amplification plot. This HPV Complete qPCR kit identifies 14 types of high risk HPV, 2 types of low risk HPV, and a human ACTIN control using 4 fluorescence channels in one tube: ROX, FAM, HEX and Cy5. As a result, this kit can not only detect the 14 high risk HPV types and 2 low risk HPV types, it is also capable of distinguishing HPV 16 and 18 from all the other types. The internal control, human ACTIN, indicates the quality of extracted DNA.

Intended Use
The GeneNav™ HPV Complete qPCR Kit is a qualitative in vitro diagnostic test that detects all 14 high risk HPV subtypes: HPV 31, HPV 33, HPV 35, HPV 39, HPV 45, HPV 51, HPV 52, HPV 56, HPV 58, HPV 59, HPV 66, and HPV 68 at clinically relevant infection levels from cervical swab specimens.

Performance Characteristics
Analytical Sensitivity: 130 copies/reaction
Analytical Specificity: Cross reaction among these 16 HPV types was not observed. A panel of bacteria, fungi, and viruses commonly found in the female anogenital tract were tested with the GeneNav™ HPV Complete qPCR Kit to assess potential cross-reactivity. The pathogens tested include: Candida albicans, Proteus vulgaris, Corynebacterium pseudodiptheriticum, Staphylococcus aureus, Enterococcus faecalis, Staphylococcus epidermidis, Escherichia coli, Streptococcus pyogenes, Herpes simplex virus, type 1 and 2 (HSV-1 and 2), Chlamydia trachomatis, Neisseria gonorrhoeae, Human ImmunoDeficiency Virus type 1 (HIV-1 pol and env regions), and Mycoplasma hominis. Negative results were obtained from all above-mentioned organisms.

Reproducibility:
Reproducibility of the GeneNav™ HPV Complete qPCR Kit was assessed at two external sites using a panel of HPV positive and negative cultured cells and HPV positive and negative cervical specimens. The results showed that the coefficient of variation (CV) for the kit performance was less than 5% among different product lots and different operators.

Registration Status
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- Health Canada-IVD
- FDA-IVD

Contact Us At: Unit Nos#313/319, Shah & Nahar, Off Dr E Moses Road, Worli, Mumbai 400 018.
Tel: 022 - 49198700 | Email: sales@krishgen.com