HPV28 Detection

Genotyping of 28 HPVs by Real-time PCR

- 19 High-risk HPV genotypes: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 73, 82
- 9 Low-risk HPV genotypes: 6, 11, 40, 42, 43, 44, 54, 61, 70

CE-IVD Marked

HIGH SENSITIVITY & SPECIFICITY
Multiplex real-time PCR with high sensitivity and specificity by utilization of DPO™ and TOCE™ technologies
Human papillomavirus (HPV) has been identified as the leading cause of cervical cancer in women. Although over 150 different HPV types have been identified, only certain types are implicated as major risk factors for cervical cancer, such as HPV types 16 and 18, which are well established causative agents. Meanwhile, the clinical significance of other factors, such as viral load, persistence and clearance rates of virus over time on the severity and progression of cervical cancer have only recently been recognized. In particular, co-infection of high- and low-risk HPV types has now been identified as a risk factor for increased morbidity and disease progression. Outcome-based clinical studies in regard to HPV vaccines have demonstrated the advantages of long-term monitoring of infected HPVs in association with persistent efficacy and cross-genotype protection. Unfortunately, current HPV diagnostic tools are restricted to use for the detection, identification and quantitation of multiple HPV genotypes.

Anyplex™ II HPV28 Detection has been specifically designed to address this unmet medical need through simultaneous detection, differentiation and quantification of 28 distinct HPV genotypes (19 high-risk and 9 low-risk) responsible for cervical cancer and/or sexually transmitted infections. Based on Seegene’s proprietary DPO™ and TOCE™ technologies, this homogeneous assay performs on real-time PCR instruments to detect and differentiate high- and low-risk HPV infections.

**Features**

- Accurate genotyping of 28 HPV types in a single reaction
- Multiplex real-time PCR with high sensitivity and specificity by utilization of DPO™ and TOCE™ technologies
- Amenable to automated sample handling and assay systems
- Utilization of the UDG system to prevent carry-over contamination
- Endogenous whole process control for assay validity
- Convenient data interpretation by Seegene Viewer

**Specimens**

- Cervical swab
- Liquid based cytology specimen (ThinPrep® and SurePath™)

**Analyses**

- 19 High-risk HPV genotypes:
  - 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 73, 82
- 9 Low-risk HPV genotypes:
  - 6, 11, 40, 42, 43, 44, 54, 61, 70
- Internal Control

**Seegene’s automated platform**

- Automated Extraction & PCR setup
  - Seegene NIMBUS / Seegene STARlet
- Automated Pre-analytic System
  - VCMS (Vial Cap Management System)
- Real-time PCR
  - CFX96™ Dx

*STARlet IVD with VCMS (vial cap management system) automates pre-analytic steps for primary vial, ThinPrep® and SurePath™, such as de-capping, aliquot and re-capping.
Purpose of HPV DNA Test

HPV DNA tests should provide maximum information (genotype, co-infection, quantitative result) about the infection to facilitate the clinical follow up of the patient.

Natural history of cervical cancer

High-risk or low-risk?
Which genotypes?
Single or co-infection?
Viral quantity?

Normal cervix
HPV infected cervix
Cancer

Cytology test
Colposcopy referral
Routine screening
Colposcopy referral

HPV 16, 18 positive
Primary HPV HR DNA test (HPV positive)

ASC-US / HPV
LSIL+ / HPV

ASC-US / Other HR type
35, 39, 51, 56, 59, 66, 68

ASC-US / Nonavalent vaccine HR type
16, 18, 31, 33, 45, 52, 58

A new screening approach is required
1. Vaccination effect: An increase of HPV vaccination coverage is likely to lead to lower prevalence
2. Low specificity: Referring HPV+ women with ASC-US to colposcopy is not efficient, because the large number of women do not have precancer or anything related to cervical cancer
3. Management trend: Risk thresholds* rather than individual results

General example of triage algorithm for primary HPV screening

1. HPV genotyping for HPV16, HPV18 and cytology in US
2. HPV positive and cytology in Europe

Women with ASC-US or higher are referred to colposcopy

Warning: The primary HPV screening program in USA.
Warning: The primary HPV screening program in the Netherlands.

For primary HPV screening, Anyplex™ II HPV28 detection can help
1. Setting risk threshold
2. Considering new alternative scenario
3. Proposing better algorithm

through identifying major high-risk HPV including vaccine-covered type
Effective tool for national cervical cancer screening in post-vaccination era

The HPV vaccination had a substantial impact on genotype distribution.

1. Monitoring infection dynamics such as type replacement or unmasking in a vaccinated population\(^5\)

Study 1. HPV prevalence and vaccine efficacy 8 years following the implementation of the vaccination program in Luxembourg

The overall prevalence of HPV showed a very similar rate between the two groups, however, the type distribution was dramatically changed in certain types covered by HPV vaccine and other types assuming cross-protection. For instance, HPV 16, 31, and 33 were significantly decreased in vaccinated women, but not in the unvaccinated group. Instead, other types such as HPV 51, 58, and 59 were found as the most frequent types in vaccinated women.

Study 2. Prevalence of vaccine type HPV in vaccinated and non-vaccinated women in Switzerland

The prevalence of four types, HPV6/11 and HPV 16/18, covered by the quadrivalent vaccine was significantly lower in vaccinated women, whereas cross-protection was not observed in this study.

2. Measuring the efficacy affecting the vaccine policies and strategies\(^6\)

The impact of Seegene's HPV assay in the post-vaccination era:

- Monitoring changes of HPV types in a vaccinated population
- Evaluating the prevalence of HPV vaccine types
- Measuring the efficacy and cross-protection of vaccine
**Anyplex™ II HPV28 Detection was proved its excellent performance in WHO evaluation**

- Excellent genotype detection even in multiple infections
- Great sensitivity, specificity and inter-lab reproducibility

**Percent proficient results of HPV types as claimed to be detected by test**

<table>
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<tr>
<th>Type of HPV assay</th>
<th>Number of data sets</th>
<th>100% proficient</th>
<th>99-90% proficient</th>
<th>89-80% proficient</th>
<th>&lt;80% proficient</th>
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100% proficiency in all tests performed by participants (11 labs worldwide)

**Information of participants**

- Total number of participants: 121 laboratories
- Distributions: Europe (70), America (14), Western Pacific (25), South East Asia (8), Africa (3), Eastern Mediterranean (1)
- Total number of datasets: 148

Anyplex™ II

HPV28 Detection

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Ordering Information

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<td>Anyplex™ II HPV HR Detection</td>
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<td>Real-time PCR _ Thermal Cycler</td>
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<td>Seegene NIMBUS</td>
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<td>Seegene STARlet</td>
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<td>STARMag 96 X 4 Universal Cartridge kit</td>
<td>Nucleic acids extraction reagent</td>
<td>744800.4.UC384</td>
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Not Available for Sale in the United States

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