Not Available for Sale in the United States

Anyplex™ II

# 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

Superior

**HIGH SENSITIVITY & SPECIFICITY**

Multiplex real-time PCR with high sensitivity and specificity by utilization of DPO™ and TOCE™ technologies

Seegene

Anyplex™ II

REAL TIME PCR | CE-IVD Marked

# HPV28 Detection

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.

## Analytes

- **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

## Specimens

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

## Features

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

## Compatible Instrumentation (CE-IVD Marked)

- **Automated Extraction & PCR setup**
  Seegene NIMBUS IVD / Seegene STARlet IVD
- **Automated Extraction**
  NucliSENS® easyMAG® (BioMérieux)
- **Real-time PCR**
  CFX96 DX

## Automation of preanalytic steps (STARlet IVD with decapping system)

STARlet IVD with decapping system automates preanalytic steps for primary vial, ThinPrep® and Surepath™, such as decapping, vortexing and recapping. This system saves hands-on time and minimizes the risk of contamination, while maintaining the reliability of results.

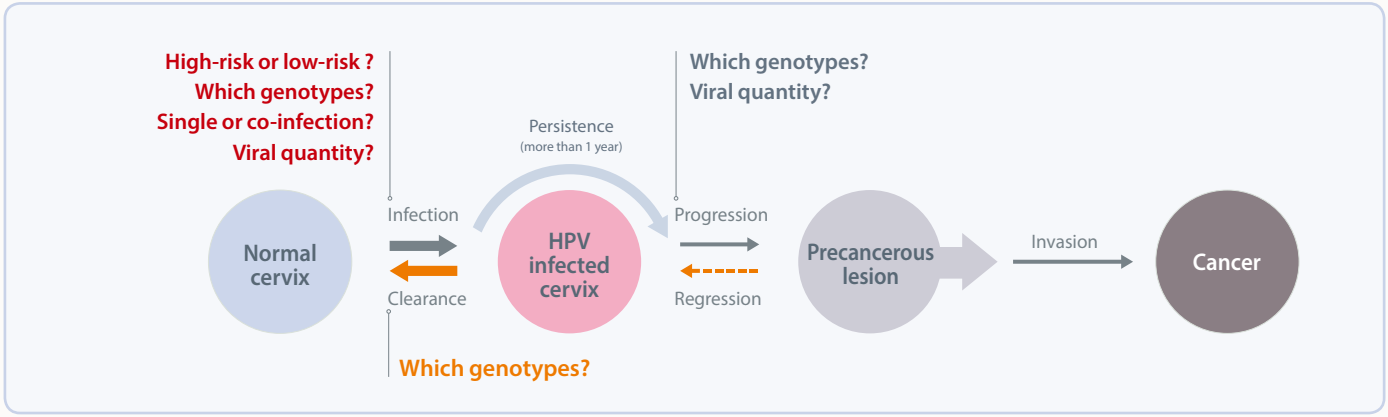
## Workflow - Accurate & Convenient Automated Platform

Automation via validated NIMBUS IVD & STARlet IVD increases user convenience and decreases hands-on time.

## 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 [1]




1) Shiffman M *et al.* The promise of global cervical cancer prevention. *N Engl J Med* (2005) **353**(20) : 2101-4

## Necessity for the HPV tracking management

### 1. Genotyping for the 28 HPV types

- **HPV16, HPV18: Detected in 70% of cervical cancer** [2, 3]
- **HPV31, HPV33: Showed significantly low clearance rate** [2]
- **HPV52, HPV31, HPV58: Reported frequently following HPV16 in precancerous stage** [3]
- **10-most prevalent HPV types detected in cervical cancer (world)** [3]

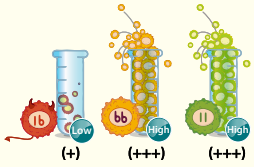
  HPV16, HPV18, HPV45, HPV53, HPV58, HPV31, HPV52, HPV35, HPV39, HPV59

### 2. Identification of Co-infection with multiple HPV types


- **Co-infection contributes to an increased infection duration.** [4, 5]
- **Co-infection increases risk of cervical cancer and accelerates time of onset.** [6, 7, 8]

1) Co-infection is reported frequently in cervical cancer and precancerous lesion [6]
2) Co-infection accelerates the rate of progression into cervical cancer and precancerous lesion [7]
3) Co-infection accelerates progression and development into cervical cancer with the cumulative number of HPV types.[7]
4) Co-infection increases the risk of cervical cancer significantly.[8]

### 3. Viral load information of infected HPV

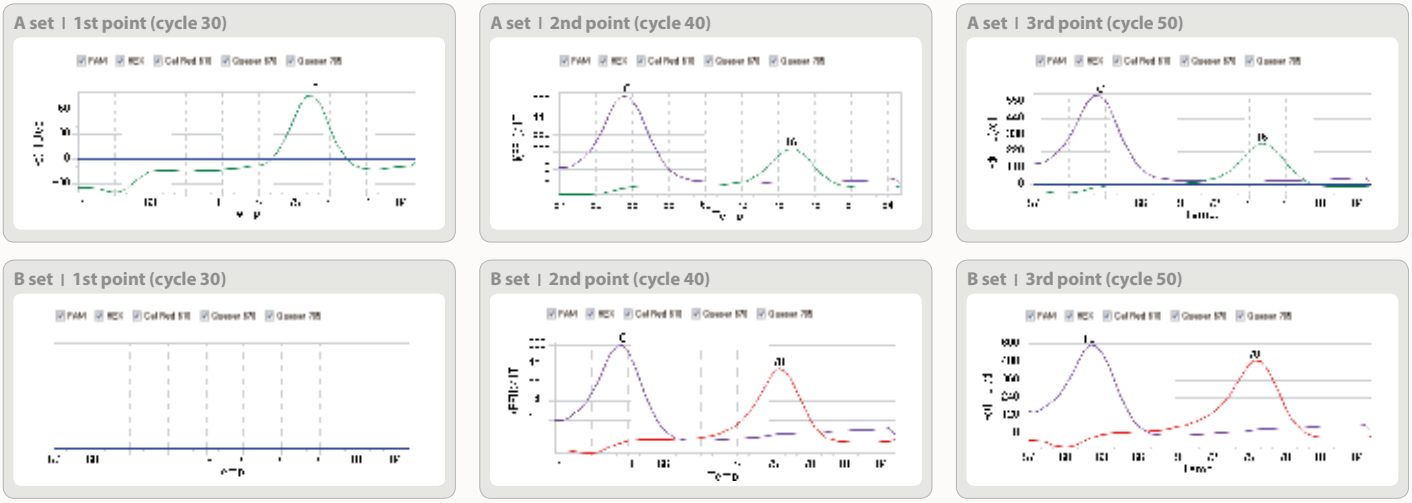



- **Viral load information of HR-HPV has significant relationship with degree of CIN.** [9]
- **10-fold increase in HPV viral load is associated with a significantly increased risk of acquiring and incident cervical cytologic abnormality in women during follow-up.** [10]
- **HR-HPV viral load information should be reported in the routine molecular HPV test.** [9]

2) NWJ Bulkmans *et al. British J Cancer* (2007) **96** : 1419-1424
3) www.hpvcentre.net (Annual report) world. ICO Information Centre
4) Trottier H *et al. J Infect Dis* (2008) **197**: 1436-47
5) Stocco Rde C *et al. BioMed Res Int.* (2014) **2014**: 879013
6) Kim NR *et al. The Korean J. Pathol.* (2014) **48**: 43-49
7) Helen Trottier *et al. Cancer Epidemiol Biomarkers Prev* (2006) **15**: 1274-1280
8) Yong Sang Song *et al. Cancer Letters 198* (2003) 187–192
9) Yuanchun Xu *et al. J Exp Pathol Int.* (2009) **2**:169-175
10) Christothea Constandinou-Williams *et al. Cancer Epidemiol Biomarkers Prev* (2010) **19**(3): 832-70

## Example Data

### Clinical samples analysis

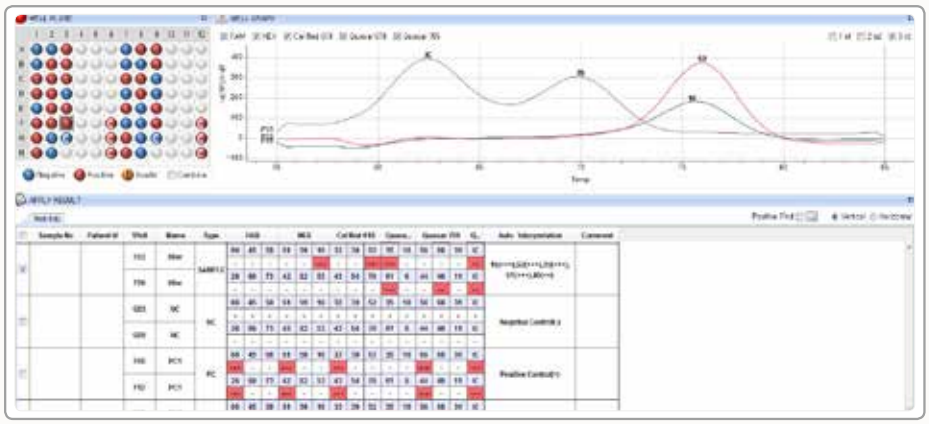



### Result interpretation

| Set | HPV genotypes | | | | | | | | | | | | | | | Auto interpretation |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A set | 16 | 18 | 31 | 33 | 35 | 39 | 45 | 51 | 52 | 56 | 58 | 59 | 66 | 68 | IC | HPV16 (+++)<br>HPV70 (++) |
| | +++ | - | - | - | - | - | - | - | - | - | - | - | - | - | ++ | |
| B set | 6 | 11 | 26 | 40 | 42 | 43 | 44 | 53 | 54 | 61 | 69 | 70 | 73 | 82 | IC | |
| | - | - | - | - | - | - | - | - | - | - | - | ++ | - | - | ++ | |

HPV16 and 70 were analyzed with the Anyplex™ II HPV28 Detection from a clinical sample. The Catcher-Tm can be measured repeatedly at 30, 40 and 50 cycles during the PCR process. The difference of points represents the amount of each virus type. HPV16 appears in the first point (cycle 30), whereas HPV70 appears in the second point (cycle 40). The results indicate that the patient carries HPV16 in high number of copies and HPV70 in intermediate number of copies .

## Result



## Seegene Viewer

### Quick and easy data analysis & interpretation

a. Interface specialized for multiplex testing
b. Interlocked with LIS
c. Patient information input via barcode scanning system or LIS system
d. Printable in various formats
e. Downloadable results in a CSV file
f. Convenient read out for quantitative analysis result

# 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 [1)]

| Type of HPV assay | Number of data sets | 100% proficient | 99-90% proficient | 89-80% proficient | <80% proficient | Not proficient |
|---|---|---|---|---|---|---|
| **All assays** | **148** | **89** | **14** | **9** | **5** | **31** |
| **Linear Array (Roche)** | 14 | 7 | 0 | 1 | 0 | 6 |
| HPV Direct Flow-chip (Master Diagnostica) | 14 | 9 | 0 | 0 | 0 | 5 |
| GenoFlow HPV array (DiagCor) | 14 | 13 | 0 | 0 | 0 | 1 |
| **Anyplex™ Ⅱ HPV28 Detection (Seegene)** | **11** | **11** | **0** | **0** | **0** | **0** |
| In-house PCR Luminex | 8 | 3 | 1 | 1 | 0 | 3 |
| In-house realtime PCR | 8 | 4 | 0 | 1 | 1 | 2 |
| In-house PGMY-CHUV | 6 | 4 | 0 | 0 | 0 | 2 |
| In-house blot | 6 | 2 | 0 | 2 | 0 | 2 |
| **Papillocheck (Greiner)** | 5 | 4 | 0 | 1 | 0 | 0 |
| **Onclarity (Becton Dickinson)** | **5** | **5** | **0** | **0** | **0** | **0** |
| **CLART HPV 2 / 4 (Genomica)** | 4 | 0 | 1 | 1 | 2 | 0 |
| **Cobas 4800 (Roche)** | **4** | **4** | **0** | **0** | **0** | **0** |
| **InnoLiPA (Fujirebio)** | 4 | 1 | 2 | 0 | 0 | 1 |
| PANA Realtyper 1001 (Panagene) | 3 | 0 | 3 | 0 | 0 | 0 |
| PANArray Genotyping Chip (Panagene) | **3** | **0** | **3** | **0** | **0** | **0** |
| Hybribio 21 HPV (Hybribio) | 3 | 3 | 0 | 0 | 0 | 0 |
| **RealTime HPV (Abbott)** | **3** | **1** | **0** | **2** | **0** | **0** |
| In-house sequencing | 3 | 0 | 0 | 0 | 0 | 3 |
| HPV SPF10-LiPA25 | 2 | 0 | 0 | 0 | 0 | 2 |
| HPV XpressMatrix™ (DNA laboratories) | 2 | 2 | 0 | 0 | 0 | 0 |
| Ampliquality (Analitica) | 2 | 0 | 1 | 0 | 0 | 1 |
| Hybribio 13 HR (Hybribio) | 2 | 2 | 0 | 0 | 0 | 0 |
| Hybribio 14 HR (Hybribio) | 2 | 2 | 0 | 0 | 0 | 0 |
| PANA Realtyper 1002 (Panagene) | 2 | 0 | 2 | 0 | 0 | 0 |
| Optiplex (DIAMEX) | 2 | 2 | 0 | 0 | 0 | 0 |
| Other Commercial assays | 14 | 9 | 1 | 0 | 1 | 3 |
| Other In-house assays | 2 | 1 | 0 | 0 | 1 | 0 |

**100% proficiency in all tests perfomed 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

Reference 1) Carina EKlund *et al.* J CLIN VIROL. (2018) 101:74-85

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## Ordering Information

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| Product | Package Volume | Cat. No. |
|---|---|---|
| Anyplex™ II HPV28 Detection | 100 rxns | HP7S00X |
| Anyplex™ II HPV HR Detection | 100 rxns | HP7E00X |
| **Instrument** | **Type** | **Cat. No.** |
| CFX96 DX | Real-time PCR _ Optical Reaction Module | 1845097-IVD |
| | Real-time PCR _ Thermal Cycler | 1841000-IVD |
| Seegene NIMBUS IVD | Automated extraction & PCR Setup | 65415-03 |
| Seegene STARlet IVD | Automated extraction & PCR Setup | 67930-03 |
| STARMag 96 X 4 Universal Cartridge kit | Nucleic acids extraction reagent | 744800.4.UC384 |


Seegene

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