Human Papillomavirus

INNO-LiPA™ HPV Genotyping EXTRA II based on SPF10 (c) (c)

- 32 genotypes - one genotype = one probe line
- Ready-to-use mastermix - automation
- Cervical cells and first-void urine (CE)
- FFPE-samples (RUO)
- Primer mix for RT-PCR application (RUO)
The power of HPV genotyping

Knowing your patient’s papillomavirus (HPV) genotype
Knowing how long the infection has persisted
Can help optimize patient management

Genotype now

• Genotype for key information: Genotyping is the only method that can inform you whether a specific carcinogenic HPV genotype is present.

• Genotype more than once: HPV type-specific monitoring allows you to check for viral persistence of specific genotypes – a key factor for possible progression to precancer.

• Genotype to determine multiple infections: Multiple infections often occur, especially in immuno-compromised individuals, and may increase the risk for cervical cancer.

• Genotype routinely after vaccination: Current vaccines do not protect against all high-risk HPV types. Elimination of HPV16 and 18 could lead to increased transmission of non-vaccine types.
**Test Procedure**

**Step 1**
- Cervical cells, first-void urine (CE)
- FFPE (RUO)
  
  DNA extraction

**Step 2**
- Ready-to-use mastermix
  
  Amplification

**Step 3**
- Hybridization on strips

**Step 4**
- Manual interpretation
- Automated interpretation
**Benefits of the Product**

- Full genotyping:
  - simultaneous detection of 32 HPV genotypes
  - SPF10 Plus provides high test sensitivity due to the precision of the short 65-base pair PCR product
  - SPF10 Plus permits simultaneous detection of multiple genotypes in a single sample

- Build-in controls:
  - Special HPV control lines to confirm and detect the presence of a broad range of mucosal HPV genotypes plus additional controls to monitor sample processing (hDNA line, conjugate control line)

- Streamlining:
  - Easy and ready-to-use master mix, with Taq DNA polymerase provided for minimum manipulation steps and hands-on time

- CE Applications:
  - cervical cells collected in Surepath medium or PreservCyt medium
  - first-void urine with preservative

- RUO Applications:
  - paraffin-embedded (FFPE) material
  - HPV Primer Mix SPF10 Plus for Real-Time PCR application

- Automation:
  - Auto-LiPA™ 48: up to 48 tests per run from sample incubation to color development
  - AutoBlot 3000H: up to 20 tests per run from sample incubation to color development
  - TENDIGOTM: up to 10 tests per run from sample incubation to color development
  - Results within ±3 hours
  - Minimum hands-on time, accurate results
  - Interpretation software for complete traceability

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**Easy and Comprehensive**

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*HR* = High Risk

*pHR* = Potential High Risk

*LR* = Low Risk
Fully automated from sample hybridization to interpretation. Flexibility according to your needs.

**Manual or automated assay performance**
Instrumentation available for processing 1 up to 48 strips in 1 run

**What you do:**
1. Bring materials to room temperature
2. Start the instrument
3. Load reagents and samples
4. Start run and ...

**walk away**

**What the instrument does:**
Fully automated test performance from sample incubation to color development ...
1. Hybridization
2. Stringent washes
3. Color development

**What you get:**
Strips ready for interpretation

**What LiRAS® for LiPA HPV does:**
Objective interpretation of developed strips ...
1. Scanning mode with integrated calibration
2. Saves electronic image of each strip
3. Audit trail
4. Genotyping result for each sample

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**Easy Manual interpretation:** One line = one genotype

or

**Automated interpretation**

**What to do:**
1. Stick strips on reading template
2. Start software
3. Select INNO-LiPA™ HPV Genotyping product
4. Choose data entry model
   - Enter data manually
   - Scan developed strips
5. Print reports

**What you get:**
Full standard report or brief summary report adjustable to your needs
## FOR ORDERING

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>ARTICLE NO.</th>
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<tr>
<td><strong>Assays</strong></td>
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<td>INNO-LiPA™ HPV Genotyping <em>Extra II</em></td>
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<td>INNO-LiPA™ HPV Genotyping <em>Extra II</em></td>
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