Simplified Positive (%)

Hybrid Capture Kit Positive
23/30 (77%)

1x mix
T
420

Negative
27
A
12/24 (50%)
22
3.8%
1 cycle
49 (83%)

The most sensitive HPV detection methodology is PCR, which readily detects a single viral copy in a human sample. Indeed, the L1 consensus primers have become the most widely used in the detection of HPV. The most recent version of the primer set includes the addition of a cytosine residue to uracils, which are subsequently amplified as thymines. This conversion essentially results in the specific detection of all high-risk strains.

The detection of multiple microbial strains in a single reaction without the need for multiplexing, which is often the case with DNA sequencing, has been the goal of several DNA simplification methods. These have included the use of nucleases (S1 nuclease, T4 DNA polymerase) to degrade both the complementary and non-complementary strands of DNA strands, sequence specific cleavage by restriction enzymes, and the digestion of RNA molecules with RNase. The methods can generally be categorized by their ability to simplify and are summarized in the Table below:

Introduction: Sensitive molecular diagnostic assays are of particular importance when the infectious agent is of low prevalence in a normal population. This is especially true for the detection of High-Risk HPV in a sample. Genotyping or specific species detection can still be performed as there is sufficient heterogeneity among the different strains.

Several nucleic acid amplification methods are available for the reliable detection of pathogens consisting of a large number of common nucleic acid sequences. The most common is the PCR method that relies on the specific amplification of target DNA sequences.

DNA simplification is a novel approach for the reliable detection of pathogens consisting of a large number of common nucleic acid sequences. The most common is the PCR method that relies on the specific amplification of target DNA sequences.

Genotyping of Normal Samples

Table 1: FOXP4 Criterion

<table>
<thead>
<tr>
<th>Sample #</th>
<th>Positive by Genotyping</th>
<th>Cytology Normal (183)</th>
<th>ASC-US (18)</th>
<th>HSIL (6)</th>
</tr>
</thead>
</table>

Table 2: Comparison of Sensitivity, Specificity and Predictive Value

<table>
<thead>
<tr>
<th>Table 2a: Comparison of Sensitivity, Specificity and Predictive Value (number positive)</th>
<th>Table 2b: Comparison of Sensitivity, Specificity and Predictive Value (number negative)</th>
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</table>

Figure 3. The result of the Human Genetic Signatures High-Risk HR-HPV test shown for the 16 HPV DNA test. A subset of 159 positive samples was used to test the accuracy of the test. The results were compared to the PrevcyCyt HPV test, and then to the HGS HR-HPV test.

The sensitivities of all 159 positive samples were tested to the 16 HPV DNA test. The HGS HR-HPV test was developed on a 157-sample set against full-length HPV DNA. The sensitivity is therefore 107/108 = 98.1% (95% CI 95.4 to 99.7%). The specificity was tested on 1,157 samples, and the results showed 1,022 samples were positive and 135 were negative, giving a specificity of 97.4% (95% CI 95.5 to 98.3%).

The Overall test characteristics of the HGS HR-HPV test were compared with the Digene test (202/312 = 64.7% (59.2 to 70.0%) but the difference between the two tests is not statistically significant (P = 0.398).

The NPV of the HGS test was 473/588 or 80.4% (95% CI 77.0% to 83.6%) and the PPV was 392/438 = 89.3% (86.6 to 91.4%). The difference in sensitivity between the two tests is statistically significant (P = 0.002). The PPV of the Digene test was 198/222 = 89.4% (88.5 to 90.3%), which is not statistically different from the HGS test's PPV.

Table 3a: Comparison of Sensitivity, Specificity and Predictive Value

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The PPV of the HGS test was 392/438 = 89.3% (86.6 to 91.4%). The PPV of the Digene test was 198/222 = 89.4% (88.5 to 90.3%), which is not statistically different from the HGS test's PPV.

Table 3b: Comparison of Sensitivity, Specificity and Predictive Value

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Table 3c: Comparison of Sensitivity, Specificity and Predictive Value

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