OncoE6™ Cervical Test
Cervical Cancer E6 Oncoprotein Biomarker Test

PROBLEM
There is a need for a test that is highly specific and predictive of cervical pre-cancer and cancer. Such a test could reduce over-treatment and decrease mortality due to more accurate detection of cervical pathology.

SOLUTION
Cervical cancer is caused by HPV (human papillomavirus) infection and transformation by the viral oncoprotein E61-4. The OncoE6™ Cervical Test detects elevated levels of the HPV types 16 or 18 E6 oncoproteins in cervical swab samples. These levels are indicative of pre-cancer and cancer. As a result Arbor Vita's OncoE6™ Cervical Test achieves unmatched clinical specificity, providing medical professionals the clarity that is lacking in PAP or HPV DNA/RNA only tests.

Clear
- Independently validated in an international study1
- 99% Specificity = fewest false-positives results
- 99% NPV = meaningful negative results

Simple
- Sample collected with a swab
- Tests can be conducted in the physician office
- Minimal equipment required
- Dipstick format – easy to use
- Same day results

Patient Management
- Positive results should be referred for follow-up
- Test results in 8-fold fewer referrals to colposcopy1.
- Half of the positives on follow-up have pre-cancer or cancer

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Simple test format with visual read.
No special equipment required.

10July2014, MKT014 Rev B.
**ONCOE6™ CERVICAL TEST CLINICAL PERFORMANCE**

<table>
<thead>
<tr>
<th></th>
<th>Specificity CIN3+ (%)</th>
<th>PPV CIN3+ (%)</th>
<th>NPV CIN3+ (%)</th>
<th>Colpo ref rate (%)</th>
<th>Prevalence CIN3+ (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OncoE6™ Cervical Test</td>
<td>98.9</td>
<td>40.8</td>
<td>99.3</td>
<td>1.8</td>
<td>1.3</td>
</tr>
<tr>
<td>HPV DNA (HC2) *</td>
<td>86.6</td>
<td>9</td>
<td>99.9</td>
<td>14.5</td>
<td></td>
</tr>
<tr>
<td>VIA**</td>
<td>93.4</td>
<td>9.4</td>
<td>98.9</td>
<td>7.3</td>
<td></td>
</tr>
</tbody>
</table>

Data from START-UP clinical study; see Reference [1]

*HC2 – Qiagen: Hybrid Capture® 2 HPV DNA Test™; **VIA - visual inspection with acetic acid

Worldwide, 10-15% (23% in the US) of women are positive for high risk human papillomavirus (HPV). Only a very small fraction of these women progress to cancer. The OncoE6™ Cervical Test detects elevated levels of the cancer causing E6 oncoprotein*. This results in high specificity, high positive predictive value and the lowest number of false positives. The OncoE6™ Cervical Test is therefore ideally designed to identify those women who need clinical follow up in a triage scenario and may also be considered for primary screening in a low resource setting. The test is easy to use, requires no complex equipment, and is stable at room temperature.

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**Test Kit Contents**

<table>
<thead>
<tr>
<th>Sample Processing Box</th>
<th>Part# 2000000</th>
</tr>
</thead>
<tbody>
<tr>
<td>- All components and materials to run 24 tests</td>
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<table>
<thead>
<tr>
<th>Sample Collection Box</th>
<th>Part# 2001000</th>
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<tbody>
<tr>
<td>- 24 polyester swabs and specimen storage tubes</td>
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<table>
<thead>
<tr>
<th>Available: Starter Kit</th>
<th>Part# 2000031</th>
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<tbody>
<tr>
<td>- Solution Stand, 2 Test Platforms, 2 Reading Guides, 1 Quick Guide</td>
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**References:**


*July 2014, MKT014 Rev B.*