

Simple Visual Interpretation

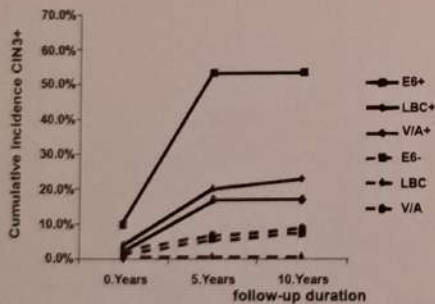
Worldwide, 10-35% of women are positive for high risk human papillomavirus (HPV). Only a very small fraction of these women progress to cancer. The OncoE6™ Cervical Test detects elevated levels of the cancer causing E6 oncoprotein<sup>4</sup>. This results in high specificity, high positive predictive 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. The test is easy to use, requires no complex equipment, and is stable at room temperature.

## ONCOE6™ CERVICAL TEST CLINICAL PERFORMANCE

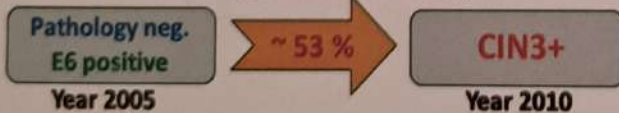
	Specificity CIN3+ (%)	PPV CIN3+ (%)	NPV CIN3+ (%)	Colpo ref rate (%)	Prevalence CIN3+ (%)
OncoE6™ Cervical Test	98.9	40.8	99.3	1.8	1.3
HPV DNA (HC2) *	86.6	9	99.9	14.5	
VIA**	93.4	9.4	98.9	7.3	

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

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



Data and figure from Reference (6)



**Left:** A 10 year follow-up study<sup>6</sup> revealed the OncoE6™ Cervical Test to provide highest prediction of future cervical malignancy, undetected at the time of testing by cytology or histology; this early detection of true pre-cancer allows for most effective treatment

### References:

- Zhao F-H, Jeronimo J, Qiao Y-L, et al. An Evaluation of Novel, Lower-Cost Molecular Screening Tests for Human Papillomavirus in Rural China. *Cancer Prev Res* 2013;6:938-948.
- Qiao YL, et al. 2013. Lower cost strategies for triage of human papillomavirus DNA-positive women. *Int J Cancer*. 2014 Jun 15;134(12):2891-901.
- Sellers, JW et al. Association of elevated E6 oncoprotein with grade of cervical neoplasia using PDZ interaction-mediated precipitation of E6. *Journal of Lower Genital Tract Disease* 2011; 15(2): 169-176; doi: 10.1097/LGT.0b013e3181f6c84d
- Schweizer, J. et al. Feasibility Study of a Human Papillomavirus E6 Oncoprotein Test for Diagnosis of Cervical Precancer and Cancer *J Clin Microbiol* 2010; 48(12), 4646-4648; doi: 10.1128/JCM.01315-10.
- Doorbar, J. Molecular biology of human papillomavirus infection and cervical cancer. *J. Clin Science* 2006;110:525-541; doi:10.1042/CS20050369
- Zhang, Q. et al., Risk stratification and long-term risk prediction of E6 oncoprotein in a prospective screening cohort in China (2017) *Int J Cancer* 141, 1110-1119



**MEDX**

**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 E6<sup>1-5</sup>. 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, VIA or HPV DNA/RNA only tests.

# OncoE6™ Cervical Test

Cervical Cancer E6 Oncoprotein Biomarker Test



## Clear

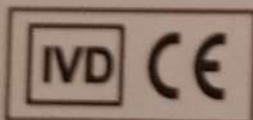
- Independently validated in international studies<sup>1,2,6</sup>
- 99% Specificity = fewest false-positives results
- 99% NPV = meaningful negative results

## Simple

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

## Patient Management

- Positive results should be referred for follow-up
- Results in 8-fold fewer referrals to follow-up than HPV test<sup>1,2</sup>.
- Half of the positives on follow-up have pre-cancer or cancer



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