

PULSE

NEWSLETTER



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HE4
OncoE6

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The OncoE6 Cervical Test

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Too Much Sodium?



Cervical Cancer Awareness Month
Spread, Smear, Screen!

PANTAI NATIONAL SYMPOSIUM 2014: CERVICAL CANCER SCREENING UPDATE



NEW TEST

OncoE6 Cervical Test

"A New Breakthrough in Cervical Cancer Screening"



Cervical Cancer

- Worldwide, cervical cancer is the **third most common** cancer among women and around **80,000 new cases** diagnosed annually¹
- Malaysia, cervical cancer ranks as the **2nd cause** of female cancer and around **2,000 new cases** diagnosed annually¹

WHO estimated more than **270,000 death** from cervical cancer every year and more than **85%** occur in **developing countries**²

Cervical cancer and Human Papilloma Virus (HPV)

» Persistent HPV infection cause cervical carcinogenesis

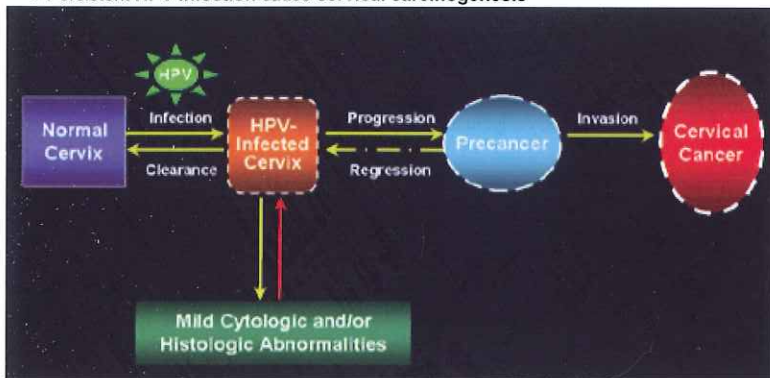


Figure: Natural History of Cervical Carcinogenesis³

» HPV 16 & 18 – causes about 70% cervical cancer²

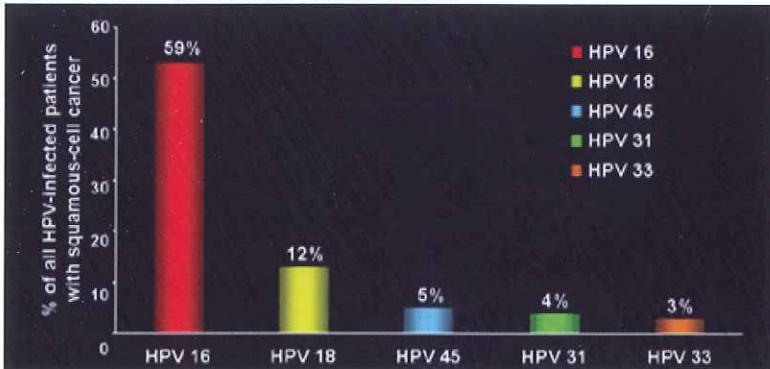


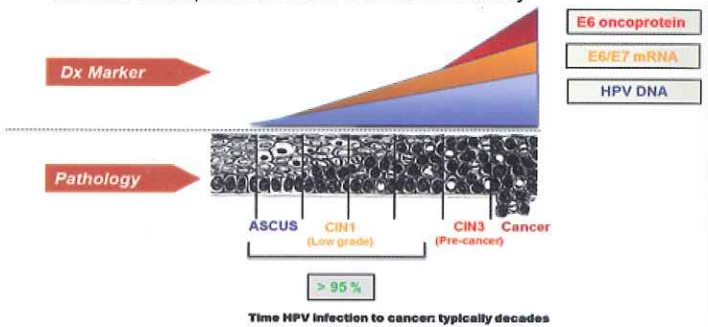
Figure: Most Prevalent HPV Types that Cause Cervical Cancer³

Reference

- Bruni L, Barrionuevo-Rosas L, Serrano B, Brotons M, Cosano R, Muñoz J, Bosch FX, de Sanjosé S, Castellsagué X. ICO Information Centre on HPV and Cancer (HPV Information Centre). Human Papillomavirus and Related Diseases in Malaysia. Summary Report 2014-03-17.
- Retrieved from WHO Fact sheets on Human papillomavirus (HPV) and cervical cancer (<http://www.who.int/mediacentre/factsheets/fs380/en/>)
- Retrieved from Epidemiology and economic impact of HPV-related Disease by Mark Spitzer, MD (http://www.medscape.org/viewarticle/508691_1)
- Zhao et al. Cancer Prev. Res., 6(9) 2013

What is HPV E6 Oncoprotein?

- Promote cell proliferation by stimulating degradation of tumour suppressor p53 protein
- Expression of HPV E6 oncoprotein cause cervical epithelial cell transformation and lead to cancer progression
- Elevated E6 oncoprotein correlates to cancerous activity



Our OncoE6 Cervical Test

- Detect HPV 16 and 18 E6 oncoprotein in one test
- CE marked
- Able to identify women in need of follow-up among the many more with clinically irrelevant HPV infection
- High specificity and high positive predictive value (PPV) to lower referral rates to clinical follow-up
- Detect disease in the age group where cancer most often occurs

Utility of the OncoE6 Cervical Test

- Primary screening:
 - As primary screening, OncoE6 Cervical Test able to detects 70-90% of cancers; no loss on follow-up
 - Allows effective screening for populations with very high HPV prevalence
- Co-testing:
 - In settings where Pap cytology is established, co-testing with OncoE6 Cervical Test enhances true positive rates and reduce loss on follow-up
- Triage:
 - OncoE6TM Cervical Test used in Triage upon positive HPV result reduces referral rate to colposcopy and to unnecessary biopsies

Code : ONCOE6
 Specimen Type : LBC (ThinPrep) / cervical swab
 TAT : 24 hours (1 working day)

Profile Test Descriptions

Code	Specimen Type	TAT
1. ONCOE6 + LBC (Thin Prep)	OE6LBC LBC	1 week

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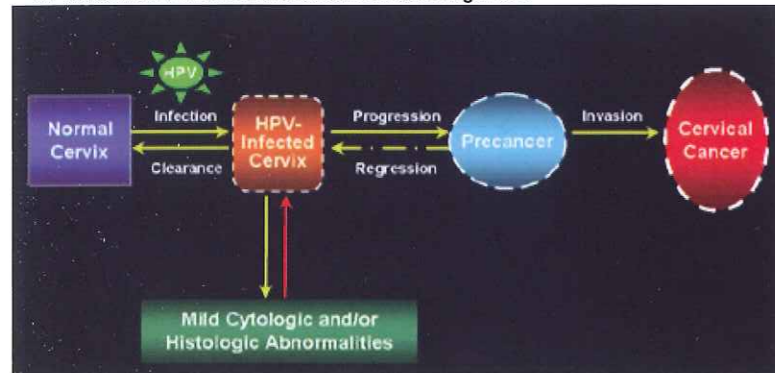


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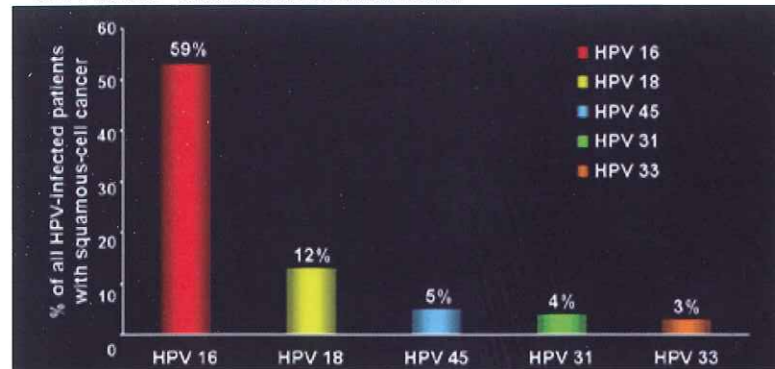


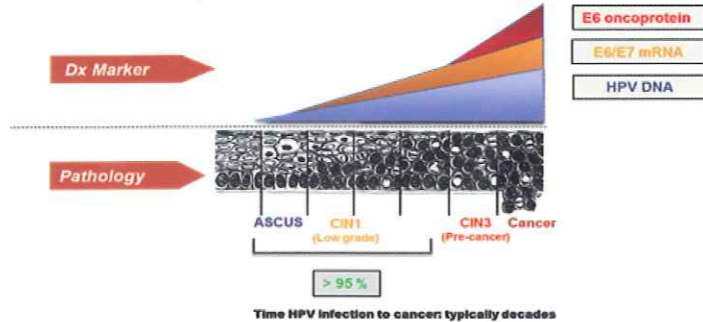
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Johannes G. Schweizer, Ph.D.

Dr. Schweizer is the Vice President, Cervical Cancer Programs and R&D at Arbor Vita Corporation, USA. He initiated PDZ cloning and development of the company's proprietary PDZ platform. Dr. Schweizer completed his postdoctoral fellowship at Howard Hughes Medical Institute, Stanford University, leading a research team's investigation of mechanisms that regulate genomic imprinting and their role in genetic disorders. He participated in the International Bacillus subtilis Genome Sequencing Programme following his research at the Pasteur Institute in Paris. Dr. Schweizer holds a Ph.D. with high honors in Genetics, Immunology, and Modern History of Biology from the Pasteur Institute and the University of Konstanz, Germany, and he received both an M.S. in Molecular Genetics and a B.S. in Biology from the University of Konstanz, Germany. He has authored numerous peer-reviewed scientific publications and is an inventor of 14 granted patents.



The OncoE6™ Cervical Test

– A New Level of Cervical Cancer Screening

Cervical Cancer is a major killer of women in Malaysia

Cervical cancer is a major cause of mortality in women worldwide, and it is the second most frequent cancer in women of Malaysia. Paradoxically, Cervical Cancer can be cured when discovered early, and as it develops typically over many years, prevention largely depends on our ability to identify those women who are at risk.

however, HPV is highly prevalent in sexually active women (10-15% in many countries), and only a very small proportion of all HPV infections will become cancerous. Consequently, a negative HPV test is informative, but a positive HPV test is much less informative and may lead to unnecessary and costly over treatment of many women.

The OncoE6™ Cervical Test is the first to directly detect the cancer causing molecule

Arbor Vita Corporation, a California based company, has developed the OncoE6™ Cervical Test. This CE marked test is very simple to implement and to perform, and allows for very efficient follow-up from doctor to patient. Importantly, and unlike any other Cervical Cancer test, the OncoE6™ Cervical Test delivers great accuracy by directly detecting elevated levels of the molecule causing the cancer. This molecule, called "E6 viral oncoprotein", is a highly informative marker of cervical cancer.



Can existing cervical cancer tests meet the challenge?

Pap Testing has reduced Cervical Cancer in developed countries, but its clinical accuracy is too low and its infrastructure requirements are too many to meet today's challenges. Lately, an emergence of tests detecting the HPV (Human Papillomavirus) is seen; infection with HPV virus is a prerequisite for Cervical Cancer,

The OncoE6™ Cervical Test: proven performance in clinical studies

In a large clinical study^{1, 2}, the OncoE6™ Cervical Test has shown an 8-fold reduction in positives compared to HPV testing, while having 99% specificity and 41% positive predictive value (PPV) for detection of cervical pre-cancer and cancer (PPV for HPV tests was <10% in this study). Thus, a positive OncoE6™ Cervical Test result is highly informative for cancerous changes to occur, unlike a positive HPV test. The study also revealed that a positive OncoE6™ Cervical Test indicates a high risk of future disease, even when cancerous changes are not yet detected by traditional methods. The OncoE6™ Cervical Test's clinical performance and the ease of use will guarantee a unique role in bringing clarity and actionable information to cervical cancer screening. In Malaysia, the OncoE6™ Cervical Test runs by Pantai Premier Pathology.

- Zhao, F.H. et al., Cancer Prev Res (Phila). 2013 Sep;6(9):938-48. doi: 10.1158/1940-6207. Epub 2013 Dec 3.
- Qiao, Y., et al., Int J Cancer. 2014 Jun 15;134(12):2891-901. CAPR-13-0091. Epub 2013 Jul 22

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