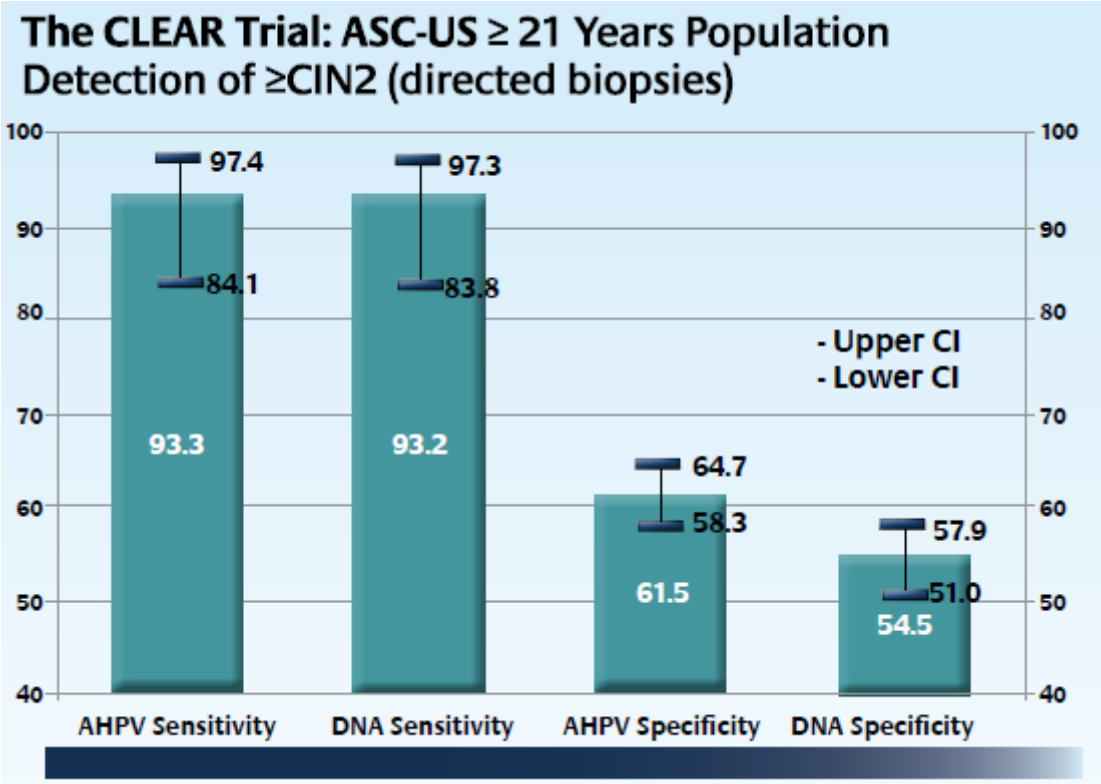
Cervical Cancer Screening

A New design with your patient and practice in Mind

Cervical cancer is the most prevalent cancer in Africa resulting in morbidity. More than 15.3 million women in South Africa are potentially at risk of developing cervical cancer. As such, there is a need to develop an optimal screening strategy to prevent cervical cancer.

The optimal screening strategy should identify those cervical cancer precursors likely to progress to invasive cancers (maximising the benefit of screening) and avoid the detection and unnecessary treatment of transient HPV infection and its associated benign lesions that are not destined to become cancerous (minimising the potential harm of screening).
Am J Clin Pathol 2012; 137:516- 542

The Aptima HPV Assay targeting E6/E7 mRNA is the next generation in cervical cancer screening. Aptima HPV targets 14 high risk serovars of HPV. Numerous studies have shown that mRNA E6/E7 identifies the presence and activity of high-risk HPV infection destined to lead to disease *(Tinelli A et al. Curr Pharm Biotechnol 2009 10 (8):767-771 & Cuschieri k et al J Med Virol 2004 73 (1): 65-70)*.



Maximising the Benefits

With the intervals between recommended screenings for cervical cancer extended, identifying those patients at risk becomes increasingly important. Excellent sensitivity means minimising false-negative test results.

The Aptima HPV assay targeting mRNA has been shown to have equivalent sensitivity to DNA assays.(Dockter 2009, Szarewski 2008, Szarewski 2012, Reuschenbach 2010, Clad 2011, Ratnam 2011, CLEAR 2011, Ovestad, Wu. 2010, Monsenego 2011, Cuzick 2011, Iftner 2012, CLEAR 2015).

Minimizing Potential Harm

Minimising false –positives helps clinicians target the right patient for colposcopy. In the NILM arm of the CLEAR trial, Aptima HPV showed 24% fewer false- positive tests compared to the HPV DNA assay. This will minimise patient anxiety and the potential of over-treatment and over burdening the health care system.

Longitudinal Data & Primary Screening

Recently (April 2016), the Aptima has obtained a primary screening claim. This is based on a longitudinal clinical trial of a large cohort of women. The conclusion of the results support the use of Aptima HPV as a safe and effective assay for primary cervical cancer screen (CLEAR Am J Clin Pathol 2015 144:473- 483). It has been shown in this trial that patients that are negative for Aptima HPV assay have a 0.3% chance of developing a CIN II + legion in the next 3 years. This allows for the increase of the screening intervals to 3 years.

The clinical performance of the Aptima HPV assay when used in a primary screening modality has been investigated in multiple studies by independent investigators. Thirteen peer-reviewed publications from ten separate clinical studiesreport the performance of Aptima HPV in primary screening in women enrolled in nine countries (China, Canada, France, Mexico, England, Denmark, The Netherlands, The United States, and Germany).

The data from these studies show that Aptima HPV has similar clinical performance compared to other clinically validated HPV tests when used for primary screening for cervical pre-cancer and cancer.

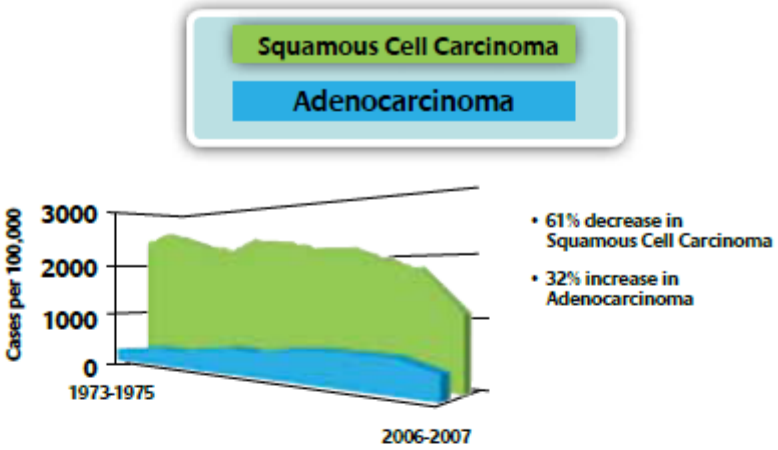
Reliability in results

The Aptima HPV assay has an in-built internal control which is added at the beginning of the specimen processing which controls all the activities of the assay to ensure confidence in the result.

Genotyping of the HPV

It has been found that squamous cell carcinomas are on the decrease and adeno carcinomas are on the increase.

Adenocarcinoma - A Rising Trend

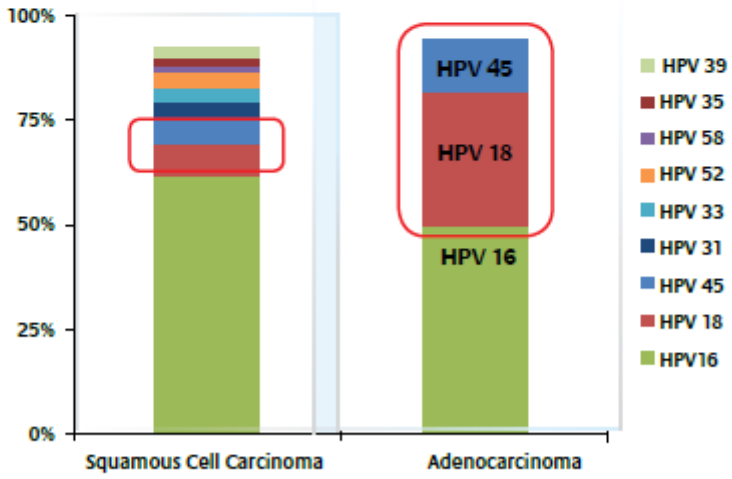


Adegoke et . al j. of women's health October 2012, 21 (10): 1031-1037

Three genotypes are responsible for adenocarcinomas 16/18/45. Aptima HPV mRNA E6/E7 is able to differentiate the HPV genotypes into four main groups

Genotype 16, Genotype 18, Genotype 45 and other groups comprising of (31, 33, 35, 39, 51, 52, 56, 58, 59, 66, 68)

HPV Types & Cervical Carcinomas*



* Any genotype that did not contribute more than 2% was not included in this chart

Figure 1 (adapted from de Banjose at al.)
Table 2: Cumulative relative contribution of the 3 most common HPV types in squamous cell carcinomas (SCC) and adenocarcinoma (ADC)