Identifying High Risk Genotypes to Determine Cervical Cancer Risk - BD OnclarityTM

From the introduction of the Pap diagnostic procedure, based on the research from Dr George Papanicolaou in 1943, to the first correlations between HPV and cervical carcinoma in 1983 by Dr Harald Zur Hausen (who earned the Nobel Prize in Physiology in 2008) there have been various cytology and molecular techniques that have been introduced to detect the virus.
Cervical cancer kills more than 300,000 women annually.[i] In 2018 alone, it was the fourth most frequent cancer in women and its high mortality rate could be reduced through a comprehensive approach that includes effective screening.

The goal of cervical cancer screening is simple but critical: to detect pre-cancer *before* it develops into cancer.

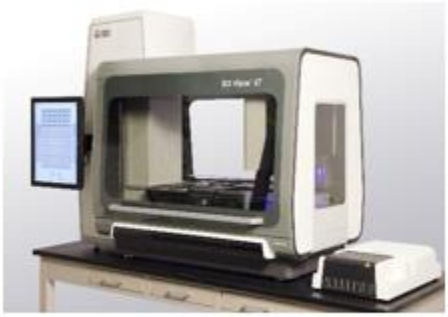
The American Cancer Society (ACS) recommends that screening for cervical cancer start at age 25 and, for women without a history of cervical pre-cancer or cancer, the *preferred method for screening for cervical cancer is by primary HPV screening every five years***.[ii]**

There are many different kinds (also called "genotypes") of human papillomavirus (HPV). The low-risk kinds can cause minor issues, like warts[iii], but the high-risk kinds can progress to cervical cancer—and persistent infection with HPV is the cause of virtually *all* cases of cervical cancer[iv].

Extended genotyping allows for the detection of several different types of high- risk HPV. It is important to know this information because not all types of high-risk HPV pose an equal risk for cervical precancer or cancer. Simply put, more genotypes mean more precise care.

How does it work ? BD Onclarity™ is a DNA-based PCR assay that will detect the E6/E7 region of the HPV genome. This region conveys oncogenic properties to the virus and will be unique to different genotypes. The sample, typically a Liquid Based Cytology (LBC) specimen, will undergo a DNA extraction and the resulting eluate will be split among 3 different master mixes each prior to PCR. Each reaction well will contain an Internal Control to ensure the amplification / detection process has been performed correctly. This process of extraction / amplification for BD Onclarity™ is automated through two different platforms: BD Viper LT™ and BD COR™.

The Viper LT™ is a medium throughput platform capable of providing results for 60 patients within an 8 hour shift with limited hands-on time. The BD COR™, which received Health Canada approval in August 2021, will generate 180-300 results (depending on configuration) in an 8 hour shift with a single hands-on intervention.



Viper LT™ System

BD COR™ System

Both systems, running on the same chemistry, will be able to produce the necessary extended genotyping report to aid in the triage and detection of high-risk HPV genotypes. Whether as a stand-alone technique, or used in conjunction with traditional cytology methods, BD Onclarity™ provides more information to the clinician than any other current HPV molecular assay.
By identifying which HPV genotype a woman tests positive for, a patient may avoid the immediate need for a diagnostic procedure called a colposcopy, if the high-risk genotype poses a lower risk for cervical precancer[v]. Colposcopies are important for detecting cervical pre-cancer and cancer, but they can be a stressful and unpleasant experience for the patient.

Conversely, a woman who tests positive for an HPV genotype that *does* carry a more immediate risk for cervical cancer can be promptly directed to further diagnostic procedures, such as colposcopy[iv]. Having further diagnostic procedures may help spot cervical disease before it develops into a potentially invasive cancer.

And again: the goal of cervical cancer screening is to detect pre-cancer before it develops into cancer. A more sensitive HPV test provides a more accurate assessment of an individual's risk for developing cervical pre-cancer.

The BD Women's Health & Cancer team, part of the company's Integrated Diagnostic Solutions business unit, is committed to providing precise and accurate ways to measure a woman's risk for developing cervical pre-cancer and cancer to help in the ongoing battle against cervical cancer.

Bibliography:

[i] World Health Organization. Cervical Cancer. Available at: https://www.who.int/cancer/prevention/diagnosis-screening/cervical-cancer/en. Assessed on September 25, 2019.

[ii] https://www.cancer.org/latest-news/acs-updates-cervical-cancer-screening-guidelines-to-start-screening-at-age-25.html

[iii] Basic Information about HPV and Cancer | CDC. Cdc.gov. https://www.cdc.gov/cancer/hpv/basic_info/index.htm. Published 2018. Accessed August 25, 2020.

[iv] Walboomers J, Jacobs M, Manos M et al. Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. *J Pathol*. 1999;189(1):12-19.

[v] Perkins R, Guido R, Castle P et al. 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. J Low Genit Tract Dis. 2020;24(2):102-131.

[vi] BD Onclarity HPV Assay US Package Insert [8089894].