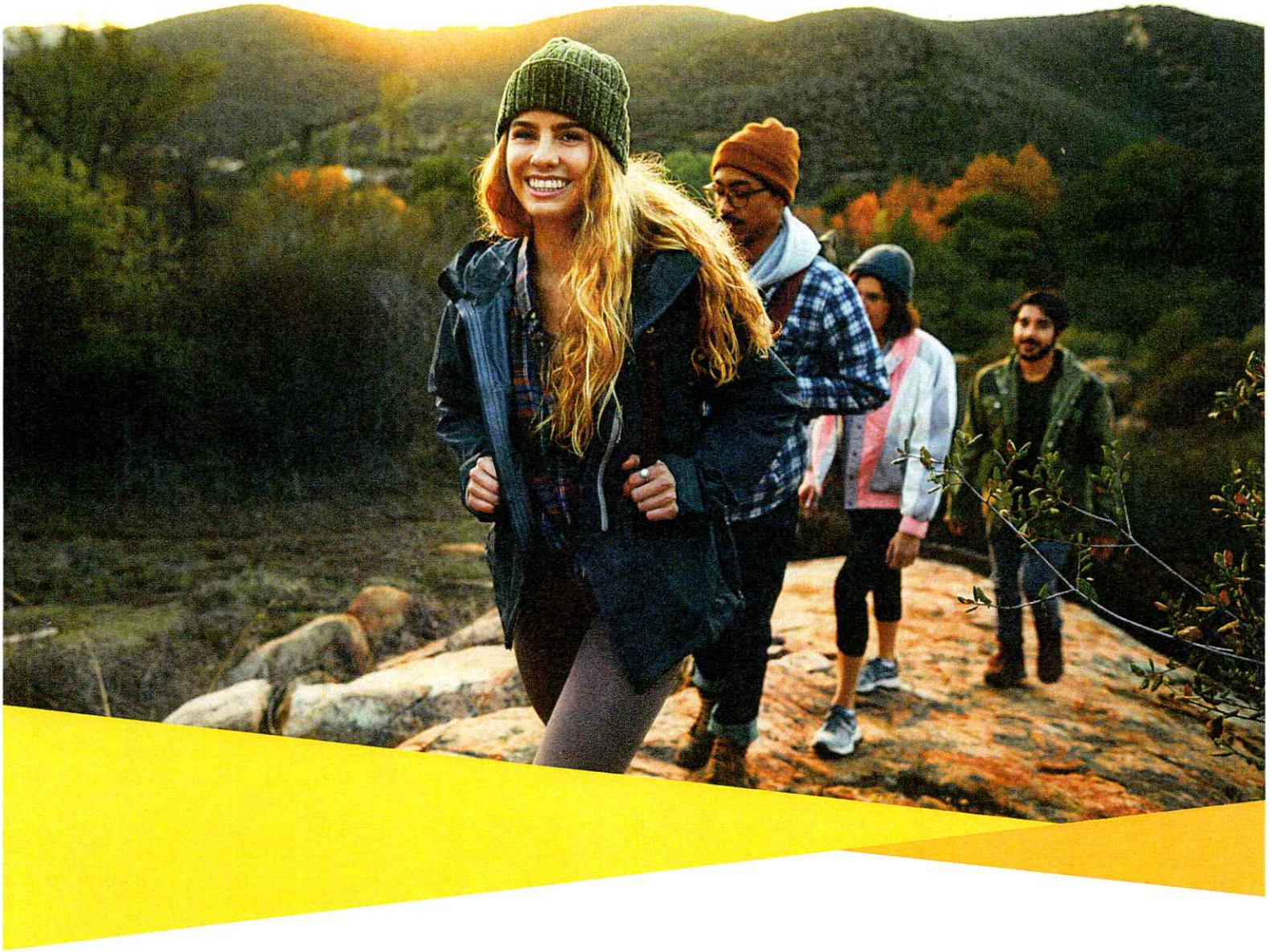


Shape the future of cervical cancer screening: Identify HPV 31

Only an HPV test with extended genotyping can identify HPV 31 and track persistence for the most high-risk genotypes.*[1-6]

The BD Onclarity™ HPV Assay is the only FDA-approved assay with extended genotyping, positioning your laboratory at the forefront of cervical cancer screening, by enabling you to provide more actionable information to clinicians.[5-10]

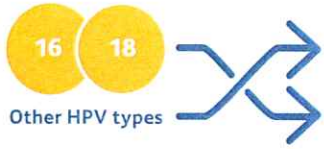
BD

*as compared to other FDA-approved HPV tests

Extended genotyping enhances laboratory capabilities and patient care

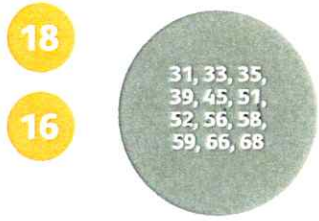
Get specific, actionable insights on an extended set of HPV genotypes

The evolving cervical cancer screening and management guidelines and changes in HPV genotype prevalence are impacting clinical management and calling for a shift towards **next-generation HPV screening with extended genotyping.**[6,11-13]



As the vaccinated population increases, HPV 16 and 18 are decreasing in prevalence, making it **crucial to identify the other high-risk HPV genotypes.**[10,11]

HPV assays with partial genotyping



All other FDA-approved HPV assays report HPV 16 and 18 or 18/45 separately and the remaining high-risk HPV genotypes in one group.[14]

BD Onclarity™ HPV Assay with extended genotyping

Only the BD Onclarity™ HPV Assay reports HPV 16, 18, 45, plus 31, 51, and 52 individually and the other 8 high-risk genotypes in strategic groupings.[3,14]

The power to track genotype-specific persistence

Multiple studies conclude **genotype-specific high-risk HPV persistence is the most important determinant of cervical cancer risk** in women who test HPV-positive, **regardless of HPV genotype.**[2-4,6]

However, all other FDA-approved HPV tests report only 16 and 18 or 18/45 individually, and the remaining 12 high-risk HPV genotypes in a single, pooled result, eliminating the possibility of monitoring genotype-specific HPV persistence beyond HPV 16 and 18.[6]

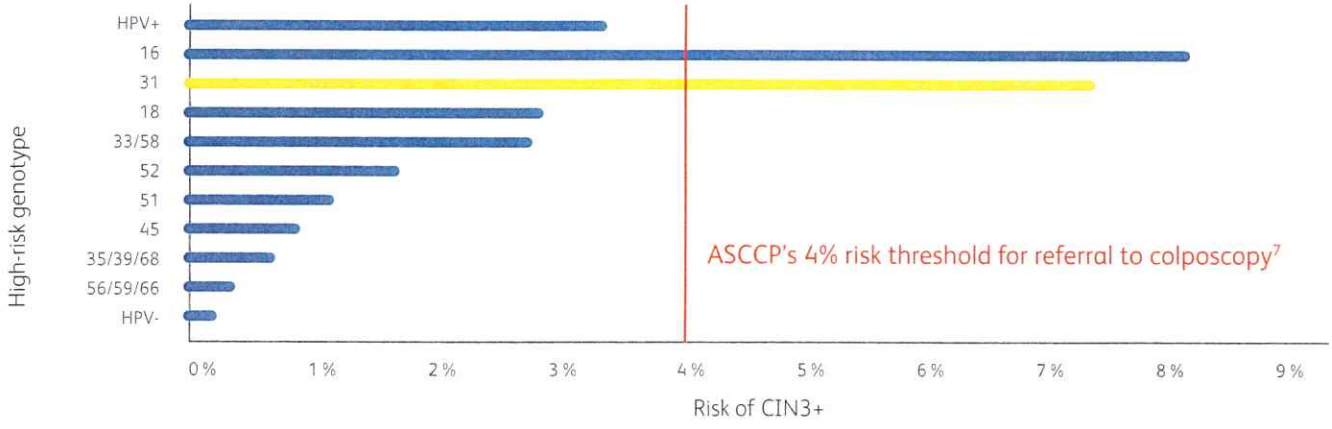
The BD Onclarity™ HPV Assay with extended genotyping allows for a **more precise, accurate** way to measure a woman's risk for developing cervical pre-cancer and cancer compared to a pooled, high-risk assay.[1-6]

Provide clinicians with actionable information through HPV 31 identification

HPV 31 identification matters. Extended genotyping is critical.

Following the American Society for Colposcopy and Cervical Pathology (ASCCP) principle of "similar management for similar risk", women with an immediate risk for CIN3+ disease above 4% should be referred to colposcopy.[11]

Risk of CIN3+ by HPV type in women ≥ 25 years with normal cytology



Created from information provided in Stoler MH et al. *Gynecol Oncol.* 2019;153(1):26-33.

- A systematic review of 16 studies shows that **HPV 31 poses a similar or higher risk for CIN3+ disease as compared to HPV 18.**[5-7]
- In the BD Onclarity™ HPV Assay FDA trial, **women 25 years and older with HPV 31 and normal cytology had an immediate risk for CIN3+ similar to HPV 16** that exceeds the colposcopy referral threshold of 4% recommended by ASCCP management guidelines.[5,11]

HPV 31

However, most HPV tests report multiple genotypes in a single result, **which may mask the true risk of CIN3+ disease due to HPV 31** and likely lead to a one-year follow-up recommendation instead of an immediate colposcopy referral.[5,6,11]

Only an HPV assay with extended genotyping can individually identify and track persistence for high-risk HPV genotypes beyond HPV 16 and 18, including HPV 31.[1-6]

The BD Onclarity™ HPV Assay adapts to every laboratory setting

The BD Onclarity™ HPV Assay can be run on two integrated solutions to meet your laboratory's throughput needs.

BD COR™ System for high-throughput HPV screening

The BD COR™ System is a scalable solution designed to meet the needs of high-volume molecular diagnostic laboratories and fully automates the processing of the BD Onclarity™ HPV Assay with extended genotyping.

BD Viper™ LT System for small to medium laboratories

The BD Viper™ LT System is a compact, integrated self-contained table-top solution tailored for the BD Onclarity™ HPV Assay with extended genotyping.

Shape the future of cervical cancer screening with the BD Onclarity™ HPV Assay.

BD partners with you to help shape the future of women's health by enabling better patient management through specific, actionable insights on an extended set of HPV genotypes.

For more information about BD Onclarity™ HPV Assay, please visit www.bd.com/onclarity

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