Shape the future of cervical cancer screening: Identify HPV 31

The BD Onclarity™ HPV Assay with extended genotyping is the only FDA-approved HPV test that individually identifies HPV 31, which poses a similar risk for cervical pre-cancer and cancer as compared to HPV 18 and should be managed similarly.[1-7]

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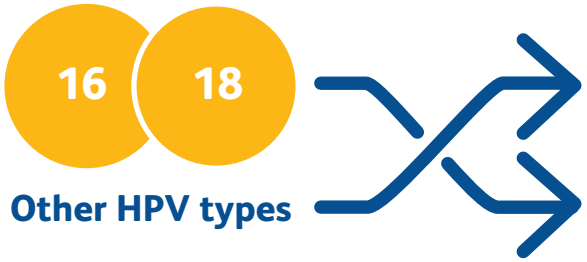
Improve cervical cancer risk assessment with HPV 31 identification[6-9]

Adapt to the evolving landscape of cervical cancer screening

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.**[5,6,10,11]

Consensus guidelines favor a **personalized risk-based management** of cervical cancer screening results with **HPV testing as the foundation for risk-estimation.**[5]



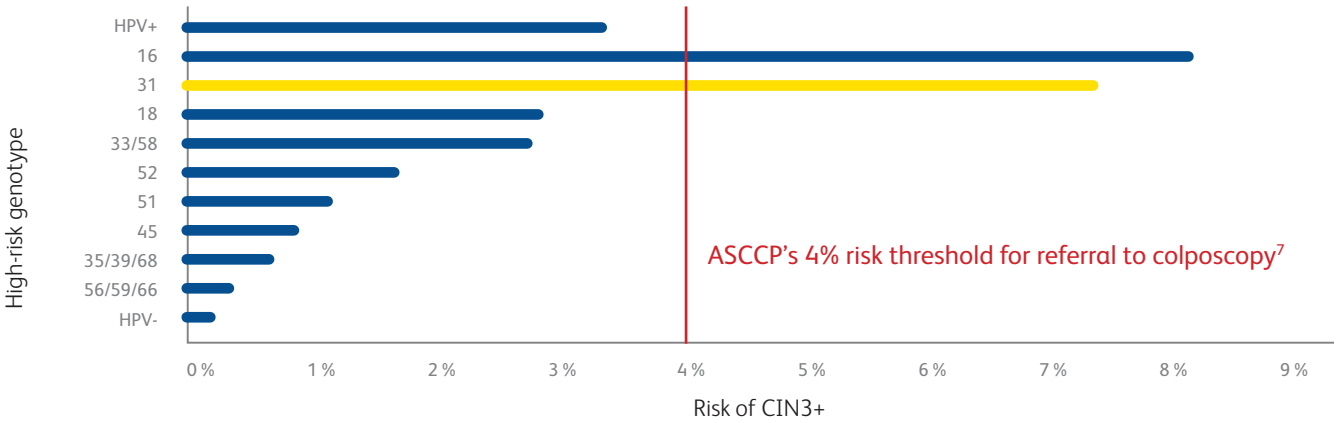
As the vaccinated population increases, HPV 16 and 18 are decreasing in prevalence, making it **crucial to identify the other high-risk HPV genotypes.**[10,11]

HPV 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.[5]

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.[5,7]

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.

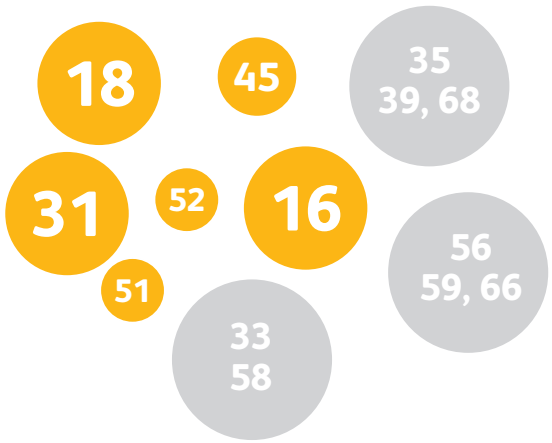
Only an HPV assay with extended genotyping can individually identify high-risk HPV genotypes beyond HPV 16 and 18, including HPV 31[6]

Extended genotyping brings value to clinical decision-making and patient care

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

HPV assays with partial genotyping

BD Onclarity™ HPV Assay with extended genotyping



Individual result | Pooled result

Report multiple high-risk HPV genotypes in a single, **pooled result**[12]

Reports **6 high-risk HPV genotypes individually** and the other 8 high-risk genotypes in strategic, small groups[12,13]

May **mask the true risk** of CIN3+ disease due to HPV 31 and will likely lead to a one-year follow-up recommendation instead of an immediate colposcopy referral[5-7]

HPV 31

Can individually **identify HPV 31**, which poses a similar risk for cervical pre-cancer and cancer as compared to HPV 18[6]

Prohibits monitoring of genotype-specific HPV persistence beyond HPV 16 and 18[6]

#1 RISK FACTOR

Can track genotype-specific high-risk HPV persistence, the most important determinant of cervical cancer risk in women who test HPV-positive, **regardless of HPV genotype**[6,9,14,15]

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 an assay with partial genotyping.[6-9,14,15]

BD Onclarity™ HPV Assay, the only FDA-approved HPV assay that offers extended genotyping:[12,13]

- Identify HPV 16, 18, 45, plus 31, 51, and 52 individually, and the other 8 high-risk HPV genotypes in strategic groupings
- Individually identify HPV 31, which poses a similar risk for cervical pre-cancer and cancer as compared to HPV 18[6]
- Choose a more precise, accurate way to measure a woman's risk for developing cervical pre-cancer and cancer compared to an assay with partial genotyping[6-9,14,15]

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

References: 1. Monsonego J et al. Gynecol Oncol. 2015;10:1016. **2.** Schiffman M et al. Gynecol Oncol. 2015;138(3):573-578. **3.** Schiffman M et al. Int J Cancer. 2016:139:2606-2615. **4.** Schiffman M et al. J Clin Microbiol. 2015;53(1):52-59. **5.** Perkins RB et al. J Low Genit Tract Dis. 2020;24:102-131. **6.** Bonde JH et al. J Low Genit Tract Dis. 2020;24(1):1-13. **7.** Stoler MH et al. Gynecol Oncol. 2019;153(1):26-33. **8.** Bonde J et al. Int J Cancer. 2019;145:1033-1041. **9.** Elfgren K et al. AM J Obstet Gynecol. 2017;216(3):264e1-264.e7. **10.** Wright TC et al. Gynecol Oncol. 2019;153(2):259-265. **11.** Drolet M et al. Lancet. 2019;394(10197): 497-509. **12.** Salazar K et al. J Am Soc Cytopath. 2019;8:284-292. **13.** BD Onclarity HPV Assay US Package Insert [8089894]. **14.** Radley D et al. Hum Vaccin Immunother. 2016;12(3):768-772. **15.** Bodily J, Laimins LA. Trends Microbiol. 2011;19(1):33-39.

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