

Shape the future of cervical cancer screening: **Identify HPV 31**

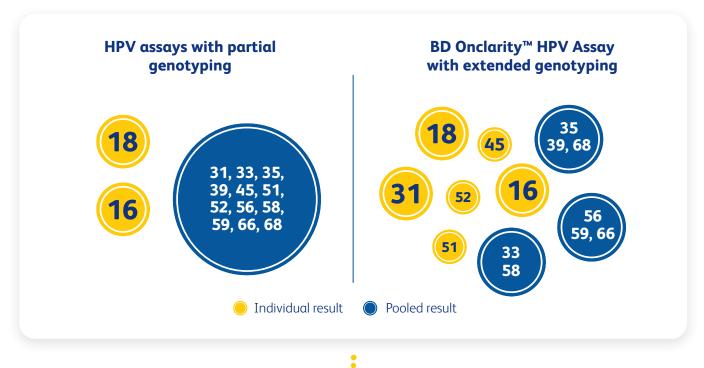
The BD Onclarity™ HPV Assay with extended genotyping is the only FDA-approved HPV test that individually identifies HPV 31, which poses a higher risk for cervical precancer as compared to HPV 18 and should be managed similarly.¹-⁴

The BD Onclarity™ HPV Assay is available out of BD SurePath™ Liquid-based Pap Test and Hologic ThinPrep® Pap Test.



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

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



Report multiple high-risk HPV genotypes in α single, **pooled result**⁵



Reports **6 high-risk HPV genotypes individually** and the other 8 high-risk genotypes in strategic, small groups^{5,6}

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 referral²⁻⁴



Can individually **identify HPV 31**, which poses a higher risk for cervical precancer as compared to HPV 18^{1,3}

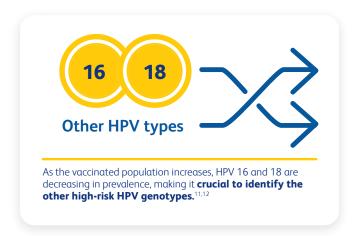
Prohibits monitoring of genotypespecific HPV persistence beyond HPV 16 and 18²

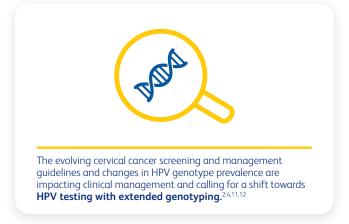


Can track genotype-specific high-risk HPV persistence, the most important determinant of cervical cancer risk in women who test HPV-positive, **regardless of HPV genotype**^{2,7-9}

The **BD Onclarity™ HPV Assay with extended genotyping** allows for a **more precise, accurate** way to measure a woman's risk for developing cervical precancer compared to an assay with partial genotyping.^{2,3,7-10}

Adapt to the evolving landscape of cervical cancer screening



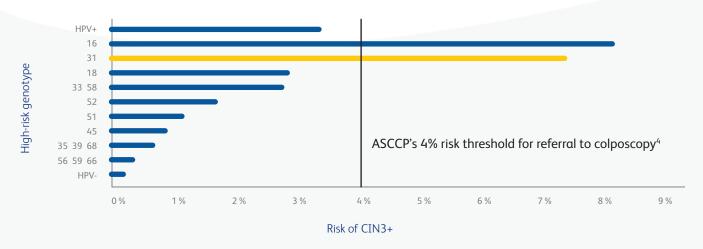


HPV 31 identification matters. Extended genotyping is critical.

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.⁴

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.^{3,4}

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 31²

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

- Provides an individual result for HPV 31, which poses a higher risk for cervical precancer as compared to HPV 18^{1,3}
- Individually identifies 6 high-risk HPV genotypes to allow for genotype-specific HPV persistence tracking, the most important determinant of cervical cancer risk in women who test HPV-positive^{2,5-9}
- The only FDA-approved HPV assay that offers extended genotyping 5,6
- FDA approved for the three most-common cervical cancer screening paradigms offering the flexibility you need to adopt to changing screening guidelines^{5,6}
- Consensus guidelines favor a personalized risk-based management of cervical cancer screening results with HPV testing as the foundation for risk-estimation⁴
- Available out of BD SurePath™ Liquid-based Pap Test and Hologic ThinPrep® Pap Test

Improve your cervical cancer screening: Identify HPV 31

Let's shape the future of women's health. Together and now.

For more information about BD Onclarity™ HPV Assay, please visit <u>womens-health-solutions.bd.com</u>

References: 1. Monsonego J et al. Gynecol Oncol. 2015;137(1):47–54. 2. Bonde JH et al. J Low Genit Tract Dis. 2020;24(1):1-13. 3. Stoler MH et al. Gynecol Oncol. 2019;153(1):26–33. 4. Perkins RB et al. J Low Genit Tract Dis. 2020;24:102–31. 5. Salazar K et al. J Am Soc Cytopath. 2019;8:284–92. 6. BD Onclarity HPV Assay US Package Insert [8089894]. 7. Elfgren K et al. AM J Obstet Gynecol. 2017;216(3):264e1–e7. 8. Radley D et al. Hum Vaccin Immunother. 2016;12(3):768–72. 9. Bodily J, Laimins LA. Trends Microbiol. 2011;19(1):33–9. 10. Bonde J et al. Int J Cancer. 2019;145:1033–41. 11. Wright TC et al. Gynecol Oncol. 2019;153(2):259–65. 12. Drolet M et al. Lancet. 2019;394(10197): 497–509.

