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.

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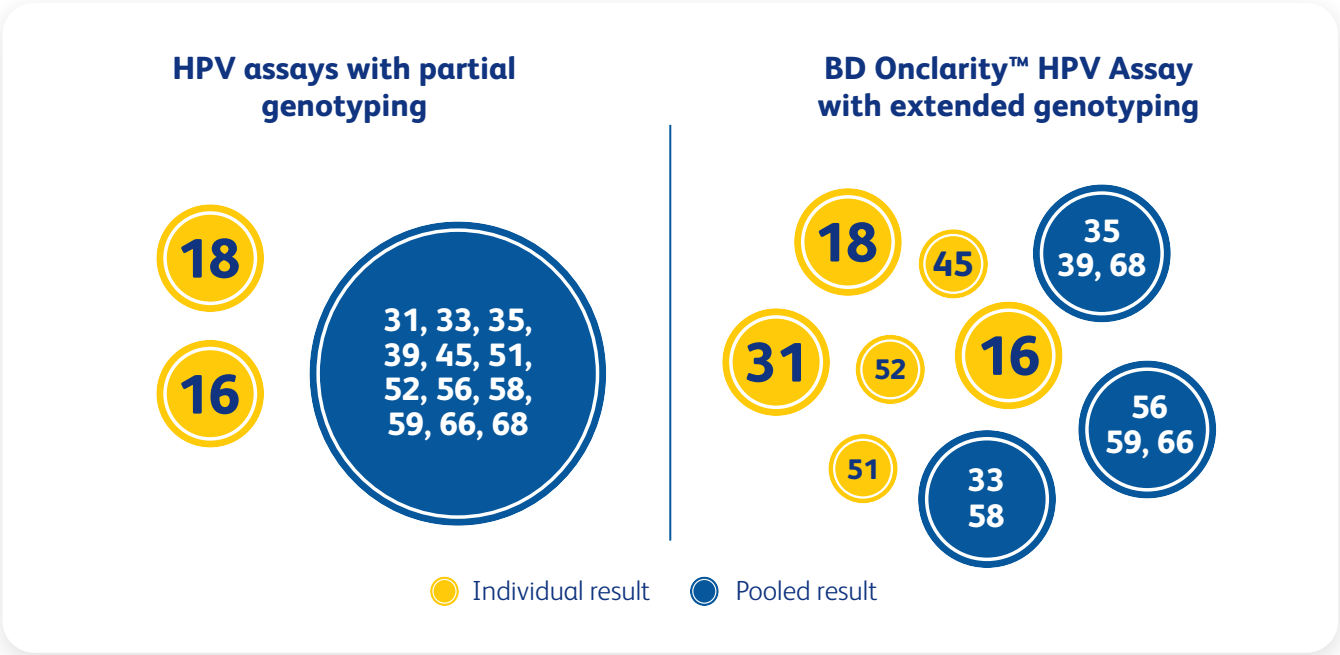
Extended genotyping brings value to clinical decision-making and patient care

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



Report multiple high-risk HPV genotypes in a 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 referral[2-4]

HPV 31

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

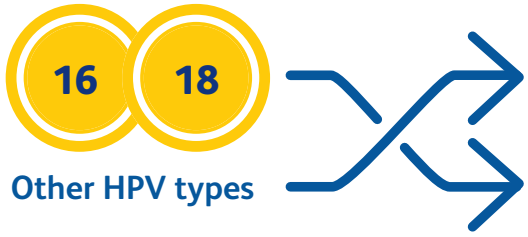
Prohibits monitoring of genotype-specific HPV persistence beyond HPV 16 and 18[2]

#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**[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



As the vaccinated population increases, HPV 16 and 18 are decreasing in prevalence, making it **crucial to identify the other high-risk HPV genotypes.**[11,12]

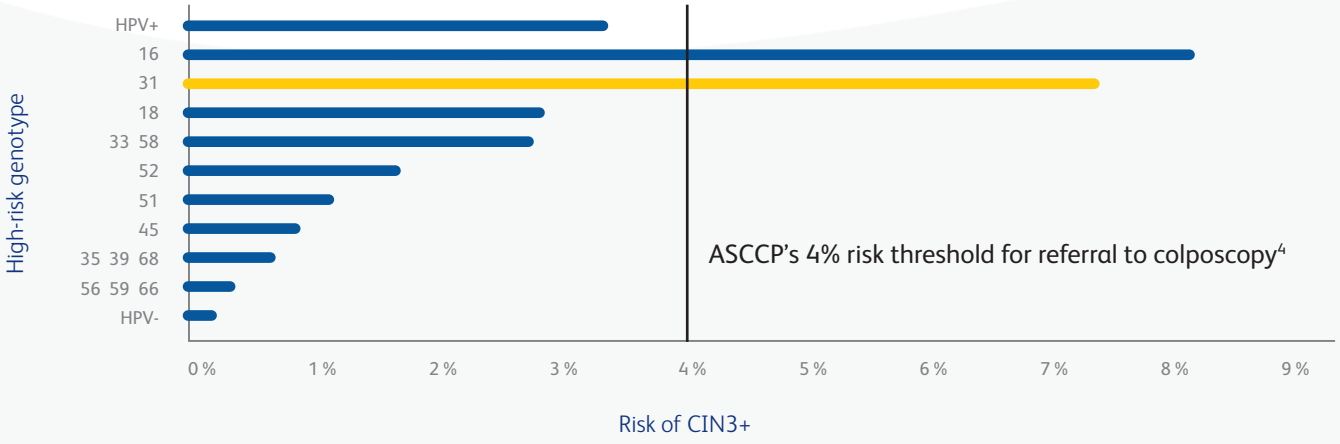
The evolving cervical cancer screening and management guidelines and changes in HPV genotype prevalence are impacting clinical management and calling for a shift towards **HPV testing with extended genotyping.**[2,4,11,12]

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 31[2]

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-estimation[4]
- 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 **womens-health-solutions.bd.com**

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.

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HPV 31 poses a higher risk **of precancer as compared to HPV 18.**[1]

You screen for HPV 18, so why not HPV 31?

Meet Tianna*

- 35 years old
- No medical conditions
- Lives a healthy lifestyle and believes in the importance of cervical cancer screening
- Has had Pap smears every 3 years from age 21 to 29 and co-testing with HPV and Pap every five years starting at age 30

Cervical cancer screening history.

- Normal cytology
- Negative for HPV 16 and 18
- Negative for high-risk HPV pool

Current results:

- Normal cytology
- Negative for HPV 16 and 18 and all other high-risk types
- Positive for HPV 31

*"I was worried when I first found out that I had HPV 31, one of the most risky types of HPV, and what it meant for my risk of cervical precancer. But my OB/GYN was very supportive and we were quickly able to discuss a plan."**

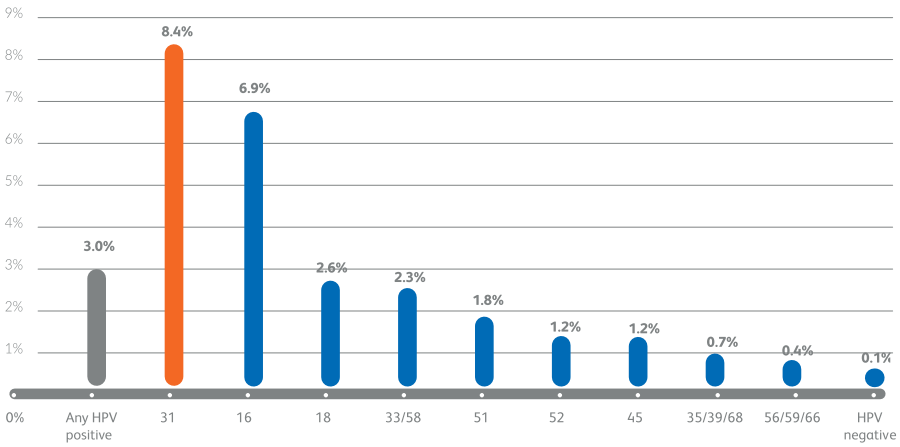
Normal cytology | HPV 16 - | HPV 18 - | HPV 31 +

What does the data say?

In a multicenter clinical trial involving 33,000 patients, the immediate risk of having precancer or cancer among women aged ≥30 with **normal cytology** and positive for **HPV 31** was 8.4%.[1]

This is similar to the risk associated with HPV 16 and is 3 times higher than the risk associated with HPV 18.[1]

Immediate CIN3+ risk by HPV type in women ≥ 30 years with normal cytology[1]



Adapted from Stoler MH et al. Gynecol Oncol. 2019,153(1):26–33.

Based on Tianna's cervical cancer screening results, what would you do?

- ☐ Follow-up in 1 year
- ☐ Follow-up in 3 years
- ☐ Colposcopy/biopsy
- ☐ Use the ASCCP Risk-Based Management App
- ☐ I'm not sure, HPV 31 is new to me

*Names and/or medical information presented on this page do not represent real people or clinical information.

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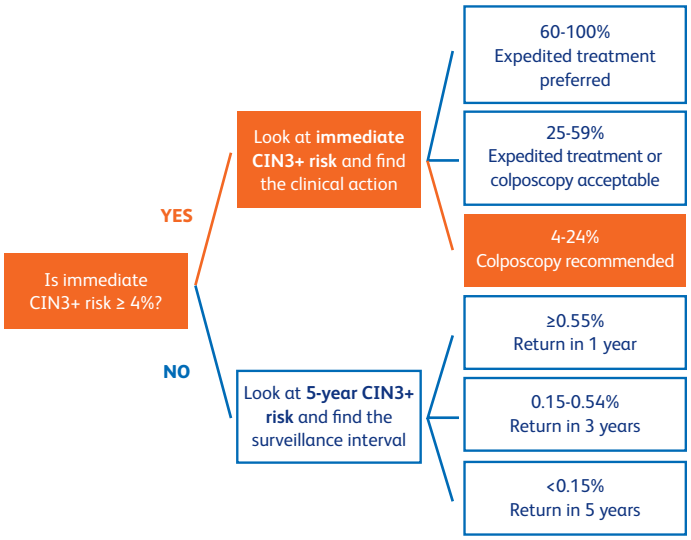
What do the guidelines say?

The 2019 ASCCP Risk-Based Management Consensus Guidelines for the management of cervical cancer screening abnormalities recommend 1 of 6 clinical actions, according to the risk of cervical precancer and cancer (CIN3+ risk).[2]

Tianna's personalized immediate CIN3+ risk is **8.4%**[1] which calls for colposcopy as next step, based on the ASCCP guidelines.[2]



Why is individually identifying HPV 31 better for your patients?

HPV 31 poses a higher risk of precancer as compared to HPV 18 and should be identified individually.[1]

Not all HPV tests are the same.

BD Onclarity™ HPV Assay is the only FDA-approved HPV test that provides an individual result for HPV 31.[1,3-8]

Most HPV tests cannot identify which HPV type is causing the infection apart from HPV 16 and 18, and group the other high-risk types (including HPV 31) in one pooled result.[9] This may underestimate the true CIN3+ risk due to HPV 31.[1,10]

You screen for HPV 16 and 18, so why not HPV 31? Learn more on womens-health-solutions.bd.com

Different HPV types carry different risk.
By using a test that can individually identify more HPV types, including HPV 31, **you offer your patients a more precise cervical cancer risk assessment** compared to an HPV test with grouped results.[11]

*Names and/or medical information presented on this page do not represent real people or clinical information.

ASCCP, American Society for Colposcopy and Cervical Pathology; CIN3+, cervical intraepithelial neoplasia grade 3, adenocarcinoma in situ, or cancer; FDA, Food and Drug Administration; HPV, human papillomavirus.

References: 1. Stoler MH et al. *Gynecol Oncol.* 2019,153(1):26–33. **2.** Perkins RB et al. *J Low Genit Tract Dis.* 2020;24(2):102–31. **3.** BD Onclarity™ HPV Assay US Package Insert [8089894]. **4.** Aptima™ HPV Assay US Package Insert. **5.** Cervista™ HPV HR US Package Insert. **6.** cobas® HPV for 4800 System US Package Insert. **7.** cobas® HPV for 6800/8800 System US Package Insert. **8.** digene® HC2 High-Risk HPV DNA Test Package Insert. **9.** Bonde J et al. *J Low Genit Tract Dis.* 2020;24(1):1–13. **10.** Egemen D et al. *J Low Genit Tract Dis.* 2020;24(2):132–43. **11.** Bonde J et al. *J Low Genit Tract Dis.* 2021;25(1):27–37.

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More genotype results. More precise care.

The BD Onclarity™ HPV Assay with extended genotyping offers a more precise, accurate way to measure a woman's risk for developing cervical cancer.[1-5]

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Evolving cervical cancer screening guidelines and changes in HPV genotype prevalence are impacting clinical management. Enhance patient management with the BD Onclarity™ HPV Assay.[1-5]

Achieve confidence in results

- Reduced risk of false-positive results due to lack of cross-reactivity with low-risk HPV types[9]
- Designed to minimize false-negative results by including an internal cellular control, ensuring that a sample is present[9]

Adapt to evolving screening guidelines

The BD Onclarity HPV Assay is FDA approved for the three most-common paradigms and is also FDA approved for extended genotyping, offering the flexibility you need to adopt to changing screening guidelines.

HPV Primary Screening

Co-testing

Cytology Primary + ASCUS Reflex

Stratify patient risk with extended genotype detection

The BD Onclarity HPV Assay reports individual results for 6 of the 14 high-risk (HR) genotypes and grouped results for the remaining 8 HR genotypes.[9]

Individual genotyping of 6 common HR HPV types:

16	18	31	45	51	52
✓	✓	✓	✓	✓	✓

Other HR HPV genotypes reported by group:

33, 58	35, 39, 68	56, 59, 66
✓	✓	✓

Why is extended genotyping so critical to patient management?

The profile of cervical cancer is changing.

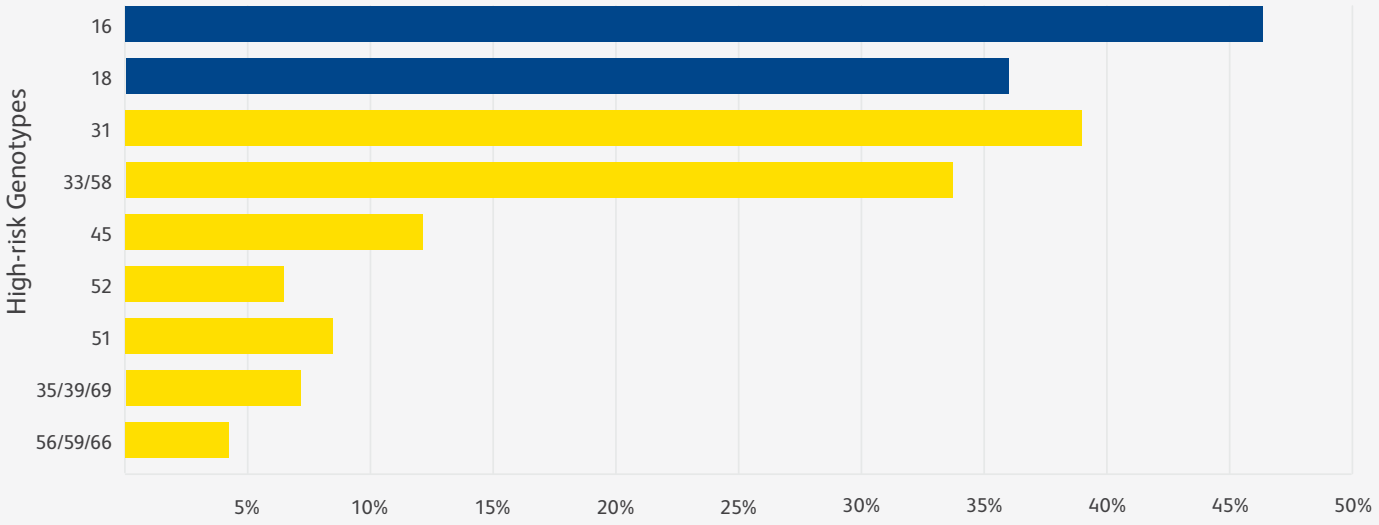
Genotypes 16 and 18 account for 70% of invasive cancer worldwide, but

their prevalence is declining as vaccination rates increase.[1-5]

There's more to the story than just 16 and 18, and **the ability to individually identify genotypes is critical** to the future of patient management.

Knowing the HPV genotype allows for better risk stratification within ASC-US and LSIL patients.[1,7]

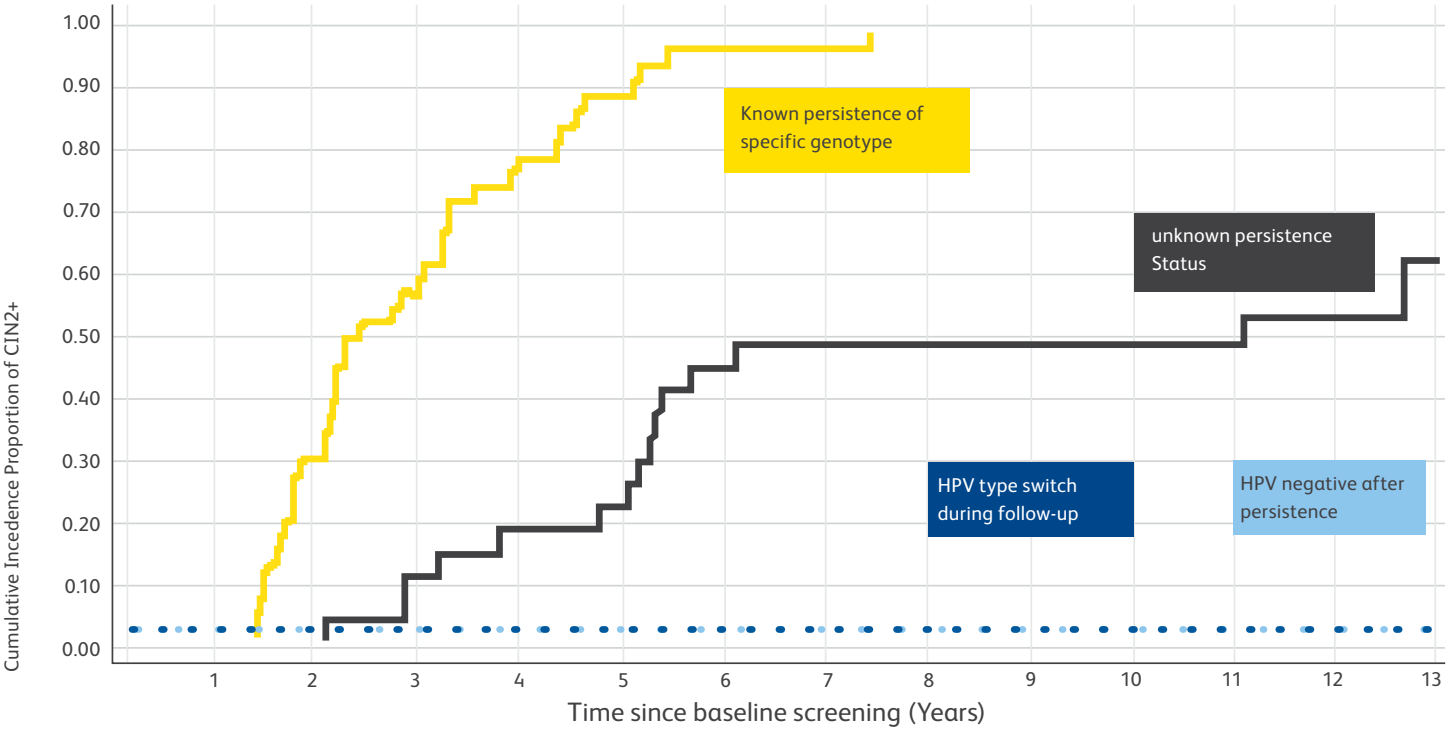
Different high-risk HPV types carry different risk to disease progression.[1,6-7]



Created from information provided in Stoler et al. Gynecologic Oncology (2018)

Measuring genotype-specific HPV persistence is the best management option for monitoring women who test HPV positive during cervical cancer screening.[3,8]

Persistence of infections by high-risk HPV types is the single greatest risk factor for malignant progression. [3,13]



Elfgren K. 2017. AM J Obstet Gynecol. 2017;216(3):264.e1-264.e7.doi: 10.1016/j.ajog.2016.10.042.Epub 2016 Nov 5.

1. The yellow line in the graph shows that persistent infections with the same HPV genotype confer the highest risk of developing cervical pre-cancer.

2. The black line indicates that persistent infections with high-risk HPV increase the risk of developing cervical cancer (or pre-cancer) relative to a transient HPV infection.

3. The lower blue lines show how HPV infections that clear between two sequential screening tests, or HPV genotype changes between tests, are both associated with a very low risk of developing cervical pre-cancer.

Extended genotyping supports risk stratification and persistence monitoring to inform patient management.

Extended genotyping offers a more precise way to screen for cervical cancer.[1-5]

1. **All genotypes are not created equal.** HPV genotypes confer different risks for CIN2+ - either at baseline colposcopy or over a 3-year interval.[1, 7]

2. **Not everyone with abnormal cervical cancer screening results may need a colposcopy.** Some HPV genotypes are associated with low enough risk that immediate colposcopy can be deferred and the patient retested within 12 months to determine clinical action.[6]

3. **Persistence monitoring can help personalize patient management.** Persistent infection confers a high risk of cervical disease progression and genotype specific persistence confers an even higher risk of developing disease.[3]

For more information about this assay, please visit www.bd.com/onclarity

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1. Stoler MH et al. Gynecol Oncol. 2019;153(1):26-33
2. Bonde J et al. *Int J Cancer.* 2019; dol: 10.1002/ljc.32291
3. Elfgren K et al. *AM J Obstet Gynecol.* 2017; 216(3):264e1-264.e7
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6. Schiffman M. et al. *J Clin Microbiol.* 2015;53(1):52-59
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8. Bodily J. et al. *Trends Microbio.* 2011;19(1):33-39 9. BD Onclarity™ HPV Assay US Package Insert (8089894)

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