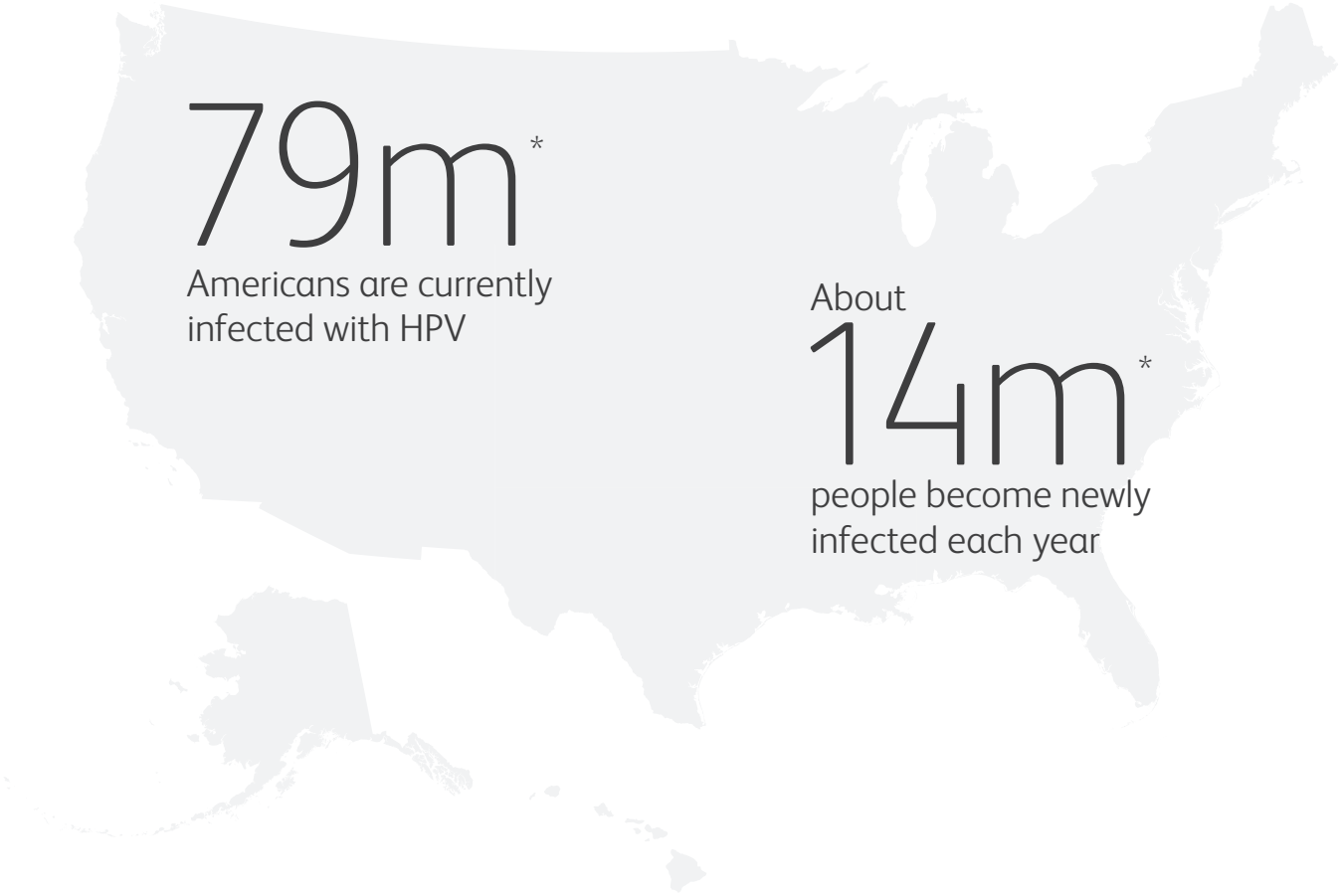
BD Onclarity™ HPV Assay with extended genotyping

More genotype results. More precise care.

BD

What is human papillomavirus (HPV)?[1]

HPV is the most common sexually-transmitted infection (STI) in the United States.



79m*

Americans are currently infected with HPV

About

14m*

people become newly infected each year

HPVs are a group of more than 150 related viruses. Each HPV virus is given a number, which is called an HPV type.

Low-risk HPV types: HPV types that tend to cause warts and rarely cause cancer are called *low-risk types.*

High-risk HPV types: HPV types that can cause cancer are called *high-risk types.* These types have been linked to certain cancers in both men and women.

*Data from CDC's 2018 STD Fact Sheet

What is extended genotyping?

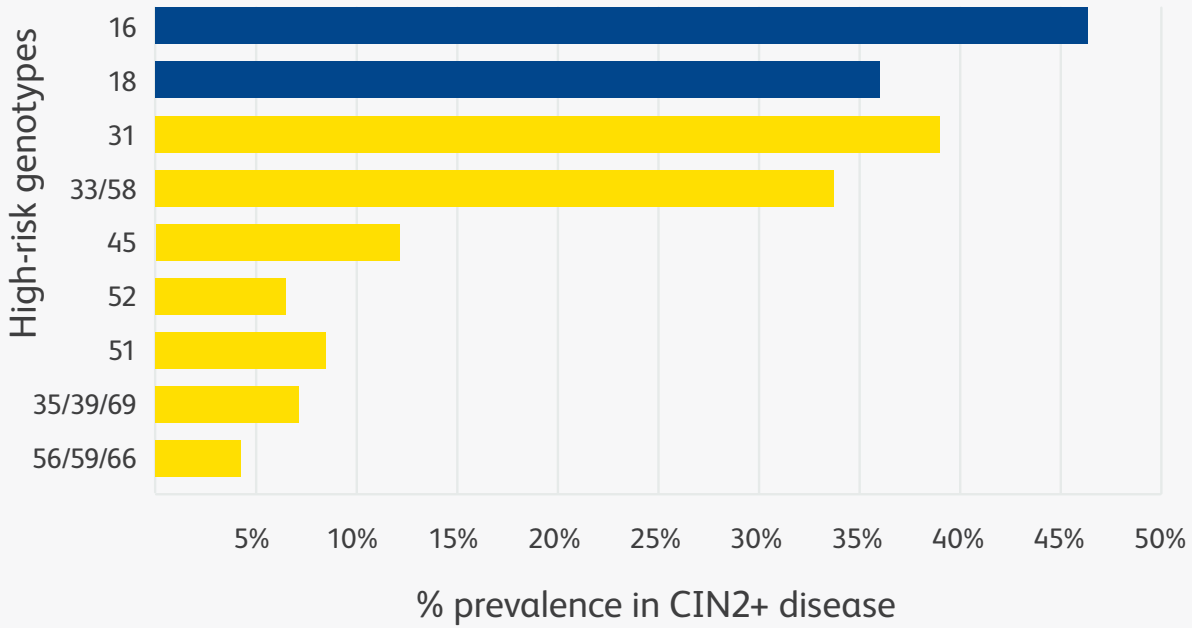
Current FDA-approved HPV assays can be divided into two categories: assays with partial genotyping and assays with extended genotyping.[12,17]

HPV assays with partial genotyping report HPV 16 and 18 or 18/45 separately and the remaining high-risk genotypes in one group.[18]

HPV assays with extended genotyping detect at least five individual high-risk HPV genotypes.[18]

Only an HPV assay with extended genotyping can individually identify high-risk HPV genotypes beyond HPV 16 and 18, including HPV 31, which poses a similar risk for cervical pre-cancer and cancer as compared to HPV 18.[12]

Different high-risk genotypes carry different risk to disease progression.[7-8]

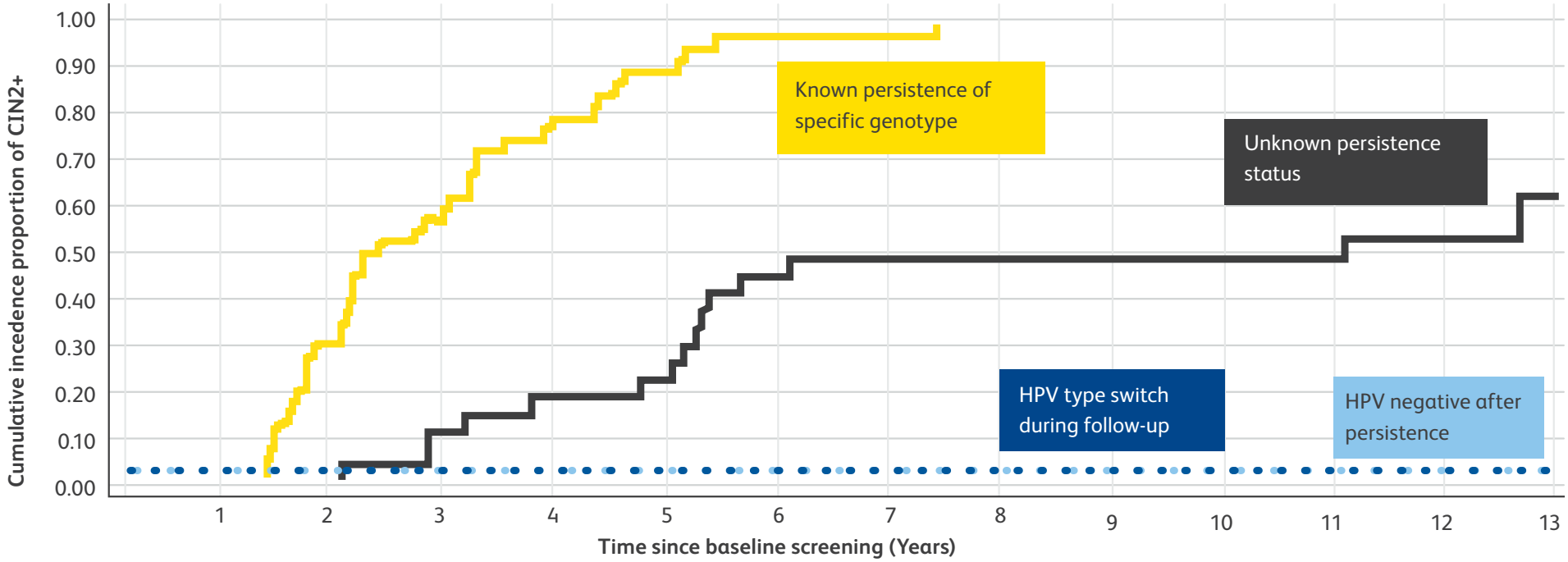


Created from information provided in Stoler et al. *Gynecologic Oncology*[2] (2019)

Genotypes 16 and 18 account for 70% of invasive cancer worldwide, but their prevalence is declining as vaccination rates increase.[2-6]

There's more to the story than just 16 and 18 and knowing the HPV genotype allows for better risk stratification and more precise patient care than a pooled, high-risk assay.[10,13-14]

Persistence of infections by high-risk HPV types is the single greatest risk factor for malignant progression.[4, 9, 12]



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

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

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.

Measuring genotype-specific HPV persistence is the most important determinator of risk when monitoring women who test HPV positive during cervical cancer screening. Only an HPV test with extended genotyping allows you to identify same genotype persistence beyond only 16 and 18.[4, 9, 12]

How can an HPV test with extended genotyping improve cervical cancer screening?

1. Extended genotyping identifies which risk group your patient is in[13]

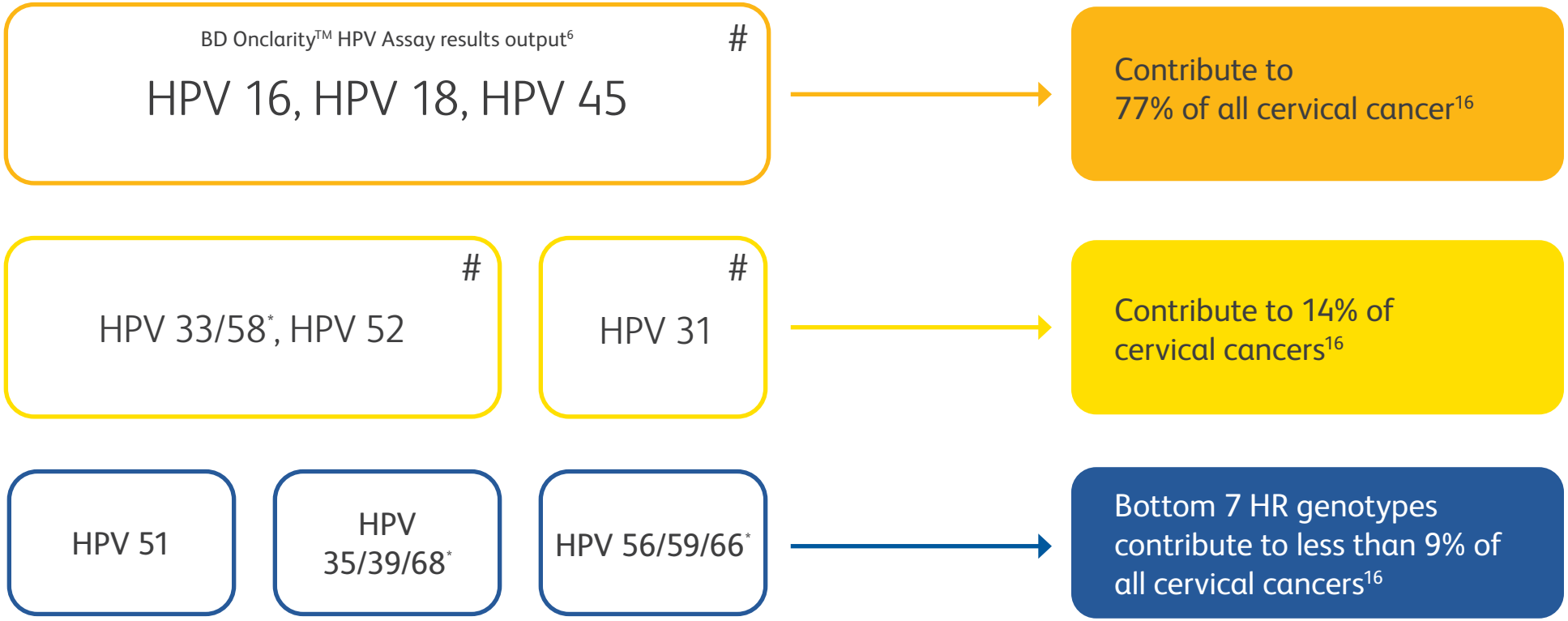
2. Extended genotyping allows you to track genotype-specific persistence which is the most important risk factor for future disease[4, 12]

3. A clinically-validated extended genotyping assay with a high negative predictive value for all high-risk HPV genotypes provides confidence that a negative result is truly a negative

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.[10,13-14]

The BD Onclarity™ HPV Assay is the only FDA-approved HPV test with extended genotyping.

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.[11]



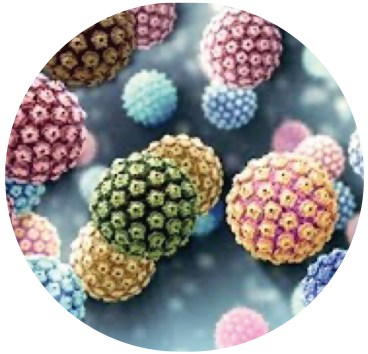
* Pooled types in BD Onclarity HPV Assay results output
#9-valent vaccine types

New patient management guidelines[13] usher in a new era in women's health

Using risk identification to determine treatment pathways

Is immediate CIN3+ risk greater or equal to 4%?

- **Yes** → Look at immediate CIN3+ risk and find the correct treatment.
  - Expedited treatment preferred: 60-100% (immediate CIN3+ risk)
  - Expedited treatment or colposcopy acceptable: 25-59% (immediate CIN3+ risk)
  - Colposcopy recommended: 4-24% (immediate CIN3+ risk)
- **No** → Look at 5-year CIN3+ risk and find the surveillance interval.
  - Return in 1 year: ≥0.55% (5-year CIN3+ risk)
  - Return in 3 years: 0.15-0.54% (5-year CIN3+ risk)
  - Return in 5 years: <0.15% (5-year CIN3+ risk)



This figure demonstrates how patient risk is evaluated. For a given current results and history combination, the immediate CIN3+ risk is examined. If this risk is 4% or greater immediate management via colposcopy or treatment is indicated. If the immediate risk is less than 4%, the 5-year CIN3+ risk is examined to determine whether patients should return in 1,3, or 5 years.

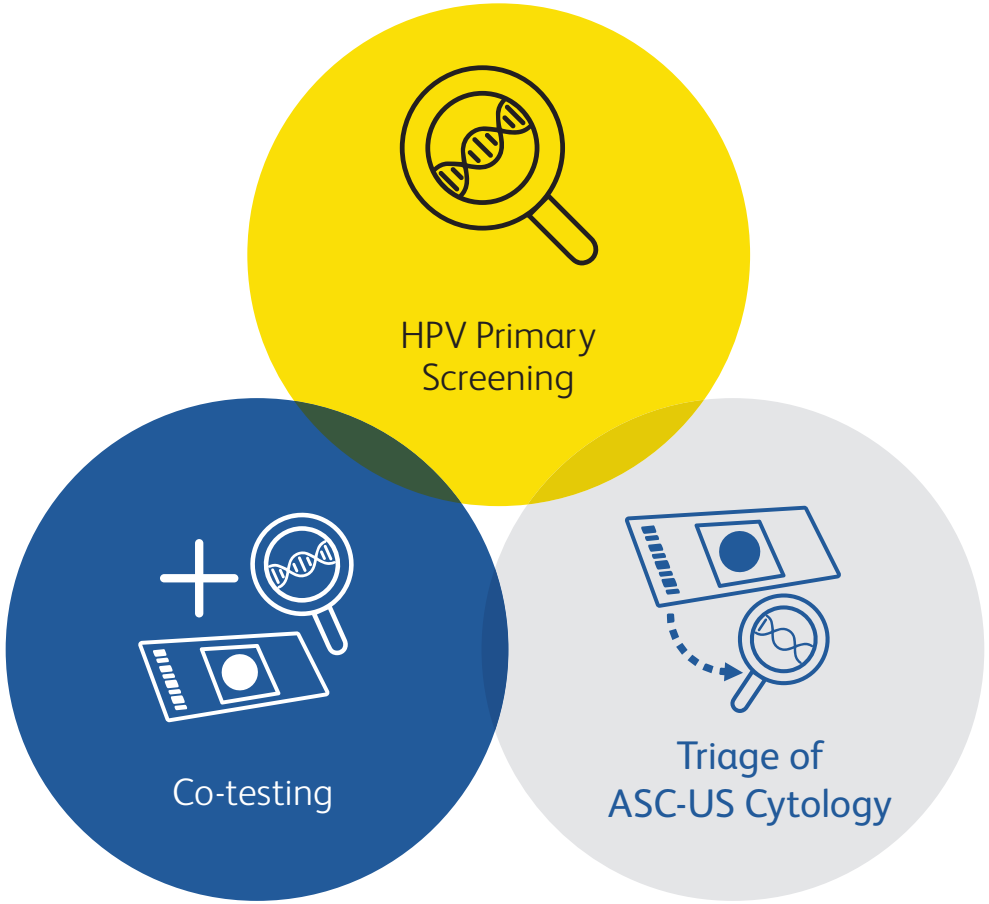
The ASCCP Management Guidelines App and web application is now available!

ANDROID APP ON Google play

Download on the App Store

or visit app.asccp.org

Cervical cancer screening paradigms



BD Onclarity™ HPV Assay is FDA-approved for all three screening paradigms[11]

BD Onclarity™ HPV Assay[11] – better by design

Assay feature	Clinical significance
Reports individual results for 6 of the 14 high-risk genotypes and grouped results for the remaining 8 genotypes	Extended genotyping allows for a more precise way to measure risk for developing cervical pre-cancer and cancer vs. a pooled, high-risk assay and provides ability to measure same genotype persistence, which is the single greatest risk factor for malignant progression.[4,10, 12-14]
FDA approved for HPV primary screening, co-testing, and ASC-US reflex	Offers the flexibility needed to adapt to recently updated patient guidelines.[13]
• Detects DNA target (vs. RNA) • Includes internal cellularity control • Detects E6/E7 oncogenes	Provides reassurance that a negative test result is truly a negative.[12]

Clinician resources/education

For more information about this assay please visit:

bd.com/onclarity

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