BD Onclarity™ HPV Assay

Keeping you ahead of the curve in cervical cancer screening

Answering the need for actionable HPV genotyping

- Genotype-specific high-risk HPV persistence is the most important determinant of cervical cancer risk, regardless of the genotype.[1–5] Tracking of HPV persistence beyond HPV 16 and 18 can be achieved through assays with extended genotyping, whose results should report at least 6 genotypes individually.[5]
- The BD Onclarity™ HPV Assay offers extended genotyping in a single sample-to-result run, providing detailed, accurate results to more precisely identify the risk of cervical disease.[1–7]

Flexibility in screening paradigm and sample type

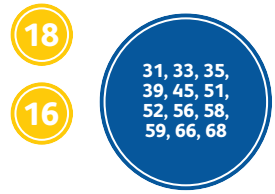
- The BD Onclarity™ HPV Assay fulfils the Meijer criteria and is CE-marked and FDA-approved for all the screening paradigms below, with the benefit of extended genotyping, thus offering the flexibility you need to adapt to evolving screening guidelines.[7–10]
- Validated for a wide range of sample types:[7]
  - Liquid-based cytology specimens, including BD SurePath™ and PreservCyt®
  - Cervical brush specimens
  - Self-collected vaginal specimens

HPV Primary Screening | Co-testing | Cytology Primary + ASCUS Reflex

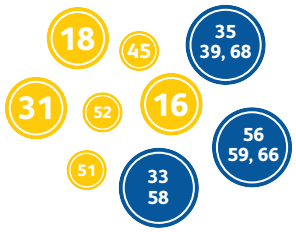
Improved patient management with extended genotyping

- Individual results for 6 HPV genotypes with highest risk for disease[7]
- Strategic grouped results for the other 8 high-risk HPV genotypes[7]

HPV assays with partial genotyping



BD Onclarity™ HPV Assay with extended genotyping



Individual result
Pooled result

Advanced Assay Design

- E6/E7 target region to reduce the risk of false negative results[7,11]
- Type-specific primers to reliably detect multiple HPV-type infections[7]
- β-globin internal control to ensure that enough sample is present[7]
- Ready-to-use reagents that can be stored at room temperature[7]

The BD Onclarity™ HPV Assay will support your laboratory to adapt to changing clinical landscape, including self-collection.

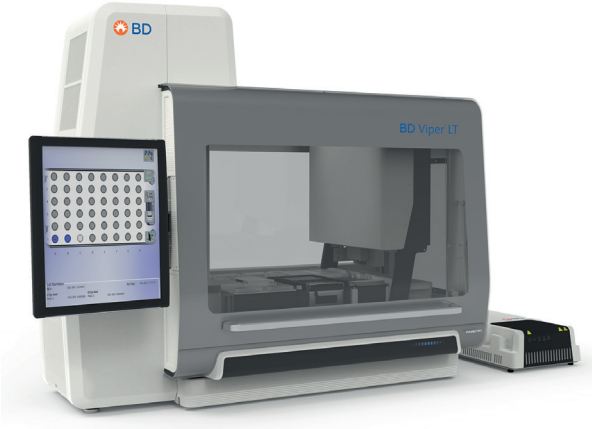
BD

Flexible HPV testing automation for any lab volume

BD COR™ System

Integrated high-throughput automation

The BD COR™ System is a scalable solution that fully automates the processing of the BD Onclarity™ HPV Assay with extended genotyping. It is suited for high-volume laboratories requiring advanced integrated automation from sample to result, with minimal user interventions and outstanding long walkaway times.[10,12,13]



BD Viper™ LT System

HPV testing automation for low- to mid-volume laboratories

The BD Viper™ LT System is a compact, self-contained table-top system, that automates sample extraction and real-time PCR for extended genotyping with the BD Onclarity™ HPV Assay all in one instrument for added ease, convenience, and walkaway time.[14,15]

Self-collection with BD Onclarity™ HPV Assay

HPV testing on self-collected samples is an integral part of the strategy to eliminate cervical cancer as a public health problem in Europe.[16]
Stay ahead of the curve with the BD Onclarity™ HPV Assay and get ready to perform HPV primary testing on patient-collected samples in your lab.[7]

Collection devices compatible with self-collection:*
*The BD COR™ System only accepts FLOQSwabs®

Acting as a single source provider for both HPV and cytology testing, BD's cervical cancer screening portfolio offers integrated solutions from sample to result, for every laboratory setting and any cervical cancer screening paradigm.

References: 1. Radley D et al. Hum Vaccin Immunother. 2016;12(3):768–72. **2.** Elfgren K et al. AM J Obstet Gynecol. 2017;216(3):264e1–e7. **3.** Bottari F et al. J Low Genit Tract Dis. 2019;23(1):39–42. **4.** Stoler MH et al. Gynecol Oncol. 2019;153(1):26–33. **5.** Bonde JH et al. J Low Genit Tract Dis. 2020;24(1):1–13. **6.** Bonde J et al. Int J Cancer. 2019;145:1033–41. **7.** BD Onclarity™ HPV Assay EU Package Insert (8089899). **8.** Arbyn M et al. Clin Microbiol Infect. 2021;27(8):1083–95. **9.** BD Onclarity HPV Assay US Package Insert (8089894). **10.** BD Onclarity™ HPV Assay for the BD COR™ System Package Insert (443982). **11.** Arroyo Mühr LS et al. J Gen Virol. 2020;101:265–70. **12.** BD COR™ PX/GX System User's Manual (L011486). **13.** BD COR™ Hands-On Setup Time (HTDI-21-0406). **14.** BD Viper™ LT System User's Manual (8089195). **15.** Ejegod DM et al. Papillomavirus Res. 2016;2:31–7. **16.** Arbyn M et al. Int J Cancer. 2021;148(2):277–84.

Learn more

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