

Stay ahead of the curve in **cervical** **cancer** screening with BD



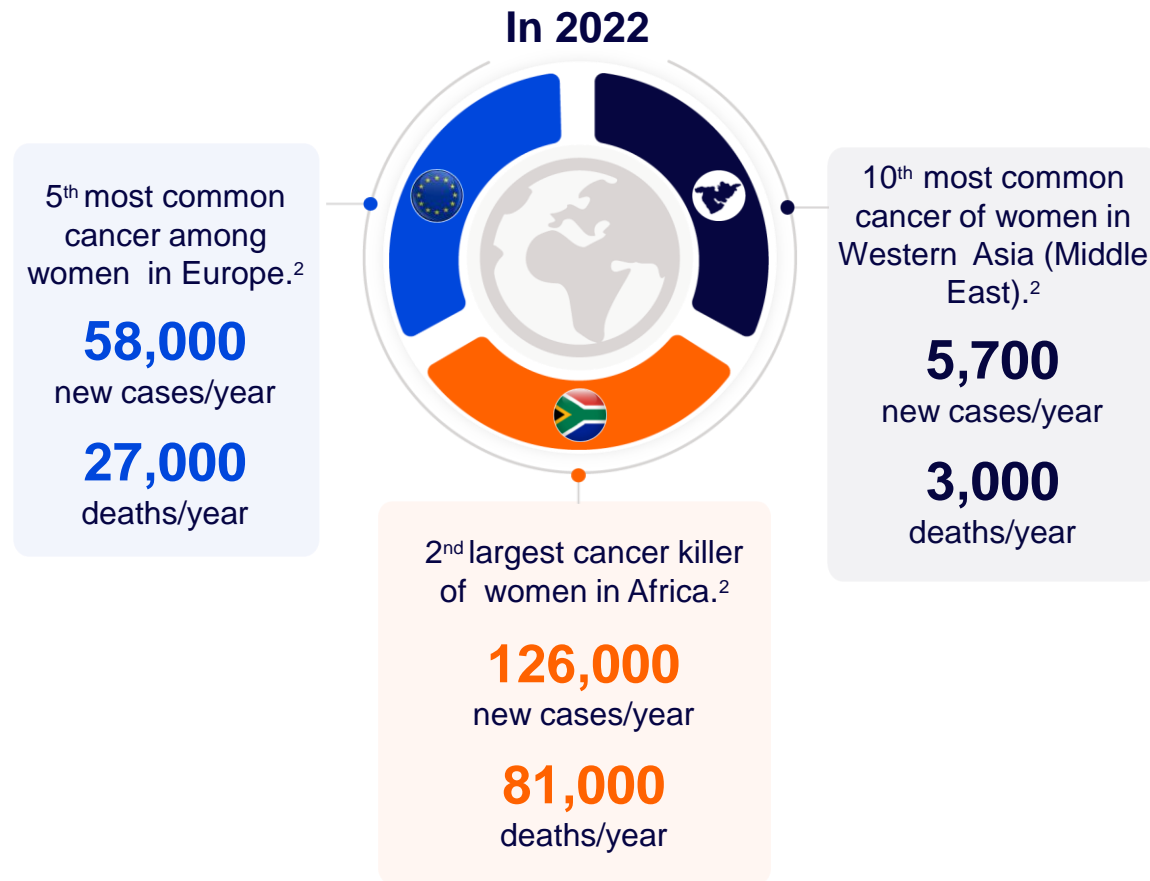
Kresimir Ferencak



Most cervical cancer is caused by HPV and is preventable¹

Cervical cancer is the **4th most common cancer** among women in the world.²

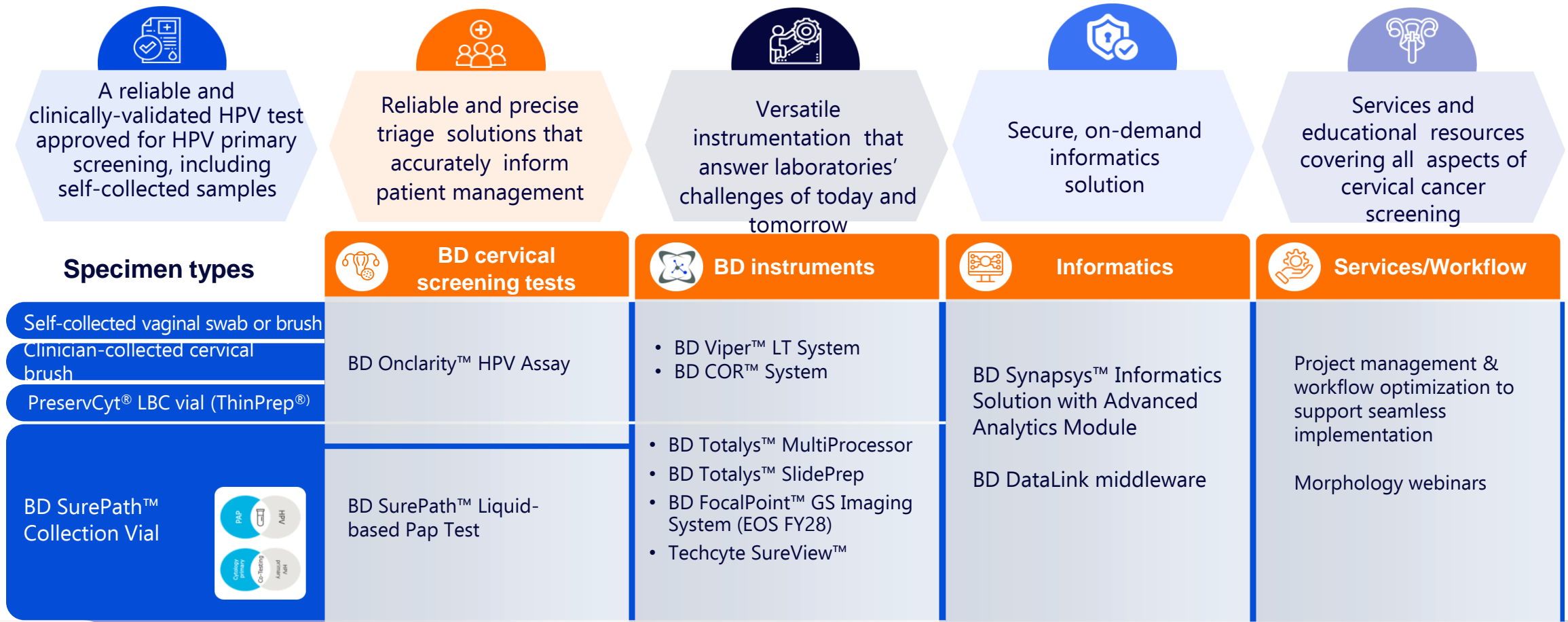
Global organisations aim to **eliminate cervical cancer as a public health problem by 2030**, stressing out the importance of 3 strategies:^{3,4}



‘All European nations should, by 2030, reach at least 90% HPV vaccine coverage [...], achieve 70% of screening coverage [...], and manage 90% of screen-positive women.’ The European response to the World Health Organization (WHO) call to eliminate cervical cancer as a public health problem, 2021.³

The BD Cervical Cancer Screening Portfolio: Solutions designed for the future

BD partners with you to help eliminate cervical cancer by offering a **complete portfolio** of collection devices, assays, and instruments **to keep you ahead of the curve.**



STAY AHEAD OF THE CURVE IN
CERVICAL CANCER SCREENING

HPV, human papillomavirus
LBC, liquid-based cytology



BD solutions for HPV testing



STAY AHEAD OF THE CURVE IN
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A reliable DNA PCR-based assay design providing high sensitivity and specificity for results that you can trust.

The BD Onclarity™ HPV Assay with **extended genotyping** detects 14 hrHPV genotypes and reports up to 9 results.¹

Individual results for 6 hrHPV						Other hrHPV genotypes reported in 3 small		
16	18	31	45	51	52	33/58	35/39/6	56/59/6
✓	✓	✓	✓	✓	✓	✓	8	6



- **Efficient detection of HPV infections with multiple genotypes** thanks to genotype-specific primers and probes (instead of consensus primers).^{1,2}



- **Minimal risk of false-positive results** due to no cross-reactivity with low-risk HPV genotypes.^{1,3,4}



Minimal risk of false-negative results by:

- Including **an internal control** to provide confidence that sample collection was adequate and that the entire assay process functioned properly.¹
- **Targeting the E6/E7 region of the HPV viral genome** rather than the L1 region, which can undergo deletion during HPV DNA integration.^{5,6}



- **Similar sensitivity and specificity on self-collected and clinician-collected samples.**⁷⁻¹⁰



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DNA, deoxyribonucleic acid; HPV, human papillomavirus; hr, high-risk; PCR, polymerase chain reaction.
1. BD Onclarity™ HPV Assay EU Package Insert [8089899]. 2. Wright TC et al. Am J Clin Pathol. 2014;142(1):43–50. 3. Preisler S et al. BMC Cancer. 2016;16:510. 4. Ejegod DM et al. Papillomavirus Res. 2016;2:31–7. 5. Vaughan LM and Malinowski DP. Rev Bras Ginecol Obstet. 2019;41(5):357–9. 6. Arroyo Mühr LS et al. J Gen Virol. 2020;101:265–70. 7. Rohner E et al. J Clin Microbiol. 2020;58(3):e01443–19. 8. Polman NJ et al. Lancet Oncol. 2019;20(2):229–38. 9. Arbyn M et al. BMJ. 2018;363:k4823. 10. Arbyn M et al. Lancet Oncol. 2022;23(7): 950–60.



Flexibility to choose sample type

BD Onclarity™ HPV Assay **is validated for use** with a variety of collection devices.¹

Liquid-based cytology vials



Cervical Brush



Self-collection devices



Clinical validation of the BD Onclarity™ HPV Assay

The BD Onclarity™ HPV Assay meets the international criteria for primary HPV screening both according to the Meijer criteria and FDA approval

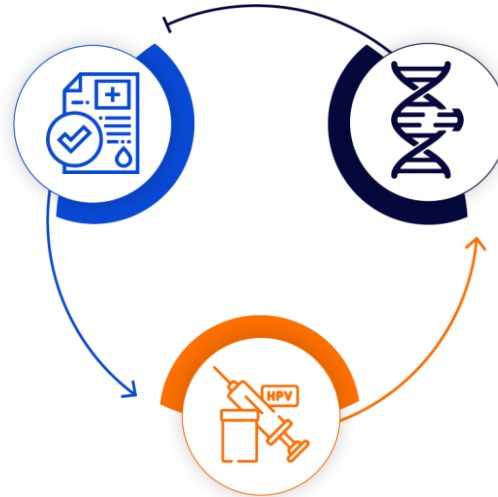
Clinical validation by several studies

FDA trial: recruited more than 33,000 women, prospective study with follow-up¹

VALGENT 2 (PreservCyt®)²

VALGENT 4 (BD SurePath™)³

VALHUDES/Extended VALHUDES4,5 (Self-collected samples)



VALGENT

Protocol⁷

VALIDation of HPV GENotyping tests

Evaluates and compare different HPV genotyping assays

Total of 1300 samples including :

1000 cervical specimens (archived or fresh samples) from women participating in cervical cancer screening program

300 cytologically abnormal samples (100 ASC-US, 100 LSIL, and 100 HSIL)

90-150 CIN2+ cases

Meijer criteria⁶

Meijer criteria for validation of HPV DNA assays

Minimum 800 samples from a screening cohort vs. Hybrid Capture 2 (HC2) &/or GP5+/GP6+ PCR-EIA with at least 60 CIN2+

Criteria:

Sensitivity for CIN2+ $\geq 90\%$ of HC2 sensitivity

Specificity for CIN2+ $\geq 98\%$ of HC2 specificity

Inter- & intra-laboratory agreement & reproducibility in time with at least 500 samples



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1. Stoler MH, et al. Gynecol Oncol. 2023;170:143-152. 2. Cuschieri K, et al. J Clin Microbiol. 2015;53(10):3272-3279. 3. Bonde JH, et al. J Clin Microbiol. 2020;58(2):e01518-19. 4. Latsuzbaia A, et al. Cancer Epidemiol Biomarkers Prev. 2022;31(12):2177-2184. 5. Van Keer S, et al. J Clin Virol. 2022;155:105271. 6. Meijer CJ, et al. Int J Cancer. 2009;124(3):516-520. 7. Arbyn M, et al. J Clin Virol. 2016;76 Suppl 1:S14-S21.

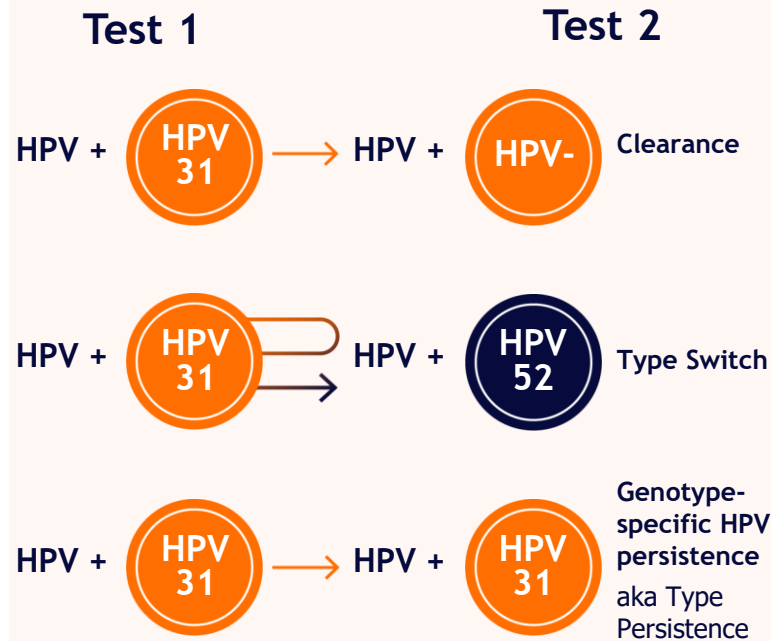
Extended genotyping allows for persistence monitoring

Genotype-specific HPV persistence is the most important determinant of cervical cancer risk in women who test HPV-positive – regardless of the HPV genotype.¹⁻⁵



Identifying which genotype results in a persistent HPV infection is key to identifying your patients at most risk for developing cervical disease – & the more genotypes you can identify, the better.¹⁻⁵ With the BD Onclarity™ HPV Assay, from one HPV test to the next, it is possible to know if there is a genotype-specific persistent infection, if there was a type switch or if the HPV infection was cleared.⁶⁻⁸

Extended genotyping can identify genotype-specific persistence beyond HPV 16 & 18, & type switch.^{7,8}



Partial genotyping cannot identify genotype-specific persistence beyond HPV 16 and 18.^{7,8}

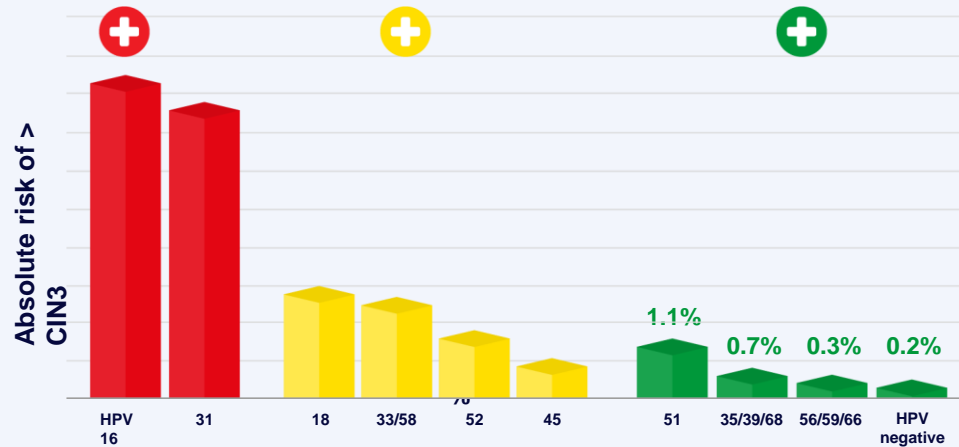


Extended genotyping provides specific actionable insights that differentiates & simplifies patient management

The cumulative CIN3+ risk in HPV positive women vary by HPV genotype, & by type persistence.^{1,2}

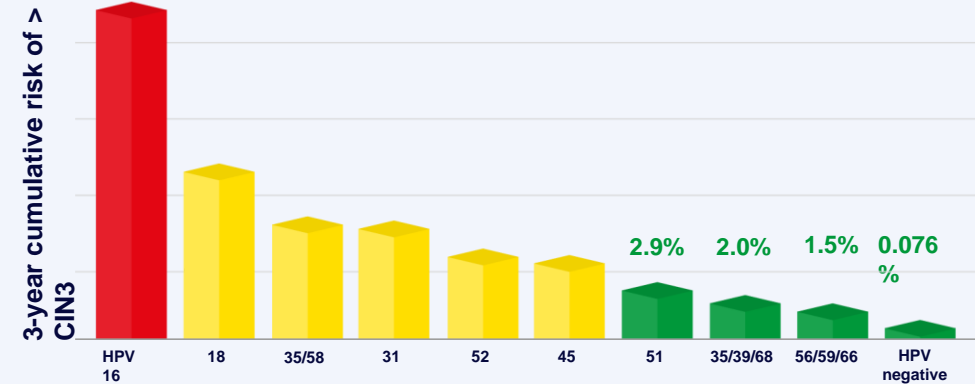
The **actionable results obtained with the BD Onclarity™ HPV Assay can help stratify the baseline & long-term risk of precancer** in women to more precisely guide clinical decision-making.²⁻⁵

Baseline risk of CIN3+ by HPV type in women ≥ 25 years with NILM cytology⁴



Adapted from Stoler 2019.

3-year cumulative risk of CIN3+ by HPV type, all cytology⁵



Adapted from Schiffman 2016.



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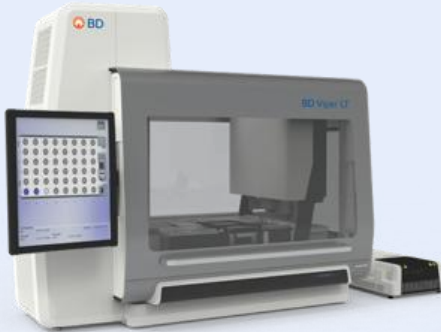
CIN3+, cervical intraepithelial neoplasia grade 3 or higher; HPV, human papillomavirus; NILM, negative for intraepithelial lesion or malignancy.
1. Gilham C et al. Health Technol Assess. 2019;23(28):1-44. 2. Bonde JH et al. J Low Genit Tract Dis. 2020;24(1):1-13. 3. Stoler MH et al. Gynecol Oncol. 2019;153(1):26-33. 4. Schiffman M et al. Int J Cancer. 2016;139:2606-15. 5. Demarco M et al. EClinicalMedicine. 2020;22:100293.

A scalable portfolio of instruments for HPV testing automation

With the BD Viper™ LT and the BD COR™ Systems, you have the choice according to the capacity and needs of your laboratory, to enable greater throughput with the same staff.

BD Viper™ LT System:

Enhancing laboratory performance with a versatile instrument



A compact, integrated, 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.^{1,2}

- 15 min hands-on time for run setup.³
- 90 to 120 results per day.³
- Sample tubes with pierceable caps to avoid manual opening.
- Ready-to-use reagents stored at room temperature.

BD COR™ System:

Unprecedented level of integrated automation in HPV screening - from primary sample to result without user intervention



Suitable for high-volume laboratories requiring advanced integrated automation from sample to result, with minimal user interventions and outstanding long walkaway times.⁴⁻⁸

- <15 minutes to fully load instrument for testing.⁵
- Requires only 1 or 2 interactions per shift at maximum throughput.^{7,8}
- Extended walk-away times of approximately 6.5 hours at maximum throughput.
- 330 HPV results with extended genotyping from an 8-hour shift.



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HPV, human papillomavirus; PCR, polymerase chain reaction.

1. Ejegod DM et al. Papillomavirus Res. 2016;2:31–7. 2. BD Viper™ LT System User's Manual (8089195). 3. Bottari F and Iacobone AD. Expert Rev Mol Diagn. 2019;19(7):565–70. 4. BD COR™ PX/GX System User's Manual. (L011486). 5. BD COR™ Hands-On Setup Time (HTDI-21-0406). 6. BD Onclarity™ HPV Assay for the BD COR™ System Package Insert (L011461). 7. Taylor SN et al. Expert Rev Mol Diagn. 2021;21(3):333–42. 8. Ejegod DM et al. Am J Clin Pathol. 2021;XX:1–9.



BD solutions for cytology testi ng



STAY AHEAD OF THE CURVE IN
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Not all Pap tests are the same

Cervical cancer incidence and mortality has declined by 70% since the introduction of Pap screening in developed countries with well-established screening programmes, and in which women are screened at regular intervals.¹

However, not all Pap tests are the same.



Conventional Pap testing comes with many limitations that may lead to inaccuracies & equivocal diagnoses.²



Liquid-based cytology (LBC) has revolutionised Pap screening by significantly enhancing specimen quality & detection of cervical lesions & reducing patient call-backs while improving cost-effectiveness.^{3,4}

Let's compare the features of a conventional Pap test versus the BD SurePath™ Liquid-based Pap Test^{1,2}

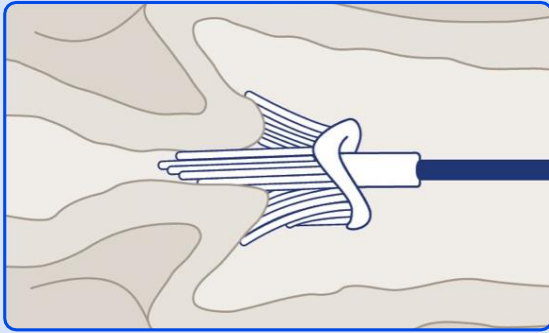


	Conventional Pap test	Liquid-based cytology (LBC)
Principle	Brush contents are smeared directly onto the slide	<ul style="list-style-type: none"> The cells from the brush are deposited into liquid preservative which is then used to make a slide A cell enrichment process can be performed to further improve the quality of the slide
Standardised sample collection	⊗ Variability in sample collection	✓
Slide preparation	Manual	Automated
Little to no obscuring material	⊗	✓
Easy slide evaluation	⊗	✓
Reduced screening time	⊗	✓
Performance	Frequent unsatisfactory reports	<ul style="list-style-type: none"> Improved specimen adequacy Reduced unsatisfactory reports Increased disease detection
Additional testing	⊗ Not always possible	<ul style="list-style-type: none"> Allows for additional molecular testing – such as HPV testing – & immunocytochemistry from the same sample Compatible with co- and reflex testing

Reliable sample collection with the BD SurePath™ Collection Vial

Collect

t



Collect the cytology sample. Follow manufacturer's collection instructions for detachable-head device(s).

Drop

p



To drop the brush head into the vial, there are different methods, e.g. Insert the head of the broom-type device into the larger of the two vial openings. Rotate the handle of the collection device while gently pulling up to detach the device head from the handle, depositing the device head into the larger of the two vial openings

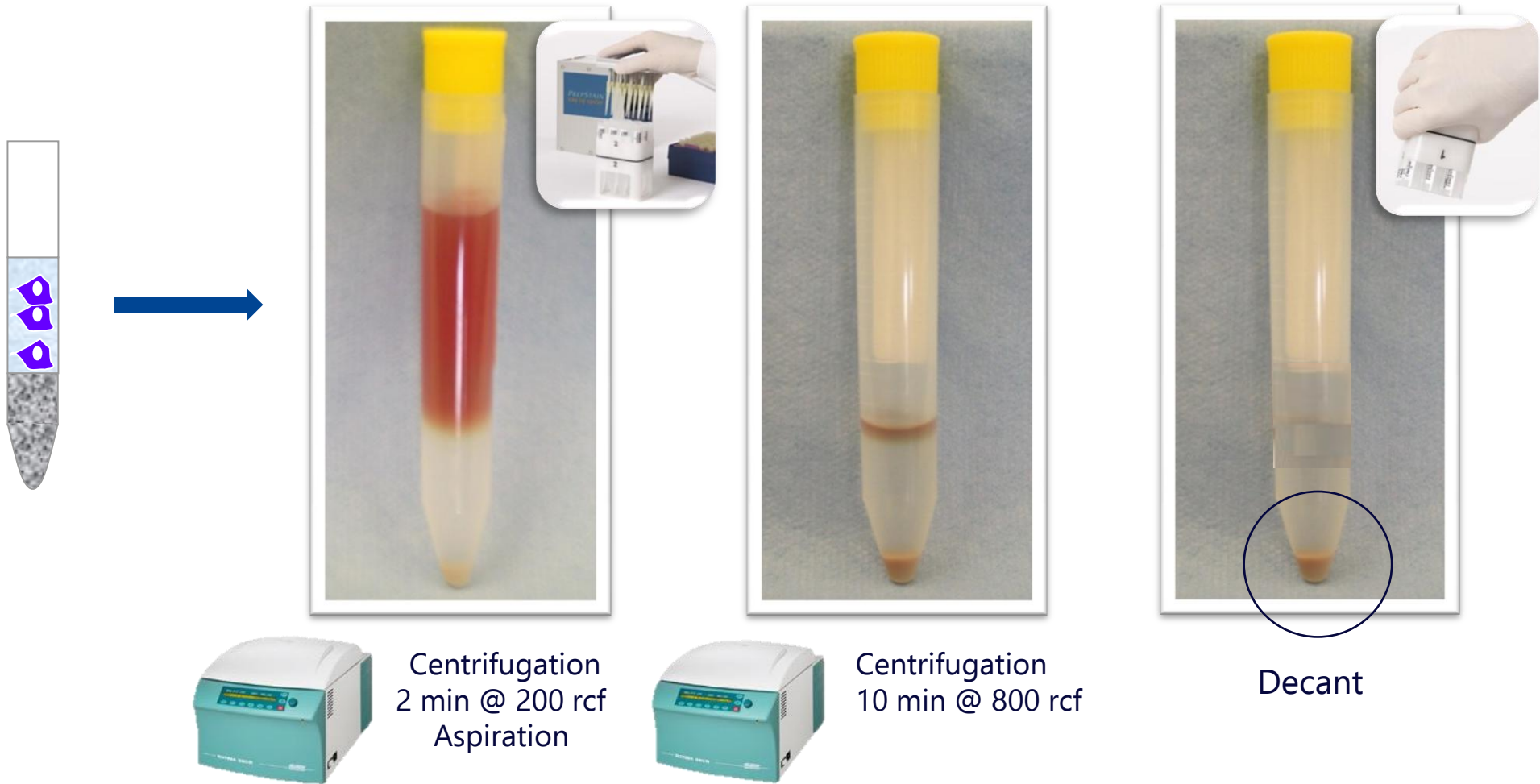
Send

d



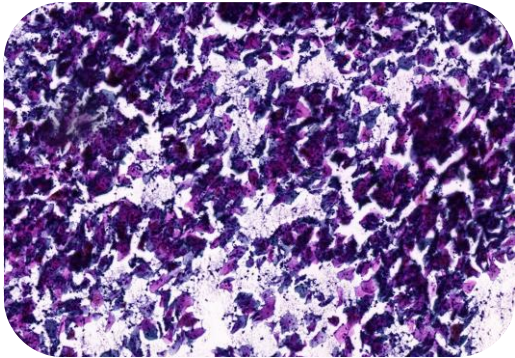
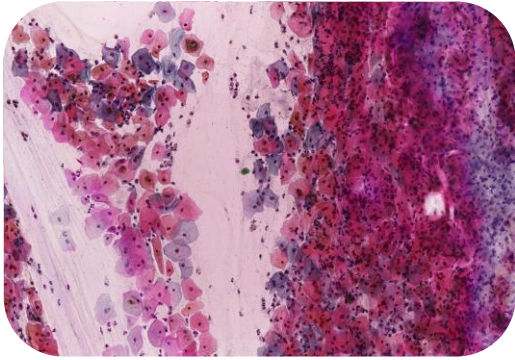
Place the cap on the vial and tighten. As an option, you can remove the top barcode and place on the requisition form to ensure positive sample identification. Send the BD SurePath™ Collection Vial to the lab for processing.

A unique and standardised cell enrichment workflow

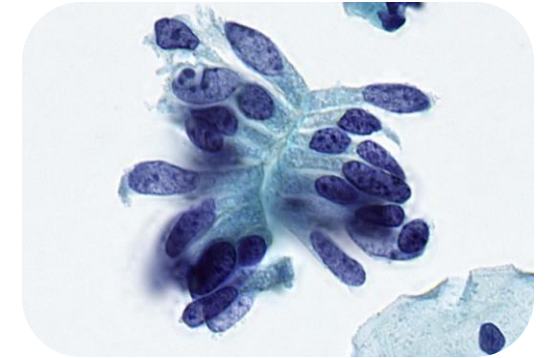
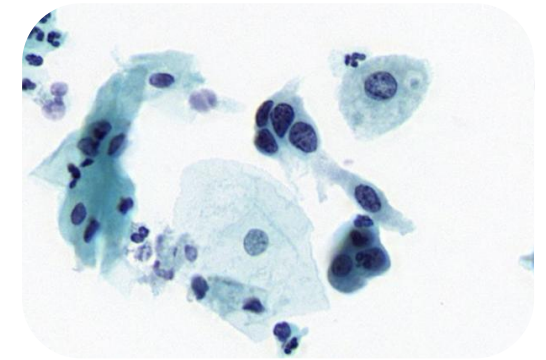
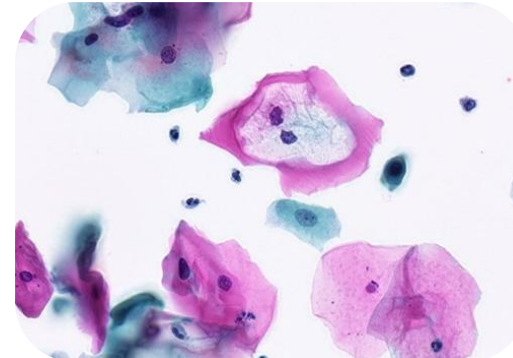
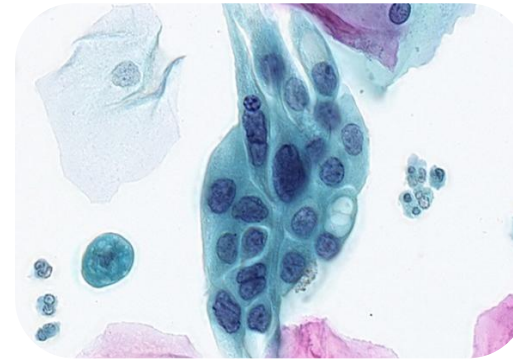
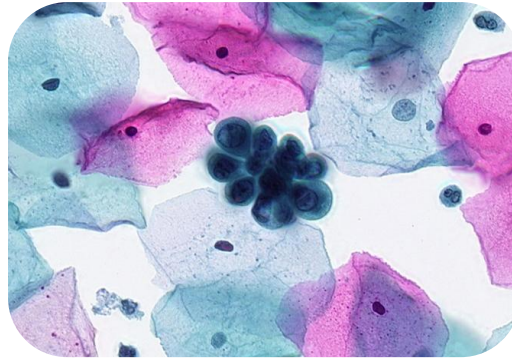
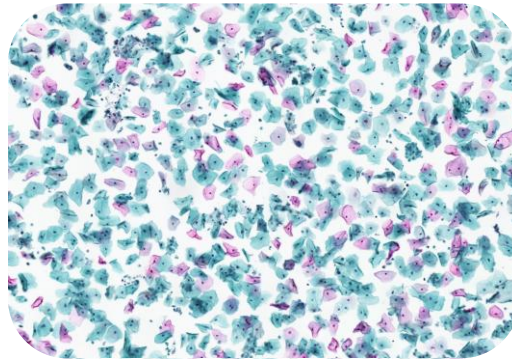


Compare microscopy images of a conventional Pap test versus the BD SurePath™ Liquid-based Pap Test


With conventional



With **BD SurePath™ Liquid-based Pap**



BD SurePath™ Liquid-based Pap Test increases the detection of cervical precancerous lesions



Using conventional cytology, **cervical precancerous lesions** may go undetected

BD SurePath™ Liquid-based Pap Test **identified more CIN1, CIN2, CIN3, and CIN2+** compared to conventional cytology, while ThinPrep® did not increase the detection of CIN.¹

Comparison of **OR to detect biopsy-confirmed disease from ASCUS+ cytology¹** (LBC vs conventional smear)

	SurePath™	ThinPrep®
CIN1 (95% CI)	1.14 (1.08-1.20)	0.98 (0.93-1.04)
CIN2 (95% CI)	1.14 (1.09-1.20)	1.04 (0.99-1.10)
CIN3 (95% CI)	1.06 (1.02-1.10)	0.98 (0.94-1.01)
Cervical Cancer (95% CI)	0.99 (0.86-1.14)	0.87 (0.75-1.01)
CIN2+ (95% CI)	1.08 (1.05-1.12)	0.99 (0.96-1.02)



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CERVICAL CANCER SCREENING

ASC-US, atypical squamous cells of undetermined significance; CI, confidence interval; CIN, cervical intra-epithelial neoplasia; LBC, liquid-based cytology; OR, odds ratio.
1. Rozemeijer K et al. Cancer Causes Control. 2016;27(1):15-25.

Low- to mid-volume laboratories: achieve efficiency and precision of cytology testing in your lab

BD PrepMate™

Compact design delivers precise sample



- Automates the initial step of the unique BD cell enrichment process by mixing, aspirating and dispensing the specimen from BD SurePath™ Collection Vials.
- Eliminates manual cap removal, reducing the risk of contamination.
- Handles up to 12 samples per cycle.
- Intuitive user interface and small footprint.

BD Totalys™ SlidePrep

Efficiency and confidence in slide



- Automates slide preparation and staining and processes BD SurePath™ and non-gynaecological samples.
- Accurate reagent pipetting and precise timing for each sample.
- Minimal hands-on time allows staff to perform other tasks.
- Prepare up to 4 identical slides from the same cell pellet, for additional analyses beyond Pap cytology.

High-volume laboratories: fulfil your automation needs with full chain of custody across instruments from sample to results

BD Totalys™ MultiProcessor

Flexibility to meet current and future screening algorithms.^{1,2}



- Automates the unique BD cell enrichment process for BD SurePath™ Liquid-based Pap Test to remove blood, mucus, and inflammatory cells.
- Adaptable loading and unloading of samples maximises flexibility.
- Process up to 336 samples, with aliquoting for ancillary testing within an 8-hour shift.
- Full chain of custody from collection vial to sample outputs.
- BD Totalys™ MultiProcessor and BD Totalys™ SlidePrep are aligned in throughput needs.

BD Totalys™ SlidePrinter



- Easily connects to your LIS through BD Totalys™ DataLink Middleware.
- Prints 1D and 2D barcodes, alphanumeric and graphics.
- Configurable to include any patient identifiers.
- Reduces labor and sources of labeling error
- Intuitive user interface.
- Dual slide input cartridge provides random access for slide loading without interruption to printing.

Sample chain-of-custody



BD SurePath™
Collection Vial



Centrifugation Tube



BD Viper™ LT Tube



Full traceability from
sample collection to result
Duplicate barcodes
connect the vial to the
order form

Pre-labeled C-tube and
molecular aliquot tube
connects to the source vial
automatically in the
software

Customized slide printing
with any information in the
LIS

Techcyte SureView™

Cervical Cytology System

Accuracy and Efficiency

Techcyte's SureView™ is an AI-assisted screening tool designed to enable cytotechs and pathologists to analyze diagnostically important cells and organisms in pap smears.

It helps medical technologists read SurePath™ or ThinPrep® slides using an AI-based algorithm, workflow, and LIS integration.



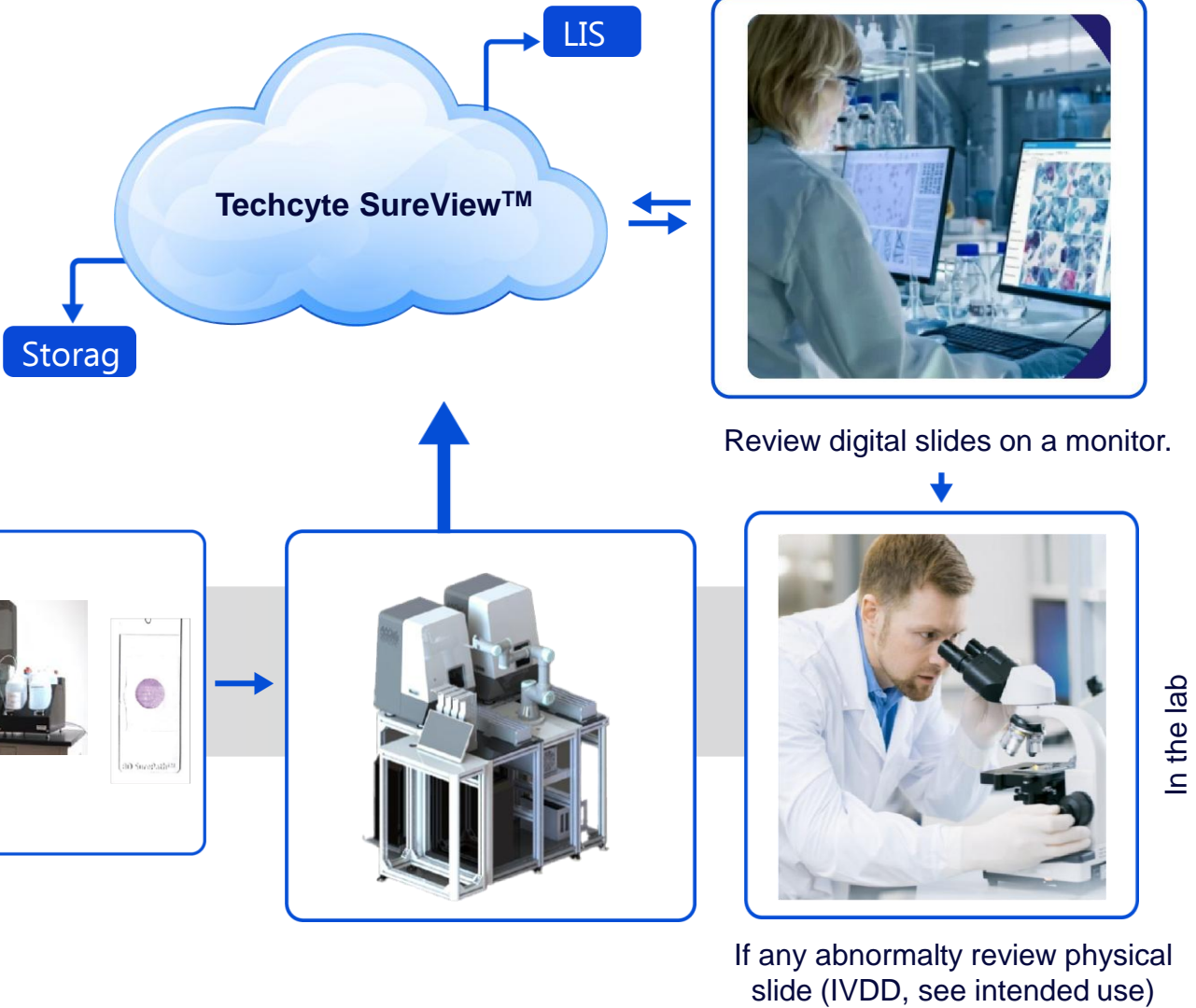
From sample to diagnose



Same barcode printed on the slide as on the SP vial- chain of custody



30 days storage of slide image included.



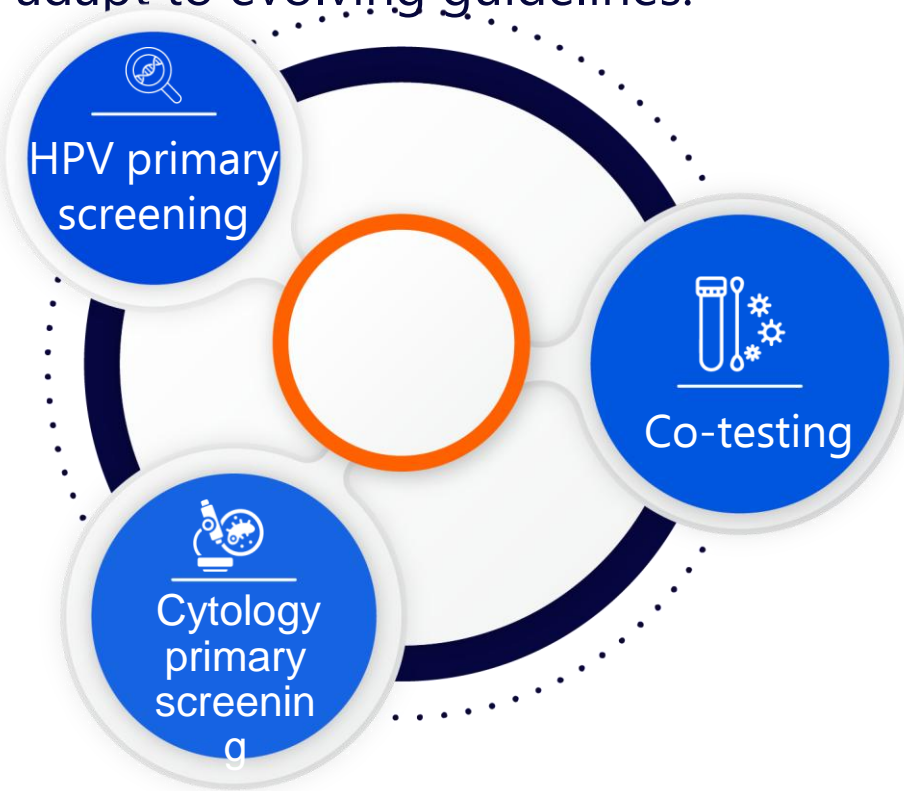
Flexible solutions so you can adapt to all screening paradigms

Acting as a single source provider for both HPV and cytology testing, **BD offers a full suite of advanced cervical cancer screening products and services** that empower clinicians and laboratories to meet the needs of the rapidly changing cervical cancer screening landscape and adapt to evolving guidelines.

BD SurePath™ Collection Vial

FDA and CE-marked for use with the **BD SurePath™ Liquid-based Pap Test** and the **BD Onclarity™ HPV Assay**.^{1,2}

A single FDA and CE-marked collection device **approved for all 3 screening paradigms**, offering the flexibility you need to adapt to changing screening guidelines.^{1,2}



Thank You

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BD Onclarity™ HPV Assay for BD COR™ is an in vitro diagnostic medical device bearing a CE mark and is CE certified by BSI Group The Netherlands B.V. (Notified Body Number – 2797).

FLOQSwabs® are medical devices bearing a CE mark and are CE certified by TUV SUD Product Service GmbH (Notified Body Number 0123)

Rovers® Evalyn®Brush, Rovers® Viba-Brush® are medical devices bearing a CE mark and are CE certified by TUV NORD CERT GmbH (Notified Body Number 0044)

