

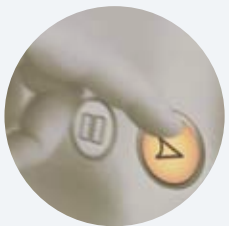


Helping all people
live healthy lives

Immunocyto-
chemistry

Liquid-based
cytology

Computer
guided
screening



Early detection and clinical management of cancer
Solutions for advanced cytology

Helping all people live healthy lives

BD, a leading global medical technology company that manufactures and sells medical devices, instrument systems and reagents, is dedicated to improving people's health throughout the world. BD is focused on improving drug therapy, enhancing the quality and speed of diagnosing infectious diseases, and advancing research and discovery of new drugs and vaccines. The Company's capabilities are instrumental in combating many of the world's most pressing diseases.

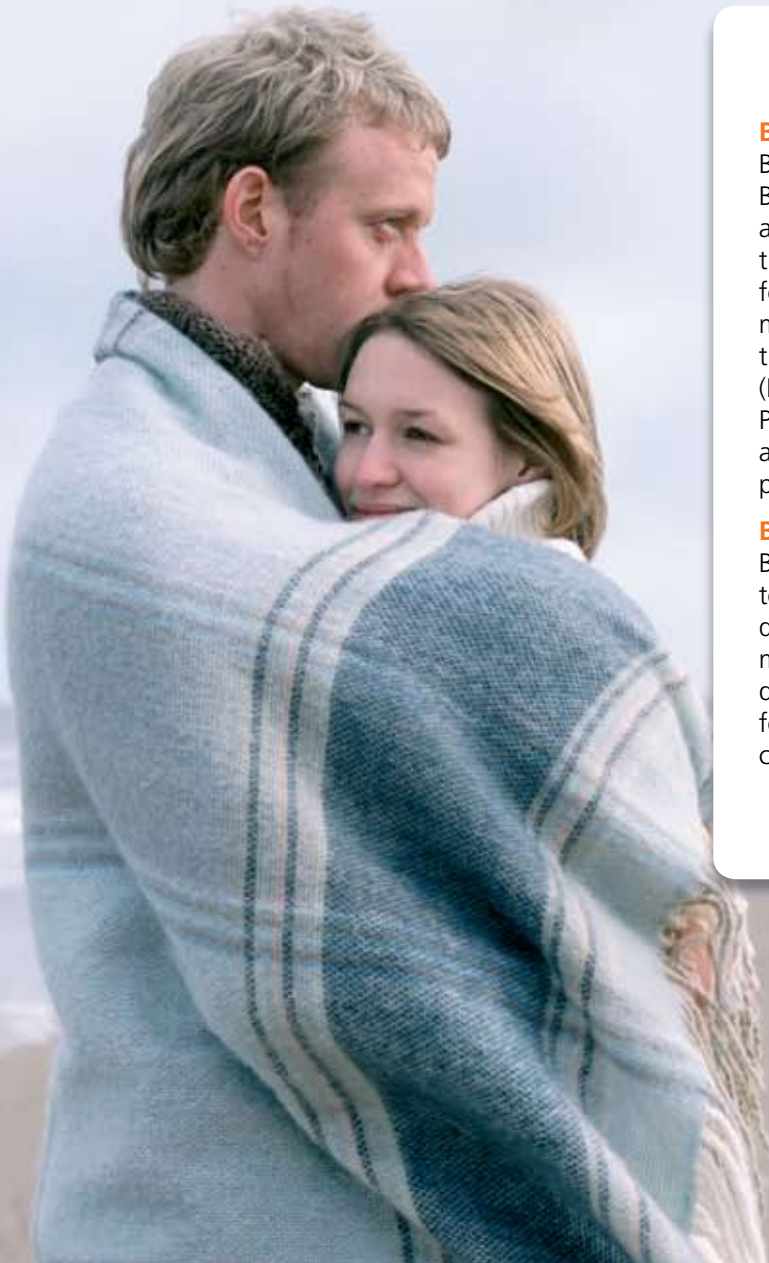
Founded in 1897 and headquartered in Franklin Lakes, New Jersey, United States, BD employs more than 25,000 people in approximately 50 countries throughout the world. The Company serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public.

BD Diagnostics

BD is organized into 3 segments, BD Medical, BD Diagnostics and BD Biosciences. BD Diagnostics is a leading provider of products for the safe collection and transport of diagnostic specimens and of instrumentation for quick, accurate analysis for a broad range of microbiology and infectious disease testing, including the growing problem of healthcare-associated infections (HAIs). The segment is composed of two operating units: Preanalytical Systems, a world leader in sample collection, and Diagnostic Systems, a leader in microbiology testing products and molecular assays.

BD Diagnostics - TriPath

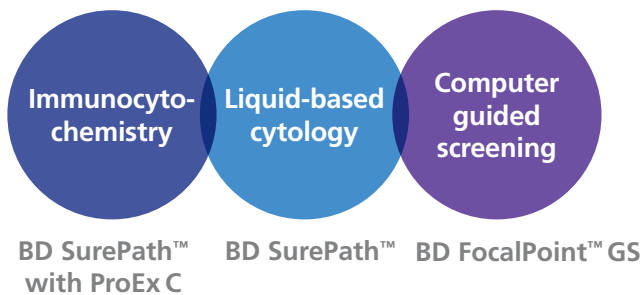
BD's TriPath product platform creates innovative solutions to improve the clinical management of cancer, including detection, diagnosis, staging, and treatment. These oncology management tools are intended to span cancer screening, diagnosis, prognosis and therapy monitoring, especially for cancers affecting women's health, including breast, cervical and ovarian.



Redefining the early detection of cancer

We provide integrated cervical cytology screening solutions that offer substantial value to laboratory customers, doctors, patients and third-party payors worldwide in screening for cervical cancer.

SOLUTIONS FOR ADVANCED CYTOLOGY



Proven Performances

TriPath has had a presence worldwide since its origin:

- BD SurePath™ liquid-based technology was officially approved through the FDA in the US in 1999.
- After a study from NICE in 2004, BD SurePath™ Pap Test has been officially approved in England and Wales.
- More than 120 scientific and clinical studies support TriPath's liquid-based technology.
- 12 European countries are covered by a highly trained distribution network.
- TriPath's proprietary technology is protected by over 100 patents.
- Over 7 million cytology slides processed worldwide every year using the BD FocalPoint™ Imaging System technology.

TriPath products are focused on next-generation clinical solutions for patients through the development of novel molecular oncology products. In cancers of the cervix, breast, ovary, prostate and skin, the proprietary reagents that we develop will be used:

- to screen and assist in the diagnosis of the presence of disease,
- to assess patient prognosis and outcome more accurately,
- to guide therapeutic selection in the management of cancers,
- to monitor for disease recurrence.



BD SurePath™ Pap Test

Immunocytochemistry

Liquid-based cytology

Computer guided screening

Reducing risks and optimizing



Simple
Standardized
Efficient

Product availability to be confirmed with our local representative

BD SurePath™ Liquid-Based Pap Test

BD SurePath™ liquid-based Pap Test gives you more confidence in results

- BD SurePath™ liquid-based Pap Test demonstrates a significant reduction, 43%⁽¹⁾ – 81%⁽²⁾, in unsatisfactory cases versus conventional Pap tests, reducing the need for unnecessary repeat testing. BD SurePath™ Pap Test is FDA approved and showed a 64.4% increase in HSIL+ detection.⁽³⁾
- On average, 37% of cellular material is lost when the collecting device is discarded.⁽⁴⁾ BD SurePath™ Pap Test is the only FDA approved liquid-based Pap test that can ensure 100% of the collected sample is sent to the laboratory for processing. No swish, no swirl, no loss of diagnostically relevant cells during sample transfer.
- 2/3 of Pap smear false negatives are the result of cells not being collected on sampling device and collected cells not being transferred to the slide.⁽⁵⁾
- Cervical samples can be collected using broom-like devices or combination broom/spatula with detachable heads.⁽⁶⁾ The Rovers Cervex-Brush Combi targets sampling of the transition zone resulting in two- to three-fold increase in harvest of endocervical cells.⁽⁷⁾

One sample: multiple significant tests

Disease examples

HPV⁽⁸⁻¹⁰⁾

CT/NG⁽¹¹⁾⁽¹²⁾

Trichomonas⁽¹³⁾

Technology examples

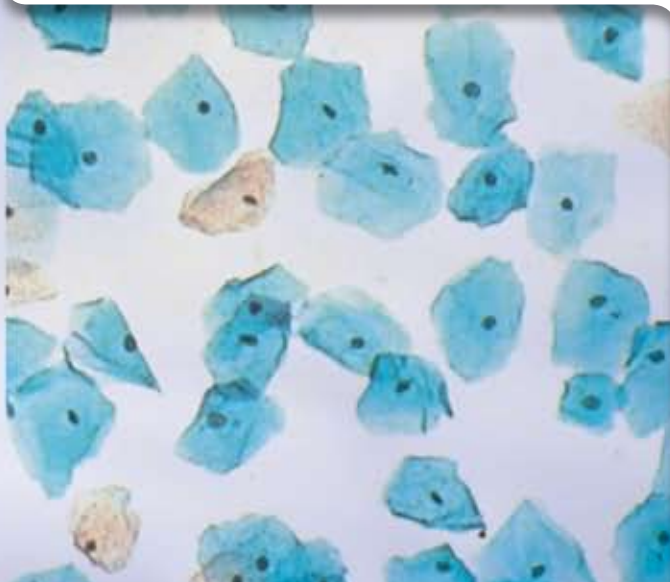
Hybrid Capture⁽⁸⁻¹⁰⁾

PCR⁽¹⁴⁾⁽¹⁵⁾

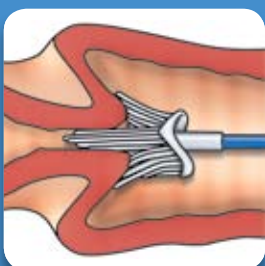
ISH⁽¹⁶⁾

Genotyping⁽¹⁴⁾

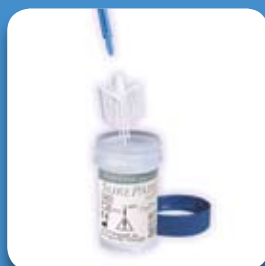
- The residual patient sample can also be used for additional immunocytochemistry tests (BD SurePath™ with ProEx C Immunocytochemical Test).
- Additional BD SurePath™ slides (at least 5) can be processed from the BD SurePath™ enriched cell pellet.



Simple sample collection



1 Collect



2 Drop



3 Send

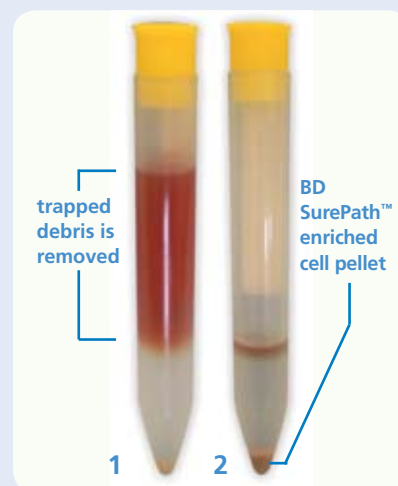
100% of the collected sample is sent to the laboratory every time

the diagnosis

BD SurePath™ Pap Test Proprietary Cell Enrichment Process

The BD SurePath™ Pap Test proprietary Cell Enrichment process separates and reduces obscuring debris (e.g. blood, mucous) and inflammatory cells, preserving background interpretation and providing better and quicker visualization of clinically relevant cells. There is no need for extra processing steps dedicated to bloody or mucoïd samples, leading to a greater standardization of sample processing and clarity of results^(17,18).

The BD SurePath™ Pap Test proprietary Cell Enrichment process separates and reduces obscuring debris, thus reducing the unsatisfactory rates^(17,18).



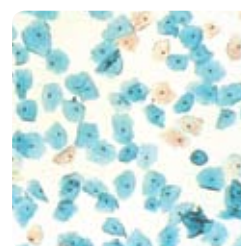
Bring more automation, standardization and productivity into your laboratory

With BD SurePath™ liquid-based Pap Test:

- Slide processing and staining are automated to provide high quality and standardized results.
- Screening time can be significantly reduced and Pap test turnaround times significantly improved compared to conventional Paps.⁽²⁾
- Visualization and interpretation of diagnostically relevant cells is easier and quicker.
- High throughput processing (96 slides per 64 minutes without staining, 48 slides per hour with staining) improves laboratory capacity.
- The processor used to prepare BD SurePath™ cervical slides is also used to prepare non-gynecological samples to meet all your cytology needs (e.g. Fine Needle Aspirations, body cavity fluids, urine).



Conventional Slide
Inflammation



BD SurePath™ liquid-based Pap test
Same sample after
Cell Enrichment

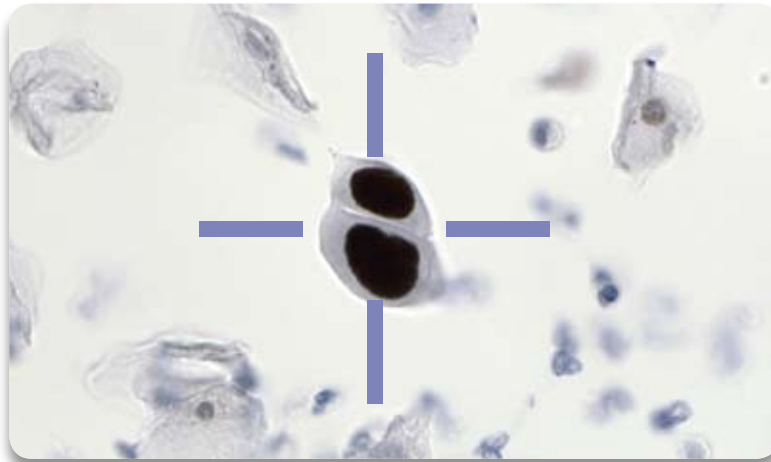


Immunocytochemistry

Liquid-based cytology

Computer guided screening

Confirming the diagnosis



Improved identification of underlying high-grade disease

See the difference

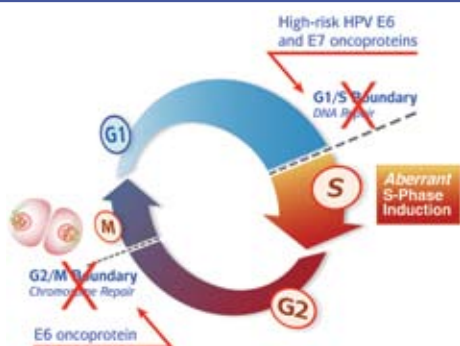
BD SurePath™ with ProEx C is an immunocytochemical test intended to aid in the identification of high-grade cervical disease (CIN2+) in routinely collected BD SurePath™ specimens.^(19,20)

This test:

- Produces a nuclear staining pattern that is easy to read, compatible with morphology and current cytopathology classification.
- Provides adjunctive information for cytology diagnosis.
- Designed for manual staining or use with automated staining platforms such as the SMS 3600™ Molecular Stainer.

Detecting Aberrant S-Phase Induction in Cervical Dysplasia

BD SurePath™ with ProEx C Immunocytochemical Test targets key proteins that are over-expressed during Aberrant S-Phase Induction, including Minichromosome maintenance proteins (MCM) and Topoisomerase II alpha (TOP2A).



In Cervical Neoplasia, HPV disrupts both the G1/S and the G2/M cell-cycle checkpoints.

HPV oncoprotein E7 inactivates the G1/S cell cycle checkpoint and accelerates the cell into Aberrant S-Phase Induction.

Measuring Aberrant S-Phase Induction is important

BD SurePath™ with ProEx C Immunocytochemical Test:

- Provides additional information that assists in morphological classification of high-grade disease (CIN2+).⁽²¹⁾
- Identifies cells that are characteristic of cervical disease and its pre-malignant precursors.^(19,20,22-24)
- Detects molecular consequences arising from persistent HPV infection.^(19,20,22,23)

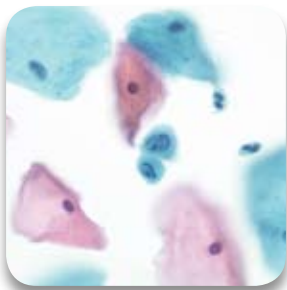
Performance is the difference

When it comes to reporting results, your customers expect accurate information. BD SurePath™ with ProEx C Immunocytochemical Test:

- Provides adjunctive information to assist the clinician in more accurate triaging of women with ASC-US+ cytology.⁽²⁵⁾
- Research studies have shown increases in the detection rate of underlying high-grade disease (CIN2+) without increasing the false positive rate.^(20,25)



BD SurePath™ liquid-based Pap Test



Cytology specimen collected in BD SurePath™ preservative fluid using a BD SurePath™ Papanicolaou stain.

BD SurePath™ with ProEx C Immunocytochemical Test



Cytology specimen from the same patient stained positive for high-grade cervical disease.



BD FocalPoint™ GS Imaging System

Immunocytochemistry

Liquid-based cytology

Computer guided screening

Providing benefits in your daily

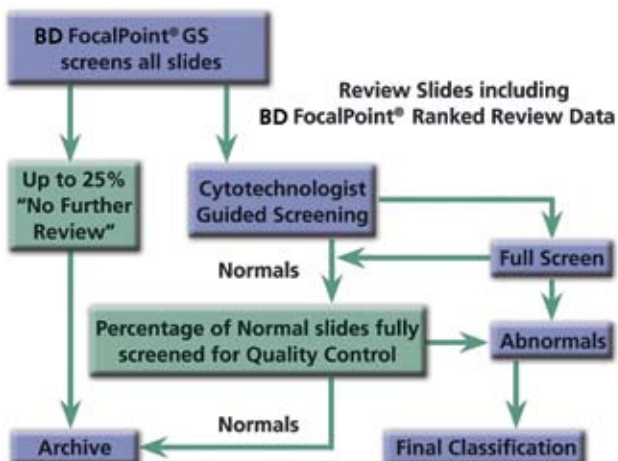


BD Focal Point™ GS Imaging System

The BD FocalPoint™ GS Imaging System improves the quality of slide reading by directing the cytotecnologist's attention to slides most likely to contain abnormality. All conventional or BD SurePath™ Pap Test slides from the laboratory are screened on the BD FocalPoint™ system. The BD FocalPoint™ system classifies the slides into "Review" and optional "No Further Review" groups and then ranks Review slides into five quintiles (1=highest risk, 5=lowest risk) helping cytotecnologists to understand the risk inherent in each slide. This information is also used to help the laboratory efficiently perform their Quality Control (QC) process. The BD FocalPoint™ GS Imaging System operates as an aid to the cytotecnologist by automatically relocating areas of interest in a prioritized order. These specific areas on the slide are most likely

to contain abnormal cells or information of diagnostic interest. The cytotecnologist then has the interactive capability to electronically mark the area of interest, move to another location on the slide manually, make annotations and track the progress of the marked slide areas during slide review. Once the BD FocalPoint™ system screens all the slides, a cytotecnologist is directed to the Fields of View most likely to contain abnormal cells.

- Each slide has a barcode for better sample tracking.
- The motorized stage of the microscope enables pre-selected Fields of View as well as Fields of View selected by the cytotecnologist for greater flexibility.



BD FocalPoint™ GS cytology Screening Workflow

Each slide is scanned by the BD FocalPoint™ GS system. Hundreds of cell features are measured and translated into an anomaly score. Each slide is ranked, based on this anomaly score. Slides that are designated as 'Review' are prioritized based on the risk for abnormality (ranking), to aid the cytotecnologist and the pathologist in diagnosis and quality control.

practice of cervical cancer screening

BD FocalPoint™ GS Imaging System showed⁽²⁶⁻²⁸⁾

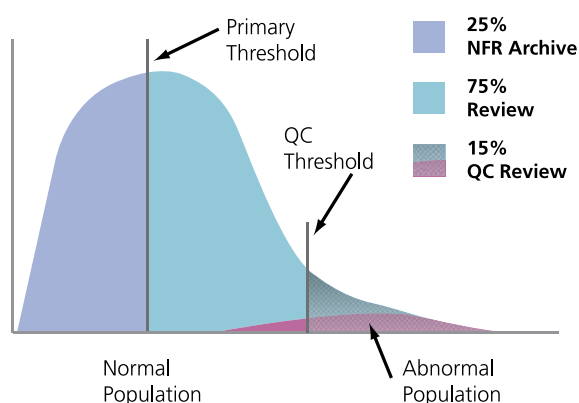
- Numerically more detection of HSIL+ slides for BD SurePath™ liquid-based cytology and conventional Pap smears as compared to the existing practice.⁽²⁶⁾
- Statistically improved LSIL+ detection on conventional slides.⁽²⁶⁾
- Improved sensitivity and specificity.^(26,28-30)
- References to the literature on the BD FocalPoint™ GS Imaging System indicates clinical performance data shows good sensitivity for various levels of cervical disease,
 - 1) 89.5% for ASC-US, 95.7% LSIL and 98.1% HSIL⁽²⁹⁾ and,
 - 2) statistically superior detection of slides with HSIL+ comparing BD FocalPoint™ GS system to manual screening.⁽²⁷⁾
- A feasibility study indicated sensitivity of 85.4% for ASC-US/atypical glandular cells of undetermined significance (AGUS), 98% for LSIL, and 100% for cancer.⁽³¹⁾
- By using the BD FocalPoint™ GS system in the cytology laboratory, there is the potential that FOV review may guide the examiner to fields containing significant abnormalities that may otherwise go undetected on human review alone.⁽³²⁾
- Assessment of No Further Review slides indicated that women in this category can safely return to periodic screening.⁽³³⁾
- Quality control measures such as rapid review or full manual reading of a random sample are probably not necessary.⁽³³⁾

BD FocalPoint™ GS Imaging System maximizes laboratory efficiency and productivity

- The BD FocalPoint™ GS system with location guided screening is an important productivity tool in the potentially understaffed cytology laboratory.^(27,31,34)
- “The AutoPap with LGS (BD FocalPoint™ GS Imaging System) can significantly speed the examination of Pap smears without lowering the detection rate of clinically important lesions, thus helping alleviate the cytotechnologist shortage.”⁽³⁵⁾
- The BD FocalPoint™ GS system can result in a substantial reduction in interpretation time.⁽³⁶⁾

Annual capacity on a single BD FocalPoint™ GS system is 65,000 conventional slides or 90,000 BD SurePath™ slides (based on 250 working days per year).

- Individual slide screening time will be reduced because the cytotechnologist concentrates on a limited number of Fields of View.
- Total number of slides to screen is reduced by up to 25% if using the “No Further Review” option.



Automated ranking
Ranking of slide anomaly

Offers a reliable and modular tool

- Automatic self-test ensures highest integrity.
- Remote service capability allows fastest possible support.
- Networking capability.
- User-friendly software compatibility with Laboratory Information System (LIS).
- Barcode reading for rapid data retrieval.

Summary Statements

- The BD FocalPoint™ GS Imaging System is effective as a method to improve the accurate practice of cervical cytology.⁽²⁷⁾

Supporting our customers

Our training and technical center located near Brussels, as well as our network of highly trained distributors, will provide your laboratory personnel with optimal support for successful integration of our cervical cytology and non-gyn cytology solutions in your laboratory.



Regular training sessions throughout the year

- Morphology training for BD SurePath™ liquid-based cytology
 - **participants:** pathologists, cytotechnologists
 - **objective:** training to screen and diagnose. A two-days training with certificate of completion.
- Product operator training for equipment and disposables (BD SurePath™ liquid-based technology, BD FocalPoint™ GS Imaging System, BD SurePath™ with ProEx C immunocytochemical tests)
 - **participants:** pathologists, cytotechnologists, laboratory technicians
 - **objective:** to provide theoretical and practical expertise on the products. The training includes 1 or 2 days hands on tutorial with numerous practical exercises in the laboratory.



Showroom

A fully-operational laboratory to perform or assist customers in evaluations and product trials using the customer's samples.



Remote maintenance and technical support

The team offers our customers:

- Remote monitoring of the BD FocalPoint™ GS system installed in your laboratory from our center in Belgium. 24 Hour intervention during working days when necessary.
- Technical assistance and support.
- Updates of the proprietary software.
- On-site revision and maintenance.

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