

Liquid-based cytology

Computer-guided screening

Immuno-chemistry



**BD**

Helping all people  
live healthy lives



**Trust BD SurePath™**

The right material for the right start

## Only 3 easy steps to take a smear

### 1. Collect



Collect the cytology sample using either a broom-like device or a combination brush/plastic spatula with detachable heads.

### 2. Prepare



Drop the detachable head into the BD SurePath™ vial. Place the cap on the vial and tighten.

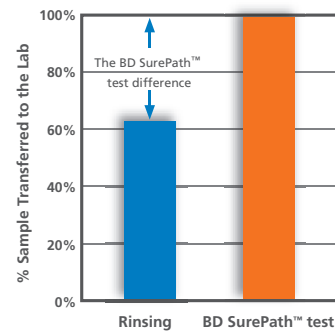
### 3. Send



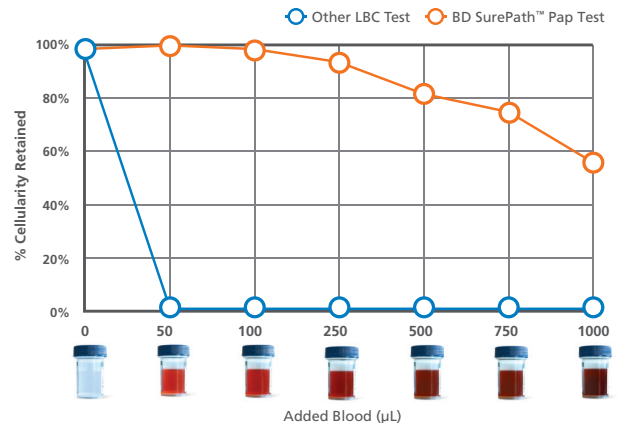
Label and send the BD SurePath™ vial to the lab for processing.

The collection devices, recommended to be used with BD SurePath™, have all a detachable head, making it simple to collect, prepare and send a complete sample for analysis.

- You can be sure your samples **have been collected in a standardized way**
- You can be sure **that 100% of the collected cells are sent to the laboratory**. In contrast, using a rinse and swirl technique can result in an average 37% loss of cells <sup>(1)</sup>.



- You can be sure to **obtain a readable result** from your samples including bloody and inflammatory samples, as well as samples from menopausal patients or patients on birth control <sup>(2)</sup>.



**With BD SurePath™, you don't need to worry about discarding cells that could mean the difference between finding dysplasia and missing it! <sup>(1)</sup>**

#### References:

- (1) Bigras, G et al. J of Lower Genital Tract Disease. Vol 7 (3), 2003: 168-174.  
 (2) Sweeney BJ, et al. Cancer Cytopathology. Vol 108 (1), 2006: 27-31.



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## Find what you are looking for

Rely on the FDA-approved  
**BD FocalPoint™ GS Imaging System**  
for efficient and optimal interpretation  
of your slides



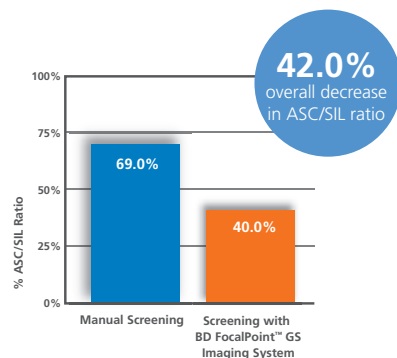
## Rely on the FDA-approved **BD FocalPoint™ GS Imaging System** for assistance in your cervical cancer screening routine.

### 1. Reduced false negatives through the detection of significantly more dysplasia <sup>(1)</sup>

**BD FocalPoint™ GS Imaging System** shows superior dysplasia detection for BD SurePath™ Liquid-based cytology and conventional Pap smears as compared to the actual practice. (2-3-4-5-6-7). A FDA-approved clinical trial, comparing the **BD FocalPoint™ GS Imaging System** with manual screening of BD SurePath™ Pap test slides, found a:

- **24.5% increase in Cancer sensitivity**
- **19.6% increase in HSIL+ sensitivity**
- **9.8% increase in LSIL+ sensitivity**
- **9.2% increase in ASC-H+ sensitivity**

### 2. Reduced unnecessary and inconvenient repeat testing by lowering your ASC-US result



### 3. Significantly increased productivity

- Only a limited number of fields of view,
- Up to 25% of the slides can be archived directly (optional)
- Up to 170 slides in an 8-hour work day
- Multiple possibilities to integrate LIS capabilities to accelerate data sharing
- Remote connectivity

#### References:

- (1) Package insert of BD FocalPoint™ GS Imaging System.
- (2) Wilbur DC., Parker EM., Foti JA. Location-Guided Screening of Liquid-Based Cervical Cytology Specimens. A Potential Improvement in Accuracy and Productivity is Demonstrated in a Preclinical Feasibility Trial. Am J Clin Path 2002;118:399-407.
- (3) Passamonti B., Bulletti S., Camilli M., D'Amico M., Di Dato E., Gustinuchi D., Martinelli N., Malaspina M., Spitta N. Evaluation of the FocalPoint GS System Performance in an Italian Population-Based Screening of Cervical Abnormalities. Acta Cytologica 2007;51(6):865-871.
- (4) Huang TW., Lin TS., Lee JS. Sensitivity studies of the AutoPap System Location Guided Screening of cervical-vaginal cytologic smears. Acta Cytologica 1999;43:363-368.
- (5) Bentz JS. Liquid-based cytology for cervical cancer screening. Future Drugs 2005; 5(6), 857-871.
- (6) Lee JS., Kuan L., Oh S., Patten F., Wilbur DC. A feasibility study of the AutoPap System Location Guided Screening. Acta Cytologica 1998;42:221-226.
- (7) Kardos T. The FocalPoint System: FocalPoint slide profiler and FocalPoint GS. Cancer Cytopathology. Dec 2004.



#### BD Diagnostics

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## Make the BD FocalPoint™ GS Imaging System your guide in cervical cytology screening

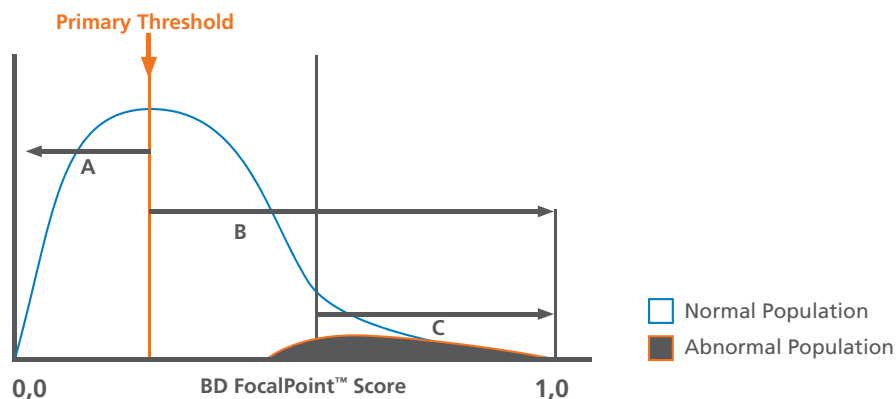
- Directs your attention to slides most likely to contain abnormalities
- Guides you to specific areas on the slide most likely to contain abnormal cells or information of diagnostic interest



## The BD FocalPoint™ GS Imaging System improves the quality of slide reading by:

- Automating the screening of both conventional and BD SurePath™ liquid-based slides
- Detecting changes associated with epithelial abnormalities and specimen adequacy using morphology and densitometric parameters
- Ranking slides and slide locations according to their likelihood of containing abnormal cells
- Relocating automatically areas of interest in a prioritized order
- Offering the capabilities to electronically mark the area of interest, make annotations and track the progress of slide review

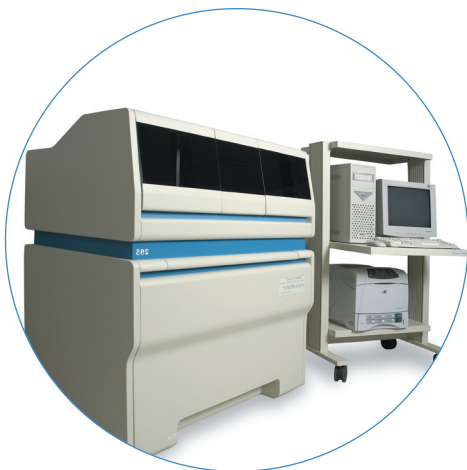
All slides from the laboratory are screened on the **BD FocalPoint™ Slide Profiler**, which uses multiple morphology and densitometric features to rank and sort slides according to the likelihood of abnormality. It differentiates and measures hundreds of features from artifacts, cells, cell groups and thick cell groups from each slide and translates this information into an anomaly score from 0.0 to 1.0. Each slide is ranked, based on this anomaly score and classified into "Review" and "No Further Review" <sup>(1)</sup>. Review slides are then ranked into five quintiles (1=highest risk, 5=lowest risk) helping to understand the risk inherent in each slide.



- A. Slides with scores below the primary threshold can be archived with no further review
- B. Slides with scores the primary threshold are reviewed by cytotechnologists
- C. Slides with scores are re-screened by cytotechnologists

Once the **BD FocalPoint™ Slide Profiler** has screened all slides, the fields on the slides, most likely to contain abnormal cells, are presented to the cytotechnologist by the BD FocalPoint™ GS workstation. The motorized stage of the microscope enables an easy and quick review of these fields on the slides.

(1) Optional Capability.



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## Choose the multi-tasker

BD SurePath™ Liquid-based Pap test  
One vial, multiple tests.

## BD SurePath™ Liquid-based Pap test is a versatile collection medium, fully compatible with a multitude of assays:

- **Immunocytochemistry**

The residual patient sample can also be used for additional immunocytochemistry tests (**BD SurePath™** with ProEx™ C Immunocytochemical Test).

Additional **BD SurePath™** slides can be processed from the **BD SurePath™** enriched cell pellet.

- A variety of molecular assays:

### Assay types

- Hybrid Capture®
- PCR
- ISH
- Genotyping
- NASBA
- Methylation-specific PCR
- Invader® Molecular Chemistry
- MicroArray

### Disease examples

- Human Papillomavirus
- *Chlamydia Trachomatis*
- *Neisseria Gonorrhoea*
- Herpes Simplex Virus
- Trichomoniasis



For further information, please contact our Sales Representative.



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## Reduce the risk of missed disease

The BD SurePath™ Pap test with the power of the BD FocalPoint™ GS Imaging System is one optimal combination to find cervical dysplasia.

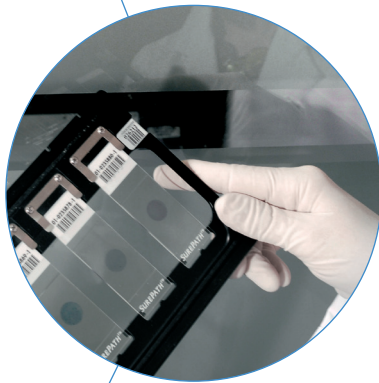


The BD SurePath™ Pap test with the power of the BD FocalPoint™ GS Imaging System is one optimal combination to find cervical dysplasia.



- Because all collected cells **are sent to the lab**

Independent studies show that 2/3 of false negative Pap smears are the result of cells not being collected into the sampling vial or not being transferred to the slide <sup>(1)</sup>. On average, 37% of cellular material may be lost using the swirl and rinse technique <sup>(2)</sup>. The BD SurePath™ collection ensures 100% of all collected cells go to the lab.



- Because diagnostically relevant cells **are visible on the slide**

Blood and obscuring materials can result in unsatisfactory slides with conventional and liquid-based Pap methods. Moreover, women with cancer have an increased likelihood of having blood in the cervical sample. The BD SurePath™ cell enrichment process <sup>(3)</sup> separates and selectively removes obscuring debris providing optimal visualization of diagnostically relevant cells .



- Because diagnostically relevant cells **are brought to your attention**

The BD FocalPoint™ GS Imaging System <sup>(4)</sup> improves the quality of slide reading by:

- Directing your attention to slides most likely to contain abnormalities
- Guiding you to specific areas on the slide most likely to contain abnormal cells or information of diagnostic interest

**One combination for reliable cytological screening.**

**References:**

- (1) Hutchinson M., Isenstein L., Goodman A., Hurley A., Douglass K., Mui K., Patten F., and Zahniser D Homogenous Sampling Accounts for the Increased Diagnostic Accuracy Using the ThinPrep™ Processor. Am J Clin Pathol. 101:215-219, 1994.
- (2) Bigras G., Rieder M., Lambery J., Kunz B., Chatelain J., Reymond O., and Cornaz D. Keeping Collecting Device in Liquid Medium Is Mandatory to Ensure Optimized Liquid-Based Cervical Cytologic Sampling. J Low Genit Tract Dis. 7:168-174, 2003.
- (3) Package insert BD PrepStain™.
- (4) Package insert of BD FocalPoint™ GS Imaging System.

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