BD FocalPoint™ Slide Profiler Product Insert

REF 490137 **REF 490138** **REF 490364** **REF 490365** **REF 490397**
REF 490398 **REF 490648** **REF 490649** **REF 490650** **REF 490651**
REF 490652 **REF 490653**

Intended Use

The BD FocalPoint™ Slide Profiler (formerly the AutoPap® System) is an automated cervical cytology screening device intended for use in initial screening of cervical cytology slides. The BD FocalPoint™ Slide Profiler identifies up to 25% of successfully processed slides as requiring no further review. The BD FocalPoint™ Slide Profiler also identifies at least 15% of all successfully processed slides for a second manual review.

The device is intended to be used on both conventionally-prepared and BD SurePath™ (formerly AutoCyte® PREP) cervical cytology slides. For both preparation methods, the device is intended to detect slides with evidence of squamous carcinoma and adenocarcinoma and their usual precursor conditions; it is not intended to be used on slides designated by the laboratory as *high risk*.

Intended users are trained cytology laboratory personnel operating under the direct supervision of a qualified cytology supervisor or laboratory manager/director.

Limitations

The BD FocalPoint™ Slide Profiler analysis of cervical cytology slides is not intended to replace laboratory slide review processes for *high-risk* slides. Such *high risk* slides are those where a primary health care provider has requested special handling of a case for a specified concern, or where the clinical laboratory, through its own procedures, has identified a need for an additional screening of the case.

The BD FocalPoint™ Slide Profiler classifies up to 25% of the slides as **No Further Review**. This **No Further Review** population of slides may contain abnormal or unsatisfactory slides. In addition, slides with infections present may be classified as **No Further Review.**

The performance characteristics of the BD FocalPoint™ Slide Profiler have not been established for the detection of the following diagnostic categories of The Bethesda System:

- Endometrial cells, cytologically benign, in a post-menopausal woman.
- Reactive changes associated with radiation and atrophy with inflammation.
- Rare malignant neoplasms, such as extrauterine and metastatic carcinomas, and sarcomas.

The BD FocalPoint™ Slide Profiler is intended to process conventional and BD SurePath™ cervical cytology slides that meet the slide, coverslip, and staining characteristics stated in the Operator's Manual.

Although the BD FocalPoint™ Slide Profiler is compatible with a wide range of staining procedures currently implemented in clinical laboratories, the device is *not* compatible with all staining methods currently in use. BD Diagnostics can assist the laboratory in ensuring that the staining method is compatible with the device.

All personnel who use the BD FocalPoint™ Slide Profiler should be trained in the use of the device. BD Diagnostics will train laboratory-designated personnel in the use of the device.

Although the BD FocalPoint™ Slide Profiler has demonstrated its effectiveness in processing conventional and BD SurePath™ slides, performance may vary from laboratory to laboratory.

Summary and Explanation of the BD FocalPoint™ Slide Profiler

The BD FocalPoint™ Slide Profiler is an automated cytology screening device that classifies slides using a high speed video microscope, image interpretation software, and morphology computers to image and analyze the complex images on a cervical cytology slide.

The device is intended to detect slides with evidence of squamous carcinoma and adenocarcinoma and their usual precursor conditions. These abnormalities fall within the following diagnostic categories of The Bethesda System:

Epithelial Cell Abnormalities

Squamous Cell

- Atypical squamous cells of undetermined significance (ASCUS)
- Low-grade squamous intraepithelial lesions (LSIL)
- High-grade squamous intraepithelial lesions (HSIL)
- Squamous cell carcinoma

Glandular Cell

- Atypical glandular cells of undetermined significance (AGCUS), including Adenocarcinoma in situ (AIS)
- Endocervical adenocarcinoma
- Endometrial adenocarcinoma

The BD FocalPoint™ Slide Profiler consists of two main components: the workstation (user interface) and the instrument (slide processor). The workstation components include a computer, monitor, keyboard, mouse, modem, and printer. The instrument is a floor standing unit designed to be placed out of the walkway. The instrument and workstation are inter-connected by an Ethernet local area network.

BD FocalPoint™ Slide Profiler Processing

Each prepared cervical cytology slide is affixed with a slide barcode label and loaded into a BD FocalPoint™ Slide Profiler slide tray, which holds up to eight slides. The trays (up to 36) are placed into the BD FocalPoint™ Slide Profiler instrument, which then automatically analyzes the slides.

After slide trays are loaded into the BD FocalPoint™ Slide Profiler instrument, they are moved automatically from the input hopper to the microscope stage. For each slide in the tray, the device checks the slide for physical integrity, reads the slide barcode label, scans and analyzes the slide at low power, and then scans and analyzes prioritized high-power fields.

Before the first tray and after each tray is processed, a comprehensive system integrity assessment of the instrument is performed automatically for quality assurance to ensure that all data collection and image analysis mechanisms are operating within specified limits. The results of all these tests are compared to specific performance limits to validate the processing result for each slide in the tray.

A slide is completely processed if the slide is checked for physical integrity, scanned and evaluated, and further qualified by system integrity checking. If slide processing is interrupted (for example, by power failure), partial, non-qualified results for slides will be stored by the device. These slides are termed *incompletely processed* and will not be validated or given slide processing results. The laboratory may print a report indicating the barcodes of these slides, which should be rerun on the instrument.

Results for completely and incompletely processed slides are validated and summarized into slide processing results. As slide processing results are computed, they may be printed in slide processing reports from the workstation.

BD FocalPoint™ Slide Profiler Slide Classification

The BD FocalPoint™ Slide Profiler algorithms are trained to detect evidence of morphologic changes associated with epithelial abnormalities, specimen adequacy, and benign cellular changes and infections. For each processed slide, the BD FocalPoint™ Slide Profiler uses this morphological information to classify slides as **No Further Review**, **Review**, or **QC Review**.

Each slide is processed only once on the BD FocalPoint™ Slide Profiler. Each successfully processed slide is assigned a score, which the device uses to rank slides according to likelihood that a slide contains abnormalities, unsatisfactory conditions, or benign cellular changes. Some slides may not be suitable for processing on the device due to problems with the slide, the coverslip, or the preparation of the specimen; these slides require manual screening.

Classification of No Further Review Slides

The BD FocalPoint™ Slide Profiler classifies up to, but no more than, 25% of all successfully processed slides as **No Further Review**.

The **No Further Review** slides have the highest probability of being normal and may be archived by the laboratory as within normal limits (WNL).

Classification of Review Slides

The remaining slide population, at least 75%, is likely to contain the abnormal or unsatisfactory slides. These slides are classified as **Review** by the BD FocalPoint™ Slide Profiler and require manual review. All **Review** slides that are classified as WNL by the cytotechnologist are eligible for rescreening.

Classification of QC Review (Rescreen) Slides

The BD FocalPoint™ Slide Profiler also classifies at least 15% of *all* successfully processed slides as eligible for rescreening. The slides in this enriched group have the highest likelihood of being abnormal. This enriched population of slides may be used as a substitute for the 10% random selection of slides that constitutes laboratory quality control review.

BD FocalPoint™ Slide Profiler Reports

The BD FocalPoint™ Slide Profiler reports including the Archive Report, Ranked Review Report, and Quality Control (QC) Ranked Review Report, provide the following information.

Ranking Information

To assist the cytotechnologist during manual review, the device ranks the slides for probable abnormality. Each slide is individually ranked from 1 to *n*, where a rank of 1 indicates a slide most likely to contain abnormality and *n* is the slide least likely to contain abnormality (*n* is the number of slides in a print set). Additionally, each slide is assigned a group ranking, ranging from 1 to 5, where a rank of 1 indicates the group most likely to contain abnormalities.

The BD FocalPoint™ Slide Profiler Archive Report for **No Further Review** slides does not provide slide ranks for probable abnormality or a slide adequacy evaluation of unsatisfactory because these slides are classified as WNL and archived.

Evaluation of Slide Adequacy

The device evaluates slide adequacy according to The Bethesda System slide adequacy criteria. For conventional and BD SurePath™ slides, the device reports three adequacy parameters: squamous component (detected, not detected), endocervical component (detected, not detected), and inflammation/obscuration (a percentage of the specimen area). Cytotechnologists may use these parameters as indicators of slide adequacy during manual review. Cytotechnologists should review the BD FocalPoint™ Slide Profiler Archive Report in depth to determine if any less-than-satisfactory slides are present in the **No Further Review** population.

Processing Information

The device confirms that the slide was completely and successfully processed.

Instructions and Instrumentation

Slide Preparation

Conventional and BD SurePath™ cervical cytology slides processed on the BD FocalPoint™ Slide Profiler generally do not require special preparation by the laboratory. Refer to the Operator's Manual for slide labeling and loading instructions.

The compatibility of a laboratory's staining process will be assessed by BD Diagnostics prior to clinical use of the device by the laboratory as described in the Operator's Manual.

Materials Provided

The BD FocalPoint™ Slide Profiler consists of the following components:

- BD FocalPoint™ Slide Profiler instrument
- Slide trays
- BD FocalPoint™ Slide Profiler workstation
- Electronic interface cables
- Power cords

Additional Items Supplied (some items are optional, at additional cost):

- Printer paper (starter package)
- Head cleaning tape
- Slide barcode labels (starter package)
- Backup tapes (starter set)
- Switch slides for processing different slide preparation types (BD SurePath™ or conventional) and/or coverslip types (glass or plastic) on the same instrument.

Materials Required but Not Provided

- Instrument: dedicated 20 amp supply, (100–120 volts), or dedicated 10 amp supply (220–240 volts)
- Workstation: dedicated 10 amp supply (100–120 volts), or dedicated 5 amp supply (100–240 volts)
- Dedicated analog telephone line
- Dustproof storage
- 70% Isopropyl Alcohol
- Cotton swabs
- Lint-free cloths
- Glass cleaning solution

Warnings

Broken Glass Hazard when Handling Slides

Do not drop or break slides during slide preparation and when loading and unloading slides into trays. If slides are broken, injuries may occur.

Moving Parts Hazard when Loading/ Unloading Trays

Remove all potentially obstructive jewelry and clothing before loading or unloading trays. After opening a hopper door, be sure all moving parts in the hopper have stopped before inserting or removing a tray. If trays are inserted before all moving parts have stopped, injuries may occur or the device may jam.

Shock Potential when Cleaning the Monitor

Failure to remove power to the monitor before performing the procedure could result in an electric shock. See the Operator's Manual.

Shock Potential when Power Applied Improperly

The symbol next to the power connector indicates potential shock hazard. Ensure that the system is connected to a power receptacle that provides voltage and current within the specified rating for the system. Use of an incompatible power receptacle may produce electrical shock and fire hazards.

Shock Potential when Improperly Grounded

Never use a two-prong plug adapter to connect primary power to the system. Use of a two-prong adapter disconnects the utility ground, creating a potential shock hazard. Always connect the system power cord directly to an appropriate receptacle with a functional ground.

Shock Potential when Cleaning with Power Applied

Always turn off the power switch and unplug the power cord before cleaning the outer surfaces or internal components of the device to avoid a potential shock hazard.

Shock Potential from Spilled Liquids

Do not place containers with liquids on the device or the workstation cart. Do not spill liquids on the system; fluid seepage into internal components creates a potential shock hazard. Shut down the device, disconnect from the power source and wipe up all spills immediately. Do not operate the system if internal components have been exposed to fluid.

Electromagnetic Fields

This is a Class A product. In a domestic environment, this product may cause radio interference with other electronic devices, such as telephones and other medical equipment, in which case the user may be required to take measures to reduce such interference.

Precautions

Slide and Coverslip Requirements

This device cannot be recommended for use with slides and coverslips that do not comply with the specifications provided in the Operator's Manual, particularly broken slides, dirty or marked slides, and non-standard slide or coverslip sizes.

Staining Procedures

Staining procedures should be conducted carefully so that as many slides as possible may be processed on the device. See the Operator's Manual for additional information.

Backup Procedures

When performing the backup procedures, BD Diagnostics recommends that two tapes be used in rotation; each tape would be used every other day. This will ensure minimum loss of data in the unlikely event of a workstation failure.

Shutdown Procedures

Except in an emergency situation, such as those described in the **Warnings** section, shutting down the BD FocalPoint™ Slide Profiler should only be performed as described in the Operator's Manual to avoid loss of data. If no emergency situation exists, consult the Operator's Manual for the appropriate procedures or contact BD Diagnostics, or its designated representative to shut down the device.

Power Down Procedures

It is important to shut down the system components in the proper order. See the Operator's Manual for additional information.

Replacement Fuses

Use replacement fuses with the required current rating and specification. Using improper fuses or short-circuiting the fuse holders may cause fire or damage the device.

Installation and Service

The device should be installed only by company authorized personnel. Only technically qualified personnel, trained by BD Diagnostics, should perform troubleshooting and service procedures on internal components.

Reports of Clinical Studies

A prospective, intended use study was conducted at five cytology laboratories to evaluate the effectiveness of the BD FocalPoint™ Slide Profiler in detecting abnormal and normal conventional Pap smears when the device was used as a combined primary screener and quality control rescreener.

An additional, intended use study was conducted at three cytology laboratories to evaluate the BD FocalPoint™ Slide Profiler effectiveness in screening BD SurePath™ slides.

Conventional Slides: Prospective, Intended Use Study

Of the 31,507 Pap smear slides in the study, 25,124 were evaluated in a two-arm study comparing Current Practice with a BD FocalPoint™ Assisted Practice. These two study arms were defined as follows:

- Current Practice consisted of 100% manual initial screening and 10% random rescreening (designated as *quality control*)

- BD FocalPoint™ Assisted Practice consisted of 100% BD FocalPoint™ Slide Profiler initial screening, at least 75% BD FocalPoint™ Slide Profiler assisted manual screening, and 15% BD FocalPoint™ Slide Profiler assisted manual rescreening

Slides not meeting the inclusion criteria for the study, such as *high risk* slides, were excluded from the analysis. The BD FocalPoint™ Slide Profiler is not intended to replace individual laboratory processes for screening *high risk* slides.

The goal of the clinical study was to demonstrate that, compared to Current Practice, the BD FocalPoint™ Slide Profiler detected more slides with epithelial abnormality in the following diagnostic categories:

ASCUS+ (All abnormal slides combined): Atypical squamous cells of undetermined significance and above; additionally includes the categories AGUS, LSIL, HSIL, AIS, and cancer

LSIL: Low-grade squamous intraepithelial lesion

LSIL+: In addition to LSIL, includes the categories HSIL, AIS, and cancer

An additional goal was to demonstrate that, compared to Current Practice, the device detected an equivalent number of satisfactory but limited by (SBLB) and unsatisfactory slides.

Slide Accountability

As shown in Table 1, the clinical study analyzed a total of 25,124 slides.

Table 1 Conventional Slide Accountability

Number of slides in study	**31,507**
Excluded (*High risk*)	–3,200
Excluded (Device exclusions)*	–1,132
Excluded (Lab exclusions)†	–1,004
Entered in study	26,171
Failed processing on BD FocalPoint™ Slide Profiler	–963
Processed on BD FocalPoint™ Slide Profiler	25,208
Excluded from analysis (no truth determination)‡	–84
Total Slides Analyzed	**25,124**

* Broken slides, slides w/plastic coverslips, etc.

† Multiple slides from one patient, dotted slides, etc.

‡ Slides not available from labs for truth determination

Study Truth (Truth Determination Process)

Study truth was determined by cytologic confirmation, not by histologic biopsy. The true diagnosis for the slides analyzed during the clinical trial was determined as follows:

- When the cytotechnologists' screening diagnoses from the BD FocalPoint™ Assisted Practice and Current Practice agreed, this diagnosis was considered to be the true cytological diagnosis for the slide, or truth.
- When the cytotechnologists' screening diagnoses from the BD FocalPoint™ Assisted Practice and Current Practice disagreed, an External Discrepancy Panel (EDP) was convened. An EDP consisted of a group of three cytopathologists who independently diagnosed a slide. If two out of three agreed, a diagnosis was determined; otherwise, the slide was reviewed at a multi-head microscope until a consensus diagnosis was achieved. A total of 24 cytopathologists, or 8 groups of 3, participated in this process.
- When adequacy determinations between the two study arms agreed, this was also considered to be truth.
- When adequacy determinations between the two study arms disagreed, a single, independent senior cytotechnologist reviewed the slide to determine truth.

Definition of High Risk

During the study, each laboratory applied its own definition of *high risk*. A *high risk* definition consisted of one or more of the reasons listed below:

> Physician-designated *high risk* patients; prior abnormal gynecological history; postmenopausal or abnormal vaginal bleeding; DES patients; previous breast cancer or history of malignancy; previous tissue or Pap diagnosis of HPV, dysplasia, or HIV infection; multiple sex partners; visible lesion; early age of sexual intercourse; smoker.

All known *high risk* slides were excluded from the study at all sites. Table 2 shows the percentage of slides excluded for *high risk* reasons at each site.

Table 2 High Risk Exclusion Rates by Site

Site	High Risk Exclusion%
1	5.7%
2	6.1%
3	7.1%
4	11.8%
5	14.3%

Clinical Study Results

In this clinical study, 25,124 slides were analyzed in a comparison of two study arms: the BD FocalPoint™ Assisted Practice and Current Practice. The slides were submitted to the truth determination process described previously so that each slide had a final cytologic diagnosis (study truth). The cytotechnologist diagnoses from one study arm could be compared to the other study arm as well as to study truth. The distribution of these 25,124 slides is shown in tables 3 and 4:

Table 3 Distribution of Conventional Study Slides

Diagnosis	Number of Slides
Unsatisfactory	171
WNL	23,556
All Abnormals	1,397
Total	25,124

Table 4 Distribution of Conventional Abnormal Slides

Diagnosis	Number of Slides
ASCUS	998
AGUS	51
LSIL	278
HSIL	67
AIS	1
Cancer	2
Total	1,397

SUMMARY OF THE ANALYSES OF DIAGNOSTIC CATEGORIES

In this study, the BD FocalPoint™ Slide Profiler was used to detect abnormal and normal Pap smears, whereby up to 25% of the slides could be classified as **No Further Review** and archived by the laboratory.

The results of this study showed that the BD FocalPoint™ Assisted Practice improved the laboratories' ability to detect abnormal cervical cells and precursors, while also effectively assessing specimen adequacy. The BD FocalPoint™ Slide Profiler improved sensitivity by increasing the detection of abnormalities in the **Review** population and by enhancing the recovery of abnormalities that may have been missed during initial manual screening in the rescreen population (termed **QC Review**), without decreasing specificity.

Table 5 compares the BD FocalPoint™ Assisted Practice to Current Practice for all diagnostic categories. The shaded diagonal values show where the two study arms agreed on the diagnosis. The off-diagonals show where the study arms disagreed. These discordances were used to compare the diagnostic performance between the two study arms.

The *total* columns in the table show the number of abnormal slides for each diagnostic category that were correctly classified by each study arm. The values shown in parenthesis are the total number of slides in each diagnostic category as determined by truth.

Table 5 BD FocalPoint™ Assisted Practice Diagnosis vs. Current Practice Diagnosis: (N) = Total Number of Conventional Slides in the Diagnostic Category as Determined by Truth

BD FocalPoint™ Assisted Practice Diagnosis	Current Practice Diagnosis: Unsat (171)	WNL (23,566)	ASCUS (998)	AGUS (51)	LSIL (278)	HSIL (67)	AIS (1)	Cancer (2)	Total
Unsat (171)	99	38	0	0	0	0	0	0	137
WNL (23,566)	34	23,556	163	8	25	1	1	0	23,788
ASCUS (998)	0	232	603	0	0	0	0	0	835
AGUS (51)	0	9	0	34	0	0	0	0	43
LSIL (278)	0	45	0	0	208	0	0	0	253
HSIL (67)	0	3	0	0	0	63	0	0	66
AIS (1)	0	0	0	0	0	0	0	0	0
Cancer (2)	0	2	0	0	0	0	0	0	2
Total	133	23,885	766	42	233	64	1	0	25,124

Epithelial Abnormalities

This section provides the results for the epithelial abnormality categories of ASCUS+, ASCUS/AGUS, LSIL, LSIL+, and HSIL+. To determine whether a statistically significant greater number of slides in these categories were detected by the cytotechnologists in the BD FocalPoint™ Assisted Practice arm, a one-sided exact conditional binomial test was used.

Note: *The lower right cells in the following 2x2 tables are blank because only abnormal slides are considered for the analysis of performance.*

ASCUS+

Table 6 shows the results for conventional slides identified by the truth determination process to be ASCUS+(includes ASCUS, AGUS, LSIL, HSIL, AIS, and cancer). The laboratories detected a statistically significant greater number of ASCUS+ slides in the BD FocalPoint™ Assisted Practice compared to Current Practice.

Table 6 Classification of Conventional ASCUS+ Slides

BD FocalPoint™ Assisted Practice	Current Practice: Abnormal (+)	Current Practice: WNL (-)	
Abnormal (+)	908	291	1,199
WNL (-)	198		198
	1,106	291	1,397

ASCUS/AGUS

Tables 7 and 8 show the results for conventional slides identified by the truth determination process to be ASCUS and AGUS, respectively. When ASCUS and AGUS are combined for analysis, the laboratories detected a statistically significant greater number of ASCUS/AGUS slides in the BD FocalPoint™ Assisted Practice arm compared to the Current Practice arm.

Table 7 Classification of Conventional ASCUS Slides

		Current Practice: Abnormal (+)	Current Practice: WNL (-)	
BD FocalPoint™ Assisted Practice	Abnormal (+)	603	232	835
	WNL (-)	163		163
		766	232	998

Table 8 Classification of Conventional AGUS Slides

		Current Practice: Abnormal (+)	Current Practice: WNL (-)	
BD FocalPoint™ Assisted Practice	Abnormal (+)	34	9	43
	WNL (-)	8		8
		42	9	51

LSIL

Table 9 shows the results for conventional slides identified by the truth determination process to be LSIL. The laboratories detected a statistically significant greater number of LSIL slides in the BD FocalPoint™ Assisted Practice compared to Current Practice.

Table 9 Classification of Conventional LSIL Slides

		Current Practice: Abnormal (+)	Current Practice: WNL (-)	
BD FocalPoint™ Assisted Practice	Abnormal (+)	208	45	253
	WNL (-)	25		25
		233	45	278

LSIL+

Table 10 shows the results for conventional slides identified by the truth determination process to be LSIL+, which includes the categories LSIL, HSIL, AIS, and cancer. The laboratories detected a statistically significant greater number of LSIL+ slides in the BD FocalPoint™ Assisted Practice compared to Current Practice.

Table 10 Classification of Conventional LSIL+ Slides

		Current Practice		
		Abnormal (+)	WNL (-)	
BD FocalPoint™ Assisted Practice	Abnormal (+)	271	50	321
	WNL (-)	27		27
		298	50	348

HSIL+

In the prospective study of over 25,100 conventional slides, only 70 HSIL+ slides were available for analysis. HSIL+ includes the categories HSIL, AIS, and cancer. Table 11 shows that the laboratories detected more HSIL+ slides in the BD FocalPoint™ Assisted Practice as compared to Current Practice. The 70 HSIL+ sample size was insufficient to determine whether this increased detection was statistically significant.

Table 11 Classification of Conventional HSIL+ Slides

		Current Practice		
		Abnormal (+)	WNL (-)	
BD FocalPoint™ Assisted Practice	Abnormal (+)	63	5	68
	WNL (-)	2		2
		65	5	70

Specimen Adequacy

This section provides the results for the specimen adequacy categories of satisfactory but limited by (SBLB) and unsatisfactory. The BD FocalPoint™ Slide Profiler evaluates slide adequacy according to The Bethesda System criteria. The device reports three adequacy parameters: squamous component (detected, not detected), endocervical component (detected, not detected), and inflammation/obscuration (a percentage of the coverslip area).

Satisfactory But Limited By (SBLB)

Out of 5,873 conventional slides identified by the truth determination process to be SBLB, the laboratories detected 5,059 slides in the BD FocalPoint™ Assisted Practice compared to 4,728 detected by Current Practice. The BD FocalPoint™ Assisted Practice is equivalent to Current Practice in identifying SBLB slides.

Unsatisfactory (Unsat)

Out of 171 conventional slides identified by the truth determination process to be unsatisfactory, the laboratories detected 137 slides in the BD FocalPoint™ Assisted Practice compared to 133 detected by Current Practice. The BD FocalPoint™ Assisted Practice is equivalent to Current Practice in identifying unsatisfactory slides.

Benign Cellular Changes (BCC)

The cytotechnologists on each arm of the study assessed the slides for evidence of epithelial abnormality and the presence or absence of benign cellular changes.

The results were compared to study truth for the slides and showed that the detection of BCC, reactive changes, and infection was equivalent in the BD FocalPoint™ Assisted Practice and Current Practice arms of the study. Out of 5,156 conventional slides identified by the truth determination process to be BCC, the BD FocalPoint™ Assisted Practice detected 3,276 compared to 3,431 detected by Current Practice.

Reactive Changes

The WNL slide population was evaluated for the presence of reactive changes. Of the 23,556 WNL conventional slides, 3,037 were noted for reactive changes by the cytotechnologists on either arm of the study. Of the 3,037 slides with reactive changes, 2,978 were noted for inflammation (without atrophy).

Infections

In the study, cytotechnologists on both study arms examined slides for the presence of infections, including actinomyces, herpes, coccobacilli, trichomonas, and candida. If a cytotechnologist on either or both study arms detected the presence of infection on a Pap smear, this was considered truth for the slide. Table 12 provides a breakdown by infection subcategories of the 2,925 conventional slides noted for infections.

Table 12 Detection of Infections: (N) = Total number of conventional slides noted for each infection category

Infections	BD FocalPoint™ Assisted Practice	Current Practice
All infections (2,925)	1,985	2,141
Actinomyces (17)	12	8
Candida (1,282)	865	983
Coccobacilli (1,375)	869	897
Herpes (14)	11	9
Trichomonas (343)	275	293

SITE-SPECIFIC COMPARISON OF SENSITIVITY PERFORMANCE

This section compares the sensitivity results by diagnostic category for each arm of the study. These results are provided for each site. The sensitivity is calculated as:

$$\frac{\text{All slides called abnormal by the cytotechnologist}}{\text{All study truth abnormal slides}}$$

In this study, the sensitivity for all abnormals, ASCUS+, (includes the categories ASCUS, AGUS, LSIL, HSIL, AIS, and cancer) for each study arm was:

BD FocalPoint™ Assisted Practice: $1{,}199 / 1{,}397 = 85.8\%$

Current Practice: $1{,}106 / 1{,}397 = 79.2\%$

Table 13 shows the site-specific sensitivity results for the categories of ASCUS+, ASCUS/AGUS, LSIL, LSIL+, and HSIL+. The BD FocalPoint™ Assisted Practice sensitivities are greater than those for Current Practice at all sites for all diagnostic categories except for HSIL+ at site 5.

Table 13 Site-Specific Sensitivity Results (Sensitivity%, (N))

		Site 1	Site 2	Site 3	Site 4	Site 5	Total
ASCUS+ (all abnormals)	**BD FocalPoint™ Assisted Practice**	90.6% (163/180)	81.3% (169/208)	90.3% (93/103)	83.5% (406/486)	87.6% (368/420)	85.8% (1,199/1,397)
	Current Practice	80.0% (144/180)	76.4 (159/208)	67.0% (69/103)	80.7% (392/486)	81.4% (342/420)	79.2% (1,106/1,397)
ASCUS/AGUS	**BD FocalPoint™ Assisted Practice**	88.4% (114/129)	78.1% (114/146)	85.1% (57/67)	81.9% (307/375)	86.1% (286/332)	83.7% (878/1,049)
	Current Practice	77.5% (100/129)	76.7% (112/146)	58.2% (39/67)	78.7% (295/375)	78.9% (262/332)	77.0% (808/1,049)
LSIL	**BD FocalPoint™ Assisted Practice**	95.7% (45/47)	87.0% (47/54)	100% (30/30)	86.5% (77/89)	93.1% (54/58)	91.0% (253/278)
	Current Practice	85.1% (40/47)	75.9% (41/54)	86.7% (26/30)	85.4% (76/89)	86.2% (50/58)	83.8% (233/278)
LSIL+	**BD FocalPoint™ Assisted Practice**	96.1% (49/51)	88.7% (55/62)	100% (36/36)	89.2% (99/111)	93.2% (82/88)	92.2% (321/348)
	Current Practice	86.3% (44/51)	75.8% (47/62)	83.3% (30/36)	87.4% (97/111)	90.9% (80/88)	85.6% (298/348)
HSIL+	**BD FocalPoint™ Assisted Practice**	100% (4/4)	100% (8/8)	100% (6/6)	100% (22/22)	93.3% (28/30)	97.1% (68/70)
	Current Practice	100% (4/4)	75% (6/8)	66.7% (4/6)	95.5% (21/22)	100% (30/30)	92.8% (65/70)

COMPARISON OF FALSE NEGATIVE PERFORMANCE

The BD FocalPoint™ Slide Profiler classified 5,109 slides as **No Further Review.** Of these, 21 had unresolved diagnostic or adequacy truth (1 and 20 slides, respectively), leaving 5,088 slides. Table 14 shows the false negatives (FNs) in this population as determined by truth.

Within the population of 5,036 WNL slides, 4,800 slides were classified as WNL by the cytotechnologists in the Current Practice arm and as **No Further Review** by the BD FocalPoint™ Slide Profiler. After the study was completed, these slides were subjected to further rescreening by a senior cytotechnologist. If the senior cytotechnologist determined that a slide was not WNL, the slide was sent for pathologist confirmation.

The results of this rescreening and confirmation showed that an additional 11 unsatisfactory, 10 ASCUS, 1 AGUS, and 3 LSIL slides were detected in the **No Further Review** population. There were no HSIL, AIS, or cancer slides found by the senior cytotechnologist.

Table 14 False Negative Performance in the No Further Review Population (As Determined by Study Truth)

Diagnosis	No Further Review FNs
Unsat	9
WNL	5,036
ASCUS	31
AGUS	1
LSIL	11
HSIL	0
AIS	0
Cancer	0
Total	**5,088**

Table 15 compares the false negative performance of the BD FocalPoint™ Assisted Practice with Current Practice. The table shows the total number of false negative slides for each study arm. In all diagnostic categories (except AIS) the BD FocalPoint™ Assisted Practice had fewer false negatives; that is, the BD FocalPoint™ Assisted Practice detected more abnormal slides.

Table 15 Comparison of False Negative Performance for the 25,124 Study Slides

Diagnosis	BD FocalPoint™ Assisted Practice FNs*	Current Practice FNs
Unsat	34	38
ASCUS	163	232
AGUS	8	9
LSIL	25	45
HSIL	1	3
AIS	1	0
Cancer	0	2
Total	232	329

* Includes the **No Further Review** FNs shown in Table 14

SITE-SPECIFIC COMPARISON OF SPECIFICITY PERFORMANCE

In this study, specificity was defined as the percentage of WNL slides determined to be normal and adequate according to the truth determination process, defined as:

$$\frac{\text{All slides called WNL by cytotech \& confirmed as WNL by truth}}{\text{All study truth WNL slides}}$$

Therefore, the specificity change is defined as:

$$\frac{\left(\text{\%Specificity of the FocalPoint Assisted Practice}\right) - \left(\text{\%Specificity of Current Practice}\right)}{\text{\%Specificity of Current Practice}}$$

In the clinical study, 23,556 slides were diagnosed as WNL according to study truth. Table 16 compares the specificity results for each arm of the study. A positive percent change in specificity indicates improved specificity for the BD FocalPoint™ Assisted Practice arm; a negative percent change indicates improved specificity for the Current Practice arm.

Table 16 Site-Specific Specificity Comparison

	BD FocalPoint™ Assisted Practice Specificity%	Current Practice Specificity%	%Change in Specificity
Site 1	96.1 (3,544/3,689)	97.1 (3,583/3,689)	-1.1
Site 2	97.8 (3,862/3,950)	98.0 (3,870/3,950)	-0.2
Site 3	96.0 (3,652/3,803)	97.9 (3,725/3,803)	-1.9
Site 4	94.9 (5,459/5,751)	93.7 (5,387/5,751)	+1.3
Site 5	93.1 (5,926/6,363)	89.1 (5,669/6,363)	+4.5
Total	95.3 (22,443/23,556)	94.4 (22,233/23,556)	+1.0

Using the data in Table 16, the combined percent change in specificity for all sites is:

$$\frac{95.3 - 94.4}{94.4} \times 100 = +1.0\%$$

These data indicate that, for all study sites combined, the BD FocalPoint™ Assisted Practice improved the specificity by 1.0%.

SITE-SPECIFIC COMPARISON OF FALSE POSITIVE PERFORMANCE

In this study, a false positive was defined as a WNL slide that the cytotechnologist incorrectly classified as abnormal and referred to a cytopathologist, defined as:

$$\frac{\text{All slides called abnormal by cytotech \& confirmed as WNL by truth}}{\text{All study truth WNL slides}}$$

Therefore, the false positive value change is defined as:

$$\frac{\left(\text{False Positive Value for Current Practice}\right) - \left(\text{False Positive Value for BD FocalPoint™ Assisted Practice}\right)}{\text{False Positive Value for Current Practice}}$$

A total of 23,556 slides were diagnosed as WNL according to study truth. Table 17 compares the false positive results for each arm of the study. A positive percent change in the false positive value indicates a reduction of false positives in the BD FocalPoint™ Assisted Practice arm; a negative percent change indicates a reduction of false positives in the Current Practice arm.

Table 17 Site-Specific False Positive Value Comparison

	BD FocalPoint™ Assisted Practice False Positive Value%	Current Practice False Positive Value%	% Change in False Positive Value
Site 1	3.9 (145/3,689)	2.9 (106/3,689)	-36.9
Site 2	2.2 (88/3,950)	2.0 (80/3,950)	-9.8
Site 3	4.0 (151/3,803)	2.1 (78/3,803)	-91.8
Site 4	5.1 (292/5,751)	6.3 (364/5,751)	+19.7
Site 5	6.9 (437/6,363)	10.9 (694/6,363)	+37.0
Total	4.7 (1,113/23,556)	5.6 (1,323/23,556)	+16.0

Using the data in Table 17, the combined false positive value change for all sites is:

$$\frac{5.6 - 4.7}{5.6} \times 100 = +16\%$$

These data indicate that, for all study sites combined, the BD FocalPoint™ Assisted Practice reduced the false positive slides by 16%.

RANKED REVIEW REPORT ANALYSIS

Table 18 shows the distribution of the study truth abnormal slides with their associated group ranks. As shown in the table, the BD FocalPoint™ Slide Profiler placed the highest proportion of slides in the top ranks for all diagnostic categories. For example, 54 of the 70 HSIL+ slides were placed in the top rank.

Table 18 EDP Confirmed and Concordant Abnormal Slides by Rank

Group Rank	ASCUS	AGUS	LSIL	HSIL+
1	465	20	153	54
2	169	8	48	8
3	139	8	31	3
4	88	5	16	3
5	106	9	19	2
Total	967	50	267	70

These data demonstrate that the BD FocalPoint™ Slide Profiler was effective in ranking conventional slides according to the potential for abnormality. It is important to note that all slides designated as **Review** by the device require screening since the potential for abnormality exists across all group ranks.

BD SurePath™ Slides: BD FocalPoint™ Slide Profiler Performance

A clinical study was conducted to evaluate BD FocalPoint™ Slide Profiler performance in classifying BD SurePath™ slides as **Review**, **QC Review**, and **No Further Review**. A total of 3,638 BD SurePath™ slides were selected from the BD FocalPoint™ Slide Profiler clinical study of BD SurePath™ slides, and a new intended use study was conducted at three clinical laboratories to compare manual screening with the BD FocalPoint™ Assisted Practice. Of the 3,638 BD SurePath™ slides enrolled in the study, 3,621 were evaluated in a two-arm study design. These two study arms were defined as follows:

BD SurePath™ Practice: 100% manual screening of BD SurePath™ slides in standard laboratory practice to arrive at site diagnoses for the slides. These site diagnoses were taken from the PMA application for the BD PrepStain™ System, the device that processes and produces BD SurePath™ slides.

BD FocalPoint™ Assisted Practice: The BD FocalPoint™ Slide Profiler used in the standard workflow of the laboratory to arrive at site diagnoses for the slides. The intended use includes 100% initial screening of slides by the BD FocalPoint™ Slide Profiler, at least 75% BD FocalPoint™ Slide Profiler assisted manual screening of slides, and 15% BD FocalPoint™ Slide Profiler assisted manual rescreening.

The purpose of the study was to compare the diagnostic performance of the BD FocalPoint™ Assisted Practice and the BD SurePath™ Practice. The original PMA studies of the BD PrepStain™ System did not distinguish *high risk* slides from non-*high risk* slides. These slides were processed on the BD FocalPoint™ Slide Profiler during clinical studies. The

performance of the device was evaluated by comparing the percentage of slides in each study arm in which the diagnoses agreed. In addition, the reliability of WNL diagnoses obtained through the BD FocalPoint™ Assisted Practice was evaluated by adjudicating a random sample of a subset of the slides classified as WNL by both study arms.

Slide Accountability

As shown in Table 19, this study analyzed a total of 3,621 BD SurePath™ slides.

Table 19 Slide Accountability

	Slides
Total number enrolled in study	**3,638**
Total number excluded from analysis	**-17**
No truth diagnosis*	–1
Missing Slides	–10
Incomplete Screening	–4
Broken Slide	–1
Bubbles under coverslip	–1
Total number included in analysis	**3,621**

* Excluded because the slide was discrepant between the two study arms and did not receive a truth diagnosis from the EDP

Study Adjudication Process

The study adjudication process compared the diagnoses of the slides between the two study arms. When the sites' screening diagnoses from the two study arms agreed, this diagnosis was considered the final diagnosis. When they disagreed, the slides were sent to an External Discrepancy Panel (EDP) for diagnostic adjudication. The EDP consisted of a total of nine cytopathologists screening in groups of three.

The EDP also adjudicated a random sample of a subset of the slides classified as WNL by both study arms. When adequacy determinations between the two study arms agreed, this was considered to be the final adequacy assessment. When they disagreed, a single senior cytotechnologist determined the adequacy of the slide.

Clinical Study Results

In this study, 3,621 slides were analyzed in a comparison of two study arms: the BD FocalPoint™ Assisted Practice and the BD SurePath™ Practice. The site diagnoses from the BD FocalPoint™ Assisted Practice study arm were compared to the site diagnoses from the BD SurePath™ Practice. Also, each study arm was compared to the final diagnoses established by the study adjudication process. These results are described in the following sections for each of the three clinical study sites.

COMPARISON OF STUDY ARMS FOR DIAGNOSTIC CATEGORIES

Tables 20–22 compare the BD SurePath™ Practice with the BD FocalPoint™ Assisted Practice for The Bethesda System categories of Unsatisfactory (Unsat), WNL, ASCUS, AGUS, LSIL, HSIL, AIS, and cancer (CA). These results are shown for each of the three study sites.

The diagonal values (shaded) in the tables show where there was agreement on the diagnosis between the BD FocalPoint™ Assisted Practice and BD SurePath™ Practice study arms. The values in the off-diagonals represent differing diagnoses between the two study arms.

Table 20 BD FocalPoint™ Assisted Practice vs. BD SurePath™ Practice—Site 801

BD FocalPoint™ Assisted Practice Diagnosis	BD SurePath™ Practice Diagnosis								
	Unsat	**WNL**	**ASCUS**	**AGUS**	**LSIL**	**HSIL**	**AIS**	**Cancer**	**Total**
Unsat	9	5	0	0	0	0	0	1	15
WNL	1	802	68	15	21	2	0	0	909
ASCUS	0	63	33	3	9	2	0	0	110
AGUS	0	3	3	2	1	0	0	1	10
LSIL	0	23	12	0	49	8	0	0	92
HSIL	0	5	5	2	20	27	0	4	63
AIS	0	2	0	1	1	0	0	3	7
Cancer	0	0	0	0	1	3	0	11	15
Total	10	903	121	23	102	42	0	20	1,221

Table 21 BD FocalPoint™ Assisted Practice vs. BD SurePath™ Practice — Site 802

BD FocalPoint™ Assisted Practice Diagnosis	BD SurePath™ Practice Diagnosis								
	Unsat	**WNL**	**ASCUS**	**AGUS**	**LSIL**	**HSIL**	**AIS**	**Cancer**	**Total**
Unsat	3	25	0	0	0	0	0	0	28
WNL	0	765	35	2	10	1	0	0	813
ASCUS	0	116	31	1	3	1	0	0	152
AGUS	0	1	0	0	0	0	0	0	1
LSIL	0	35	33	1	62	2	0	0	133
HSIL	0	6	12	0	19	39	0	0	76
AIS	0	0	1	0	0	1	0	0	2
Cancer	0	0	0	0	0	0	0	2	2
Total	3	948	112	4	94	44	0	2	1,207

Table 22 BD FocalPoint™ Assisted Practice vs. BD SurePath™ Practice — Site 803

BD FocalPoint™ Assisted Practice Diagnosis	BD SurePath™ Practice Diagnosis								
	Unsat	WNL	ASCUS	AGUS	LSIL	HSIL	AIS	Cancer	Total
Unsat	4	75	11	1	1	0	0	0	92
WNL	0	616	157	5	23	3	0	0	804
ASCUS	0	74	42	1	24	6	0	0	147
AGUS	0	3	2	0	0	0	0	0	5
LSIL	0	19	13	0	54	5	0	0	91
HSIL	0	5	8	1	12	25	0	1	52
AIS	0	0	0	0	0	0	0	0	0
Cancer	0	0	0	0	0	2	0	0	2
Total	4	792	233	8	114	41	0	1	1,193

COMPARISON OF STUDY ARMS TO ADJUDICATED RESULTS FOR DIAGNOSTIC CATEGORIES

This section provides results for BD SurePath™ slides that the study adjudication process identified as ASCUS+, LSIL+, or HSIL+ according to the adjudication process described previously. These adjudicated results cannot be directly correlated with the slide results shown in tables 20–22, which compare the two study arms without slide adjudication.

The study adjudication process identified slides as ASCUS+, LSIL+, or HSIL+. ASCUS+ is defined as ASCUS and above and additionally includes the categories AGUS, LSIL, HSIL, AIS and cancer. LSIL+ is defined as *low-grade squamous intraepithelial lesion* and above and additionally includes the categories HSIL, AIS, and cancer. HSIL+ is defined as *high-grade squamous intraepithelial lesion* and above and additionally includes the categories AIS and cancer.

For sites 801, 802, and 803, respectively, the study adjudication process determined 248, 216, and 229 ASCUS+ slides; 178, 144, and 139 LSIL+ slides; and 81, 63, and 44 HSIL+ slides. Out of these totals, the EDP adjudicated all slides with differing diagnoses between the two study arms. Slides with the same diagnoses for both study arms were not adjudicated.

Each study arm was compared to the EDP adjudicated results for ASCUS+, LSIL+, and HSIL+ at each site. The BD FocalPoint™ Assisted Practice detected numerically more HSIL+ slides at all three sites, and numerically more LSIL+ and ASCUS+ slides at two of the three sites:

ASCUS+

Out of 123 (site 801), 82 (site 802), and 108 (site 803) BD SurePath™ slides identified by the EDP to be ASCUS+, the BD FocalPoint™ Assisted Practice detected 109, 74, and 81, respectively. The BD SurePath™ Practice detected 81, 57, and 83, respectively.

LSIL+

Out of 88 (site 801), 41 (site 802), and 60 (site 803) BD SurePath™ slides identified by the EDP to be LSIL+, the BD FocalPoint™ Assisted Practice detected 65, 37, and 33, respectively. The BD SurePath™ Practice detected 44, 22, and 34, respectively.

HSIL+

Out of 40 (site 801), 22 (site 802), and 19 (site 803) BD SurePath™ slides identified by the EDP to be HSIL+, the BD FocalPoint™ Assisted Practice detected 30, 19, and 12, respectively. The BD SurePath™ Practice detected 10, 2, and 6, respectively.

COMPARISON OF STUDY ARMS FOR ADEQUACY CATEGORIES OF UNSATISFACTORY AND SBLB

For each of the three study sites, the following tables compare the BD SurePath™ Practice with the BD FocalPoint™ Assisted Practice for the specimen adequacy categories of Unsatisfactory and SBLB.

Table 23 Classification of BD SurePath™ Unsatisfactory Slides — Site 801

		BD SurePath™ Practice		
		Unsat	Not Unsat	
BD FocalPoint™ Assisted Practice	Unsat	9	6	15
	Not Unsat	1	1,205	1,206
		10	1,211	1,221

Table 24 Classification of BD SurePath™ Unsatisfactory Slides — Site 802

		BD SurePath™ Practice		
		Unsat	Not Unsat	
BD FocalPoint™ Assisted Practice	Unsat	3	25	28
	Not Unsat	0	1,179	1,179
		3	1,204	1,207

Table 25 Classification of BD SurePath™ Unsatisfactory Slides — Site 803

		BD SurePath™ Practice: Unsat	BD SurePath™ Practice: Not Unsat	
BD FocalPoint™ Assisted Practice	Unsat	4	88	92
	Not Unsat	0	1,101	1,101
		4	1,189	1,193

Table 26 Classification of BD SurePath™ SBLB Slides — Site 801

		BD SurePath™ Practice: SBLB	BD SurePath™ Practice: Not SBLB	
BD FocalPoint™ Assisted Practice	SBLB	61	43	104
	Not SBLB	35	0	35
		96	43	139

Table 27 Classification of BD SurePath™ SBLB Slides — Site 802

		BD SurePath™ Practice: SBLB	BD SurePath™ Practice: Not SBLB	
BD FocalPoint™ Assisted Practice	SBLB	82	124	206
	Not SBLB	21	8	29
		103	132	235

Table 28 Classification of BD SurePath™ SBLB Slides — Site 803

		BD SurePath™ Practice: SBLB	BD SurePath™ Practice: Not SBLB	
BD FocalPoint™ Assisted Practice	SBLB	68	17	85
	Not SBLB	48	2	50
		116	19	135

WNL RELIABILITY ANALYSIS

To evaluate the reliability of WNL diagnoses in the clinical study, 299 slides diagnosed as WNL by both study arms (approximately 5%) were randomly chosen and seeded into the slide population sent to the EDP for diagnosis. Table 29 shows the results of their determinations.

Table 29 Reliability of WNL Diagnoses

	Truth			
Unsat	**WNL**	**ASCUS**	**HSIL**	**Total**
3	287	8	1	299

The reliability of WNL diagnoses may be estimated as follows:

$$100 \times \frac{287}{299} = 95.98\% = 96.0\ \%$$

These data demonstrate that, for all sites combined, the reliability of the BD FocalPoint™ Assisted Practice in detecting WNL slides was 96.0%. The 95% exact confidence interval was 93.2% to 97.9%.

BD FOCALPOINT™ SLIDE PROFILER SLIDE RANKING ANALYSIS

The BD FocalPoint™ Slide Profiler Ranked Review Report contains a quintile rank for every **Review** slide that corresponds to the slide's likelihood of abnormality. The quintile rank is expressed as a number between 1 and 5, where quintile 1 indicates that the slide is ranked in the highest scoring 20% of the **Review** slides. The lower the quintile rank, the higher the likelihood the slide is abnormal.

Table 30 shows the number of abnormal slides, as determined by the study adjudication process, with their associated ranks. These data demonstrate that, with increasing severity of disease, the proportion of abnormal slides in the lower ranks (higher potential of abnormality) increases: 51.2% (350/683) of abnormal slides were placed in rank quintile 1. Therefore, the BD FocalPoint™ Slide Profiler is effective in ranking BD SurePath™ slides in accordance with the likelihood of abnormality.

Table 30 Abnormal Review Slides by Rank

Group Rank	ASCUS	AGUS	LSIL	HSIL	AIS	CA*	Total
1	93	1	137	104	0	15	350
2	56	0	58	27	1	6	148
3	32	2	33	11	0	1	79
4	18	1	25	11	0	0	55
5	23	1	16	10	0	1	51
Total	222	5	269	163	1	23	683

* CA = Cancer

FALSE NEGATIVE PERFORMANCE

The BD FocalPoint™ Slide Profiler classified 1,184 slides as **No Further Review.** Of the 1,184 slides, two were excluded due to slide physical characteristics. The classification of the remaining 1,182 slides in the BD FocalPoint™ Assisted Practice arm is shown in Table 31:

Table 31 BD FocalPoint™ Assisted Practice Performance in the No Further Review Population

Study Diagnosis	No Further Review
Unsat	3
WNL	1,169
ASCUS	5
AGUS	0
LSIL	4
HSIL	1
AIS	0
Cancer	0
Total	1,182

The BD FocalPoint™ Slide Profiler classified 10 abnormal slides (5 ASCUS, 4 LSIL, and 1 HSIL) as **No Further Review**. The total number of abnormal BD SurePath™ slides was 693 (683 slides from Table 30 + 10 slides in **No Further Review**). Therefore, the false negative fraction was 10/693, or 1.4%. For Unsatisfactory BD SurePath™ slides, the BD FocalPoint™ Slide Profiler classified 3 as **No Further Review** for a false negative fraction 3/106, or 2.8%.

Storage and Operation

Do not expose the system to direct sunlight or temperature extremes (i.e., airflow from heating or cooling systems). The operating temperature range is 10–30° C, 50–86° F.

Technical Service and Product Information

For technical service and assistance related to use of the BD FocalPoint™ Slide Profiler, contact BD Diagnostics – Women's Health and Cancer

Technical Support
USA
Telephone: 1-877-822-7771
Fax: 1-336-290-8333
E-mail: tripathtechsupport@bd.com

Europe
Telephone: +32 (0)53 720 673
Fax: +32 (0)53 720 678

TriPath Imaging, Inc.
780 Plantation Drive
Burlington, NC 27215 USA

EC REP
Benex Limited
Rineanna House
Shannon Free Zone
Shannon, County Clare,
Ireland

CE

BD
Helping all people
live healthy lives