

I N T E L L I G E N T

I N N O V A T I V E

I N T U I T I V E

FX

Visibly better

BD BACTEC™ FX



BD

Helping all people
live healthy lives

BD BACTEC™

FX



BD BACTEC™ FX Blood Culture System

BD, the leader in blood culture instrumentation and media for the last 40 years, continues to provide your laboratory with new solutions in blood culturing.

The BD BACTEC™ FX builds on the proven superior fluorescence detection technology, exceptional media performance and instrument reliability of the BD BACTEC™ 9000 blood culture systems.

This is now combined with:

- the most efficient, **INTUITIVE** workflow for reduced hands-on time,
- the most compact, **INNOVATIVE** system design for maximum ergonomics and laboratory space utilization,
- **INTELLIGENT** cutting-edge data management with enhanced blood culture observation in and out of the laboratory for reduced workflow interruptions and optimized communication of preliminary or final results to caregivers.



Actionable results

Today for the majority of laboratories resources are a constant challenge: the laboratory is expected to do more with fewer resources whilst maintaining the highest level of diagnostic quality.

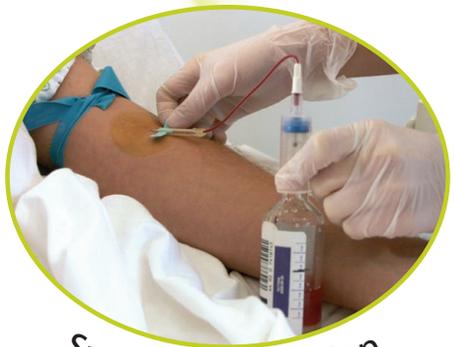
The new BD BACTEC™ FX System is designed for performance, efficiency, ease of use and flexibility - keeping pace with the rapidly changing needs of the laboratory. The system can streamline workflow and minimize process steps - two factors which are key to reducing labour costs.

In addition, with earlier detection and notification of positive blood cultures, clinicians can more quickly implement optimal therapy, positively affecting patient outcome and reducing length of stay: yet another way to maximise total hospital savings.

BD BACTEC™ FX – Superior efficiency in blood culture from specimen collection to actionable results!



Hospital

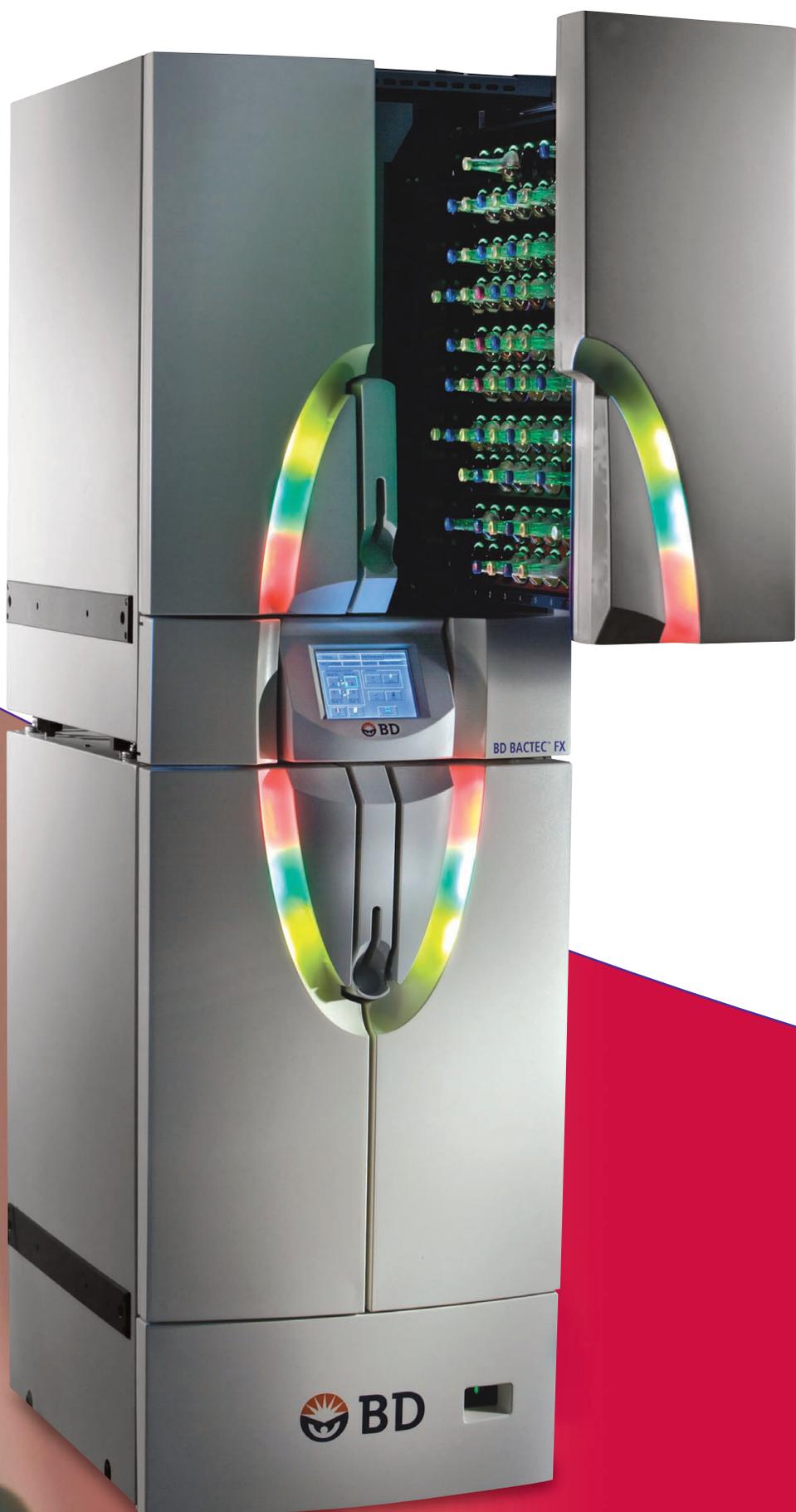


Specimen collection



Laboratory

Visibly better



Vial-Activated Workflow - Reduced Hands-On Time

The unique vial-activated workflow means that the instrument knows from the user's first action with a vial what the next step should be. Sensors in the station associate patient and testing data to the vial. There is no need to touch a button or screen to process blood culture vials. The movement of a vial indicates to the instrument the workflow needed based on the vial status (e.g. load new vials, remove positives and negatives, identify anonymous).

**Blood culture processing has never been easier!
The BD BACTEC™ FX will save you precious time.**

VIAL LOADING



Scan barcodes



Open drawer

VIAL UNLOADING



Remove negative or positive vials



Load vials



Close drawer



Scan barcode (not needed in case of batch removal of negatives)

Anonymous made easy

Anonymous blood culture vials can be flagged positive by using a group of algorithms which is common for routine media. Identification of anonymous vials is just as easy as loading vials.

To identify anonymous vials:

- open a drawer with anonymous vials
- scan the vial and accession barcode if available
- place the vial in the green flashing station or in any other available station

ID Anonymous

Accession:

Sequence:

Medium: Unknown

Status: Ongoing

Protocol: 5

Last Location: 01-B-H10

TIP 00:01:03

Drawer B

+	0	●	33
-	2	?	1
⊗	0	○	65

Discard Return Rescan Save Exit

ID Anonymous display

Audible Tones and Alarms

Several unique sounds can be generated by the BD BACTEC™ FX system as you perform operations. These tones are designed to assist you with workflow such as loading and unloading of bottles, and to interact with the instrument when messages appear on the screen. For example, there is an audible alert if anonymous vials are loaded or if a drawer is not fully closed. Other tones confirm correct operations or alert to incorrect ones further adding to the user-friendliness of the BD BACTEC™ FX instrument.

Enhanced Visual Indicators

Locating the appropriate vials is made easier by the use of very visible light pipes at each station, eliminating any confusion as to the test status. Bold flashing lights around the top of the station indicate the following:

- | | | |
|---|----------------|---------------------|
|  | Flashing Red | Positive vials |
|  | Flashing Green | Completed negatives |
|  | Flashing Amber | Anonymous vial |

Available stations are indicated by a steady green light.

Superior User Interface - Streamlined Workflow

Conveniently located touch screen LCD on each bench top or stack configuration

- In direct view below or above barcode scanner for improved accessibility, flexibility and functionality in daily workflow.
- Maximum accessibility without the need to reach too far for vial manipulation or walk away from direct screen viewing.
- Enables a smooth “one hand” motion in addressing vial status and specimen and patient data.
- Allows unique multi-technologists instrument/vial/data access with no waiting in case of multiple stack or bench top configurations.

Enhanced visual status Indicators on the drawer front

- Allows the monitoring of the instrument even from a distance. Red LEDs are illuminated in the case of positive vials, green LEDs in the case of negatives and yellow LEDs in the case of system messages.

Barcode scanner at each module for improved accessibility/functionality

- Barcode scanner flexibility in label scanning. The barcode scanner will accept the vial sequence scan and accession number scan in any order to minimize error. The high-performing barcode reader also calculates a total sum on each accession number to ensure the accuracy of the read.

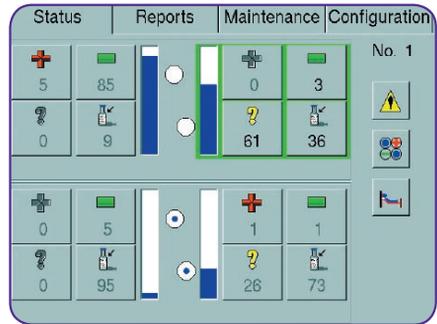


Maximum Ease of Use



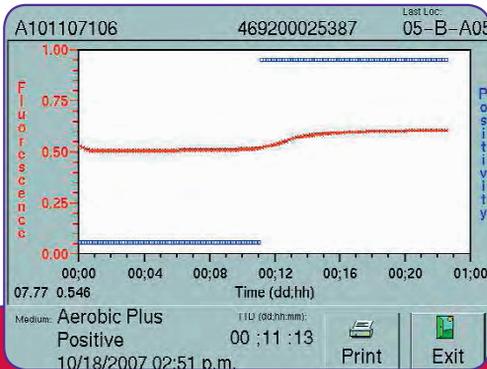
Operating a blood culture system has never been easier. It's child's play!

- The combination of vial-activated workflow, the "any vial anywhere" capability and clear-cut station indicators virtually eliminate vial-operating errors and reduce staff-training to a minimum.
- Obvious instrument status with one glance at the touch screen – always right in front of you.
- Instant view of available stations per drawer using blue "fill bars".
- Easy observation of the number of negative, positive and anonymous vials.
- Clear graphic icons and touch screen capabilities intuitively guide you through daily operations.
- Possibility to change vial position within a top model or stack, or within multiple instruments in case of a BD EpiCenter™ configuration. The data goes with the vial.



BD BACTEC™ FX status display

- Simple access to vial and patient data and statistical reports such as unloaded positive vials, contaminated vials, QC report etc. Growth curves can be easily retrieved and zoomed with one touch.



BD BACTEC™ FX growth plot display

Minimum Maintenance

- **Daily:** Station and system - LEDs, audible alarms, system temperature and printer paper supply.
Periodical (optional): Air filters.
- Easy front access to all components and electronics.

Superior Laboratory Space Utilization & Ergonomics

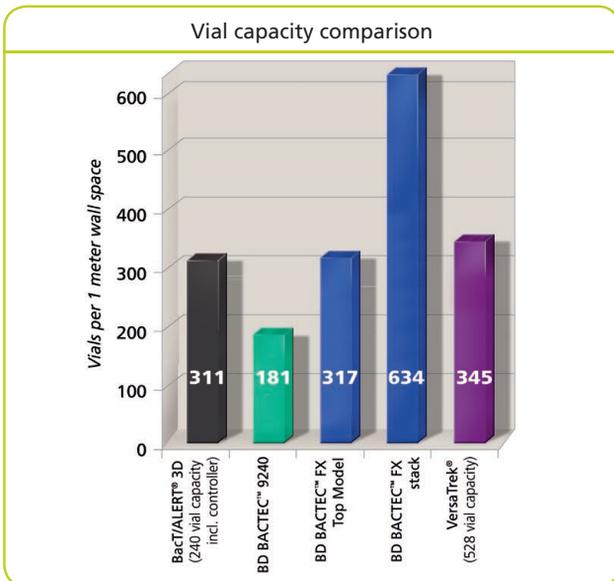
The BD BACTEC™ FX System was designed for maximum ergonomics combined with maximum capacity in a minimal footprint. Its expandable, modular design easily accommodates the changing capacity requirements of laboratories.

The most common configuration of the FX is a two-module system designed as a stack. The stack contains four drawers, each with a 100-vial capacity. Smaller volume laboratories can choose a single, top-unit system. For high volume capacity, multiple (up to 20) stack/top-units can be seamlessly integrated into a single system using BD EpiCenter™. Existing BD BACTEC™ 9120/9240 instruments can also be easily combined with BD BACTEC™ FX modules via BD EpiCenter™.

Technologists find that the height of both the top bottle and the lowest bottle of a stack is a very comfortable reach. The convenient location of the touch screen and barcode scanner also improves ergonomics.

Save space!

- Most compact blood culture system with highest ratio of bottles to wall and floor space, providing a higher space utilization rate: > 80% higher capacity compared to competitive systems.
- Highest capacity per drawer compared to other systems (> 66%) reduces time-consuming opening/closing procedures.
- As all basic data management is available on the embedded computer, no external PC is needed for stand-alone configurations.



BD Safety Solutions: A Commitment to Healthcare Workers



BD, the worldwide leader in safety-engineered medical devices, has designed its BACTEC blood culture bottles to be fully compatible with the widely available BD Vacutainer™ safety blood collection systems, thus reducing the risk of accidental needle-stick injuries during blood collection and sub-culturing.

Integrated solutions for safety during blood collection

- Split-second in-vein needle retraction with the unique BD Vacutainer™ Push Button Blood Collection Sets with memory-free tubing virtually eliminates the risk of needle-stick injuries.
- Closed direct draw of blood with BD Vacutainer™ Blood Collection Systems helps to keep contamination rates down.
- Training by BD experts for clinicians/nurses/phlebotomists on best blood collection practices improves safety and patient care (fewer contaminants).
- Unlike other automated blood culture systems, BACTEC bottles are fully compatible with Vacutainer blood specimen collections because of the use of the same single holder, thus reducing the number of exposures to sharps.
- Safety-engineered needles, syringes and transfer devices for quantitative blood culture (differential time to positivity studies for diagnosis of catheter-related blood stream infections).

Integrated solutions for safety in the lab

For improved lab-worker safety, BD offers:

- A safety engineered sub-culturing unit fully compatible with BD BACTEC™ vials for the safe sub-culturing of instrument positive blood cultures.
- A special tray for the safe transportation of vials in the laboratory.
- Re-usable containers for the safe transportation of BD BACTEC™ vials in pneumatic tube systems.

"Blood culture bottles should be transported in a container that prevents them from falling, knocking into each other, or rolling off the surface. They should never be carried from one area of the laboratory to another in the hands of laboratorians, but should be placed in a carrier device."⁽¹⁾



Superior Patient Care
through Superior Performance

BD BACTEC™ Media: the Core of the System

Historically, BACTEC™ Blood Culture Systems have always offered enhanced recovery of isolates from blood cultures to help identify bacteremia episodes sooner.

The BD BACTEC™ FX has been designed to continue the media and performance excellence that thousands of microbiologists have come to expect from the BD BACTEC line, and with similar instrument reliability. The FX utilizes the breadth of current media – from Plus, and Lytic to PEDs and special media for yeast, fungi or mycobacteria recovery – to support your different patient population and blood culture needs.



Media range, fluorescence technology and algorithms

- Increased flexibility with the widest range of blood culture media.
- Highly sensitive, fluorescence detection technology.
- > 16 medium-specific, kinetic software algorithms optimize recovery rate for the widest range of micro-organisms at different phases across the growth curve.
- This combination of media-specific algorithms with growth phase-specific kinetic algorithms enhances the sensitivity and time to detection, even in the case of delayed vial entry. A threshold algorithm is not employed; it has been demonstrated that this can lead to false negatives⁽³⁾ or false positives.
- Proven delayed vial entry capabilities for up to 20 hours pre-incubation at 35°C, or up to 48 hours storage at room temperature.⁽²⁾

BD BACTEC™ Plus Resin Media



BD BACTEC™ resins

Blood cultures are among the most important specimens diagnosed by the clinical microbiology laboratory. Recovery rate and time to detection are the key performance indicators of any blood culture system.

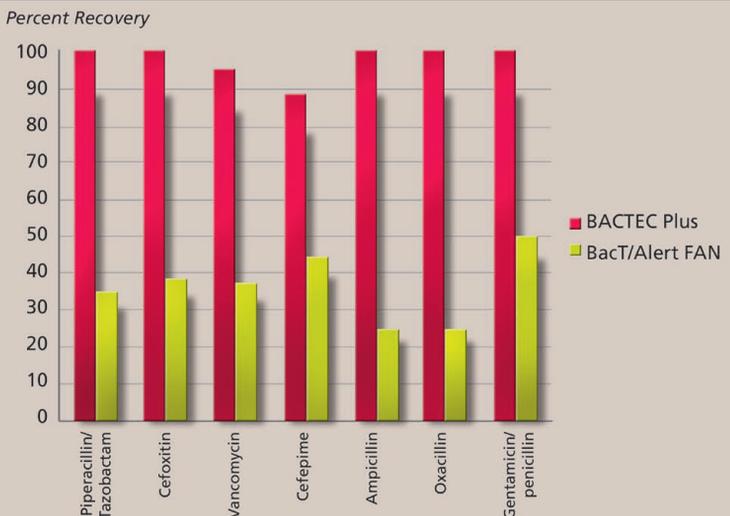
However, one of the greatest challenges in blood culture is the fact that among patients from whom blood cultures have been obtained, 28-63% are on antibiotic therapy at the time of blood draw. This can negatively affect the recovery of the etiologic agent⁽⁴⁾. It is therefore essential to choose the most effective antibiotic neutralization system for maximum performance and superior patient care.

Don't compromise on quality. Go for Plus - Go for Resins!

- Superior recovery of pathogens from blood with an unmatched false negative rate of 0.03%⁽⁵⁾ and false positive rate of 0.1%⁽⁶⁾
- Proven effective neutralization of a wide variety of antimicrobials improves recovery and shortens time to detection compared to other systems.^{(7),(8),(9)}
- Best neutralization of widely used β -lactam drugs and vancomycin compared to other systems.^{(4),(7),(10)}
- Advantageous also for the culture of normally sterile body fluids from patients receiving antibiotic therapy.⁽¹¹⁾
- No interference with Gram stain readings – improves workflow and reporting time.^{(11),(13)}
- Increasing hospital revenues (DRG reimbursements) as a result of enhanced recovery of significant pathogens associated with septicemia.⁽⁸⁾



Percent recovery of control and challenge organisms in BACTEC™ PLUS and BacT/Alert® FA bottles containing antibiotics ⁽¹⁾



BD BACTEC™ TwinSet: A Unique Combination

- A pair of one BD BACTEC™ Plus Aerobic/F and one BD BACTEC™ Plus Anaerobic/F vial in one conveniently packaged set (25 sets per box).
- Helps to ensure the collection of blood culture sets and thus sufficient volumes of blood.
- Streamlines the logistics of blood culture vial distribution on the wards.

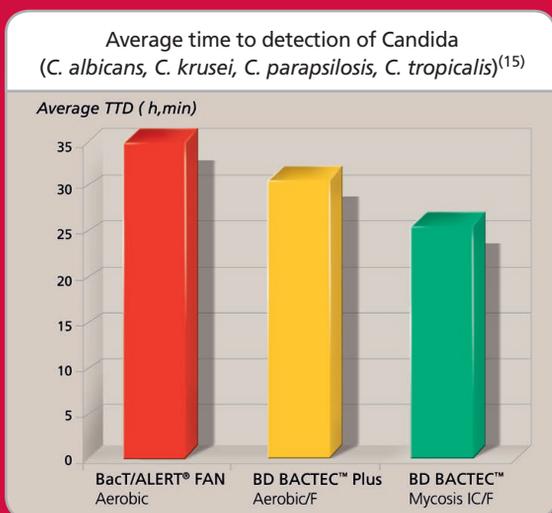


BD BACTEC™ Blood Culture Media Selection

	Medium
Plus Aerobic/F	Enriched soybean-casein digest broth. Aerobic atmosphere enriched with CO ₂ .
Plus Anaerobic/F	Pre-reduced enriched soybean-casein digest broth. Anaerobic atmosphere enriched with CO ₂ .
Lytic/10 Anaerobic/F	Pre-reduced enriched soybean-casein digest broth with CO ₂ and N ₂ . Contains saponin.
PEDS PLUS/F	Enriched soybean-casein digest broth. Aerobic atmosphere enriched with CO ₂ .
Mycosis IC/F	Soybean-casein digest broth enriched with yeast extract and BHI. Contains saponin and chloramphenicol & tobramycin. Aerobic atmosphere enriched with CO ₂ .
Standard Aerobic/F	Enriched soybean-casein digest broth. Aerobic atmosphere enriched with CO ₂ .
Standard Anaerobic/F	Pre-reduced enriched soybean-casein digest broth. Anaerobic atmosphere enriched with CO ₂ .
Myc/F Lytic	Modified Middle-brook 7H9 broth, contains Brain Heart Infusion. Aerobic atmosphere enriched with CO ₂ .

BD BACTEC™ Mycosis IC/F Medium

- Optimal growth medium for a wide variety of yeast and fungi supplemented with saponin in order to release phagocytosed fungi and yeasts from leukocytes.
- Selective medium containing chloramphenicol and tobramycin to suppress bacterial growth, thus providing a considerable advantage when yeasts are present concomitantly with bacteria which can occur in up to 21% of fungemias.⁽¹⁴⁾
- Significantly faster time to detection of yeast and fungi compared to other automated blood culture media.⁽¹⁵⁾
- Recommended to be used as third vial for blood cultures of immunocompromised, neutropenic patients or other patients at risk for invasive fungal infections.⁽¹⁶⁾⁽¹⁷⁾



Suspicion of systemic mycosis?

Choose BD BACTEC™ - Mycosis IC/F Medium, because
"... every hour of earlier detection is crucial."⁽¹⁸⁾

Application	Specimen	Resins
Recovery of aerobic bacteria, yeasts and fungi from blood or sterile body fluids. Recommended for patients already under antimicrobial therapy.	3 - 10 ml Optimal 8 - 10 ml	Yes
Recovery of obligate and facultative bacteria from blood or sterile body fluids. Recommended for patients already under antimicrobial therapy.	3 - 10 ml Optimal 8 - 10 ml	Yes
Recovery of obligate and facultative anaerobic bacteria from blood or sterile body fluids. Improved recovery of organisms due to lysis of leukocytes.	3 - 10 ml Optimal 8 - 10 ml	No
Recovery of aerobic bacteria, yeasts and fungi from pediatric patients or other low volume blood specimens or sterile body fluids. Recommended over other media for patients already under antimicrobial therapy.	0.5-5.0 ml Optimal 1 - 3 ml	Yes
Designed for increased selective recovery of yeasts and fungi from blood of immunosuppressed or neutropenic patients. Improved recovery of organisms due to lysis of leukocytes.	3 - 10 ml Optimal 8 - 10 ml	No
Recovery of aerobic bacteria and fungi from blood. Less recommended for patients already under antimicrobial therapy.	3 - 10 ml Optimal 8 - 10 ml	No
Recovery of obligate and facultative anaerobic bacteria from blood. Less recommended for patients already under antimicrobial therapy.	3 - 7 ml Optimal 5 - 7 ml	No
Originally designed for non-selective recovery of mycobacteria, yeasts and fungi from blood of HIV/AIDS patients. Used as an adjunct to Plus Aerobic/F. Does not require addition of any supplement.	1 - 5 ml	No

Proven Performance with body fluids other than blood

BD BACTEC™ Fastidious Organism Supplement Kit (FOS™)

- Special growth supplement for improved performance with normally sterile body fluids other than blood.
- Contains NAD and hemin to compensate for the absence of blood.
- Substitutes the usage of donor blood for culture of fastidious organisms such as *Haemophilus spp.* and *Neisseria spp.*
- Neutralizes the potential toxic effects of SPS when no blood is added to the culture medium, thus enhancing the recovery of SPS-sensitive organisms such as *Neisseria spp.*, *Streptobacillus moniformis* and *Peptostreptococcus anaerobius*.

Routine Mycobacteria Testing and Blood Culture on the same System?

- For activities involving the propagation and manipulation of *M. tuberculosis* grown in culture, biosafety level 3 practice, containment equipment, and facilities are required as recommended by CDC and NIH guidelines. As a minimum, the instrument should be placed in a contained environment with controlled access which has a tuberculosis exposure control plan.
- Therefore, BD recommends to keep routine mycobacteria testing and blood culture separated from each other.

Mycobacteria Testing



Blood Culture





Improving the Management of *S. aureus* Bloodstream Infections

BD BACTEC™ & BD GeneOhm™ StaphSR

The BD GeneOhm™ StaphSR assay is the first FDA-approved rapid real-time PCR test, which simultaneously identifies *S. aureus* (SA) and methicillin-resistant *S. aureus* (MRSA) from positive blood cultures. Results are available within two hours allowing the lab to provide physicians with critical information 2-3 days sooner than traditional microbiology methods.

The BD GeneOhm™ StaphSR assay has been shown to be a very valuable diagnostic tool for quickly differentiating bacteremia caused by MSSA and MRSA⁽¹⁸⁾. Together, the BD BACTEC™ Blood Culture Systems and the BD GeneOhm™ StaphSR assay can improve the management of *S. aureus* blood stream infections by:

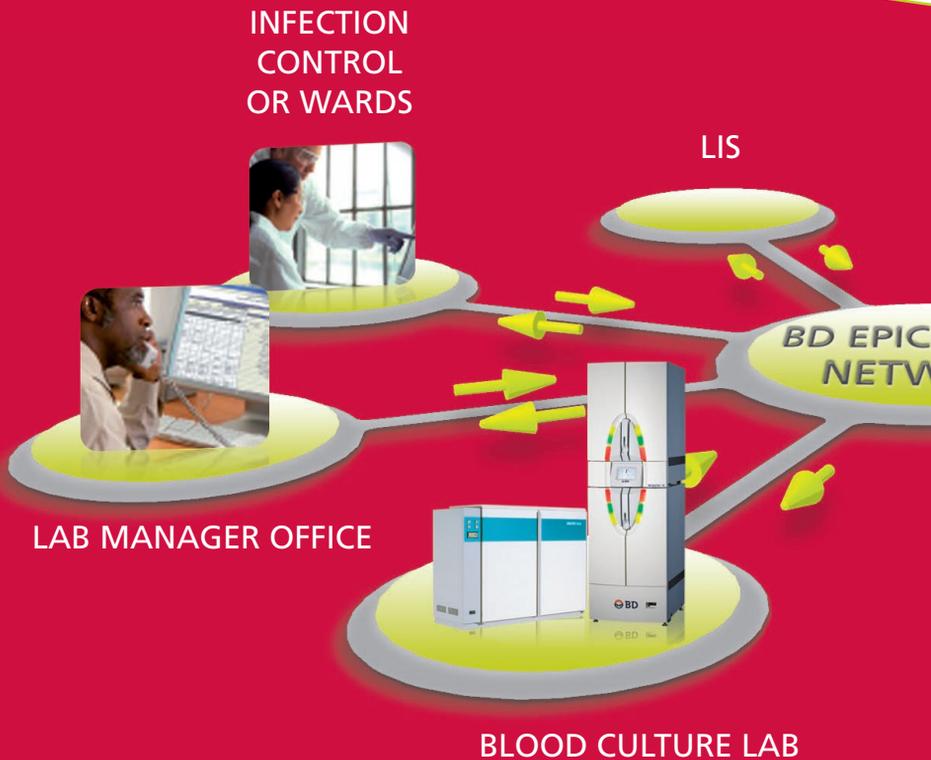
- Recovering *S. aureus* from positive blood cultures more rapidly and frequently – even in the presence of vancomycin.⁽⁴⁾
- Identifying and differentiating SA and MRSA directly from positive blood cultures, thereby allowing clinicians to treat patients more effectively.
- Promoting better antibiotic stewardship to prevent the emergence of vancomycin-resistant organisms.
- Facilitating earlier isolation of patients infected with MRSA to prevent further transmission and infection.
- Reducing healthcare costs.



Intelligent Information Management

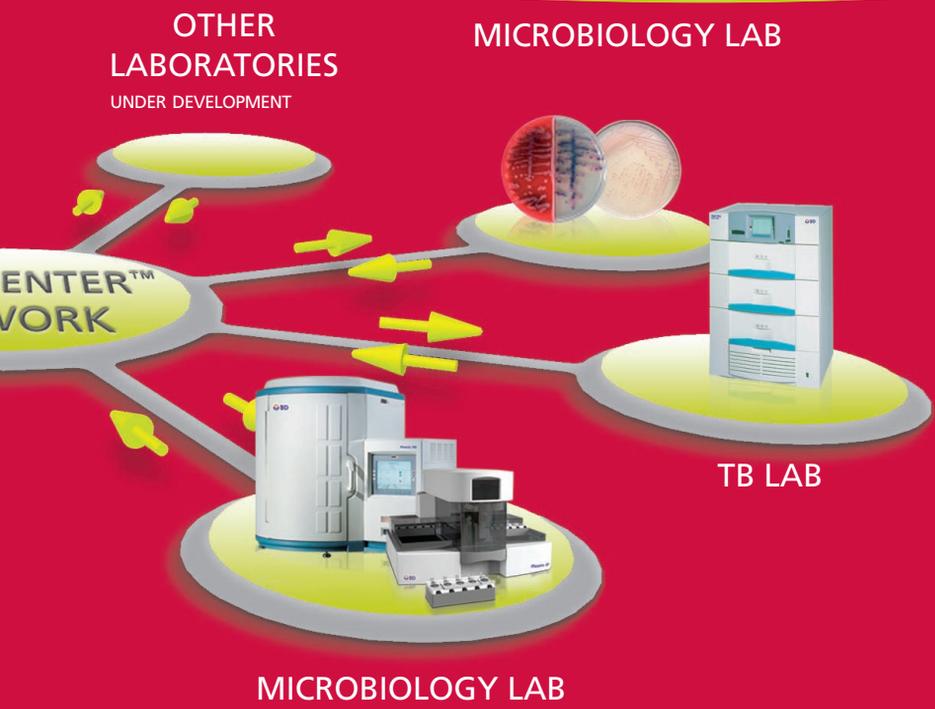
BD EpiCenter™: Improving Efficiency and Patient Care via Real-Time Communication

The BD EpiCenter™ data management system is a **UNIQUE** solution for microbiology laboratories to efficiently communicate and track all the information needed by every professional involved in infection control and patient treatment.



Full Data Access and Information delivery in Real-Time

- BD EpiCenter™ directly interfaces with BD Phoenix™, BD Phoenix AP™, BD BACTEC™ Blood Culture Systems, BD BACTEC MGIT™ 960 for multi-instrument integration and complete data observation.
- Efficiently organizes workflow on one system – full data access at any time, anywhere, enhancing real-time data flow and result communication while reducing technician bottlenecks.
- Operates in a true multi-user environment – BD EpiCenter™ can be loaded on other existing computers within your facility, thus providing multiple access points inside and outside of the laboratory.
- Concentrates patient data and test results into a single bi-directional LIS interface for all systems, thus reducing costs and maintenance.
- Comprehensive real-time monitoring and analyzing of data and reporting of actionable results at every BD EpiCenter™ workstation enabling a faster impact on patient care decisions
- Large array of ready-to-use and customizable reports and analysis tools facilitating whole-house surveillance and data sharing.
- Additional modules are available for: customizable expert interpretation of ID/AST results (BDXpert™ and BD EpiCARE™ system -an innovative open expert system allowing customization of rules), surveillance, epidemiology, "Pro-Active" alerting (Sentinel) and for second line drug testing of mycobacteria (TB eXIST)
- Open for any off-line tests such as Gram stains, BBL CHROMagar™ MRSA etc. allowing consolidation of automated and manual test results.
- Provides both text and graphic reports - electronically exportable directly to Microsoft applications.
- Barcode printing and scanning capabilities eliminate mistakes when managing data.



BD EpiCenter™: Management of Bloodstream Infections

"Unlike many other laboratory results, positive blood cultures can have an immediate impact on patient care decisions, and clinically relevant results must be reported to caregivers as quickly as they are available".⁽¹⁾

To answer this need, BD has developed a "Sentinel" module on BD EpiCenter™ with "Pro-Active" alerting capabilities.

Enhanced Blood Culture Observation and Reporting, In and Out of the Microbiology Laboratory

- Improved information access on all shifts and in any department with "Remote Blood Culture Observation" and remote alerts on all BD EpiCenter™ Workstations.
- Immediate notification of positives with audible alerts and real-time system status displays.
- Growth curves and detailed result review in just "one-click".
- Reduced workflow interruptions by allowing continuous remote monitoring for positive blood cultures or errors.
- Positive blood culture alerts on evenings or nights where staffing is at a reduced level.
- Culture data can be accessed to make the best "informed" personnel decisions.
- Extensive array of blood culture related reports.
- Allows immediate notification to physicians, infection control personnel and pharmacists via existing e-mail systems, SMS or PDA of user-defined "Sentinel Events", such as the detection of MRSA.

“

In our institution, the BD EpiCenter™ System with BD Sentinel Software allows integration of infection control, pharmacy, and the microbiology laboratory in an efficient user customizable system.

”

Toni Beavers-May, B.S., MT(ASCP)
Technical Chief of Microbiology,
Arkansas Children's Hospital, USA

BD BACTEC™ FX

Superior patient care with leading microbial recovery and time to detection uniquely combined with safe blood collection, the most intuitive and innovative design and intelligent, cutting edge data management.

Superior efficiency in blood culture from specimen collection to actionable results!



BD BACTEC™ FX Stack



BD BACTEC™ FX Top Unit

BD BACTEC™ FX Instrument Specifications

Physical Dimensions	Top Unit	Stack
Height	88,9 cm	199,5 cm
Width	63,5 cm	63,5 cm
Depth	86,4 cm	86,4 cm
Clearance (rear, left, right)	1,3 cm, 0 cm, 0 cm	1,3 cm, 0 cm, 0 cm
Clearance (front)	68,6 cm	68,6 cm
Vial capacity	200	400
Annual maximum through-put on a 5 day protocol	14.600 vials	29.200 vials

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