



# Adding Value to your Manufacturing Process

BD's Rapid Microbiology  
BD FACSMicroCount™



# Challenges

## In Production....

- Contamination detection
- Scaling-up Operations
- Loss of materials, intermediates and finished products
- production time and profit
- LEAN manufacturing
- Risk Evaluation

## At the QA/QC ....

- Labour & Resources
- Time to Results
- Storage Requirements – Fridge/Incubator Capacity
- Repeatable and Reproducible results
- Subjectivity
- OOS Management

## For Management....

- Overall operation of the plant
- Profitability
- LEAN manufacturing
- Reduction of overhead cost
- Reduction of inventory/warehouse
- Return Of Investment



# Current status RMM

Regulatory guidance documents since 2000

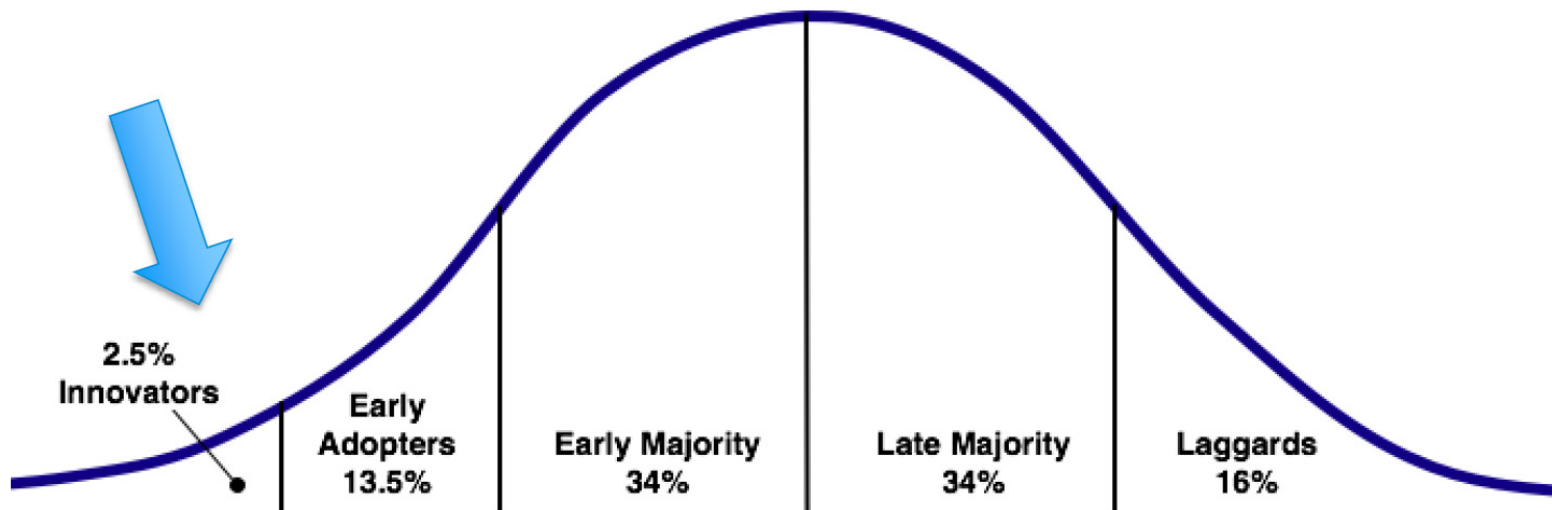
Easier registration process of your RMM application

> 10 new RMM applications filed in US in 2011

+/- 50 RMM Technologies available on the market:

<http://rapidmicromethods.com/files/matrix.html>

Everyone is considering/evaluating RMM applications



Source: Everett Rogers, Diffusion of Innovations model

# BD FACSMicroCount™

- Unique proven technology counts living cell
- Quantitative direct results in minutes
- Presence/Absence tests in hours
- Direct labelling and detection technology



# The BD FACSMicroCount™ Solution

SAVES TIME

with rapid results

SAVES MONEY

by minimizing media & product loss

by reducing warehousing costs

by reducing labor costs

IMPROVES

through constant monitoring &

PROCESS

optimizing



# The BD FACSMicroCount™ Solution

An easy-to-use, fully automated system

Provides rapid, objective results

Replaces time and labor-intensive microbiological methods



# The BD FACSMicroCount™ System

- Versatile system
  - ✓ Quantitative
  - ✓ Qualitative
- Automated, high throughput analysis with continuous processing capability
- Reagents stable at room temperature for 10 days
- Differentiate microorganism type
  - ✓ Bacteria
  - ✓ Yeast
  - ✓ Mould
- Objective results
  - ✓ Counts/mL
  - ✓ Pass/Fail
- 21 CFR part 11-compliant software







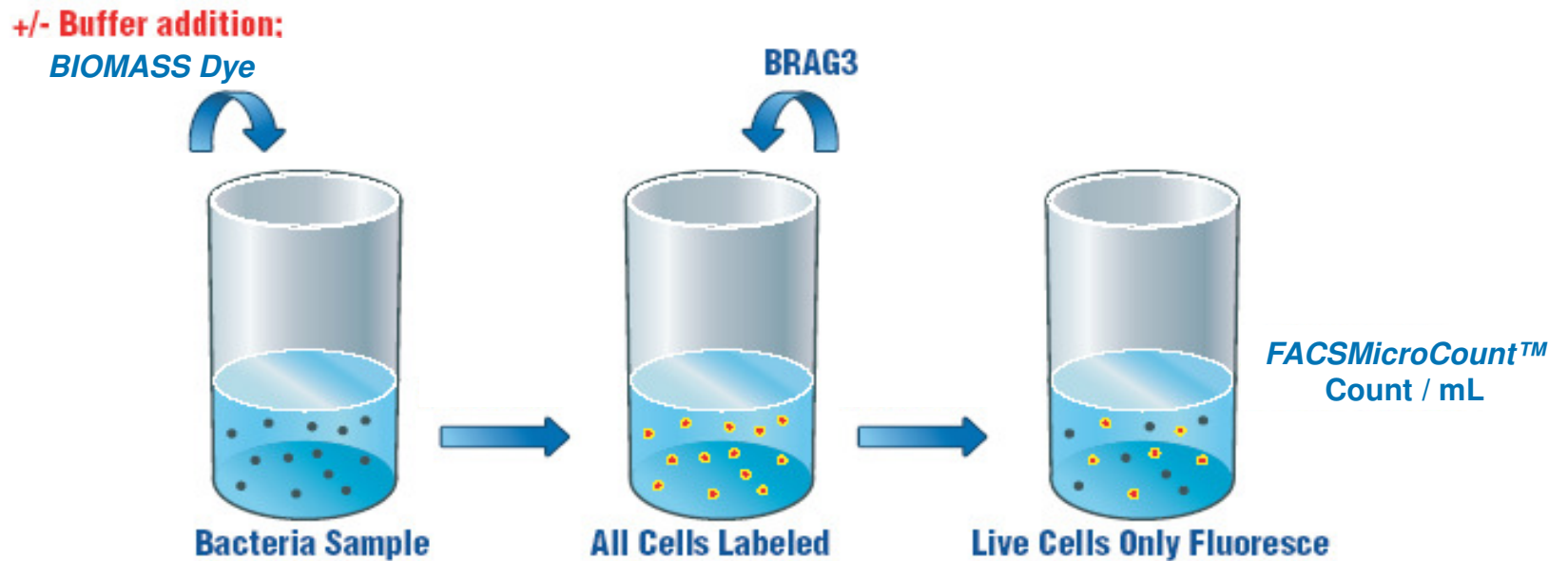
# The Technology

## Based on Flow Cytometry

- Cells in a sample are labeled with a fluorescent dye
- Each labeled cell passes through the laser beam emitting fluorescent and scattered laser light
- The optic and electronic systems capture and record each of the signals as 1 count
- Provides quantification of microorganisms per volume, yielding counts/mL results



# General Labeling Protocol for BD FACSMicroCount™

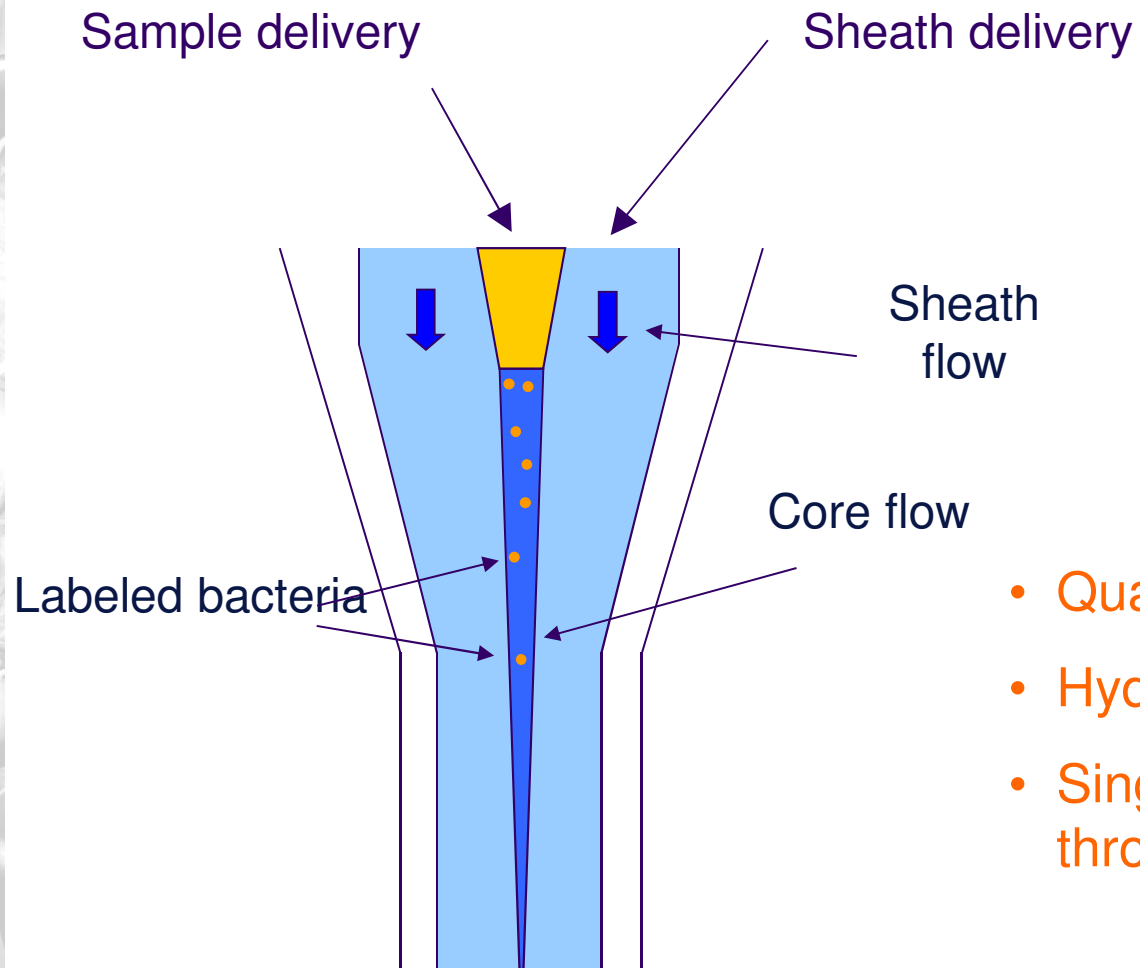


BIOMASS Dye= permeable, labels nucleic acid in and out of the intact cells

BRAG3= non-permeable, quenches fluorescence out of intact cells

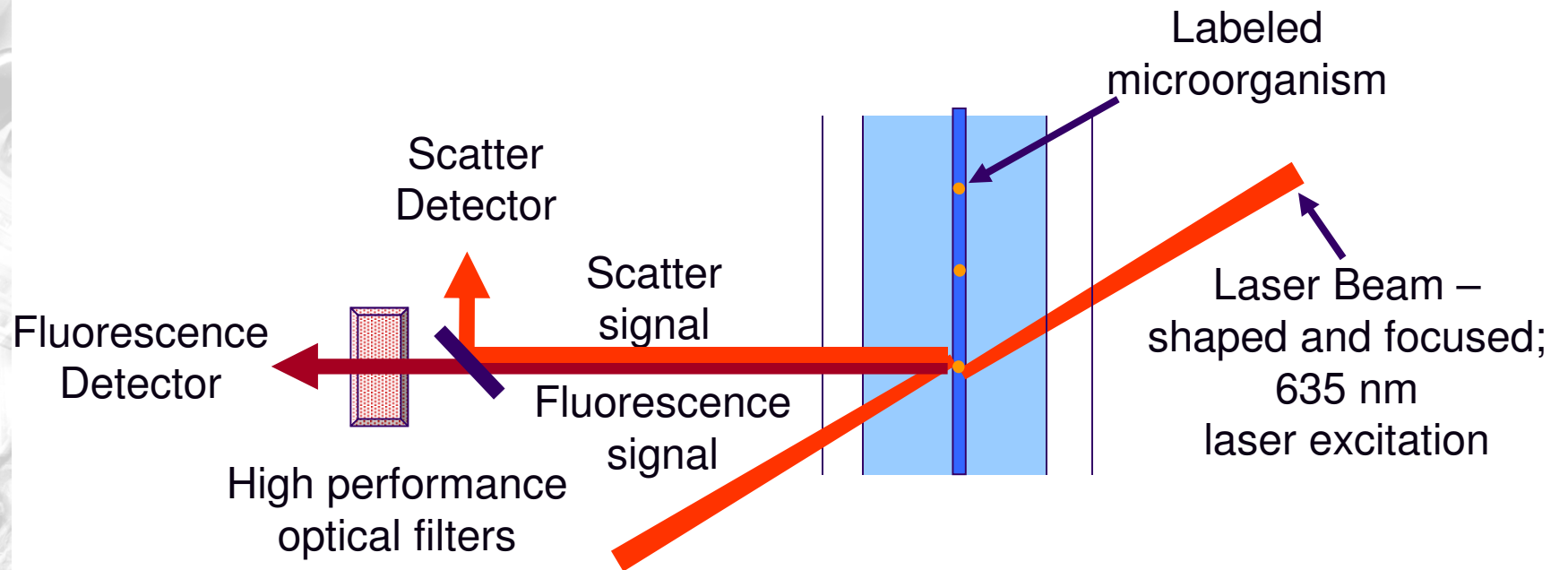


# Fluidic System



- Quantitative cell delivery
- Hydrodynamic Focusing
- Single File Passage through detection region

# Optic System



**Fluorescence plus Scatter  
= One Count**



# Automated, High-Throughput Analysis

- Qualitative Analysis (Presence/Absence)  
20 samples/hour
- Quantitative Analysis (Enumeration)  
12-15 samples/hour
- Holds up to 42 samples at once
- Automatically
  - ✓ adds reagents
  - ✓ mixes samples
  - ✓ cleaning



# Workflow of BD FACSMicroCount™



- BD FACS MicroCount



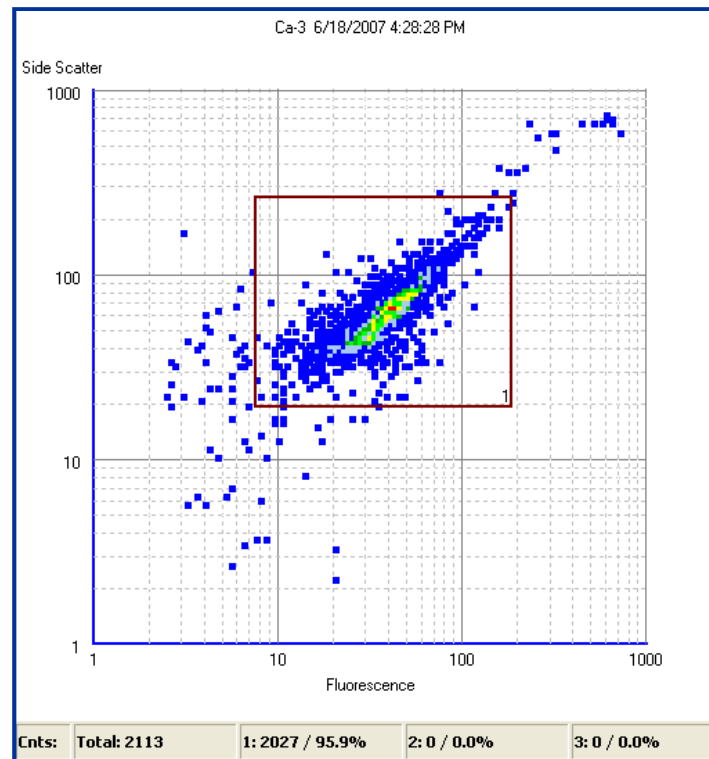
# Example of BD FACSMicroCount™

## INTENSITY PLOT

2D picture of each count detected and recorded in the sample

Each blue dot = 1 count; colors indicate multiple counts at same point

**Cell  
size**



**Amount of label**



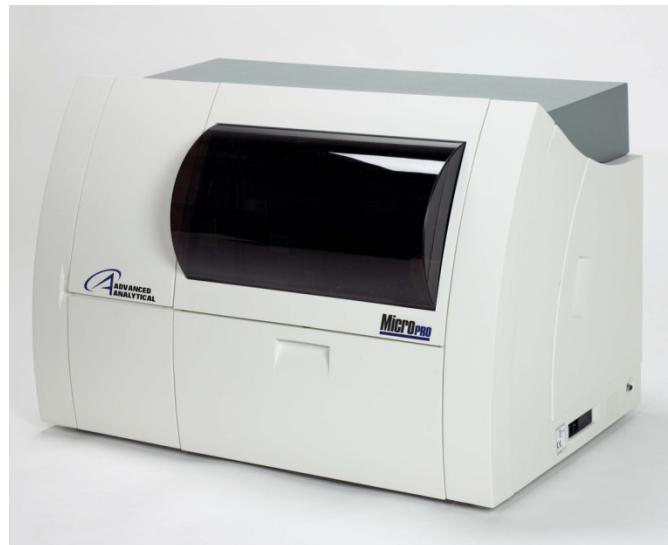
# BD FACSMicroCount™ All Applications

Cosmetics

General

Fermentation

Vaccines



Mycoplasma

Water

Stock cultures

Surface

Support

Product test





# Quantitative Analysis

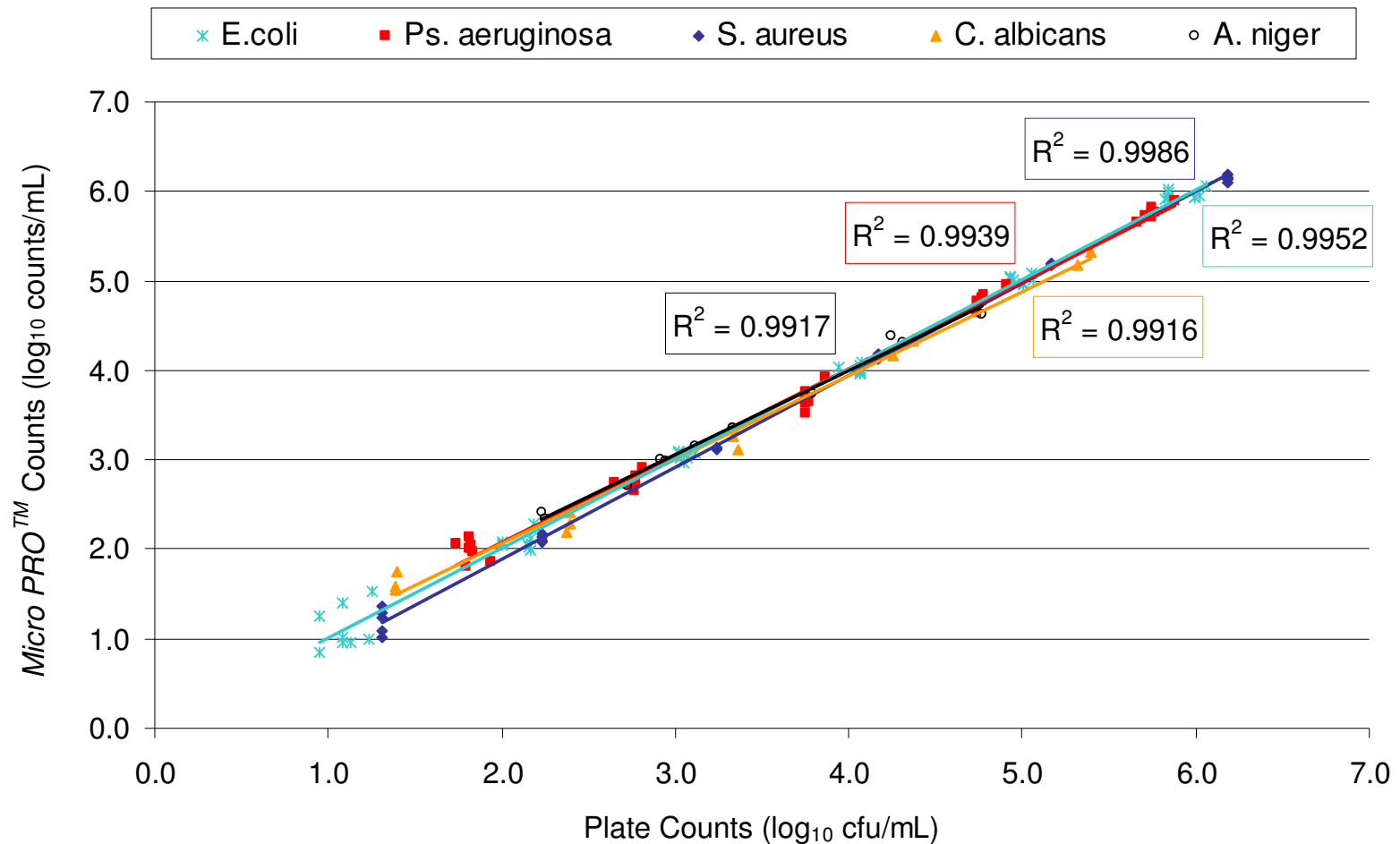
- Detects bioburden in viral vaccine intermediates (egg-harvest material)
- Microbial Fermentation Monitoring
- Screening Process Water
- Counting QC Stock Cultures
- Detecting Surface Contamination



- Easy-to-use
- Rapid screening solution
- Reliable, quantitative results in less than 5 minutes



# Correlation of BD FACSMicroCount™ vs. Plate Counts



***E. coli* ATCC 25922 (n=48); *Ps. aeruginosa* ATCC 9027 (n=35);  
*S. aureus* ATCC 6538 (n=30); *C. albicans* ATCC 10231 (n=15); *A. niger* ATCC 16404 (n=12)**

# Microorganisms Enumerated with BD FACSMicroCount™

- *Aeromonas caviae*
- *Aeromonas hydrophila*
- *Aspergillus niger* spores
- *Bacillus atrophaeus*
- *Bacillus atrophaeus* spores
- *Bacillus pumilus*
- *Bacillus pumilus* spores
- *Bacillus subtilis*
- *Bacillus subtilis* spores
- *Bordetella bronchiseptica*
- *Brachyspira hyodysenteriae*
- *Burkholderia cepacia*
- *Campylobacter jejuni*
- *Candida albicans*
- *Candida glabrata*
- *Citrobacter freundii*
- *Clostridium perfringens*
- *Cryptococcus* spp.
- *Cryptosporidium parvum* oocysts
- *Enterobacter aerogenes*
- *Enterobacter cloacae*
- *Enterococcus casseliflavus*
- *Enterococcus durans*
- *Enterococcus faecium*
- *Enterococcus faecalis*
- *Enterococcus gallinarum*
- *Enterococcus hirae*
- *Enterococcus mundtii*
- *Erysipelothrix rhusiopathiae*
- *Escherichia coli*
- *Escherichia coli* O157:H7
- *Escherichia coli* O25:HN
- *Escherichia coli* O15:NM
- *Escherichia coli* O1:NM
- *Escherichia coli* O7:NM
- *Escherichia coli* O78:NM
- *Escherichia coli* ON:H8
- *Escherichia coli* ON:NM
- *Escherichia coli* O8:HN
- *Geobacillus stearothermophilus*
- *Geobacillus stearothermophilus* spores
- *Giardia lamblia* cysts
- *Haemophilus parasuis*
- *Haemophilus somnus*
- *Halobacterium salinarum*
- *Klebsiella pneumoniae*
- *Lactobacillus acidophilus*
- *Lactobacillus casei*
- *Lactobacillus delbrueckii*
- *Lactobacillus lindneri*
- *Lactobacillus plantarum*
- *Lactococcus lactis*
- *Lawsonia intracellularis*
- *Leptospira pomona*
- *Listeria grayi*
- *Listeria innocua*
- *Listeria ivanovii*
- *Listeria monocytogenes*
- *Listeria seeligeri*
- *Listeria welshimeri*



# Microorganisms Enumerated with BD FACSMicroCount™

- *Micrococcus candidans*
- *Micrococcus luteus*
- *Moraxella bovis*
- *Mycoplasma bovis*
- *Mycoplasma hyopneumoniae*
- *Nannocystis exedens*
- *Oxalobacter formigenes*
- *Pantoea agglomerans*
- *Pasteurella multocida*
- *Pediococcus acidilactici*
- *Pediococcus damnosus*
- *Proteus mirabilis*
- *Pseudomonas aeruginosa*
- *Pseudomonas fluorescens*
- *Pseudomonas putida*
- *Ralstonia pickettii*
- *Raoutella terrigena*
- *Saccharomyces cerevisiae*
- *Salmonella adelaide*
- *Salmonella anatum*
- *Salmonella choleraesuis*
- *Salmonella dublin*
- *Salmonella enteritidis*
- *Salmonella hadar*
- *Salmonella heidelberg*
- *Salmonella iverness*
- *Salmonella schalwijk*
- *Salmonella typhimurium*
- *Salmonella worthington*
- *Serratia marcescens*
- *Shigella boydii*
- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Staphylococcus saprophyticus*
- *Stenotrophomonas maltophila*
- *Streptococcus bovis*
- *Streptococcus equinus*
- *Streptococcus pyogenes*
- *Tsukamurella paurometabola*





# **Qualitative Analysis**

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## **Product Screening**



# Product Screening

## Presence/Absence Test

- Screen products for microbial contamination  
Raw materials, in-process samples, finished products
- Detect bacteria, yeast & mold in 1 test
- Next day results for product release
- Various Matrices:
  - liquids                      powders
  - gels                              tablets
  - emulsions                      natural extracts
  - ointments
- Complete Kit with media & consumables



# BD FACSMicroCount™ versus Traditional

- No need to use different protocol and media to culture Bacteria, Yeasts and Moulds

**Growth Enhancement  
Media**



**TSA + SDA**

- No need to wait additional days until results for Yeasts and Moulds are also available. Length of incubation is the same for Bacteria, Yeasts and Moulds.

**24 Hours of incubation  
and 5 min. testing**



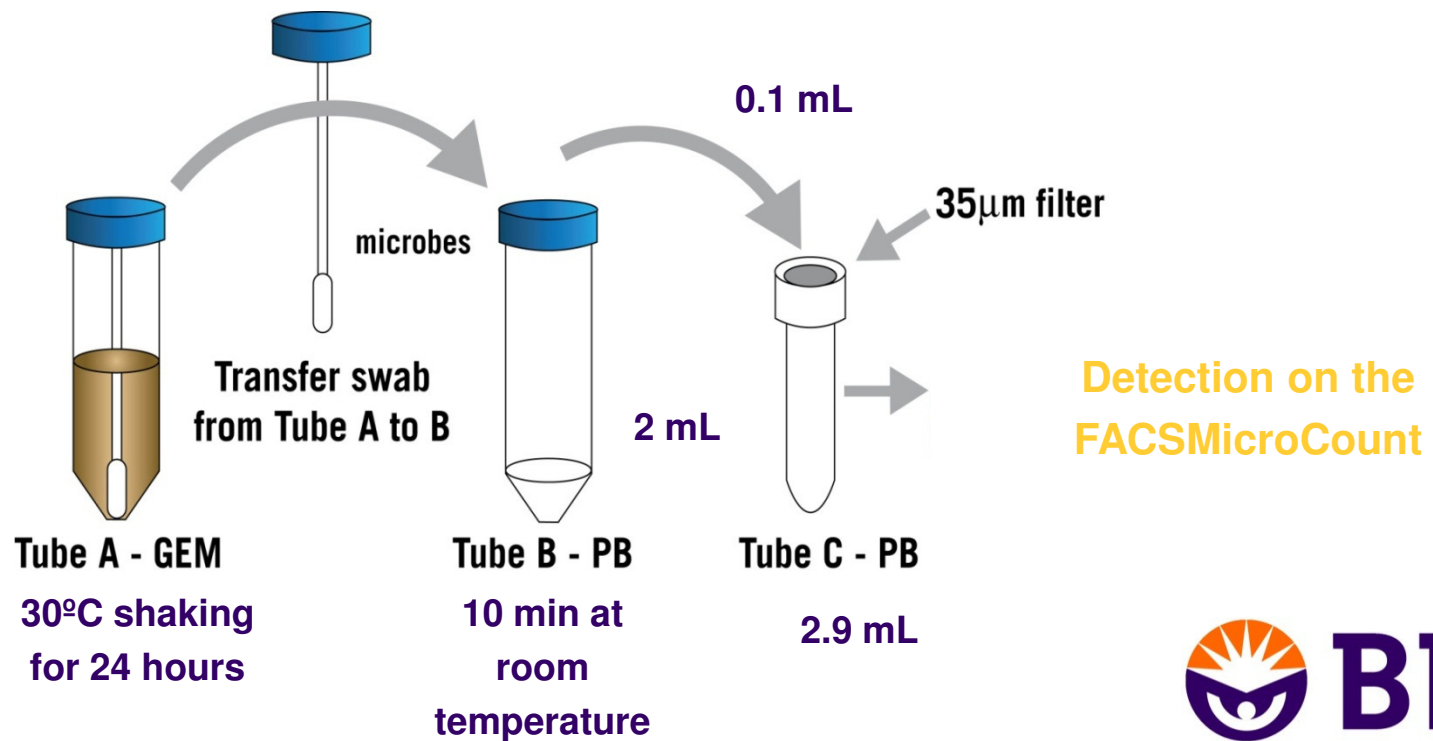
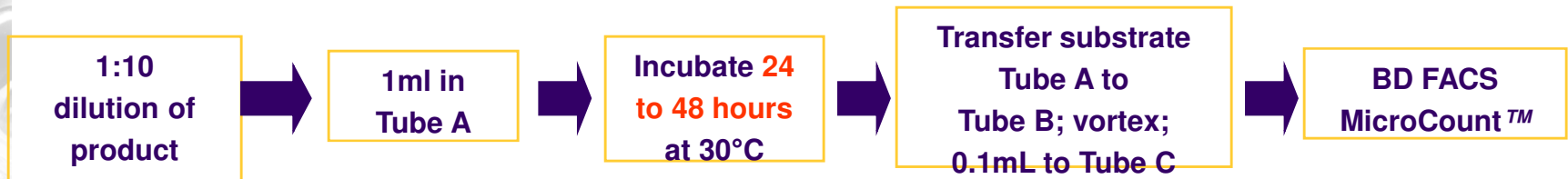
**Upto 5-7 Days for final  
results incl. Bacteria, Yeasts  
and Moulds**

- For most of the matrices results are available within 24 hours for Bacteria, Yeasts and Moulds in a single sample



# BD FACSMicroCount™ Protocol

## Bacteria, Yeast & Mold

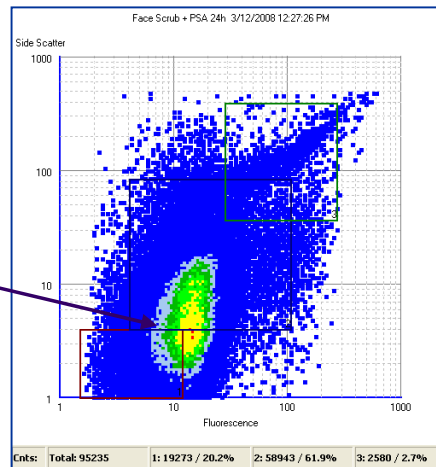




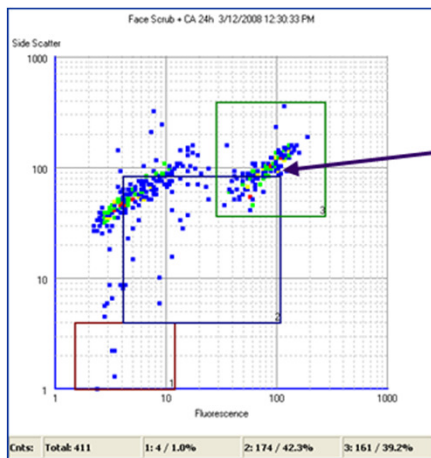
# Results

- BD FACSMicroCount™ output shows many counts within the area definition ( $\geq 3x$  product baseline)
- **Fail** result indicates that the sample contains microbial contamination

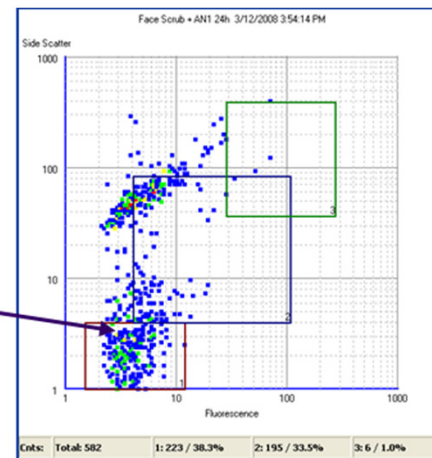
Bacteria



Yeast



Mold




# Result Summery

<b>Personal Care Products</b>	<b>Enrichment Time – Positive for Bacteria, Yeast &amp; Mold</b>
Face scrub	24 hrs
Hair gel	24 hrs
Hand soap, antibacterial	24 hrs
Lotion	24 hrs
Mouthwash	24 hrs
Shampoo	24 hrs
Shave gel	24 hrs
Sunscreen	24 hrs
Toothpaste	30 hrs

<b>Others</b>	<b>Enrichment Time – Positive for Bacteria, Yeast &amp; Mold</b>
Excipients	24 hrs
Household cleaner	24 hrs
Industrial Emulsions	24 hrs
Antioxidant water	24 hrs
Cranberry juice	24 hrs
Lemonade	24 hrs
Vegetable juice	48 hrs





# **Cosmetics Screening**

## **Using the BD FACSMicroCount™**

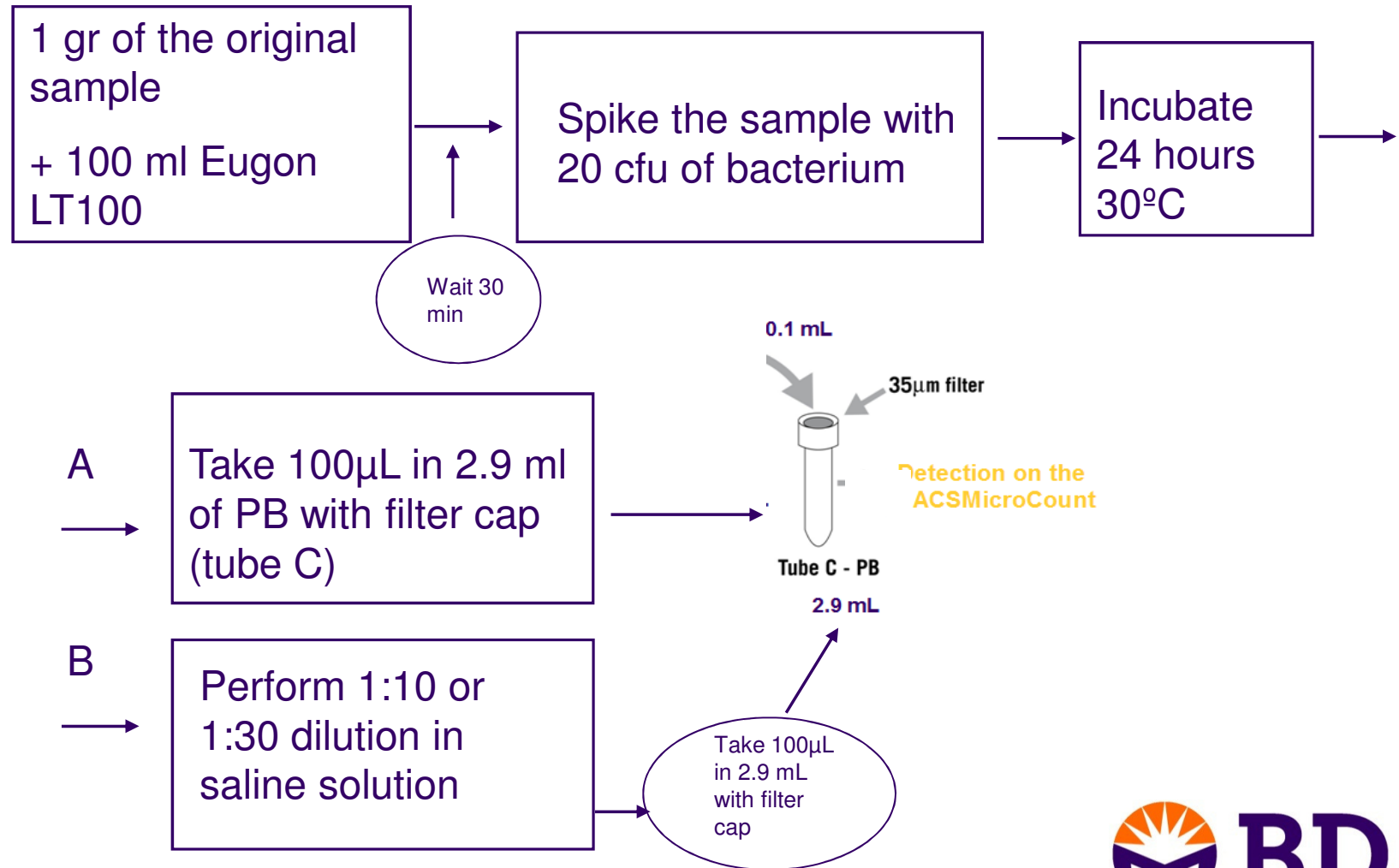


# Objective

- Demonstrate the **capability** of MicroCount™ Product Screening procedure to detect low-levels of microorganisms in various products commonly used (shampoo, brown tinted make up and facial cream) within 24 – 48 hours.
- To detect at least 20 cfu of *Escherichia coli*, ATCC 25922 and *Candida albicans*, ATCC 60193 in 1 gram of the original product
- To perform and demonstrate that the **EUGON** broth as enrichment medium can be used in combination with the BD FACS MicroCount™ platform, providing a pass/ fail (presence/ absence) result.

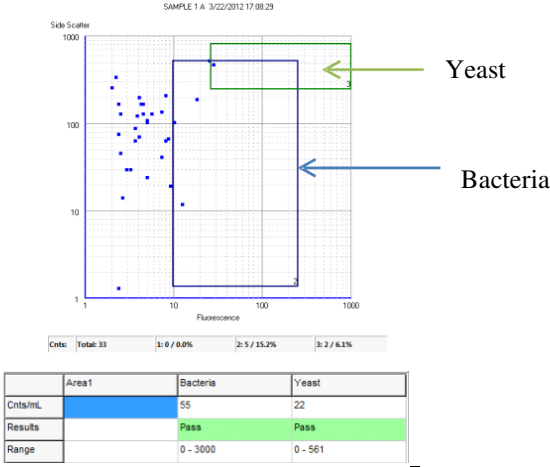


# Experimental procedure

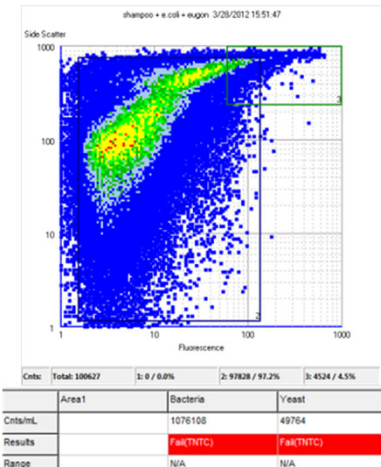


# Results on Shampoo

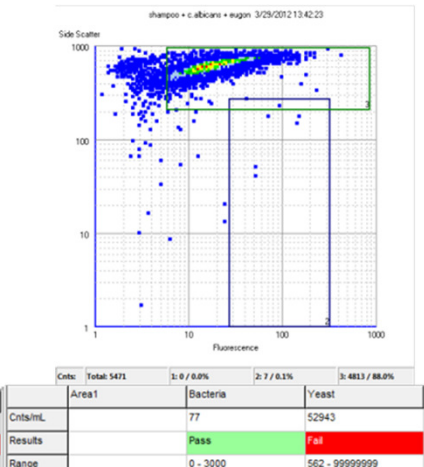
Shampoo undiluted



*E.coli*



*C. albicans* (48 hours)



The growth of *E.coli* is clearly visible after 24hr of incubation.

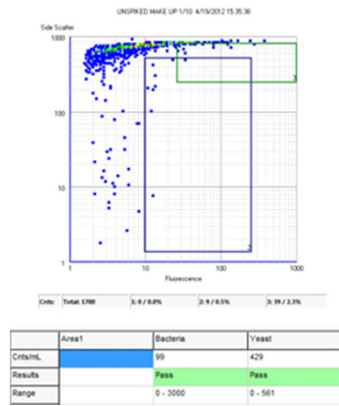
*C. albicans* was visible after 48 hours.



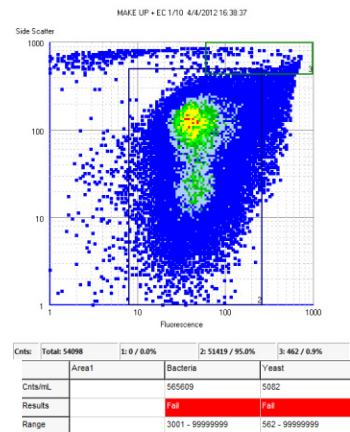
# Results make-up and facial cream

## Make up

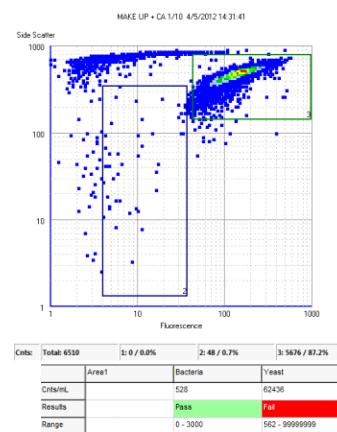
Makeup 1/10 diluted



*E. coli*



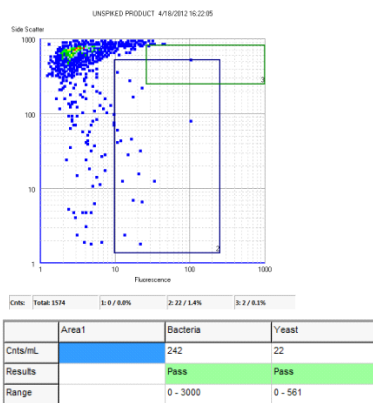
*C. albicans* (48 hours)



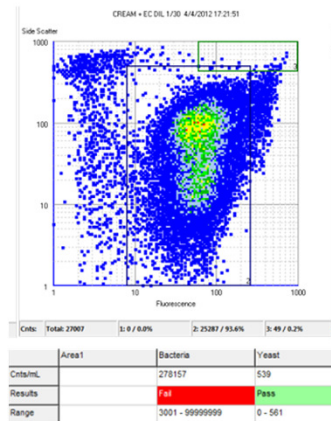
The growth of *E. coli* is clearly visible after 24hr of incubation.

*C. albicans* was visible after 48 hours.

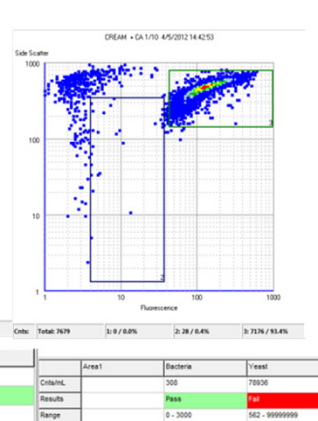
Facial cream 1/10 diluted



*E. coli*



*C. albicans* (48 hours)



# Conclusion

This feasibility study shows that BD FACS MicroCount™ Product Screening method **can be used** to detect yeast and bacteria in a variety of personal care and cosmetic products.

This broth shows to be an **acceptable** growth enhancement medium to be used. It was shown that we can meet the requirement of detect presence/ absence in 1 gram of product within 24-48 hours after growth enhancement in Eugon medium.

Early time to result ( $\leq 48$  hours) using the BD FACS MicroCount™ for microbiology samples translates directly to **savings** from reduced manufacturing cycle times and inventory levels, improved warehouse utilization and reduction in labor and waste costs. Additional water and environmental testing using the BD FACS MicroCount™ may prevent manufacturing at risk and exposing product to potential microbial contamination.





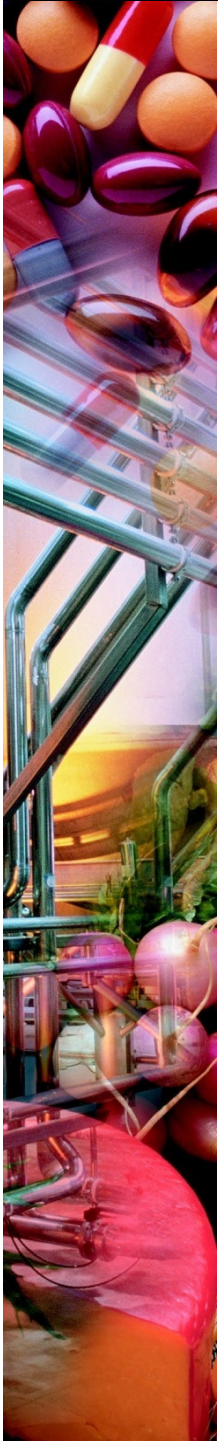
# Customer Cases

- **Direct Enumeration**
  - **Medimmune** → Egg-based vaccine production; Allantoic fluid.
    - In-process control to avoid loss of batches
  - **Bacardi** → Control of filtered water
    - Ongoing Control to determine the replacement time of filter cartridges
- **Product Screening**
  - **Baby Wipes** → Detection of bioburden in finished product
  - **Tablets & capsules** → Detection of bioburden in finished products
  - **BTG** → Detection of contamination in FSH and Hyaluronic Acid
  - **Cosmetics** → Product Screening



# BD FACSMicroCount™





**BD**

# **Nuevas soluciones para el análisis rápido y automatizado en microbiología industrial**

## **BD Diagnostics – Diagnostic Systems**

**X workshop sobre Métodos Rápidos y Automatización en Microbiología Alimentaria (MRAMA)**

# BD Diagnostics – Diagnostics Systems

## Líneas de producto en microbiología industrial

- Control de ambiente y pruebas de esterilidad.
- Control de calidad.

# Control de ambiente y pruebas de esterilidad

## Placas estériles

- Isolator pack – Isolator pack XT (SAL  $10^{-5}$ ).
  - **TSA, RODAC**
- Sterile pack (SAL  $10^{-5}$ ).
  - **TSA con lecitina y polisorbato 80**
- Irradiadas (SAL  $10^{-3}$ ).

## Botellas estériles

- Sterile pack.

## Torundas

- Sterile pack.

# Control de ambiente y pruebas de esterilidad

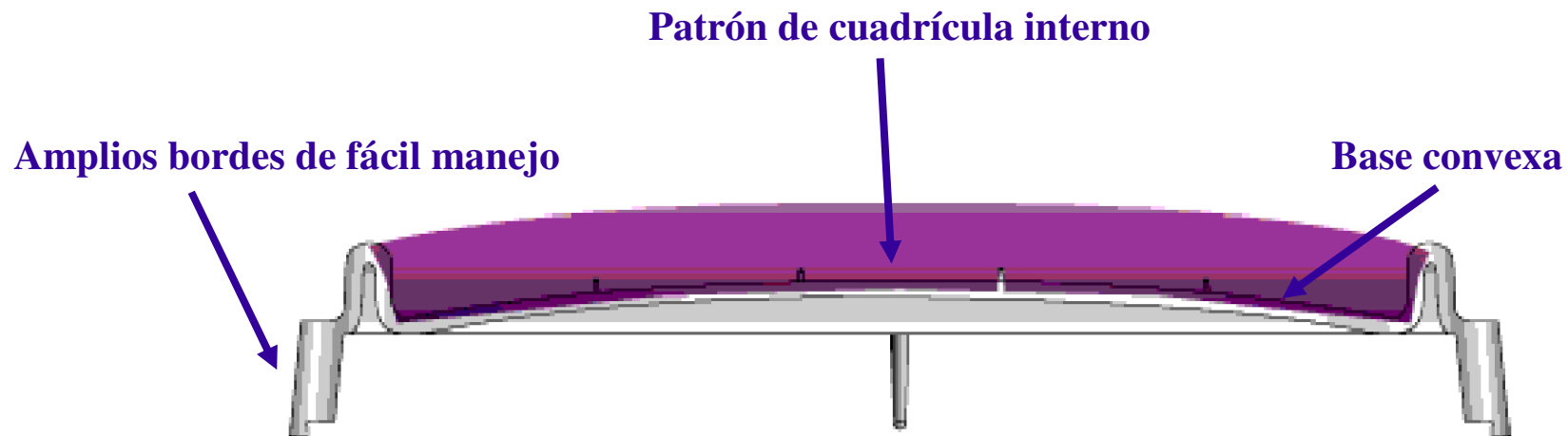
## Características BD BBL™ Isolator™ Pack XT

- Triple envoltorio impermeable, cierre hermético y transparente.
- Uso en salas limpias y aisladores.
- Protección frente a VHP.
- Temperatura de almacenaje 5-25 °C.
- Vida útil: 24 semanas.
- SAL  $10^{-5}$

# Control de ambiente y pruebas de esterilidad

## Placas de contacto BD RODAC™

- Base ancha fácil de agarrar y de aplicar a superficies.
- Patrón de cuadrícula interno que no interfiere con los marcadores
- La base convexa de la placa ofrece un mejor contacto entre el agar y la superficie a evaluar.

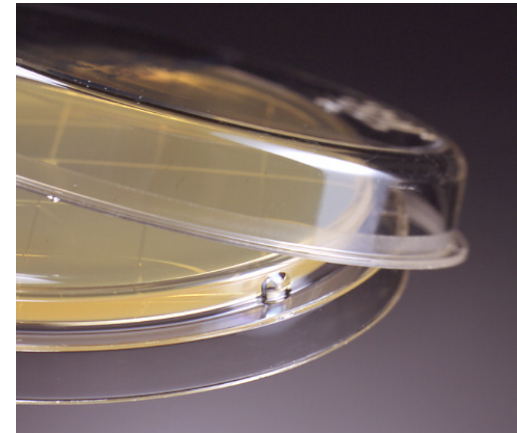




# Control de ambiente y pruebas de esterilidad

## BD RODAC™

- Proporciona un ajuste suelto entre tapa y base.
- Su diseño facilita la manipulación con una sola mano.
- Permite una toma rápida de muestras.



## BD RODAC™ SL™

- Proporciona una conexión fija entre la base y la tapa.
- Reduce la contaminación accidental.
- Mejora la seguridad de la muestra



# Control de calidad

Medios de cultivo generales, selectivos y diferenciales.

- Medios deshidratados.
- Medios preparados en botellas – placa – tubo

Medios específicos para cultivo e identificación:

- Medios cromogénicos: **BD BBL CHROMagar™**
- **BD HyCheck™**

Sistemas miniaturizados de identificación:

- **BD Enterotube™ II – BD Oxi/Ferm II**
- **BD BBL Crystal™**

Sistemas automáticos de identificación:

- **BD Phoenix™ 100**

# Control de calidad

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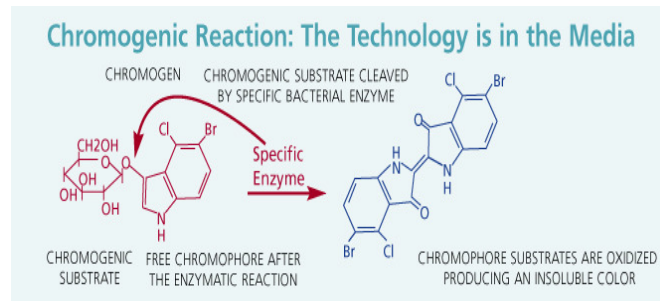
- **BD Phoenix™ 100**

# Control de calidad

## Medios específicos para cultivo e identificación

### BD BBL CHROMagar™

Medios preparados en placa que permiten un rápido aislamiento e identificación de diferentes grupos microbianos.

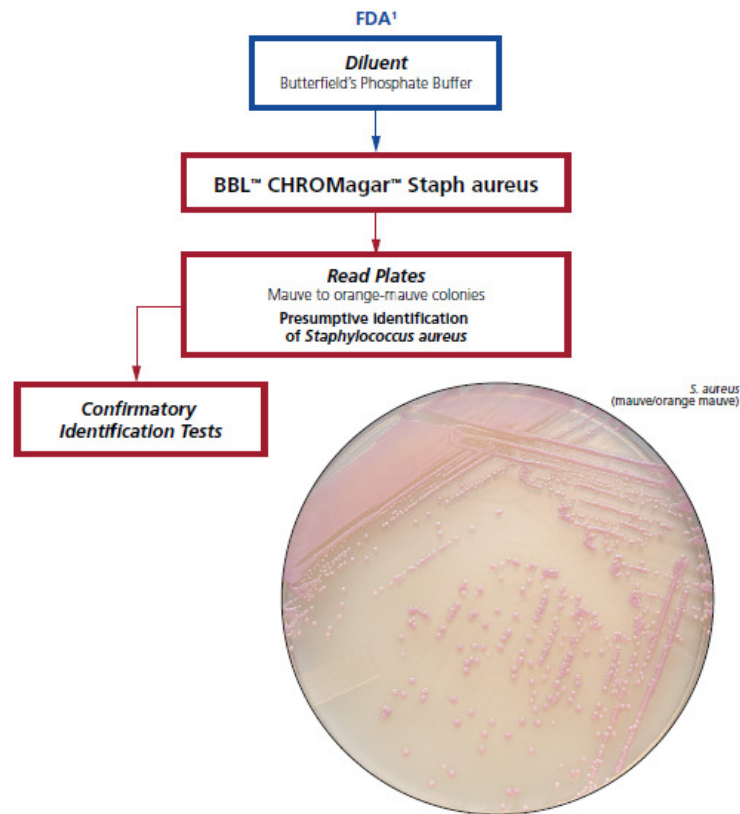


- BD BBL CHROMagar™ *Staphylococcus aureus*.
- BD BBL CHROMagar™ *Salmonella*.
- BD BBL CHROMagar™ O157.
- BD BBL CHROMagar™ *Listeria*.

# Control de calidad

## Medios específicos para cultivo e identificación

### BD BBL CHROMagar™ Staph aureus



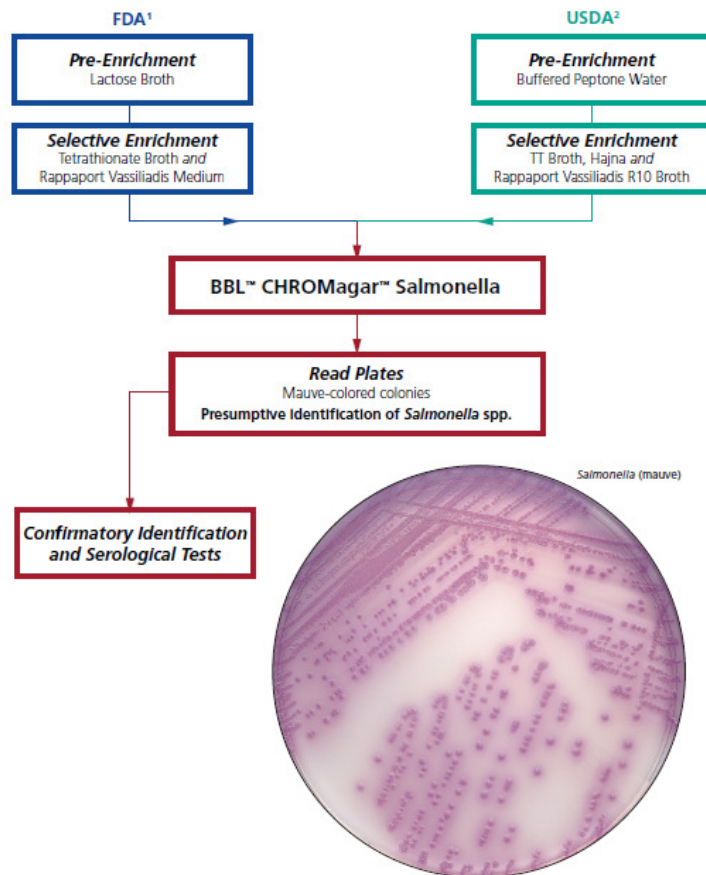
BBL CHROMagar Staph aureus (prepared plated medium) has been validated by the AOAC™ Research Institute under the Performance Tested Methods Program for the **analysis of shell eggs, smoked salmon and cooked roast beef when using AOAC and ISO methods.**

An advantage BBL CHROMagar Staph aureus has over some traditional media, such as Baird-Parker Agar, **is the ability to identify S. aureus in 24 h as opposed to 48 h.**

# Control de calidad

## Medios específicos para cultivo e identificación

### BD BBL CHROMagar™ Salmonella

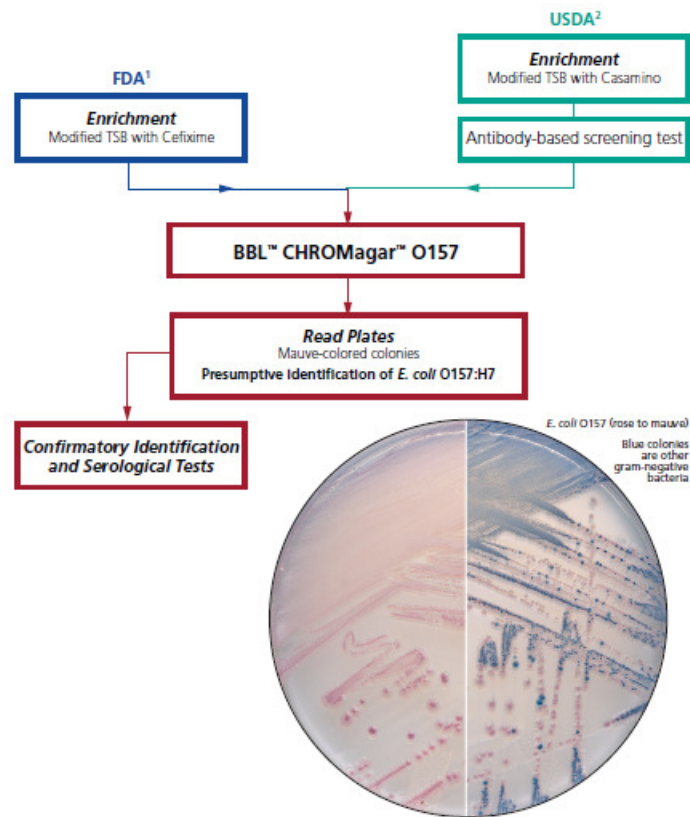


BBL CHROMagar Salmonella has been validated by the AOAC™ Research Institute under the Performance Tested Methods program only for the **analysis of raw ground beef, raw chicken, raw fish, lettuce and shell eggs**. ISO, USDA, FSIS, and FDA, BAM methods were used for method comparison testing. BBL CHROMagar Salmonella was found to be equivalent to the plated media recommended in the ISO, FDA and USDA methods.

# Control de calidad

## Medios específicos para cultivo e identificación

### BD BBL CHROMagar™ O157

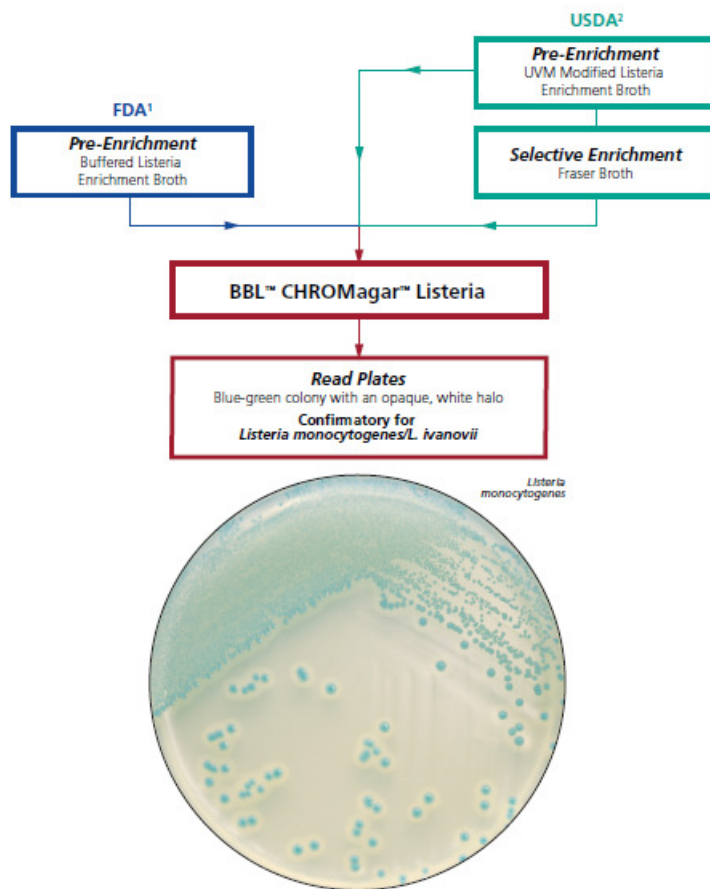


BBL CHROMagar O157 has been validated by the AOAC™-Research Institute under the Performance Tested Methods Program for the analysis of raw ground beef and unpasteurized apple cider

# Control de calidad

## Medios específicos para cultivo e identificación

### BD BBL CHROMagar™ Listeria



### Intended Use

BBL™ CHROMagar™ Listeria\* is a selective medium for the isolation, differentiation and identification of *Listeria monocytogenes* and *L. ivanovii* from food and environmental samples.

BBL CHROMagar Listeria has been validated by the AOAC™ Research Institute under the Performance Tested Methods™ Program for the analysis of raw ground beef, smoked salmon, lettuce and Brie cheese when using FDA/BAM, USDA/FSIS, AOAC and ISO methods<sup>1-4</sup> with no confirmatory biochemical tests required for the identification of *Listeria monocytogenes*/*L. ivanovii*.

Confirmatory testing of isolates from food matrices other than those that have been validated, and from environmental samples, is recommended.

\*U.S. Patent Pending



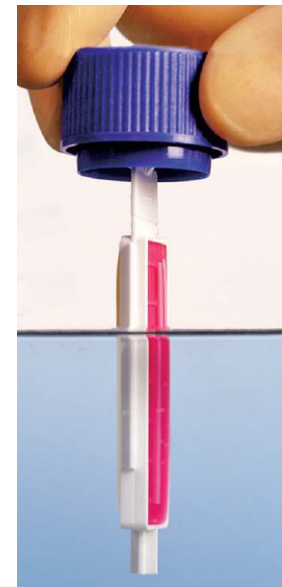
# Control de calidad

## Medios específicos para cultivo e identificación

### BD HyCheck™

**Tarjetas de contacto diseñadas para control de higiene ambiental de superficies y líquidos.**

- Las láminas están impregnadas por ambas caras con un medio de cultivo (idéntico o diferente) y ensambladas sobre un eje flexible, que facilita el muestreo.
- Dependiendo del tipo de medio, permiten la selección de un determinado grupo de microorganismos.
- Fácil de transportar en un tubo con cierre a rosca.

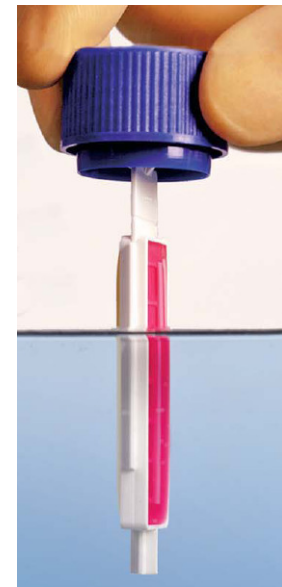


# Control de calidad

## Medios específicos para cultivo e identificación

### BD Hycheck™ - tipo de medios de cultivo

- BD Hycheck™ para la detección de **Enterobacteriaceae**, con agar peptona de soja y de caseína por una cara y agar glucosa-bilis-rojo neutro y cristal violeta.
- BD Hycheck™ para el control de desinfección,
  - Agar D/E Neutralizing en ambas caras
  - Agar D/E Neutralizing y agar peptona de soja y caseína
- BD Hycheck™ para **hongos y levaduras**, con TSA y rosa de bengala con cloranfenicol.
- BD Hycheck™ para **hongos y levaduras**, con TSA + 0,01 % TTC y agar rosa de bengala con cloranfenicol.
- BD Hycheck™ Plate Count Agar más TTC.
- BD Hycheck™ Total Count, con PCA y PCA + TTC.



# Control de calidad

Medios de cultivo generales, selectivos y diferenciales.

- Medios deshidratados.
- Medios preparados en botellas – placa – tubo

Medios específicos para cultivo e identificación:

- Medios cromogénicos: **BD BBL CHROMagar™**
- **BD HyCheck™**

Sistemas miniaturizados de identificación:

- **BD Enterotube™ II – BD Oxi/Ferm II**
- **BD BBL Crystal™**

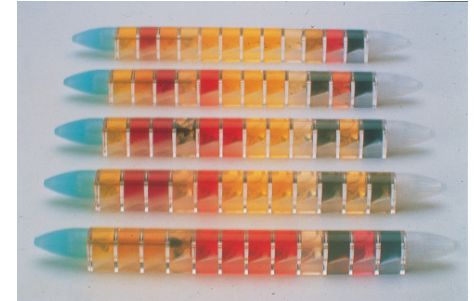
Sistemas automáticos de identificación:

- **BD Phoenix™ 100**

# Control de calidad

## Sistemas miniaturizados de identificación

- Sistemas **rápidos** (4-48 horas), **seguros** y con resultados **fiables**.
- Sistemas herméticos de **fácil manipulación**, **< 1 minuto por test**.
- Gran número de sustratos bioquímicos (15-30) para realizar una **identificación más precisa**.
- Pocas **pruebas previas** – **sin revelado de resultados**
- Gran **base de datos** de identificación de microorganismos, incluyendo gran cantidad de bacterias ambientales.
  - **Más de 80 especies con BD BBL Enterotube™ II – BD BBL Oxi/Ferm II.**
  - **370 especies con BD BBL Crystal™ (paneles para GP, EN/F, ANR y N/H).**

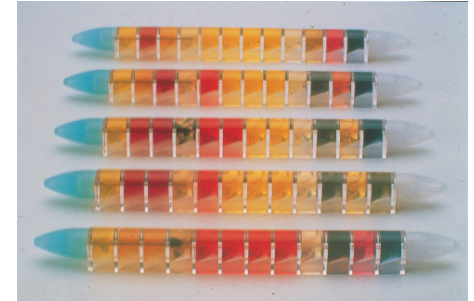


# Control de calidad

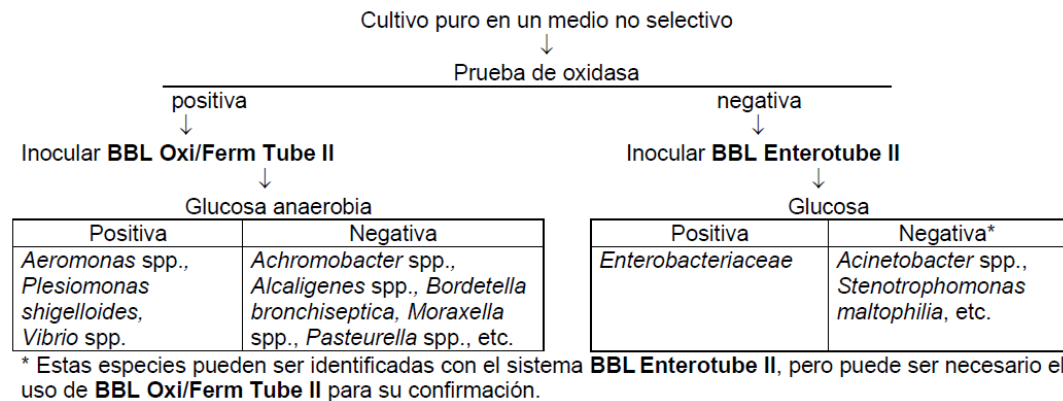
## Sistemas miniaturizados de identificación

### BD BBL Enterotube™ II – BD BBL Oxi/Ferm II

BBL Enterotube II es un sistema de identificación listo para usar que se emplea en la identificación de *Enterobacteriaceae* y otros bacilos gram negativos con resultado negativo a la oxidasa.



BBL Oxi/Ferm Tube II es un sistema de identificación listo para usar en bacterias gram negativas fermentadoras positivas a la oxidasa y no fermentadoras gram negativas, aisladas a partir de muestras clínicas.



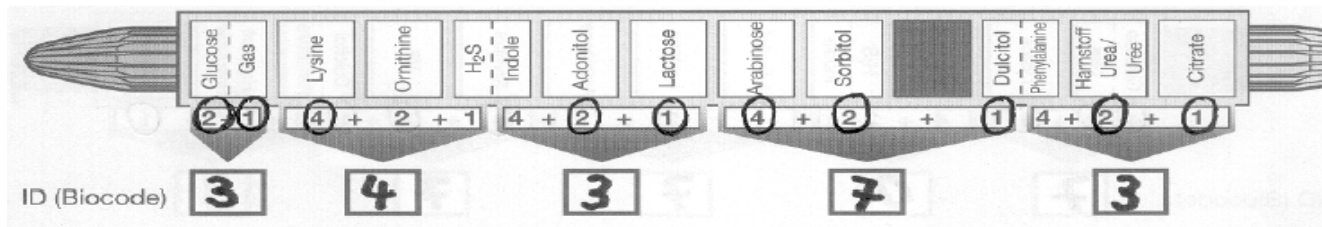
# Control de calidad

## Sistemas miniaturizados de identificación

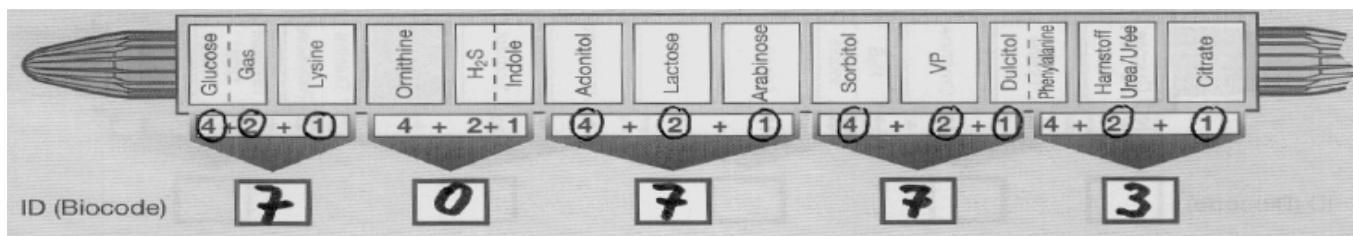
BD BBL Enterotube™ II

Lectura de la prueba

Sin Voges-Proskauer



Con Voges- Proskauer

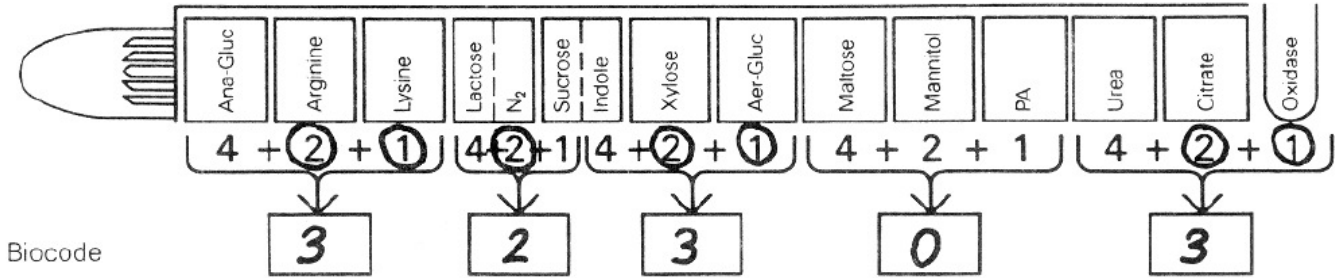


# Control de calidad

## Sistemas miniaturizados de identificación

BD BBL Oxi/Ferm II

Lectura de la prueba



Biocode

# Control de calidad

## Sistemas miniaturizados de identificación

### BD BBL Enterotube™ II – BD BBL Oxi/Ferm II

Bases de datos:

BD BBL Enterotube II *Biocode manual* (con o sin VP)

- Bacterias Gram negativas, oxidasa negativas y fermentadoras.
- Bacterias Gram negativas, oxidasa negativas y no fermentadoras: *Acinetobacter*, *Stenotrophomonas*, *Burkholderia*, ...

BD BBL Oxi/Ferm II *Biocode manual*

- Bacterias Gram negativas, oxidasa positivas



# Control de calidad

## Sistemas miniaturizados de identificación

### BD BBLCrystal™

- Sistema de identificación manual o semiautomático (BD BBL Crystal™ Autoreader).
- 29 ó 30 sustratos bioquímicos: fluorogénicos, cromogénicos y azúcares).
- Paneles específicos para determinados grupos de bacterias:
  - Entéricos/No Fermentadores (E/NF)
  - Gram Positivos (GP)
  - Microorganismos exigentes: *Neisseria/Haemophilus* (N/H)
  - Microorganismos anaerobios (ANR).
- Base de datos BD BBL Crystal™ MIND



# Control de calidad

## Sistemas miniaturizados de identificación

### BD BBLCrystal™

#### Calculo del perfil bioquímico

- Manual, utilizando **BD BBL Crystal™ Panel Viewer**



	A	B	C	D	E	F	G	H	I	J
4	ctrl	+	+	-	-	-	-	+	-	-
2	+	-	-	-	+	-	-	+	+	+
1	-	+	-	-	+	+	+	-	-	+
P	2	5	4	0	3	1	1	6	2	3

- Automático, utilizando **BD BBL Crystal™ Autoreader**.



# Control de calidad

## Sistemas miniaturizados de identificación

### BD BBLCrystal™

### Interpretación del perfil bioquímico

- BD BBL Crystal™ MIND



# Control de calidad

## Sistemas miniaturizados de identificación

### BD BBLCrystal™

#### Base de datos

- Gram positivos (165): *Micrococcus*, *Staphylococcus*, *Stomatococcus*, *Streptococcus* (*S. pneumoniae*, beta-hemolíticos, otros), *Alloiococcus*, *Lactococcus*, *Globicatella*, *Gemella*, *Helcococcus*, *Enterococcus*, *Pediococcus*, *Leuconostoc*, *Erysipelothrix*, *Listeria*, *Corynebacterium*, *Bacillus*, *Gardnerella*.
- Gram negativos (140): *Acinetobacter*, *Achromobacter*, *Actinobacillus*, *Aeromonas*, *Agrobacterium*, *Alcaligenes*, *Brevundimonas*, *Burkholderia*, *Cardiobacterium*, grupos CDC, *Edwardsiella*, *Eikenella*, *Enterobacter*, *Escherichia*, *Klebsiella*, *Moraxella*, *Pasteurella*, *Proteus*, *Providencia*, *Pseudomonas*, *Salmonella*, *Serratia*, *Shigella*, *Stenotrophomonas*, *Vibrio*, *Yersinia*.

# Control de calidad

Medios de cultivo generales, selectivos y diferenciales.

- Medios deshidratados.
- Medios preparados en botellas – placa – tubo

Medios específicos para cultivo e identificación:

- Medios cromogénicos: **BD BBL CHROMagar™**
- **BD HyCheck™**

Sistemas miniaturizados de identificación:

- **BD Enterotube™ II – BD Oxi/Ferm II**
- **BD BBL Crystal™**

Sistemas automáticos de identificación:

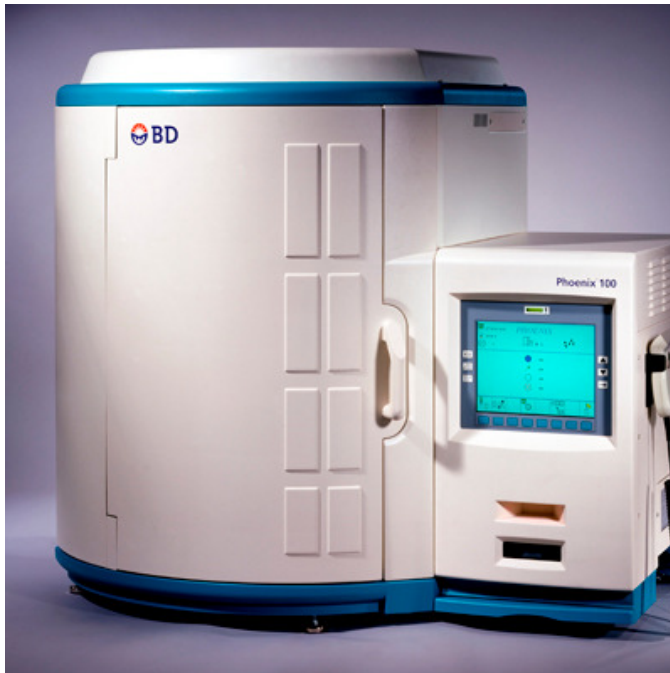
- **BD Phoenix™ 100**

# Control de calidad

## Sistemas automáticos de identificación

### BD Phoenix™ 100

Sistema automático para realizar pruebas de identificación de microorganismos (bacterias Gram positivas, Gram negativas y levaduras) y pruebas de sensibilidad a antimicrobianos (bacterias Gram positivas y Gram negativas)



### Gran capacidad

- 100 paneles – 200 pruebas

### Acceso aleatorio

- Ahorro de tiempo
- Flexibilidad

# Control de calidad

## Sistemas automáticos de identificación

### BD Phoenix™ 100

#### Consumibles

##### Diseño

- 51 pocillos de ID (45 substratos)
- 85 pocillos de AST ( CMI real)

##### Formato

- Solo Identificación – solo sensibilidad
- Combo: identificación y sensibilidad

##### Tipos

- Gram negativos (ID, AST, Combo)
- Gram positivos (ID, AST, Combo)
- Estreptococos (AST, Combo)
- Levaduras (ID)

##### Almacenamiento a temperatura ambiente



# Control de calidad

## Sistemas automáticos de identificación

### BD Phoenix™ 100

#### Características

##### Flexibilidad de inóculo:

- 0,5 McFarland o 0,25 McFarland

##### Doble tecnología de detección para una identificación más precisa

- 46 sustratos cromogénicos y fluorogénicos.

##### Identificación rápida:

Gram negativos

- Enterobacterias: 5,1 h
- No fermentadores: 6,0 h

Gram positivos

- Estreptococos: 5,8 h
- No estreptococos: 7,3 h

Levaduras: más del 80 % en menos de 8 h.

##### Base de datos con más de 300 microorganismos

- Gram negativos – 161
- Gram positivos – 145
- Estreptococos – 62
- Levaduras - 64



# BD Diagnostics – Diagnostics Systems

## Certificados y regulación

<http://www.bd.com/europe/regulatory/documents.asp>

The screenshot shows the BD website's 'Regulatory Documents' page for Europe. The page features a navigation menu on the left with options like 'About this site', 'Regulatory Documents', 'Contact Us', and 'Home'. A 'Did you know?' section provides information about the In Vitro Diagnostic Medical Devices Directive (IVD Directive). The main content area lists various regulatory documents, including ISO Certificates, MSDS, Instructions for Use, Certificates of Analysis, and Declarations of Conformity. Specific links are provided for ISO 13485 and ISO 9001 Certificates, with locations Heidelberg, Germany and Sparks, MD, USA mentioned.

**BD**

BD Worldwide | Privacy | Terms & Conditions

Search

Site Map | Advanced Search

Europe  
Select another location

**Diagnostic Systems - Regulatory**

- About this site
- Regulatory Documents**
- Contact Us
- Home

**Did you know?**  
The In Vitro Diagnostic Medical Devices Directive (IVD Directive), numbered 98/79/EC, was published in the Official Journal of the European Union on December 7, 1998.

**Regulatory Documents**

E-mail | Bookmark | Print

ISO Certificates | MSDS | Instructions for Use |  
Certificates of Analysis | Declarations of Conformity |  
Industry Specific

**ISO CERTIFICATES**

**Heidelberg, Germany**

- [ISO 13485 Certificate.](#)
- [ISO 9001 Certificate](#)

**Sparks, MD, USA**

# BD Diagnostics – Diagnostics Systems

## Página web Industria

<http://www.bd.com/es/ds/industry/>

The screenshot shows the BD Diagnostics website for the Industry section. At the top right, there are links for "BD Worldwide", "Privacidad", and "Términos y Condiciones". Below these is a search bar with a "Search" button and a "Búsqueda Avanzada" link. A navigation menu includes "Mapa del sitio" and "Búsqueda Avanzada". The main header features the BD logo and a navigation bar with categories: "Cáncer", "ID/AST", "HAI", "Sepsis", "ITS", "TB", and "Industria" (highlighted). A sidebar on the left lists "España" and "Diagnostic Systems" with sub-links: "Acerca de BD", "Productos", "Iniciativas Globales de BD", "Servicios", "Noticias y Eventos", "Contáctenos", and "Página de Inicio". The main content area has a banner image of a woman holding a child, with the text "Soluciones de diagnóstico para:". Below this is a section titled "Su socio global en la calidad industrial." with a globe image and text: "BD ofrece una amplia gama de soluciones microbiológicas para aplicaciones en la Industria. Desde control de calidad de las materias primas hasta el producto terminado, BD ha demostrado la capacidad de satisfacer sus necesidades de microbiología. Tendrá la garantía de un suministro continuo de un socio fiable y global." Below this is a section titled "Obtenga mas información sobre..." with a small image of a BD FACSMicroCount™ machine and text: "BD FACSMicroCount™, la mejor solución para el recuento rápido de microorganismos »". On the right, there is a section titled "Productos & Servicios" with a sub-link "1.1 - Aditivos y medios".