



BIOBALL[®] *B. CEPACIA*

QUALITY CONTROL FOR OBJECTIONABLE ORGANISMS

Starved* and Non-Starved Reference Material
Containing a Precise Number of *B. cepacia* Organisms
for Quantitative Microbiological Quality Control



PIONEERING DIAGNOSTICS



BIOBALL® *B. CEPACIA*

QUALITY CONTROL FOR OBJECTIONABLE ORGANISMS



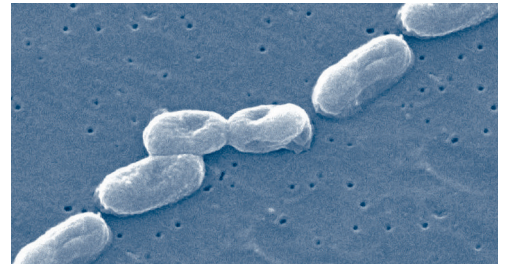
BIOBALL® *B. cepacia* starved* and non-starved are designed to manage the quality control of your *B. cepacia* Complex (BCC) microbial monitoring programs.

- Precise and Accurate CFU count
- Consistent number of CFU batch to batch
- Available in 3 different product formats Starved (Single Shot), Non-Starved (SingleShot & MultiShot)
- 1 year shelf life from date of manufacture stored between -18°C and -33°C

▶ Products Contaminated With *B. cepacia* Pose A Serious Threat To Susceptible Patients¹


Non-sterile finished drug products are expected to meet the requirements of 21 CFR 211.113(a) "Control of microbiological contamination".

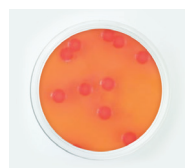
Appropriate written procedures, designed **to prevent objectionable microorganisms in drug products not required to be sterile**, shall be established and followed.²



▶ bioMérieux Solution For Total Aerobic Microbial Control

Enhance your TAMC quality control with CHROMID® *B. cepacia*.

| | | | |
|---|-----------------------------------|-------------------|-------------|
|  | BIOBALL <i>B. cepacia</i> | 10 tests per vial | Ref. 414301 |
| | BIOBALL starved <i>B. cepacia</i> | 10 tests per vial | Ref. 419829 |

| | | | |
|--|---------------------------|-------------|-------------|
|  | CHROMID <i>B. cepacia</i> | 2x10 plates | Ref. 413454 |
|--|---------------------------|-------------|-------------|

* Starvation is performed in sterile purified water at 22°C for 3 days following the Japanese Pharmacopoeia methodology (reference JP G8 Water 4.4.2 Media Growth Promotion Test).
 1. 2013 PDA Europe Conference on Pharmaceutical Microbiology, February 26-27, 2013, Berlin, Germany, Robert J. Mello, Ph.D.
 2. 21 CFR 211.113(a) "Control of microbiological contamination".