BIOBALL™

...Delivering Confidence in Quantitative Microbiology

BIOMÉRIEUX

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BIOBALL™

What is BioBall

BioBall® is a small water soluble ball containing a precise number of micro-organisms delivering unprecedented accuracy for Quantitative Microbiological Quality Control.

Over 25 individual strains are available in BioBall with application in the pharmaceutical, food and water testing industries.

Pharmaceutical Applications

The pharmaceutical industry must follow a range of compendial methods to satisfy regulators and assure product quality and safety. Some methods demand inocula with less than 100 cfu. BioBall SingleShot and BioBall MultiShot 550 are ideal for these applications.

Pharmaceutical and cosmetic preparations often require antimicrobial or preservative efficacy testing, where pharmacopoieal methods seek to demonstrate microbial stasis or reduction. BioBall MultiShot 10E8 is ideal for this application.

Below is a table identifying industry methods and pharmacopeial chapters where BioBall could be used as a quantitative reference standard.

	USP	EP	JP15
Sterility Tests	71	2.6.1	4.06
Validation of Microbial Recovery	1227	5.1.6	Gen Info 30
Microbial Enumeration Tests	61	2.6.12	4.05.1
Tests for Specified Organisms	62	2.6.13	4.05.2
Antimicrobial Effectiveness Testing	51	5.1.3	Gen Info 19

BioBall Technology

BTF uses patented technology and proprietary techniques to manufacture BioBall products for unprecedented precision and maximum viability.

A flow cytometer is used to select and dispense individual cells within a culture and count them into a single droplet. Each droplet therefore contains a precise number of viable cells that have been individually selected for maximum recovery rate on non-selective media.

This technology is capable of distinguishing between single cells and cell clusters in cultures such as *Staphylococcus aureus.* Droplets are frozen in liquid nitrogen, dispensed in vials, freeze-dried and sealed under vacuum for maximum shelf-life and recovery.

BioBall Quality

BioBall is produced to the world's highest quality standards, achieving ISO Guide 34 accreditation. ISO Guide 34 is a standard for reference material producers.

BTF as a Reference Materials producer is the first company worldwide accredited for quantitative microbiological reference standards, including BioBall.

ISO Guide 34 accreditation means that BioBall customers can have total confidence in the Certificates of Analysis and in the traceability of the strains used in BioBall.

ISO Guide 34 accreditation is issued by NATA, Australia's government endorsed provider of accreditation for laboratories and similar testing facilities.

NATA
ACCREDITED FOR TECHNICAL COMPETENCE

Growth Promotion Testing and Validation

BIOBALL™
MultiShot - 550

BioBall MultiShot 550 used with BioBall Re-Hydration Fluid

Designed to provide 10 precise inoculations

- Each BioBall® has a batch mean between 500 and 600 cfu
- Standard Deviation is less than or equal to 10% of the batch mean
- When rehydrated into 1.1 mL of rehydration fluid, one BioBall provides 10 x 100 µL doses, each containing 50 cfu
- 8 hour stability when rehydrated with BioBall Re-Hydration Fluid and stored at 2 to 8°C
- Ideal when several controls are needed at the same time or within the same day

Growth Promotion Test using BioBall MultiShot 550 and BioBall Re-Hydration Fluid

1. Tip the BioBall into BioBall Re-Hydration Fluid, replace the cap, wait 30 seconds

2. Vortex 5 seconds

3. Draw 100 µL aliquot

4. Pipette 100 µL onto plate

5. Spread, dry and incubate

6. Plate with 50 colonies

BioBall Advantages over other multi dose products

- Far less preparation time and fewer steps
- Excellent recovery rates even with difficult micro-organisms such as *Pseudomonas aeruginosa*
- Long shelf life after rehydration – 8 hours
- Greater precision with a known number of cfu
- Consistent number of cfu batch to batch
- Reduces risk of "failed QC" due to variability of the inoculum

BIOBALL™ MultiShot - 550

BioBall MultiShot 550 used with BioBall 14 Day Re-Hydration Fluid

Designed for convenience and greater efficiency where lower numbers of quantitative tests are performed daily.

- Each BioBall® has a batch mean between 500 and 600 cfu
- Standard Deviation is less than or equal to 10% of the batch mean
- When rehydrated into 1.1 mL of rehydration fluid, one BioBall provides 10 x 100 µL doses, each containing 50 cfu
- 14 day stability when rehydrated with BioBall 14 Day Re-Hydration Fluid and stored at -18°C to -33°C
- Ideal when several controls are needed at the same time or over a two week period

Growth Promotion Test using BioBall MultiShot 550 and BioBall 14 Day Re-Hydration Fluid

1. Tip the BioBall into BioBall 14 Day Re-Hydration Fluid, replace the cap, wait 3 minutes

2. Vortex 5 seconds

3. Draw 100 µL aliquot

4. Pipette 100 µL onto plate

5. Spread, dry and incubate

6. Determine how many aliquots to be frozen

7. If aliquots are to be used over separate days use a separate microcentrifuge tube for each aliquot. Label the microcentrifuge tubes, mark the date of rehydration and an expiry date

8. Pipette 110 µL of the remaining BioBall 14 Day Re-Hydration Fluid into each tube

9. Store the microcentrifuge tubes upright within 2 hours of rehydration in a freezer at -18°C to -33°C, this will provide a 14 day shelf life

BioBall Advantages over other multi dose products

- Longer shelf life after rehydration – 14 days
- Far less preparation time and fewer steps
- Excellent recovery rates even with difficult micro-organisms such as *Pseudomonas aeruginosa*
- Greater precision with a known number of cfu
- Consistent number of cfu batch to batch
- Reduces risk of "failed QC" due to variability of the inoculum

BIOBALL™
SingleShot

Designed for a single precise inoculation

- Each BioBall® has a batch mean between 28 and 33 cfu
- Standard Deviation of 3 cfu or less (unless otherwise stated)
- BioBall SingleShot is ideal when only one or a few inoculations are used within the day, or the highest level of precision is required

Growth Promotion Test using BioBall SingleShot

1. Tip BioBall on the plate centre

2. Re-hydrate the BioBall

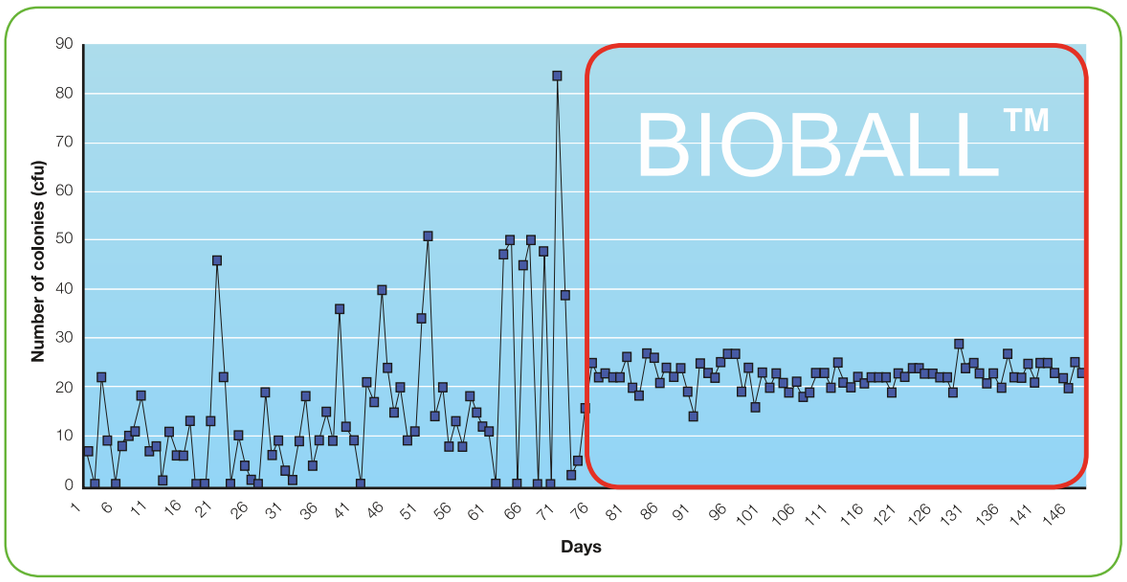
3. Spread, dry and incubate

4. Plate with 30 colonies

BioBall Advantages over serial dilution

- Little or no preparation time
- Easy to use
- Precise known number of cfu
- Consistent number of cfu batch to batch
- Reduces risk of "failed QC" due to variability of the inoculum

Serial dilution compared to BioBall



From an Australian official body involved in water testing:

Routine QC data of *E. coli* using the IDEXX Colilert® / Quantitray® test (January 05 to October 05).

Initially this laboratory was spiking 100 mL water samples with a spike dose prepared in their laboratory by serially diluting a culture. They then switched to BioBall SingleShot.

Sterility Assurance Testing

Sterility testing is a critical requirement in the manufacture of sterile pharmaceuticals and medical devices. Sterility testing media must undergo growth promotion testing using prescribed microbial strains (USP <71>, EP 2.6.1, JPXV 4.06), and sterility testing methods must be validated (i.e. method suitability test) to assure their capacity to recover compendial strains when present in very low numbers (USP <1227>, EP 2.6.1, JPXV General Information section 30). Alternative or rapid microbiological methods (RMMs) also require validation to verify equivalency with traditional sterility testing methods (USP <1223>, EP 5.1.6). For these purposes, use of very reliable and consistent inocula is essential to eliminate variation attributable to factors other than the performance of the media, processes or systems being tested. BioBall® SingleShot and BioBall MulitShot 550 strains are certified reference materials with ISO Guide 34 certification, delivering the exceptional accuracy and precision required for growth promotion testing and validation studies.

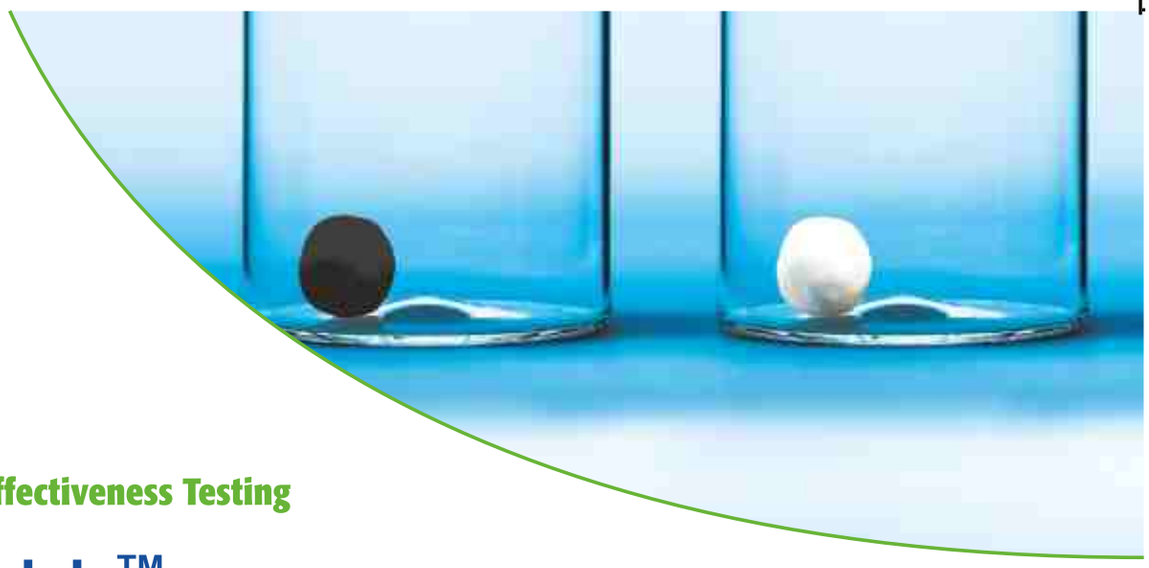
Increasingly, sterility testing is applicable to cells and tissues, including cell and tissue therapies, blood products, and other biopharmaceuticals (EP 2.6.27). These advanced therapeutics sometimes have the potential to be contaminated with more diverse micro-organisms because of their origin or handling, and are often tested by alternative or rapid methods due to their instability or a requirement for their immediate use. Nevertheless, alternative and rapid sterility test methods must be validated against traditional sterility tests. A wider array of strains might be appropriate for growth promotion testing and validation in these circumstances, but the need for exceptional accuracy and precision of the inocula remains. The range of BioBall strains with potential application in sterility testing of cell and tissue therapeutics is growing.

Storage

BioBall needs to be stored frozen between -18^{o}C to -33^{o}C.
BioBall Re-Hydration Fluid needs to be stored between 18 to 25^{o}C.
BioBall 14 Day Re-Hydration Fluid needs to be stored between 2 to 8^{o}C

Shipping

BioBall is shipped in polystyrene boxes with freezer bricks. During long shipments BioBall may reach temperatures above freezing. However, BioBall can be kept at 22^{o}C for up to 7 days without any impact on product performance. Shipping trials have been undertaken to validate that BioBall will not exceed 22^{o}C during shipment.



Antimicrobial Effectiveness Testing

BIOBALL™

MultiShot-10E8

Pharmaceutical & Cosmetic applications

Pharmaceutical and cosmetic preparations often require antimicrobial activity to prevent microbial proliferation or to limit the effects of contamination. The Pharmacopoeias require testing of these products for the efficacy of antimicrobial preservation (e.g. USP 51, EP 5.1.3, JP19). Preparing consistent inocula for these tests can be laborious and is often unreliable, necessitating time consuming repeat assays.

BioBall® MultiShot 10E8 is ideal for this application and simplifies preparation and provides a precise inoculum.

Designed to provide 10 precise inoculations

- Each BioBall MultiShot 10E8 has a batch mean between 0.7 and 1.5 x 10^8 cfu
- Standard deviation is less than or equal to 20% of the batch mean
- When rehydrated with 1.1 mL of rehydration fluid it provides 10 x 100µL doses of 10^7 cfu
- 2 hour stability when rehydrated with BioBall Re-Hydration Fluid and stored at 2 to 8°C
- Each 100 µL aliquot can be used to inoculate "for example" 20 mL of product, resulting in the required final concentration of 10^5 – 10^6 cfu/mL product

Antimicrobial Effectiveness Test using BioBall MultiShot 10E8 and BioBall Re-Hydration Fluid

1. Tip the BioBall into BioBall Re-Hydration Fluid, replace the cap, wait 30 seconds

2. Vortex 5 seconds

3. Draw 100 µL aliquot

4. A 100 µL aliquot provides a target concentration of 500,000 cfu per mL when inoculated into 20 mL of sample product

BioBall MultiShot 10E8 advantages over serial dilution

- Far less preparation time and fewer steps
- Excellent recovery rates even with difficult micro-organisms such as *Pseudomonas aeruginosa*
- Greater precision and reliability with a known number of cfu
- Excellent stability after rehydration – 2 hours
- Consistent number of cfu batch to batch
- Reduces risk of "failed QC" due to variability of the inoculum

BIOBALL™ Available Strains

BIOMÉRIEUX

BIOBALL contains a precise number of microorganisms in a water soluble ball delivering unprecedented accuracy for Quantitative Microbiological Quality Control.

SingleShot - mean of between 28 and 33 cfu with a standard deviation of 3 cfu or less (unless otherwise stated).

MultiShot 550 - mean of between 500 and 600 cfu with a standard deviation ≤ 10% of the mean (unless otherwise stated).

HighDose 10K - mean of between 8,000 and 12,000 cfu with a standard deviation of ≤ 15% of the mean.

MultiShot 10E8 - mean of between 0.7 and 1.5 x 10^8 with a standard deviation of ≤ 20% of the mean.

BIOBALL is a Reference Material manufactured under accreditation to ISO Guide 34.

BIOBALL™ SingleShot

Reference 20 vials/ 20 tests	Reference 10 vials/ 10 tests	Organism	BIOBALL Strain	Corresponding Strains	Cell Type	Shelf life from date of manufacture^
56022	N/A	*Aspergillus brasiliensis***	NCPF 2275	CIP1491.83, IMI149007, NBRC9455, WDCM00054	Spore	2 Years
56023	N/A	*Bacillus cereus*	NCTC 7464	NCIMB8078, NRRL-B68	Spore	2 Years
56024	N/A	*Bacillus subtilis subsp. spizizenii*	NCTC 10400	CIP60.43, NCIMB8054, NBRC3134	Spore	2 Years
56068	N/A	Blank BIOBALL *(containing no microorganisms)*	N/A		N/A	3 Years
N/A	414301	*Burkholderia cepacia**	NCTC 10743	DSM7288	Cell	1 Year
423232	419829^^^	*Burkholderia cepacia****	NCTC 10743	DSM7288	Starved Cell^^	2 Years
56026	N/A	*Candida albicans**	NCPF 3179	CIP48.72, NBRC1594, WDCM00054	Cell	2 Years
56027	N/A	*Citrobacter freundii***	NCTC 9750	DSM30039, NBRC12681, CIP57.32	Cell	1 Year
56028	N/A	*Clostridium perfringens**	NCTC 8798		Spore	2 Years
56029	N/A	*Clostridium sporogenes*	NCTC 12935	NBRC14290, NCIMB12343, CIP100651, DSM1448	Spore	2 Years
56030	N/A	*Enterobacter aerogenes*	NCTC 10006	DSM30053, CDC619-56	Cell	2 Years
56031	N/A	*Enterococcus faecalis*	NCTC 12697	WDCM00087	Cell	2 Years
56032	N/A	*Enterococcus faecalis*	NCTC 775	DSM2478, WDCM00009	Cell	2 Years
56035	N/A	*Escherichia coli**	NCTC 12241	DSM1103, NCIMB12210, WDCM00013	Cell	2 Years
56034	N/A	*Escherichia coli*	NCTC 12923	NCIMB8545, CIP53.126, NBRC3972, WDCM00012	Cell	2 Years
56033	N/A	*Escherichia coli*	NCTC 9001	DSM30083, CIP54.8, WDCM00090	Cell	2 Years
412690	N/A	*Kocuria rhizophila****	NCTC 8340		Cell	2 Years
56038	N/A	*Listeria innocua*	NCTC 11288	DSM20649, WDCM00017	Cell	2 Years
56039	N/A	*Listeria monocytogenes*	NCTC 11994	WDCM00019	Cell	2 Years
423233	418118^^^	*Methylobacterium extorquens *****	NBRC 15911		Starved Cell^^	2 Years
421876	N/A	*Propionibacterium acnes****	DSM 1897	CIP 53.117, DSM 1897, JCM 6425, NCTC 8314, NCTC 737	Cell	2 Years
56040	N/A	*Pseudomonas aeruginosa**	NCTC 12924	NCIMB8626, CIP82.118, NBRC13275, WDCM00026	Cell	2 Years
56041	N/A	*Salmonella abaetetuba*	NCTC 8244	CDC4936-81	Cell	2 Years
56042	N/A	*Salmonella enterica, subsp. enterica, serotype abony*	ACM 5080	NCTC 6017, NBRC100797, CIP80.39, DSM4224, WDCM00029	Cell	2 Years
56043	N/A	*Salmonella salford****	IMVS 1710		Cell	2 Years
56044	N/A	*Salmonella enterica subsp. enterica, serovtype typhimurium*	NCTC 12023	DSM18587, NCIMB13284, WDCM00031	Cell	2 Years
56045	N/A	*Staphylococcus aureus****	NCTC 10788	CIP4.83, NCIMB9518, NBRC13276, FDA209, WDCM00032	Cell	2 Years
56092	N/A	*Staphylococcus epidermidis***	NCTC 6513		Cell	2 Years
56046	N/A	*Streptococcus pyogenes*	NCTC 12696	CIP104226	Cell	2 Years

^All BIOBALL strains and Re-Hydration Fluid products are shipped with a minimum of 6 months shelf life remaining.
^^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).
^^^ 10 Pack to be discontinued during 2018
*Standard deviation <3.5, ** Standard deviation < 4, *** Standard deviation <4.5, ****Mean of between 40 and 60 cfu with a standard deviation of 7 cfu or less, ***** Mean of between 67 and 83 cfu with a standard deviation of ≤ 15%.

NCTC National Collection of Type Cultures
Operated by Public Health England

BIOBALL™ Available Strains

BIOMÉRIEUX

BIOBALL™ MultiShot—550

Reference 20 vials / 200 tests	Reference 10 vials / 100 tests	Organism	BIOBALL Strain	Corresponding Strains	Cell Type	Shelf life from date of manufacture^
56011	56001	*Aspergillus brasiliensis*	NCPF 2275	CIP1431.83, IMI149007, NBRC9455, WDCM00053	Spore	2 Years
56012	56002	*Bacillus subtilis subsp. spizizenii*	NCTC 10400	CIP52.62, NCIMB8054, NBRC3134	Spore	2 Years
N/A	416589	*Burkholderia cepacia* #	NCTC 10743	DSM7288	Cell	1 Year
56013	56003	*Candida albicans*	NCPF 3179	CIP48.72, NBRC1594, WDCM00054	Cell	2 Years
56014	56004	*Clostridium sporogenes*	NCTC 12935	NBRC14295, NCIMB12343, CIP100651, DSM1448	Spore	2 Years
56015	56005	*Enterococcus faecalis*	NCTC 12697	WDCM00087	Cell	2 Years
56016	56006	*Escherichia coli*	NCTC 12923	NCIMB8545, CIP53.126, NBRC3972, WDCM00012	Cell	2 Years
N/A	416600	*Propionibacterium acnes*	DSM 1897	CIP 53.117; DSM 1897; JCM 6425; NCTC 3914; NCTC 737	Cell	2 Years
56017	56007	*Pseudomonas aeruginosa*	NCTC 12924	NCIMB8626, CIP82.118, NBRC13275, WDCM00026	Cell	2 Years
56018	56008	*Salmonella enterica, subsp. enterica, serotype abony*	ACM 5080	NCTC 6017, NBRC100797, CIP80.39, DSM4224, WDCM00029	Cell	2 Years
56019	56009	*Staphylococcus aureus*	NCTC 10788	CIP4.83, NCIMB9518, NBRC13276, FDA209, WDCM00032	Cell	2 Years
56021	N/A	Re-Hydration Fluid				5 Years
410386	N/A	14 Day Re-Hydration Fluid				2 Years

BIOBALL™ HighDose—10K

Reference 20 vials	Reference 10 vials	Organism	BIOBALL Strain	Corresponding Strains	Cell Type	Shelf life from date of manufacture^
56049	413776	*Aspergillus brasiliensis*	NCPF 2275	CIP1431.83, IMI149007, NBRC9455, WDCM00053	Spore	2 Years
56143	413777	*Bacillus subtilis subsp. spizizenii*	NCTC 10400	CIP52.62, NCIMB8054, NBRC3134	Spore	2 Years
56050	413778	*Candida albicans*	NCPF 3179	CIP48.72, NBRC1594, WDCM00054	Cell	2 Years
56051	413779	*Clostridium perfringens*	NCTC 8798		Spore	2 Years
56052	56158	*Enterobacter aerogenes*	NCTC 10006	DSM30053, CDC619-56	Cell	2 Years
56053	56160	*Escherichia coli*	NCTC 9001	DSM30083, CIP54.8, WDCM00052	Cell	2 Years
56054	N/A	*Lactobacillus fermentum*****	NCIMB 6991		Cell	2 Years
56144	413831	*Pseudomonas aeruginosa*	NCTC 12924	NCIMB8626, CIP82.118, NBRC13275, WDCM00026	Cell	2 Years
56055	56159	*Staphylococcus aureus*	NCTC 10788	CIP4.83, NCIMB9518, NBRC13276, FDA209, WDCM00032	Cell	2 Years

BIOBALL™ MultiShot—10E8

Reference 10 vials / 100 tests	Organism	BIOBALL Strain	Corresponding Strains	Cell Type	Shelf life from date of
410106	*Aspergillus brasiliensis*	NCPF 2275	CIP1431.83, IMI149007, NBRC9455, WDCM00053	Spore	2 Years
56145	*Candida albicans*	NCPF 3179	CIP48.72, NBRC1594, WDCM00054	Cell	2 Years
56146	*Escherichia coli*	NCTC 12923	NCIMB8545, CIP53.126, NBRC3972, WDCM00012	Cell	2 Years
56147	*Pseudomonas aeruginosa*	NCTC 12924	NCIMB8626, CIP82.118, NBRC13275, WDCM00026	Cell	2 Years
56148	*Staphylococcus aureus*	NCTC 10788	CIP4.83, NCIMB9518, NBRC13276, FDA209, WDCM00032	Cell	2 Years
416228	*Burkholderia cepacia*	NCTC 10743	DSM7288	Cell	1 Year
56021	Re-Hydration Fluid				5 Years
416721	*Bacillus subtilis* ##	ATCC® 19659™		Spore	2 years

^All BIOBALL strains and Re-Hydration Fluid products are shipped with a minimum of 6 months shelf life remaining.
Mean of between 500 and 600 cfu with a standard deviation ≤ 15% of the mean
ATCC Licensed Derivative Emblem for products derived from ATCC® cultures.*
****Mean of between 7,000 and 13,000 with a standard deviation of ≤ 20% of the mean

NCTC National Collection of Type Cultures
Operated by Public Health England

BIOBALL™ Available Strains

BIOMÉRIEUX

BIOBALL™ Luminate

Reference 20 vials	Organism	Colony Forming Units (CFU)	Cell Type	Shelf life from date of manufacture^
422190	*Salmonella typhimurium*	30	Cell	2 Years
56057	*Listeria monocytogenes 4b*	30	Cell	1 Year

*BIOBALL Luminate is a Genetically Modified Organism (GMO) and may need special regulatory requirements for use in your region Please check with your local bioMerieux representative if this product is available in your region.

BIOBALL Mixed Kit Configurations
BIOBALL SingleShot and BIOBALL MultiShot 550 mixed kit for Growth Promotion Testing
SingleShot mixed kit - Reference: 412541
MultiShot 550 mixed kit - Reference: 412540

Quantity of vials	Organism	BIOBALL strain	Corresponding Strains
2	*Aspergillus brasiliensis*	NCPF 2275	CIP1431.83, IMI149007, NBRC9455, WDCM00053
2	*Bacillus subtilis*	NCTC 10400	CIP52.62, NCIMB8054, NBRC3134
2	*Candida albicans*	NCPF 3179	CIP48.72, NBRC1594, WDCM00054
2	*Escherichia coli*	NCTC 12923	NCIMB8545, CIP53.126, NBRC3972, WDCM00012
2	*Pseudomonas aeruginosa*	NCTC 12924	NCIMB8626, CIP82.118, NBRC13275, WDCM00026
2	*Staphylococcus aureus*	NCTC 10788	CIP4.83, NCIMB9518, NBRC13276, FDA209, WDCM00032

BIOBALL SingleShot and BIOBALL MultiShot 550 mixed kit for Sterility Assurance Testing
SingleShot mixed kit - Reference: 412646
MultiShot 550 mixed kit - Reference: 412647

Quantity of vials	Organism	BIOBALL strain	Corresponding Strains
2	*Aspergillus brasiliensis*	NCPF 2275	CIP1431.83, IMI149007, NBRC9455, WDCM00053
2	*Bacillus subtilis*	NCTC 10400	CIP52.62, NCIMB8054, NBRC3134
2	*Candida albicans*	NCPF 3179	CIP48.72, NBRC1594, WDCM00054
2	*Clostridium sporogenes*	NCTC 12935	NBRC14293, NCIMB12343, CIP100651, DSM1446
2	*Pseudomonas aeruginosa*	NCTC 12924	NCIMB8626, CIP82.118, NBRC13275, WDCM00026
2	*Staphylococcus aureus*	NCTC 10788	CIP4.83, NCIMB9518, NBRC13276, FDA209, WDCM00032

BIOBALL MultiShot 10E8 mixed kit for Antimicrobial Effectiveness Testing

Quantity of vials	Organism	BIOBALL strain	Corresponding Strains
2	*Aspergillus brasiliensis*	NCPF 2275	CIP1431.83, IMI149007, NBRC9455, WDCM00053
2	*Candida albicans*	NCPF 3179	CIP48.72, NBRC1594, WDCM00054
2	*Escherichia coli*	NCTC 12923	NCIMB8545, CIP53.126, NBRC3972, WDCM00012
2	*Pseudomonas aeruginosa*	NCTC 12924	NCIMB8626, CIP82.118, NBRC13275, WDCM00026
2	*Staphylococcus aureus*	NCTC 10788	CIP4.83, NCIMB9518, NBRC13276, FDA209, WDCM00032

Strains sourced from NCTC, NCPF, IMVS, ACM, ATCC and DSMZ. ATCC is a trademark belonging to the American Type Culture Collection. NCTC is a trademark of the Public Health England

NCTC National Collection of Type Cultures Operated by Public Health England

DELIVERING CONFIDENCE
IN QUANTITATIVE MICROBIOLOGY

BIOBALL™

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

BIOMÉRIEUX

BioBall® *B. cepacia*

QUALITY CONTROL FOR OBJECTIONABLE ORGANISMS

BIOBALL™

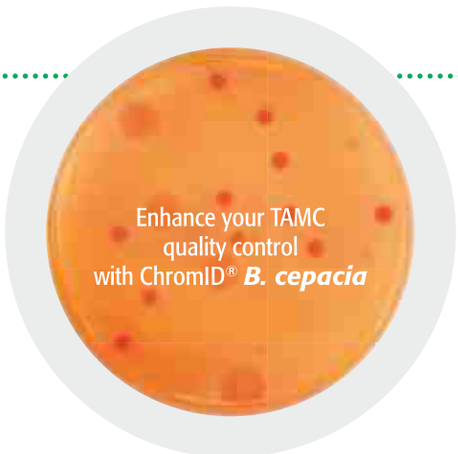
BioBall® *B. cepacia* starved* and non-starved are designed to manage the quality control of your *B. cepacia* Complex (BCC) microbial monitoring programs.

Products contaminated with *B. cepacia* pose a serious threat to susceptible patients[1]

- 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

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 Microbical Control

BioBall® *B. cepacia* : 10 tests / vial ..... Ref. 414301

BioBall® starved *B. cepacia* : 10 tests / vial ..... Ref. 419829

ChromID® *B. cepacia* : 2 x 10 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".

BIOBALL™
Custom Services

BioBall® Custom Services provides a new level of capability for quantitative microbiology in pharma, food and other Industry Microbiology application areas. Such applications might include product-specific verification and validation studies, process control, diagnostic product QC, and a range of other testing that demands very consistent, precisely quantified, viable microorganisms on a project or routine basis.

We can now manufacture BioBall using your wild-type strains through the BioBall Plant Isolate service, or strains from a nominated culture collection (or proprietary strains) can be manufactured to your specification through the BioBall Select service. Not only can this save your laboratory time and resources, it meets your needs by providing a quantitative, precise, easy to use microbiological reference material in the innovative BioBall format.

BIOBALL™
Plant Isolate

BioBall Plant Isolate is a service offering, allowing you to order BioBall® with the wild-type strain(s) that you require. BioBall Plant Isolate is manufactured in Sydney Australia and maintains the high level of quality you are accustomed to with standard BioBall® products..

What strains can be used?

Any strains from your in-house collection can be used to manufacture a BioBall Plant Isolate, whether they are environmental monitoring isolates or contaminants of products or raw materials. The BioBall® process will add two passages to your strain, i.e. a strain sent in the second passage will result in a BioBall Plant Isolate at passage four.

Available in these formats:

	AVAILABLE STANDARD FORMATS		
	Single Dose (60)	**Multi Dose (550)**	**Multi Dose (10E8)**
Mean cfu	60 ± 20%	450 - 650	5 x 10^7 to 1.4 x 10^8
Coefficient of variation (CV)	≤ 20%	≤ 20%	≤ 20%
Minimum number of vials per strain	100 Vials (100 tests)	100 Vials (1,000 tests)	100 Vials (1,000 tests)
Expiration from date of manufacture	12 Months	12 Months	12 Months
Rehydrated stability	N/a	Two hours if used with standard bioball rehydration fluid	Two hours if used with standard bioball rehydration fluid

How long will it take?

A BioBall Plant Isolate will take approximately 12 weeks from the strain arriving at our BioBall® manufacturing site in Sydney, for development, manufacturing, stability testing and shipment back to you in BioBall® format. Our BioBall Custom Services Department will provide an estimated delivery date once the order is placed.

BIOBALL™ Select

BioBall Select is manufactured in Sydney Australia and maintains the high level of quality you are accustomed to with our BioBall® Reference Strains products. It is manufactured with any strain selected from specified culture collections (preferably DSMZ or NCTC) and at any CFU level required. BioBall Select can also be made using any proprietary strain with commercial or analytical value where third party intellectual property rights are not infringed.

How long will it take?

A BioBall Select service will take approximately 12 weeks from the strain arriving at BioBall manufacturing site in Sydney, Australia, for development, manufacturing, quality control, stability testing and shipment back to you in BioBall® format. We will provide an estimated delivery date once the order is placed.

Specifications available:

cfu range	From 7 cfu to 10E8 cfu
Minimum number of vials per strain	100 vials
Single Dose or Multi Dose	Both options are available. The Multi Dose product will come with a two hour rehydrated stability if used with BioBall Re-Hydration Fluid.
Expiration from date of manufacture	12 months
Rehydrated Stability	Two hour rehydrated stability in BioBall Re-Hydration Fluid may be possible, depending on the strain.

Our Commitment

We guarantee to provide your strains in BioBall® format with the standard specification as outlined. You will receive a Certificate of Analysis showing the actual Mean and Standard Deviation of the batch. We guarantee that any strains and customer information sent to our BioBall Custom Services Department, will be dealt with in strict confidence and your strains are used only for the production of the BioBall Plant Isolate ordered.

Five reasons to choose the BioBall Plant Isolate Service over other methods:

a. NO upfront costs and if the specification cannot be met, you will not be charged for the order or any work completed

b. The BioBall brand represents 10 Years in quantitative microbiological controls = REAL EXPERIENCE!

c. BioBall Plant Isolate has a 12 month expiry (from date of manufacture) based on an established stability testing protocol.

d. Worry free ordering - We will organize everything from collecting your strains to delivery of the BioBall back to your site.

e. Second and subsequent orders of the same strain are eligible for a discount.

The next step

Once you have placed the order with your bioMérieux representative and completed the BioBall Custom Services Order Form, BioBall Custom Services Department will liaise with you directly regarding the next steps in your order, including shipment of your strains to our BioBall® manufacturing site in Sydney, Australia.

BioBall Custom Services advantages over other methods:

- ✓ No upfront costs and if the specification cannot be met, you will not be charged for the order or any work completed
- ✓ The BioBall brand represents 10 Years in quantitative microbiological controls = REAL EXPERIENCE!
- ✓ BioBall is produced to the world's highest quality standards, achieving ISO Guide 34 accreditation. ISO Guide 34 is a quality systems standard for reference material producers. We use patented technology and proprietary techniques to manufacture BioBall products with unprecedented precision and maximum viability
- ✓ Certificate of Analysis supplied, stating actual Mean cfu and Standard Deviation for each batch
- ✓ BioBall Custom Services have a 12 month expiry (from date of manufacture) based on an established stability testing protocol
- ✓ Worry free ordering – We will organize everything from collecting your strains to delivery of the BioBall back to your site

Further information

For further information on BioBall Custom Services, please contact your local bioMérieux office, bioMérieux distributor or visit **www.bioball.com**

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