



# BioBall™

Custom Services

...Delivering Confidence in  
Quantitative Microbiology



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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

## What strains can be used?

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 <sup>7</sup> to 1.4 x 10 <sup>8</sup>
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.

## 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 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:

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

## 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](http://www.bioball.com)

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