BioBall™ Custom Services

Single Dose and Multi Dose Instructions For Use

Issue: 2 | **Date:** 01/12/2015

BIOMÉRIEUX INDUSTRY

PIONEERING DIAGNOSTICS

BioBall™
Custom Services

Single Dose
Instructions For Use

To Open BioBall® Aseptically remove stopper

Agar Plate
1. Tip BioBall into the centre of the plate
2. Rehydrate by pipetting 100 µL of sterile water or 0.9% saline solution directly onto BioBall
3. Wait 30 seconds for BioBall to dissolve
4. Use a sterile plate spreader to evenly spread the dissolved BioBall over the plate surface
5. Ensure plate is dry before inverting and incubating

Membrane Filtration
1. Tip BioBall into liquid sample
2. Mix by repeatedly inverting sample
3. Filter the sample using standard test method
4. Follow standard test method for incubation

Pour Plate
1. Pipette 1ml of sterile water or 0.9% saline solution into pour plate
2. Tip BioBall into the sterile water/saline solution
3. Wait 30 seconds for BioBall to dissolve
4. Add molten agar and mix according to standard test method
5. Incubate as required

Petrifilm®
1. Tip BioBall onto the centre of Petrifilm®
2. Rehydrate by pipetting 1mL of sterile water or 0.9% saline solution directly onto BioBall
3. Follow standard test method
4. Incubate as required

Adding to Samples/Broths
1. Tip BioBall into sample/broth
2. Mix
3. Incubate as required

BioBall™
Custom Services

Multi Dose
Instructions For Use

BioBall Multi Dose product used with Re-Hydration Fluid (bioMérieux Ref: 56021)

1. Remove cap from BioBall Re-Hydration Fluid

2. Remove the stopper from the glass vial containing the BioBall

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

Note: BioBall Re-Hydration Fluid needs to be at room temperature when the BioBall is added. It is important NOT to pour the rehydration fluid into the glass vial.

4. Vortex for 5 seconds

5. BioBall is now ready to use. Aliquot the correct dose from the rehydration fluid vial

7. The rehydrated BioBall can be used up to 2 hours after re-hydration, if the re-hydrated BioBall is stored in a refrigerator at 2ºC to 8ºC. Re-vortex the re-hydrated BioBall for 5 seconds before each use

Note: BioBall Custom Services Multi Dose products have **not** been validated for 8 hour stability in BioBall Re-Hydration Fluid or 14 Day Re-Hydration Fluid. If extended stability is required, it is recommended that users generate their own supporting data.

BioBall™
Custom Services

Intended Use
BioBall is a microbiological reference material containing a precise number of viable bacterial cells. It is designed for use as a quantitative quality control sample.

Description
BioBall is a freeze dried water soluble ball containing a precise number of micro-organisms. The ball is a white sphere approximately 3mm in diameter.

Quality Control
BioBall delivers a level of precision previously unobtainable in microbiology. Each batch of BioBall is quality controlled by testing a minimum of 10% of the batch up to a maximum of 50. Vials are selected at random from throughout the batch and plated onto non-selective media (unless otherwise stated on the certificate of analysis).

Certificate of Analysis
Certificates of Analysis will be emailed to you once the order is dispatched. The certificate states the mean cfu and standard deviation of the batch. It also states the 95% Prediction Interval. The standard deviation is a measure of variability within the batch, the mean is the average cfu count tested on non-selective agar (unless otherwise stated on the certificate of analysis. The Prediction Interval is a statistical analysis of the quality data stating that 95% of expected results (counts) will fall within this range. Our team of technical experts can be contacted regarding the interpretation of results.

Limitations
CFU count (mean, CV and standard deviation) stated in this document and BioBall promotional literature, and batch-specific Quantification Data reported on BioBall Certificates of Analysis, are determined on non-selective culture media (unless otherwise stated).Selective media vary greatly in their inhibitory properties amongst different formulations and amongst brands with similar formulations.Recovery rates from BioBall may be reduced relative to the selectivity of the media.Users of BioBall with selective media are advised to establish their own expectations for recovery rate for each BioBall strain on selective media and to base their performance expectations on data derived from the specific formulations and brands of selective media used in their laboratories.Where recovery rates are reduced on very selective media, users should consider using a greater inoculum to meaningfully assess the limits of detection of their media.

Safety Precautions
BioBall contains viable and potentially pathogenic bacteria and should only be handled by experienced laboratory personnel trained in the safe handling of these micro-organisms. The number of micro-organisms contained within BioBall is low. However, BioBall should be handled as if potentially infectious. Refer to your national safety guidelines. After use, dispose of packaging in accordance with appropriate biohazard disposal practices. Do not use the product if the packaging is damaged. Do not use the product after the expiry date. The product should be used according to the procedure described in this instruction for use document. Any modifications may affect the results.

Intended use and intellectual property rights
The customer acknowledges that BioBall products supplied through the BioBall Custom Services may contain BTF proprietary strains (such as those containing *gfp* genes) or strains for which third parties hold intellectual property rights. All BTF strains and third party strains are provided for use only in the BioBall format, and the customer agrees to this restricted use. The customer undertakes not to re-use, subculture, maintain, store, distribute, sell, lend, transfer, analyze, genetically sequence, or otherwise deal with BTF strains or third party strains provided in the BioBall format. In the case of GFP labeled strains, the following patent applications apply: WO 2006/029449 and US 20110039254.

BioBall™ Custom Services

Warranty

BTF warrants to the original purchaser only that the products will conform to the quantity and contents stated on the product labels and quality certificate for the duration of the stated shelf life.

Limits of Liability

BTF's sole obligation and the purchaser's exclusive remedy under the above warranty is limited either to replacement, at BTF's expense, any products which are defective in manufacture (provided that the purchaser must return the products, transportation prepaid, to BTF) or, at BTF's option, refund the purchase price. All claims must be notified to BTF within 14 days of using the product. The above warranty does not apply to any products which have been altered outside BTF, nor to any products which have been subjected to misuse or mishandling, or use, storage or handling other than in accordance with instructions supplied by BTF. ALL OTHER WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, ARE HEREBY SPECIFICALLY EXCLUDED, INCLUDING BUT NOT LIMITED TO WARRANTIES OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT. BTF's maximum liability is limited in all events to the price of the products sold by BTF. IN NO EVENT SHALL BTF BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOSS OF PROFITS. The limitations set out above apply to the fullest extent permitted by law. If any provision of these terms and conditions is held to be invalid, illegal or unenforceable, the enforceability of the remaining provisions will be unaffected.

Use and Indemnity

The purchaser assumes all risk and responsibility in connection with the use, storage, handling and disposal of the products. The purchaser must ensure that all use, storage, handling and disposal of the products is in compliance with all applicable laws, regulations and guidelines and in accordance with any instructions supplied by BTF, and must take all appropriate safety precautions. The purchaser indemnifies BTF and its directors, officers and employees and agents from and against all claims, actions, liabilities, costs and expenses arising directly or indirectly from the use, storage, handling and disposal of the products, except to the extent arising directly from the negligence of BTF.

Manufactured by:
BTF Pty Ltd.
Sydney Australia
Tel. 61 (0) 2 8877 9150
Fax. 61 (0) 2 8221 9589 www.bioball.com

Sales & General Enquires:
bioMérieux S.A
69280 Marcy l'Etoile
France Tel. 33 (0) 4 78 87 20 00 **Fax.** 33 (0) 4 78 87 20 90
www.biomerieux.com www.biomerieux-industry.com

BIOMÉRIEUX INDUSTRY
PIONEERING DIAGNOSTICS