BIOMÉRIEUX

BIOBALL®

Take Control of your Microbiological Quality Control

In-House Isolate Services

Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS

In-house isolates are increasingly popular and recommended.

Using in-house isolates has gained popularity in the last decade. The FDA has issued warning letters about failure to use in-house isolates in microbiological testing, while more and more regulators are asking for it. In-house isolates are the best challenge to culture media and validation studies, like sterility test validations.[1] Based on US FDA guidance, quality control laboratories are expected to determine if compendial organisms sufficiently represent production-related isolates and should suggest adding in-house isolates to the growth promotion challenge if needed.[2]

United States Pharmacopoeia

Growth Promotion and Sterility Tests need to demonstrate that media used in the microbiological environmental monitoring program, or in media-fill runs, are capable of supporting growth of indicator microorganisms and of **environmental isolates** from samples obtained through the monitoring program or their corresponding ATCC strains.[3]

European Pharmacopoeia

Performance qualification of a microbiological testing program is typically done with a panel of microorganisms, including pharmacopoeia strains, **in-house isolates,** or stressed/slow-growing microogranisms.[4]

Japanese Pharmacopoeia

In relation to selection of growth promotion, **testing organisms which are frequently isolated in environmental monitoring should be used.**[5]

References

1. Sandle, T. (2018) Microbiological Culture Media: A Complete Guide for Pharmaceutical and Healthcare Manufacturers, "Chapter 9: The Use of Environmental Isolates in Pharmaceutical Microbiology", DHI/PDA, Bethesda, MD, USA pp. 219-239
2. United States Food and Drug Administration: Guidance for Industry (2004) - Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practices.
3. USP 42 Chapter <1116> Microbiological control and monitoring of aseptic processing environments.
4. European Pharmacopeia 9.8 Chapter 5.1.6. Alternative methods for control of microbiological quality.
5. Japanese Pharmacopoeia 17th Edition (2016) XV, General Information section 11.4.1 concerned with Media Fill Tests.

Consistent, convenient, and efficient in-house isolate testing

BIOBALL® In-house Isolate Services develop and produce BIOBALL® with wild-type strain(s) from your facility. The service maintains the high quality for which standard BIOBALL® products are known. Not only can this save your laboratory time and resources, it also meets your needs by providing a quantitative, precise, accurate, and easy-to-use microbiological reference material.

ACCURATE

PRECISE

EFFICIENT

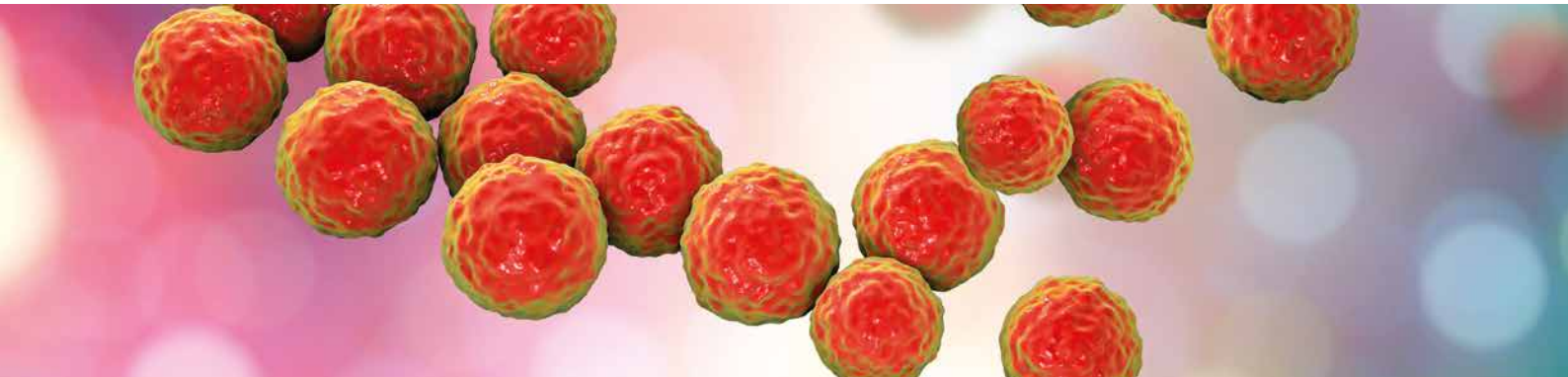
CONSISTENT

The bioMérieux Difference

- No upfront costs
- Strain collection included
- No charge unless a working product can be delivered
- Lead time of approximately 12 weeks from arrival
- 12-month expiration, possible to extend to 24 months with testing
- Stocks of in-house isolates are stored and maintained free of charge

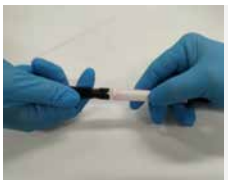
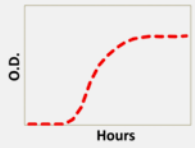
Available Formats

- Single Dose: 60 CFU
- Multi Dose: 550 CFU (50 CFU per dose)
- Customized CFU format to fit your needs



BIOBALL® In-house Isolate Services Workflow

In just 12 weeks from the time we receive your in-house isolate, we can manufacture and ship a custom BIOBALL® product for testing in your lab.

WEEK 0		Receive in-house isolate.
WEEK 1-2		Check purity and prepare stock.
WEEK 3-4		Verify ID and determine growth pattern.
WEEK 5-8		Develop in-house isolate into chosen BIOBALL® format.
WEEK 9-10		Manufacture BIOBALL® batch and confirm quality.
WEEK 11-12		Package and ship.

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