

BIOMÉRIEUX

BIOBALL®

Take Control of your Microbiological Quality Control
GPT of selective media



Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS



Growth Promotion Testing of Selective Media

Growth promotion testing (GPT) of selective media following Microbiological Examination of Non-Sterile Products: Tests for Specified Microorganisms Ph.Eur.2.6.13 / USP<62> / JP 4.05 can be quite challenging. Achieving proficiency in selective media GPT requires a strong understanding of the pharmacopeia guidelines and the role of selective media.

Selective media are designed to provide a conducive environment for growth of some types of microorganisms but not to others. They provide the ability to control what will and will not grow on a culture plate. However, it is important to note that a microorganism will not grow as well on a selective media compared to a non-selective media. This is entirely due to non-selective media being well balanced with all the elements that most bacteria need to grow and flourish, whereas in selective media, due to the presence of either activating or inhibiting elements, selected microorganism will grow but not thrive.

Therefore, compendial test requirements for selective media are not quantitatively evaluated. Instead, pharmacopeia requirements for selective media testing state:

“ Growth of the microorganism comparable to that previously obtained with a pre-tested and approved batch of medium occurs. ”

No percent recovery requirement must be achieved when testing a selective media batch. The qualification is based on growth of the new batch of selective media comparable to growth of pre-tested and approved batch of the same selective media.

Note: Do not try to compare recovery amounts to non-selective media (TSA) or product “Certificate of Analysis.”

BIOBALL® Product Description

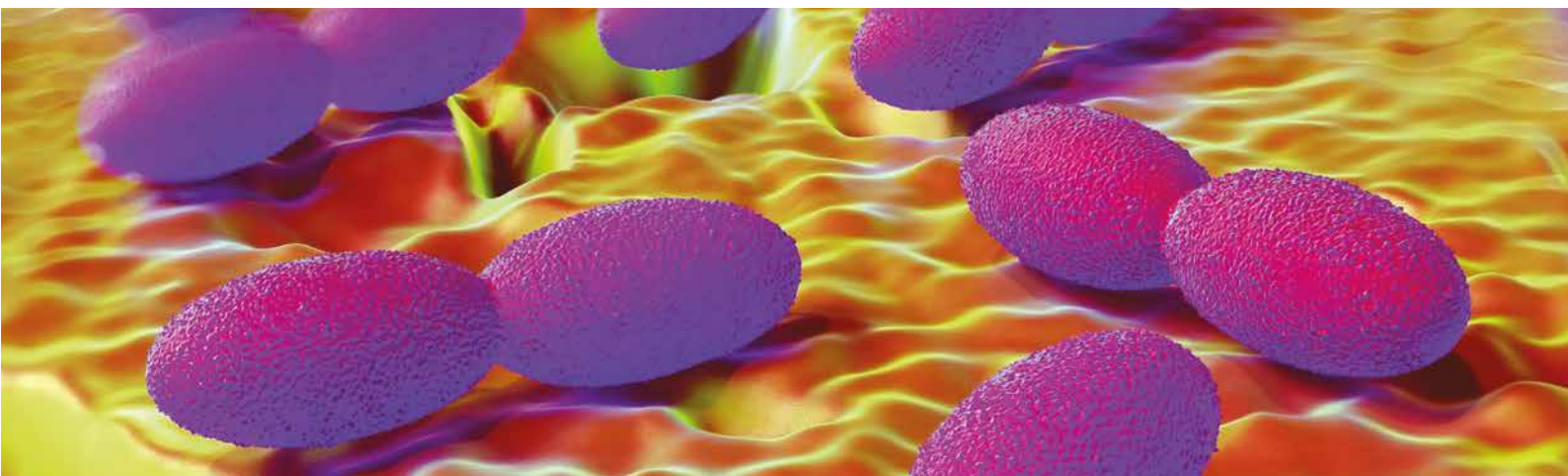
Alt-RHF (417843) is designed for use with BIOBALL® MULTISHOT 550 strains and has been designed specifically to enhance the recovery of BIOBALL® strains with selective media.

Testing of this formulation was performed with *Pseudomonas aeruginosa* on Cetrimide Agar and with *Escherichia coli* on MacConkey and VRBG Agar. In these scenarios, recovery rates of 50% and greater of the mean count reported on batch-specific BIOBALL® Certificates of Analysis were achieved.

BIOBALL® Strain	Medium	T0 Immediately after rehydration				T8 8 hours after rehydration			
		Standard BIOBALL® RHF <i>No pre-incubation</i>		Alt-RHF <i>Pre-incubation 15 mins / 32.5°C</i>		Standard BIOBALL® RHF <i>No pre-incubation</i>		Alt-RHF <i>Pre-incubation 15 mins / 32.5°C</i>	
		CFU	%Rec	CFU	%Rec	CFU	%Rec	CFU	%Rec
<i>Pseudomonas aeruginosa</i> NCTC 12924	Nutrient Agar	524.63	97.94	506.73	94.60	472.41	88.19	478.43	89.31
	Cetrimide Agar Ref 43565	0	0	349.07	65.16	0	0	279.11	52.10
<i>Escherichia coli</i> NCTC 12923	Nutrient Agar	592.09	102.80	580.95	100.86	481.65	83.62	524.77	91.11
	MacConkey Agar Ref 43141	257.11	44.64	480.04	83.34	380.16	66.01	505.56	87.78
<i>Escherichia coli</i> NCTC 12923	Nutrient Agar	529.09	102.80	580.95	100.86	481.65	83.62	524.77	91.11
	VRBG Agar Ref AEB623207	250.07	43.42	475.20	82.47	397.17	68.96	479.75	83.30

Limitations of BIOBALL®

Alt-RHF cannot be substituted for 14-day rehydration fluid (410386), nor can it be used with BIOBALL® MULTISHOT 10E8 strains, as these applications have not been validated. Users must validate any protocols that differ from the BIOBALL® MULTISHOT 550 IFU for alt-RHF at biomerieux-industry.com.





BIOBALL® Recommendations for Growth Promotion Testing of *Pseudomonas aeruginosa* on Cetrimide Media

Products needed

- BIOBALL® MultiShot 550 *Pseudomonas aeruginosa* (56017)
- BIOBALL® Alternative Rehydration Fluid (417843)
- bioMérieux Selective Media Cetrimide (43565)

Steps to follow*

1. Add BIOBALL® MultiShot 550 to the BIOBALL® Alternative Rehydration Fluid (Make sure Alt-RHF is at room temperature.)
2. Vortex for 5 seconds.
3. Incubate at $32.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for a minimum of 15 minutes.
4. Draw aliquots of 100 μL and pipette onto selective media.
5. Spread, dry, and incubate as per facility procedures.

Suggestions for Troubleshooting

- Increase length of incubation time.
- Increase inoculation amount (max use up to 180 μL <100CFU).
- Test a non-selective media in parallel to confirm viability and methods.