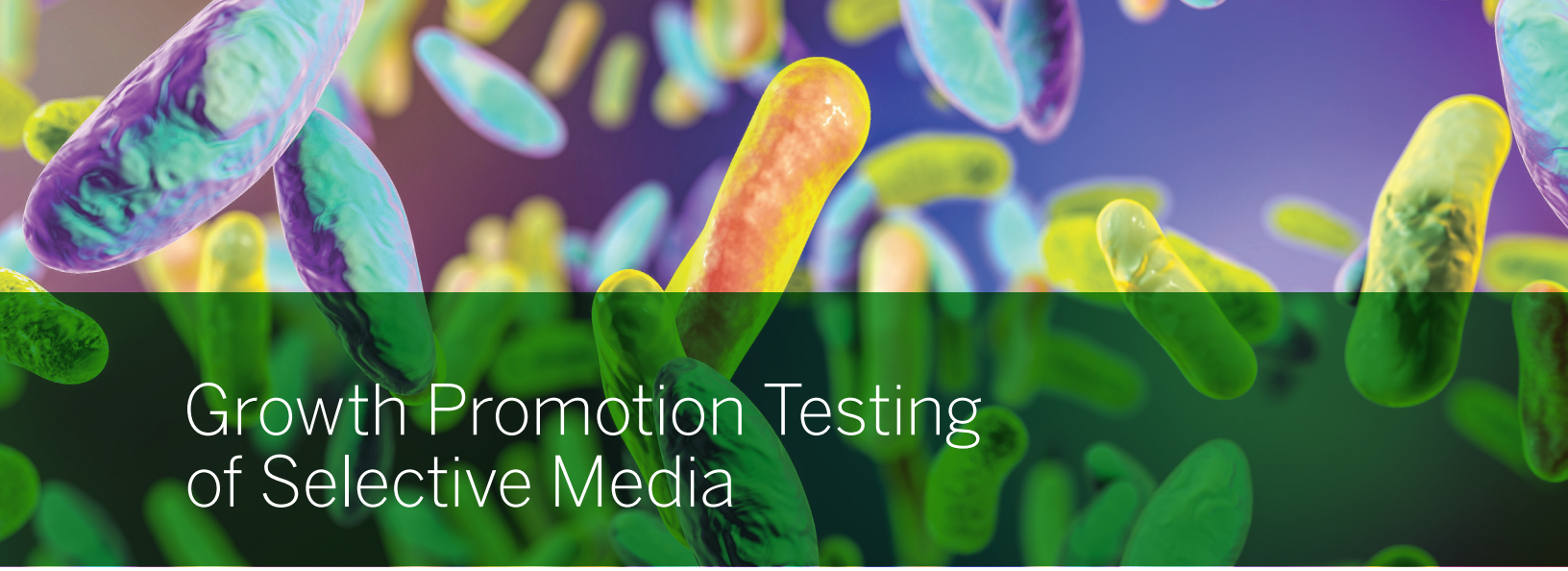
BIOMÉRIEUX

BIOBALL®
GPT OF SELECTIVE MEDIA

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 previously 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 previously 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.

		T0 **Immediately after rehydration**				**T8** **8 hours after rehydration**			
		Standard BIOBALL RHF *No pre-incubation*		**Alt-RHF** *Pre-incubation* *15 mins / 32.5°C*		**Standard BIOBALL RHF** *No pre-incubation*		**Alt-RHF** *Pre-incubation* *15 mins / 32.5°C*	
BIOBALL Strain	**Medium**	**CFU**	**%Rec**	**CFU**	**%Rec**	**CFU**	**%Rec**	**CFU**	**%Rec**
Pseudomonas aeruginosa 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**
Escherichia coli 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**
Escherichia coli 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 BIOBALL.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°C ± 2°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 180µL <100CFU).
- Test a non-selective media in parallel to confirm viability and methods.

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