

# BIOBALL®

Take Control of your Microbiological Quality Control  
Test for *Burkholderia Cepacia Complex*



*Burkholderia Cepacia Complex* (BCC) and other water-borne opportunistic pathogens are among the contaminants that can be found in pharmaceutical water systems. BCC can survive or multiply in a variety of non-sterile and water-based products because it is resistant to certain preservatives and antimicrobial agents.<sup>(1)</sup>

Your Ally in Advancing Quality



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## FDA Guidance for BCC Detection

Detecting BCC bacteria is also a challenge and requires validated testing methods that take into consideration the unique characteristics of different BCC strains. The FDA advised drug manufacturers of non-sterile, water-based drug products to establish suitable methods to prevent objectionable microorganisms contamination <sup>(2)</sup>, and the USP has introduced a new chapter “**Tests for *Burkholderia Cepacia Complex*.”**<sup>(3)</sup>



## BIOBALL® MultiShot 550 available *Burkholderia Cepacia Complex* Testing Strains

BIOBALL MultiShot 550 *Burkholderia Cepacia Complex* (BCC) strains are designed specifically for “Growth Promotion Testing” and “Method Suitability” following Microbiological Examination of Non-Sterile products - Tests for BCC.

Property	Organism	Bioball Strain	Corresponding Strains	Cell Type	Shelf Life from Date of Manufacture
Growth-Promoting and Indicative	<i>Burkholderia cepacia</i>	NCTC10743	ATCC25416, DSM7288, CIP 80.24	Cell	2 Years
	<i>Burkholderia cenocepacia</i>	NCTC13227	ATCC BAA-245, LMG 16656	Cell	2 Years
	<i>Burkholderia multivorans</i>	NCTC13007	ATCC BAA-247, LMG13010, CCUG34080, CIP105495, DSM13243	Cell	2 Years
Inhibitory	<i>Pseudomonas aeruginosa</i>	NCTC12924	ATCC9027, NCIMB8626, CIP82.118, NBRC13275, WDCM00026	Cell	2 Years
	<i>Staphylococcus aureus</i>	NCTC10788	ATCC6538, CIP4.83, NCIMB9518, NBRC13276, FDA209, WDCM00032	Cell	2 years

## Reminder

BCC organisms pose a clear and present danger to patient health and safety. The challenge is undeniable; now is the time to remove BCC from our pharmaceutical manufacturing areas and products. <sup>(4)</sup>

**Speak to your local bioMérieux representative for more details and availabilities.**