
Microbiologics
PHARMACEUTICAL MICROBIOLOGY CONTROLS
WE CREATE CONFIDENCE IN SCIENCE
HARDY DIAGNOSTICS
A Culture of Service™

www.microbiologics.com

TABLE OF CONTENTS


Getting the
big stuff right
starts with doing
the small stuff
perfectly.

Test Methods	Microbiologics Product Formats					
	EZ-Accu Shot/Select	EZ-CFU/One Step	EZ-PEC	KWIK-STIK Plus	Epower	Enumerated Mycoplasma
Growth Promotion Testing	✓	✓		✓		
Suitability of Counting Methods	✓	✓		✓	✓	
Suitability of Sterility Testing	✓	✓		✓		
Suitability of Specified Microorganism Testing	✓	✓		✓		
Antimicrobial Effectiveness Testing			✓	✓		
Disinfectant Qualification				✓	✓	
Mycoplasma Testing				✓		✓

GROWTH PROMOTION TESTING

Pharmacopoeias created quite the challenge when they designed the growth promotion test (GPT). Inoculate with less than 100 CFU, make sure strains are no more than 5 passages, incubate with specific temperatures and times, results must be comparable to previously approved media and this test is required for each new batch of media. While these strict GPT requirements may intimidate some, savvy microbiologists know the power of using Microbiologics test-ready, quantitative microbial controls to simplify and accelerate their processes without compromising accuracy. Offering multiple convenient formats and the most diverse collection of strains, we have all your GPT needs covered!

USP Chapter Strains

Growth Promotion Testing

<60>

Tests for Burkholderia Cepacia Complex
USP <60>

Burkholderia cepacia complex (Bcc) organisms are consistently a leading cause for microbiological recalls in the United States when contamination is identified. Requirements for Bcc testing were officially added to United States Pharmacopeia (USP) General Chapter <60> in 2019. Laboratories are tasked with demonstrating that the media and methods they use to detect Bcc microorganisms are suitable. We offer the USP required Bcc test strains in our signature ready-to-use microbial control products to help labs meet these regulations and standards with ease.

Strains used for USP <60>:

Growth Promoting + Indicative:
- *Burkholderia cenocepacia*
- *Burkholderia cepacia*
- *Burkholderia multivorans*

Inhibitory:
- *Pseudomonas paraeruginosa*
- *Staphylococcus aureus*

<61>

Microbial Enumeration Tests
USP <61> | PH. EUR. 2.6.12 | JP 4.05, I.3

For non-sterile pharmaceutical and personal care product microbiologists, the Microbial Enumeration Test makes a regular appearance in their schedules. After all, it is an essential part of making sure their products are safe for consumers. When it comes to ensuring your Microbial Enumeration Test methods and material are consistently producing reliable results, we have the challenge microorganisms you need in a convenient format to save your laboratory time and money.

Strains used for USP <61>:

- *Aspergillus brasiliensis*
- *Bacillus spizizenii*
- *Candida albicans*
- *Pseudomonas paraeruginosa*
- *Staphylococcus aureus*

<62>

Tests for Specified Microorganisms
USP <62> | PH. EUR. 2.6.13 | JP 4.05, II.2

The title of this pharmacopeia chapter says it all, the *Tests for Specified Microorganisms* is designed to determine the presence or absence of specific microorganisms that are indicative of the product's microbiological quality. With a little help from our test-ready quantitative controls, demonstrating your laboratory's methods and materials are suitable for detecting and counting microorganisms is a breeze.

Strains used for USP <62>:

- *Candida albicans*
- *Clostridium sporogenes*
- *Escherichia coli*
- *Pseudomonas paraeruginosa*
- *Salmonella Typhimurium*
- *Staphylococcus aureus*

<71>

Sterility Testing
USP <71> | PH. EUR. 2.6.1 | JP 4.06, 3.02

Sterility testing is performed during the sterilization validation process, as well as for routine release testing. The test demonstrates process control and is a general indicator of the product's microbiological quality. Laboratories must perform suitability and growth promotion tests in tandem to ensure their methods and materials are appropriate for the test method. Microbiologics makes this process easy by providing the required test strains in convenient formats that reduce prep time and minimize the chance for errors.

Strains used for USP <71>:

- *Aspergillus brasiliensis*
- *Bacillus spizizenii*
- *Candida albicans*
- *Clostridium sporogenes*
- *Pseudomonas paraeruginosa*
- *Staphylococcus aureus*

ez accu shot™
GROWTH PROMOTION TESTING

Growth Promotion Testing (GPT) of culture media can be a resource-consuming and tedious task. We created EZ-Accu Shot™ as a convenient, efficient and reliable alternative to preparing and maintaining control microorganisms in-house. Each instant-dissolve lyophilized microorganism pellet delivers 10-100 CFU per inoculum and provides 8 hours of stability after rehydration, so you can meet pharmacopeia standards with ease.

Highlights

- Accredited reference material under ISO 17034 standard
- Delivers 10-100 CFU per 0.1 ml
- Strains are less than or equal to three passages from reference culture
- Instant dissolve pellet reduces preparation time
- No dilutions required for simplified test procedure
- Up to 8 hours stability allows for ultimate flexibility
- 50 tests per kit, ideal quantity for labs of any size
- Refrigerated storage is easy and economical
- Traceability to reference cultures ensures authenticity
- Online Certificate of Analysis provides detailed strain information

Applications and Test Methods

- Growth Promotion Testing
- Media Challenge Testing
- Suitability of Counting Methods
- Suitability of Sterility Tests
- Suitability of Tests for Specified Microorganisms
- Microbial Limits Testing
- Microbial Enumeration Testing
- Validation of Neutralization Methods
- Methods requiring a low CFU concentration

Package Details

- Five vials of a single, quantitated microorganism (one lyophilized pellet per vial)
- Five vials of Hydrating Fluid (1.2 ml in each vial)
- Up to 50 tests per kit

Strains Available

- 0392A *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0486A *Bacillus spizizenii* derived from ATCC® 6633™*
- 01269A *Burkholderia cenocepacia* derived from ATCC® BAA-245™*
- 0488A *Burkholderia cepacia* derived from ATCC® 25416™*
- 01270A *Burkholderia multivorans* derived from ATCC® BAA-247™*
- 0443A *Candida albicans* derived from ATCC® 10231™*
- 0487A *Clostridium sporogenes* derived from ATCC® 11437™*
- 0317A *Clostridium sporogenes* derived from ATCC® 19404™*
- 0419A *Cutibacterium acnes* derived from ATCC® 11827™*
- 0366A *Enterococcus faecalis* derived from ATCC® 29212™*
- 0483A *Escherichia coli* derived from ATCC® 8739™*
- 0306A *Klebsiella aerogenes* derived from ATCC® 13048™*
- 0957A *Klebsiella pneumoniae* subsp. *pneumoniae* derived from ATCC® 33495™*
- 0242A *Micrococcus luteus* derived from ATCC® 4698™*
- 0484A *Pseudomonas paraeruginosa* derived from ATCC® 9027™*

The EZ-Accu Shot Select kit is perfect for use in your laboratory for USP <60>, <61>, and <62> testing!

There are two kits available, Item 8172 which contains one instant dissolve pellet of each of the five compendial strains needed for USP<61> and the E.coli for USP <62>, and 6 vials of Hydrating Fluid. Item 7009 contains one instant dissolve pellet of the 5 strains required for USP <60> testing and 5 vials of Hydrating Fluid.

ez accu shot™ GROWTH PROMOTION TESTING *Select*

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ez·CFU™ One Step

Is your lab still preparing microorganism suspensions the old-fashioned way for Growth Promotion Testing of culture media? Allow us to introduce you to your new favorite lab supply, EZ-CFU™ One Step. We designed this product specifically for Growth Promotion Testing. These ready-to-use quantitative microorganisms are just 3 passages from the reference culture and deliver 10-100 CFU per inoculum, as required by the Pharmacopeias, with minimal prep time and 8-hours stability for ultimate flexibility.

Highlights

- Accredited reference material under ISO 17034 standard
- Delivers 10-100 CFU per 0.1 ml as required by USP/Ph. Eur./JP
- No dilutions required for simplified test procedure
- Up to 8 hours stability allows for ultimate flexibility
- 19 tests per set-up, 190 tests per kit
- Strains are less than or equal to three passages from reference culture – meets USP/Ph. Eur./JP requirements
- Refrigerated storage is easy and economical
- Online Certificate of Analysis provides detailed strain information
- Traceability to reference cultures ensures authenticity

Package Details (two options):

- 20 quantitated lyophilized microorganism pellets
- 10 vials of Hydrating Fluid (2 ml in each vial)

Applications and Test Methods

- Growth Promotion Testing
- Media Challenge Testing
- Suitability of Counting Methods
- Suitability of Sterility Tests
- Suitability of Tests for Specified Microorganisms
- Microbial Limits Testing
- Microbial Enumeration Testing
- Validation of Neutralization Methods
- Methods requiring a low CFU concentration

Strains Available

- 0392Z *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0998Z *Bacillus cereus* derived from ATCC® 10876™*
- 0486Z *Bacillus spizizenii* derived from ATCC® 6633™*
- 0805Z *Brevundimonas diminuta* derived from ATCC® 19146™*
- 0443Z *Candida albicans* derived from ATCC® 10231™*
- 0487Z *Clostridium sporogenes* derived from ATCC® 11437™*
- 0317Z *Clostridium sporogenes* derived from ATCC® 19404™*
- 0366Z *Enterococcus faecalis* derived from ATCC® 29212™*
- 0483Z *Escherichia coli* derived from ATCC® 8739™*
- 0871Z *Geobacillus stearothermophilus* derived from ATCC® 7953™*
- 0688Z *Kocuria rhizophila* derived from ATCC® 9341™*
- 0687Z *Listeria monocytogenes* derived from ATCC® 19115™*
- 0242Z *Micrococcus luteus* derived from ATCC® 4698™*
- 0484Z *Pseudomonas paraeruginosa* derived from ATCC® 9027™*
- 0890Z *Salmonella enterica* subsp. *enterica* serovar Abony derived from NCTC 6017
- 0363Z *Salmonella enterica* subsp. *enterica* serovar Typhimurium derived from ATCC® 14028™*
- 0485Z *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 6538™*
- 0371Z *Staphylococcus epidermidis* derived from ATCC® 12228™*
- 0385Z *Streptococcus pyogenes* derived from ATCC® 19615™*

ez·CFU™

With EZ-CFU™ ready-to-use reference cultures, Growth Promotion Testing doesn't have to be a hassle. Delivering 10-100 CFU per 0.1 ml inoculum, following a simple 1:10 dilution step, each microorganism suspension provides up to 90 tests. These handy kits allow for fast, reliable Growth Promotion Testing. Plus, EZ-CFU microorganisms are just three passages from the reference strains. All in all, EZ-CFU makes meeting Pharmacopeia standards for Growth Promotion Testing easier than ever.

Highlights

- Accredited reference material under ISO 17034 standard
- Delivers 10-100 CFU per 0.1 ml following a 1:10 dilution step
- 900+ tests per kit, ideal for high volume Growth Promotion Testing
- Strains are less than or equal to three passages from reference culture – meets USP/Ph. Eur./JP requirements
- Refrigerated storage is easy and economical
- Online Certificate of Analysis provides detailed strain information
- Traceability to reference cultures ensures authenticity

Package Details

- 20 quantitated lyophilized microorganism pellets
- 10 vials of Hydrating Fluid (2 ml in each vial)

Applications and Test Methods

- Growth Promotion Testing
- Media Challenge Testing
- Suitability of Counting Methods
- Suitability of Sterility Tests
- Suitability of Tests for Specified Microorganisms
- Microbial Limits Testing
- Microbial Enumeration Testing
- Validation of Neutralization Methods
- Methods requiring a low CFU concentration

Strains Available

- 0392C *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0486C *Bacillus spizizenii* derived from ATCC® 6633™*
- 0443C *Candida albicans* derived from ATCC® 10231™*
- 0487C *Clostridium sporogenes* derived from ATCC® 11437™*
- 0317C *Clostridium sporogenes* derived from ATCC® 19404™*
- 0366C *Enterococcus faecalis* derived from ATCC® 29212™*
- 0483C *Escherichia coli* derived from ATCC® 8739™*
- 0871C *Geobacillus stearothermophilus* derived from ATCC® 7953™*
- 0306C *Klebsiella aerogenes* derived from ATCC® 13048™*
- 0688C *Kocuria rhizophila* derived from ATCC® 9341™*
- 0813C *Lactobacillus fermentum* derived from ATCC® 9338™*
- 0687C *Listeria monocytogenes* derived from ATCC® 19115™*
- 0484C *Pseudomonas paraeruginosa* derived from ATCC® 9027™*
- 0890C *Salmonella enterica* subsp. *enterica* serovar Abony derived from NCTC 6017
- 0902C *Salmonella enterica* subsp. *enterica* serovar Choleraesuis derived from ATCC® 10708™*
- 0363C *Salmonella enterica* subsp. *enterica* serovar Typhimurium derived from ATCC® 14028™*
- 0485C *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 6538™*
- 0371C *Staphylococcus epidermidis* derived from ATCC® 12228™*
- 0385C *Streptococcus pyogenes* derived from ATCC® 19615™*

METHOD SUITABILITY TESTING

Antimicrobial and preservative ingredients used to keep products safe can also interfere with the detection of potential microbial contaminants during product release testing. To address this challenge, Pharmacopeias include guidelines for Method Suitability Testing, which is designed to confirm if antimicrobial activity in products would impact recovery of microorganism, impacting microbiological product safety. Our quantitative and user-friendly microbial controls help laboratories conduct Method Suitability Tests simply and reliably.

Epower™

Savvy microbiologists love the versatility of simply using one product for all their microbiological QC needs – from media QC and presence/absence testing to enumeration testing, water testing, and disinfectant testing. Enter Epower™ quantitative microbial controls. Each quantitative microorganism pellet delivers a specific range of CFU, so you can easily manipulate Epower to deliver virtually any concentration. You can also use a single strain or combine multiple strains for a mixed population. We know you'll appreciate the ease and adaptability that Epower offers.

Highlights

- Accredited reference material under ISO 17034 standard
- Available in concentrations ranging from 10^2 to 10^8 CFU per pellet
- Strains are less than or equal to three passages from reference culture
- Can be combined for a mixed microorganism population
- Easily manipulated to deliver a wide variety of concentrations
- Ready-to-use format to save you time and money
- Refrigerated storage is easy and economical
- Traceability to reference cultures ensures authenticity
- Online Certificate of Analysis provides detailed strain information

Package Details

- Vial of 10 quantitated lyophilized pellets

Applications and Test Methods

- Microbial detection
- Enumeration
- Verification and Validation
- Equipment calibration
- Method validation
- Disinfectant qualification
- Water tests
- Proficiency tests
- Mixed microorganism population challenge

Strains Available

- 0392 *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0998 *Bacillus cereus* derived from ATCC® 10876™*
- 01269 *Burkholderia cenocepacia* derived from ATCC® BAA-245™*
- 0488 *Burkholderia cepacia* derived from ATCC® 25416™*
- 01270 *Burkholderia multivorans* derived from ATCC® BAA-247™*
- 0443 *Candida albicans* derived from ATCC® 10231™*
- 0791 *Escherichia coli* derived from ATCC® 51813™*
- 0483 *Escherichia coli* derived from ATCC® 8739™*
- 0306 *Klebsiella aerogenes* derived from ATCC® 13048™*
- 0813 *Lactobacillus fermentum* derived from ATCC® 9338™*
- 0687 *Listeria monocytogenes* derived from ATCC® 19115™*
- 0484 *Pseudomonas paraeruginosa* derived from ATCC® 9027™*
- 0353 *Pseudomonas aeruginosa* derived from ATCC® 27853™*
- 0699 *Saccharomyces cerevisiae* derived from ATCC® 9763™*
- 0698 *Saccharomyces kudriavzevii* derived from ATCC® 2601™*
- 0817 *Salmonella enterica* subsp. *enterica* serovar Abaetetuba derived from ATCC® 35640™*
- 0421 *Salmonella enterica* subsp. *enterica* serovar Typhimurium derived from ATCC® 13311™*
- 0485 *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 6538™*
- 0371 *Staphylococcus epidermidis* derived from ATCC® 12228™*
- 0803 *Zygosaccharomyces rouxii* derived from ATCC® 28253™*

ATCC Licensed Derivative

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ez accu shot™
GROWTH PROMOTION TESTING

Let's face it; Growth Promotion Testing of culture media is likely not at the top of your "favorite lab activities" list. We get it, which is why we created EZ-Accu Shot™. It provides a fast, convenient and reliable solution for Growth Promotion Testing, Media Challenge Testing and more. Each instant-dissolve microorganism pellet is designed to deliver 10-100 CFU per inoculum and provides 8 hours of stability after rehydration, so you can meet required guidelines with ease.

Highlights

- Accredited reference material under ISO 17034 standard
- Delivers 10-100 CFU per 0.1 ml
- Strains are less than or equal to three passages from reference culture
- Instant dissolve pellet reduces preparation time
- No dilutions required for simplified test procedure
- Up to 8 hours stability allows for ultimate flexibility
- 50 tests per kit, ideal quantity for labs of any size
- Refrigerated storage is easy and economical
- Traceability to reference cultures ensures authenticity
- Online Certificate of Analysis provides detailed strain information

Applications and Test Methods

- Growth Promotion Testing
- Media Challenge Testing
- Suitability of Counting Methods
- Suitability of Sterility Tests
- Suitability of Tests for Specified Microorganisms
- Microbial Limits Testing
- Microbial Enumeration Testing
- Validation of Neutralization Methods
- Methods requiring a low CFU concentration

Package Details

- Five vials of a single, quantitated microorganism (one lyophilized pellet per vial)
- Five vials of Hydrating Fluid (1.2 ml in each vial)
- Up to 50 tests per kit

Strains Available

- 0392A *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0486A *Bacillus spizizenii* derived from ATCC® 6633™*
- 01269A *Burkholderia cenocepacia* derived from ATCC® BAA-245™*
- 0488A *Burkholderia cepacia* derived from ATCC® 25416™*
- 01270A *Burkholderia multivorans* derived from ATCC® BAA-247™*
- 0443A *Candida albicans* derived from ATCC® 10231™*
- 0487A *Clostridium sporogenes* derived from ATCC® 11437™*
- 0317A *Clostridium sporogenes* derived from ATCC® 19404™*
- 0419A *Cutibacterium acnes* derived from ATCC® 11827™*
- 0366A *Enterococcus faecalis* derived from ATCC® 29212™*
- 0483A *Escherichia coli* derived from ATCC® 8739™*
- 0306A *Klebsiella aerogenes* derived from ATCC® 13048™*
- 0957A *Klebsiella pneumoniae* subsp. *pneumoniae* derived from ATCC® 33495™*
- 0242A *Micrococcus luteus* derived from ATCC® 4698™*
- 0484A *Pseudomonas paraeruginosa* derived from ATCC® 9027™*

The EZ-Accu Shot Select kit is perfect for use in your laboratory for USP <60>, <61>, and <62> testing!

There are two kits available, Item 8172 which contains one instant dissolve pellet of each of the five compendial strains needed for USP<61> and the E.coli for USP <62>, and 6 vials of Hydrating Fluid. Item 7009 contains one instant dissolve pellet of the 5 strains required for USP <60> testing and 5 vials of Hydrating Fluid.

ez accu shot™ GROWTH PROMOTION TESTING *Select*

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ANTIMICROBIAL EFFECTIVENESS TESTING

USP <51> | PH. EUR. 5.1.3 | JP 19 | ISO 11930 | PCPC

Antimicrobial Effectiveness Testing, also called Preservative Efficacy Testing, is performed to determine if the antimicrobials or preservatives in non-sterile or sterile multi-dose aqueous products can effectively prevent the proliferation of microorganisms.

Strains used for USP <51>:

- *Aspergillus brasiliensis*
- *Candida albicans*
- *Escherichia coli*
- *Pseudomonas paraeruginosa*
- *Staphylococcus aureus*

ez·PEC™

Microbiologists are no strangers to the fact that safety and effectiveness are crucial elements of developing pharmaceutical and personal care products. We created our EZ-PEC™ quantitative microorganisms to help laboratories conduct Antimicrobial Effectiveness and Preservative Efficacy testing with convenience and confidence. Following a few simple steps, EZ-PEC delivers a final concentration of 1.0×10^5 to 1.0×10^6 CFU per ml of the product being tested. It's a simple solution that can save you time and resources while helping you meet Pharmacopeia and other standards and guidelines.

Highlights

- Accredited reference material under ISO 17034 standard
- Delivers 1.0×10^5 to 1.0×10^6 CFU per ml of product tested
- Strains are less than or equal to three passages from the reference culture
- Ready-to-use format saves time and money
- Refrigerated storage is easy and economical
- Online Certificate of Analysis provides detailed strain information
- Traceability to reference cultures ensures authenticity

Package Details

- 20 lyophilized pellets of a single enumerated QC microorganism
- 10 vials of Hydrating Fluid (2 ml in each vial)

Applications and Test Methods

- Antimicrobial Effectiveness Testing
- Applications requiring a high CFU concentration
- Preservative Efficacy Testing

Strains Available

- 0392-PEC *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0486-PEC *Bacillus spizizenii* derived from ATCC® 6633™*
- 0443-PEC *Candida albicans* derived from ATCC® 10231™*
- 0483-PEC *Escherichia coli* derived from ATCC® 8739™*
- 0581-PEC *Escherichia coli* derived from NCIMB 8545
- 0484-PEC *Pseudomonas paraeruginosa* derived from ATCC® 9027™*
- 0363-PEC *Salmonella enterica* subsp. *enterica* serovar Typhimurium derived from ATCC® 14028™*
- 0360-PEC *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 25923™*
- 0485-PEC *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 6538™*

KWIKSTIK™ 2 Passages plus

Some laboratory applications require strains that are fewer passages from the original reference culture. For those special instances, we offer KWIK-STIK™ Plus, which combines two passage microorganisms with our signature KWIK-STIK format. Each device features a qualitative lyophilized microorganism pellet, ampoule of hydrating fluid and inoculating swab; so everything you need for growing control cultures is included in one simple device.

Highlights

- Accredited reference material under ISO 17034 standard
- Designed for applications requiring strains that are fewer passages from the reference culture
- All-in-one design reduces the risk of contamination
- Ready-to-use format saves time and money
- Refrigerated storage is easy and economical
- Online Certificate of Analysis provides detailed strain information
- Traceability to reference cultures ensures authenticity

Package Details

- User-friendly design with a lyophilized microorganism pellet, ampoule of hydration fluid and inoculating swab
- Pack of five STIKs
- Peel-off identification label on each STIK

Applications and Test Methods

- Antibiotic assays
- Instrument validations
- Validation of neutralization methods
- Water tests
- Disinfectant qualification

Strains Available

- 0392X *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0486X *Bacillus spizizenii* derived from ATCC® 6633™*
- 0671X *Bordetella bronchiseptica* derived from ATCC® 4617™*
- 0805X *Brevundimonas diminuta* derived from ATCC® 19146™*
- 0836X *Burkholderia cenocepacia* derived from ATCC® 25608™*
- 0488X *Burkholderia cepacia* derived from ATCC® 25416™*
- 0443X *Candida albicans* derived from ATCC® 10231™*
- 0317X *Clostridium sporogenes* derived from ATCC® 19404™*
- 0487X *Clostridium sporogenes* derived from ATCC® 11437™*
- 0366X *Enterococcus faecalis* derived from ATCC® 29212™*
- 0335X *Escherichia coli* derived from ATCC® 25922™*
- 0483X *Escherichia coli* derived from ATCC® 8739™*
- 0306X *Klebsiella aerogenes* derived from ATCC® 13048™*
- 0688X *Kocuria rhizophila* derived from ATCC® 9341™*
- 0689X *Micrococcus luteus* derived from ATCC® 10240™*
- 0484X *Pseudomonas paraeruginosa* derived from ATCC® 9027™*
- 0693X *Pseudomonas aeruginosa* derived from ATCC® 15442™*
- 0698X *Saccharomyces kudriavzevii* derived from ATCC® 2601™*
- 0363X *Salmonella enterica* subsp. *enterica* serovar Typhimurium derived from ATCC® 14028™*
- 0485X *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 6538™*

DISINFECTANT EFFICACY TESTING

Disinfectant Efficacy Testing or Disinfectant validation studies are necessary for demonstrating that cleaning, disinfecting and sanitizing agents and procedures are effective in inactivating or eliminating contaminating microorganisms from surfaces and components in manufacturing environments. Because manufacturing environments, surface types and potential contaminants vary greatly, there are many nuances for designing and performing a thorough disinfectant study. Microbiologics offers the challenge microorganisms laboratories need for Disinfectant Efficacy Testing in simple, reliable formats.

Epower™ is the embodiment of "flexibility is your friend." You'll love the versatility of simply using one product for all of your QC needs – from media QC and presence/absence testing to enumeration testing, water testing, and disinfectant testing. Use a single strain or combine multiple strains for a mixed population. Each quantitative microorganism pellet delivers a specific range of CFU, so you can easily manipulate Epower to deliver virtually any concentration. We know you'll appreciate the ease and adaptability that Epower offers.

Highlights

- Accredited reference material under ISO 17034 standard
- Available in concentrations ranging from 10^2 to 10^8 CFU per pellet
- Strains are less than or equal to three passages from reference culture
- Can be combined for a mixed microorganism population
- Easily manipulated to deliver a wide variety of concentrations
- Ready-to-use format to save you time and money
- Refrigerated storage is easy and economical
- Traceability to reference cultures ensures authenticity
- Online Certificate of Analysis provides detailed strain information

Package Details

- Vial of 10 quantitated lyophilized pellets

Applications and Test Methods

- Microbial detection
- Enumeration
- Verification and Validation
- Equipment calibration
- Method validation
- Disinfectant qualification
- Water tests
- Proficiency tests
- Mixed microorganism population challenge

Strains Available

- 0392 *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0998 *Bacillus cereus* derived from ATCC® 10876™*
- 01269 *Burkholderia cenocepacia* derived from ATCC® BAA-245™*
- 0488 *Burkholderia cepacia* derived from ATCC® 25416™*
- 01270 *Burkholderia multivorans* derived from ATCC® BAA-247™*
- 0443 *Candida albicans* derived from ATCC® 10231™*
- 0791 *Escherichia coli* derived from ATCC® 51813™*
- 0483 *Escherichia coli* derived from ATCC® 8739™*
- 0306 *Klebsiella aerogenes* derived from ATCC® 13048™*
- 0813 *Lactobacillus fermentum* derived from ATCC® 9338™*
- 0687 *Listeria monocytogenes* derived from ATCC® 19115™*
- 0484 *Pseudomonas paraeruginosa* derived from ATCC® 9027™*
- 0353 *Pseudomonas aeruginosa* derived from ATCC® 27853™*
- 0699 *Saccharomyces cerevisiae* derived from ATCC® 9763™*
- 0698 *Saccharomyces kudriavzevii* derived from ATCC® 2601™*
- 0817 *Salmonella enterica* subsp. *enterica* serovar Abaetetuba derived from ATCC® 35640™*
- 0421 *Salmonella enterica* subsp. *enterica* serovar Typhimurium derived from ATCC® 13311™*
- 0485 *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 6538™*
- 0371 *Staphylococcus epidermidis* derived from ATCC® 12228™*
- 0803 *Zygosaccharomyces rouxii* derived from ATCC® 28253™*

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KWIKSTIK™ 2 Passages plus

Some laboratory applications require strains that are a fewer passages from the original reference culture. For those special instances, we offer KWIK-STIK™ Plus, which combines microorganisms that are just two passages from their reference strains, with our signature KWIK-STIK format. Each device features a qualitative lyophilized microorganism pellet, ampoule of hydration fluid and inoculating swab; so everything you need for growing control cultures is included in one handy device.

Highlights

- Accredited reference material under ISO 17034 standard
- Designed for applications requiring strains that are fewer passages from the reference culture
- All-in-one design reduces the risk of contamination
- Ready-to-use format saves time and money
- Refrigerated storage is easy and economical
- Online Certificate of Analysis provides detailed strain information
- Traceability to reference cultures ensures authenticity

Package Details

- User-friendly design with a lyophilized microorganism pellet, ampoule of hydration fluid and inoculating swab
- Pack of five STIKs
- Peel-off identification label on each STIK

Applications and Test Methods

- Antibiotic assays
- Instrument validations
- Validation of neutralization methods
- Water tests
- Disinfectant qualification

Strains Available

- 0392X *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0486X *Bacillus spizizenii* derived from ATCC® 6633™*
- 0671X *Bordetella bronchiseptica* derived from ATCC® 4617™*
- 0805X *Brevundimonas diminuta* derived from ATCC® 19146™*
- 0836X *Burkholderia cenocepacia* derived from ATCC® 25608™*
- 0488X *Burkholderia cepacia* derived from ATCC® 25416™*
- 0443X *Candida albicans* derived from ATCC® 10231™*
- 0317X *Clostridium sporogenes* derived from ATCC® 19404™*
- 0487X *Clostridium sporogenes* derived from ATCC® 11437™*
- 0366X *Enterococcus faecalis* derived from ATCC® 29212™*
- 0335X *Escherichia coli* derived from ATCC® 25922™*
- 0483X *Escherichia coli* derived from ATCC® 8739™*
- 0306X *Klebsiella aerogenes* derived from ATCC® 13048™*
- 0688X *Kocuria rhizophila* derived from ATCC® 9341™*
- 0689X *Micrococcus luteus* derived from ATCC® 10240™*
- 0484X *Pseudomonas paraeruginosa* derived from ATCC® 9027™*
- 0693X *Pseudomonas aeruginosa* derived from ATCC® 15442™*
- 0698X *Saccharomyces kudriavzevii* derived from ATCC® 2601™*
- 0363X *Salmonella enterica* subsp. *enterica* serovar Typhimurium derived from ATCC® 14028™*
- 0485X *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 6538™*

ATCC Licensed Derivative

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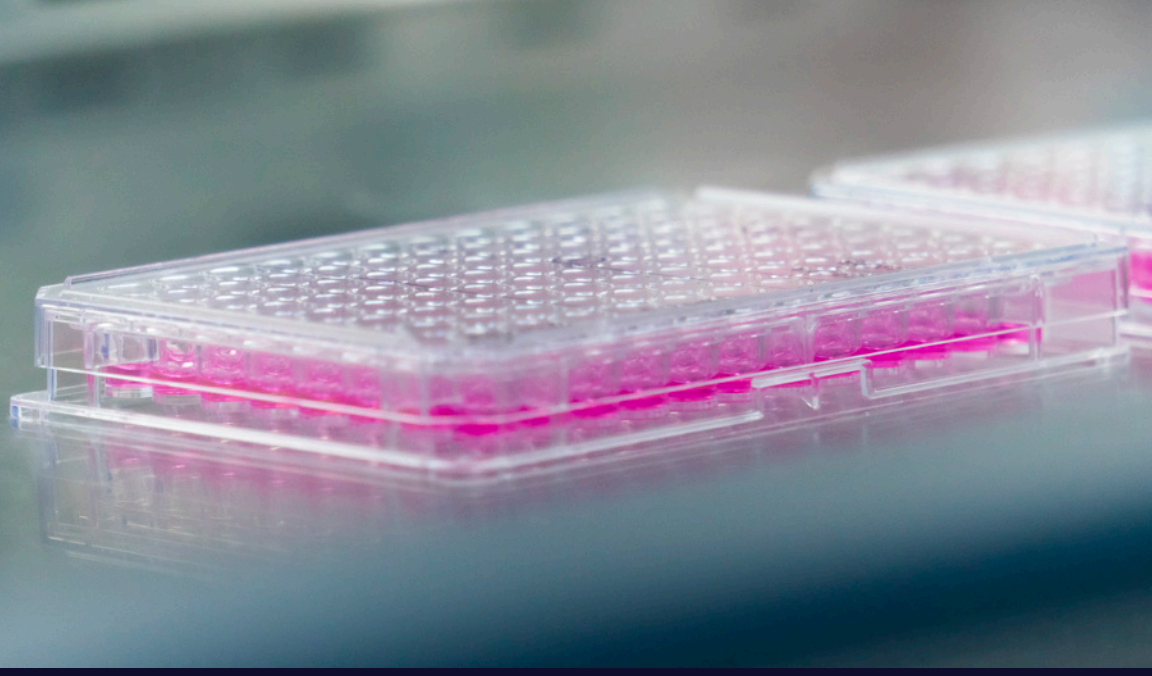
MYCOPLASMA TESTING

USP <63> | PH. EUR. 2.6.7

As the use of cell lines to produce biopharmaceuticals continues to increase, Mycoplasma testing is a growing quality control challenge. Because of its unique properties, Mycoplasma poses many challenges for detection and management. Mycoplasma contamination can spread quickly, yet common quality control methods can be time-consuming and complicated. To alleviate these challenges and simplify compliance with USP <63> and Ph. Eur.2.6.7, Microbiologics offers test-ready Enumerated Mycoplasma microbial controls.



ENUMERATED MYCOPLASMA

Enumerated Mycoplasma simplifies compliance with USP <63> / Ph. Eur. 2.6.7 by eliminating the need for manual enumeration. Ready for immediate plating, Enumerated Mycoplasma can quickly confirm the ability of agar or broth growth media to support the growth and detection of Mycoplasma organisms that may be present in the test inoculum.

Highlights

- Ready-to-use format saves time and money
- Eliminates the 48 hours to 4 weeks of wait time prior to plating
- Strains are less than or equal to fifteen passages from reference culture to comply with USP <63>/Ph. Eur. 2.6.7
- Delivers 10,000 – 99,000 CFU/ml (E4)
- Traceability to reference cultures ensures authenticity
- Online Certificate of Analysis provides detailed strain information
- Shipped frozen on dry ice
- Stored in a -80°C freezer

Applications and Test Methods

- Microbial detection
- Enumeration
- Verification
- Method validation
- Validation/verification of Identification Systems
- Growth Promotion Testing

Package Details

- Five cryovials of 0.5 ml frozen suspension

Strains Available

- 01156ME4 *Acholeplasma laidlawii* derived from NCTC 10116
- 01176ME4 *Mycoplasma fermentans* derived from NCTC 10117
- 01155ME4 *Mycoplasma gallisepticum* derived from NCTC 10115
- 01178ME4 *Mycoplasma hyorhinis* derived from NCTC 10130
- 01158ME4 *Mycoplasma orale* derived from NCTC 10112
- 01177ME4 *Mycoplasma pneumoniae* derived from NCTC 10119

MEDIA GROWTH PROMOTION TESTING

JP G8

Laboratories following Japanese Pharmacopeia (JP) guidelines know the challenges of performing Media Growth Promotion Testing on R2A agar. The JP states that R2A media should be challenged with strains that have been starved for 3 days prior to conducting the test. To simplify and accelerate test procedures for growth promotion of R2A agar, we have developed EZ-Accu Shot™ Starved Cells. These test-ready control strains have been starved prior to lyophilization and deliver the required concentration of 50-200 CFU/ml when rehydrated in 10 ml.

ez accu shot™ STARVED CELLS

Laboratories following Japanese Pharmacopeia (JP) guidelines know the challenges of performing Media Growth Promotion Testing on R2A agar. The JP states that R2A media should be challenged with strains that have been starved for 3 days prior to conducting the test. To simplify and accelerate test procedures for growth promotion of R2A agar, we have developed EZ-Accu Shot™ Starved Cells. These test-ready control strains have been starved prior to lyophilization and deliver the required concentration of 50-200 CFU/ml when rehydrated in 10 ml.

Highlights

- Delivers 50-200 CFU/ml when rehydrated in 10 ml on R2A agar as required by the Japanese Pharmacopeia
- Strains are less than or equal to three passages from reference culture – meets JP requirements
- Instant dissolve pellet reduces preparation time
- No dilutions required for simplified test procedure
- 50 tests per kit, ideal quantity for labs of any size
- Refrigerated storage is easy and economical
- Traceability to reference cultures ensures authenticity
- Online Certificate of Analysis provides detailed strain information

Package Details

- Five vials of a single, quantitated microorganism (One lyophilized pellet per vial)
- Five vials of Hydrating Fluid (1.2 ml in each vial)
- Up to 50 tests per kit

Applications and Test Methods

- Growth Promotion Testing
- Media Challenge Testing
- Suitability of Counting Methods
- Suitability of Sterility Tests
- Suitability of Tests for Specified Microorganisms
- Microbial Limits Testing
- Microbial Enumeration Testing
- Validation of Neutralization Methods
- Methods requiring a low CFU concentration

Strains Available

- 01110SC *Methylobacterium extorquens* derived from ATCC® BAA-2500™*
- 0524SC *Pseudomonas protegens* (G) derived from ATCC® 17386™*

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PHARMACEUTICAL WATER TESTING

<1231>

Water is widely used in a variety of ways throughout the development, manufacture and analysis of pharmaceutical products and control of microbiological water quality is important for many of those uses. Though the USP monographs for Purified Water and Water Injection do not include microbial requirements, the informational chapter <1231> states that "users should establish their own quantitative microbial Specifications suited to their water uses." Microbiologics offers a variety of quantitative microbial controls designed to simplify water QC and help labs meet regulations and standards.


4
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Epower™

For water testing QC, nothing beats the versatility and simplicity of Epower™. Each quantitative microorganism pellet delivers a specific range of CFU (from 10^2 and 10^8), allowing combinations with virtually any concentration of single strain or mixed populations. The test-ready format minimizes time without sacrificing precision.

Highlights

- Accredited reference material under ISO 17034 standard
- Available in concentrations ranging from 10^2 to 10^8 CFU per pellet
- Strains are less than or equal to three passages from reference culture
- Can be combined for a mixed microorganism population
- Easily manipulated to deliver a wide variety of concentrations
- Ready-to-use format to save you time and money
- Refrigerated storage is easy and economical
- Traceability to reference cultures ensures authenticity
- Online Certificate of Analysis provides detailed strain information

Package Details

- Vial of 10 quantitated lyophilized pellets

Applications and Test Methods

- Microbial detection
- Enumeration
- Verification and Validation
- Equipment calibration
- Method validation
- Disinfectant qualification
- Water tests
- Proficiency tests
- Mixed microorganism population challenge

Strains Available

- 0392 *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0260 *Arthrobacter psychrolactophilus* derived from ATCC® 700733™*
- 0392 *Aspergillus brasiliensis* derived from ATCC® 16404™*
- 0486 *Bacillus spizizenii* derived from ATCC® 6633™*
- 0488 *Burkholderia cepacia* derived from ATCC® 25416™*
- 01270 *Burkholderia multivorans* derived from ATCC® BAA-247™*
- 0443 *Candida albicans* derived from ATCC® 10231™*
- 0487 *Clostridium sporogenes* derived from ATCC® 11437™*
- 0756 *Cronobacter muytjensii* derived from ATCC® 51329™*
- 0366 *Enterococcus faecalis* derived from ATCC® 29212™*
- 0795 *Escherichia coli* (O157:H7) derived from ATCC® 43888™*
- 0791 *Escherichia coli* derived from ATCC® 51813™*
- 0483 *Escherichia coli* derived from ATCC® 8739™*
- 0306 *Klebsiella aerogenes* derived from ATCC® 13048™*
- 0814 *Listeria innocua* (6a) derived from ATCC® 33090™*
- 0687 *Listeria monocytogenes* derived from ATCC® 19115™*
- 0353 *Pseudomonas aeruginosa* derived from ATCC® 27853™*
- 0484 *Pseudomonas paraeruginosa* derived from ATCC® 9027™*
- 0363 *Salmonella enterica* subsp. *enterica* serovar Typhimurium derived from ATCC® 14028™*
- 0485 *Staphylococcus aureus* subsp. *aureus* derived from ATCC® 6538™*
- 0803 *Zygosaccharomyces rouxii* derived from ATCC® 28253™*

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CUSTOM ENVIRONMENTAL MONITORING CONTROLS

Your strain. Your format. Your convenience.

We simplify environmental isolate and objectionable organism testing by providing a complete solution to help you meet FDA, USDA and other regulations and guidelines. Using your environmental isolate or targeted objectionable organism, we manufacture test-ready controls quantitated for specific Pharmacopeia methods and more.

Our experts have developed custom environmental isolate and objectionable organism controls for thousands of pharmaceutical and personal care manufacturers. If you are curious about our capabilities, see examples of strains we have successfully developed in various Microbiologics product formats below.

Examples of strains made into custom controls:

- *Bacillus cereus*
- *Burkholderia multivorans*
- *Enterobacter aerogenes*
- *Enterobacter cloacae*
- *Enterococcus species*
- *Escherichia coli* (O157:H7)
- *Klebsiella pneumoniae*
- *Kocuria rhizophila*
- *Legionella pneumophila*
- *Listeria monocytogenes* (serotype 4b)
- *Pseudomonas aeruginosa*
- *Salmonella Weltevreden*
- *Serratia marcescens*
- *Staphylococcus aureus*
- *Vibrio cholerae*

PHARMACEUTICAL AND PERSONAL CARE PARTNERSHIPS

Controls designed for your unique instrument and assay.

We partner with biotechnology instrument and assay manufacturers to provide the most advanced biological control materials in support of their important work. Whether it's for research and development, validation, verification or routine quality control, Microbiologics is a globally trusted partner for simple, reliable biomaterials. We combine our extensive expertise, state-of-the-art technologies and world-class support to produce the highest quality microbial controls tailored to your specifications.

We specialize in developing user-friendly products that accelerate commercialization and increase adoption of your assay in the market. Analyzing your unique approach, we help you design a qualification program and ongoing control strategy tailored to your platform and assays. When you are ready to submit your assay for regulatory clearance, you will have a fully tested product with a guided path for launch.

Microbiologics®

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