



PHARMACEUTICAL  
MICROBIOLOGY  
CONTROLS

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WE CREATE CONFIDENCE IN SCIENCE



[www.microbiologics.com](http://www.microbiologics.com)

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# ABOUT MICROBIOLOGICS

## MICROBIOLOGICS.COM

In support of our commitment to quality service, we have designed our website to be a helpful, easy-to-use resource for customers. The website is updated regularly and is the best place to obtain the most current information. Listed below are examples of the resources available:

- Digital catalog
- Product descriptions and applications
- End user registration
- Instructions for Use (multiple translations)
- Online ordering
- Contact Us form
- Order management
- Locate a distributor by country
- Safety Data Sheets (multiple translations)
- Customer & Technical Support documents
- Easy-to-use product and document search
- Frequently asked questions (FAQs)
- Certificates of Analysis

## CUSTOMER SERVICE

We take pride in providing you with exceptional customer service. Customer calls are answered by a team of experts ready to assist you with everything from account set up to questions with an order.

All international customers should contact an authorized distributor for ordering information. Locate a distributor in your area by visiting [microbiologics.com](http://microbiologics.com). If an authorized distributor is not listed in your country, please contact Microbiologics Customer Service.

## TECHNICAL SUPPORT

Our team of experienced Technical Support experts are always eager to help customers use our product successfully. They can provide guidance for selecting the right strains and product formats for your unique testing needs, and help problem solve when issues arise in your lab.

Contact Customer Service	
Hours	7:30 a.m. - 5 p.m. (CST)
Phone	1.320.253.7400
US Toll Free	1.800.599.2847
Email	<a href="mailto:info@microbiologics.com">info@microbiologics.com</a>

Contact Technical Support	
Hours	8:00 a.m. - 5 p.m. (CST)
Phone	1.320.229.7045
US Toll Free	1.866.286.6691
Email	<a href="mailto:techsupport@microbiologics.com">techsupport@microbiologics.com</a>

## SAFE, SIMPLE, STABLE CONTROLS

Microbiologics products are compatible with a variety of instruments, kits and applications. Our independent external controls provide accurate, reliable results with convenient test-ready formats that save you time and money. Our controls offer easy and economical storage with no freezing required.

# CUSTOMER INFORMATION

## WORLDWIDE DISTRIBUTION

Our extensive distribution network allows us to reach every corner of the world, from Afghanistan to Zambia. We select distributors that are customer focused and demonstrate a commitment to our mission of providing the highest quality biomaterials for a safer, healthier world. Locate a distributor in your area by visiting [microbiologics.com](http://microbiologics.com).

## INTERNATIONAL CUSTOMERS

All international customers must contact an authorized distributor within their country to place an order. To search for distributors by country, visit [microbiologics.com](http://microbiologics.com). If an authorized distributor is not listed in your country, please contact Microbiologics Customer Service at [info@microbiologics.com](mailto:info@microbiologics.com) or +1.320.253.7400

## U.S. CUSTOMERS

Customers located in the United States may purchase Microbiologics products directly or through an authorized distributor. Visit [microbiologics.com](http://microbiologics.com) to search for distributors in the United States. Orders can be placed online at [microbiologics.com](http://microbiologics.com) or by contacting Customer Service. Be prepared to provide the following information with your order:

- Customer account number
- Registration number
- Billing address
- Telephone number
- Email address
- Fax number
- Shipping address
- Purchase order number
- Credit card information
- Quantities
- Tax exemption information (certified exemption form must be kept on file)
- Microbiologics catalog number or reference culture numbers

Online orders can be placed at [microbiologics.com](http://microbiologics.com) by signing in on the homepage or clicking "Register" to create an account.

## PRODUCT WARRANTY

Microbiologics guarantees results when the product is stored, handled and used as directed (as per the expiration date, Microbiologics Recommended Growth Requirements, Illustrated Instructions and Instructions for Use). Please report concerns to Microbiologics Technical Support immediately. For more information, see the document titled Product Warranty and Product Replacement located at [microbiologics.com](http://microbiologics.com).

## END USER REGISTRATION

An authorized representative from your organization must agree to the terms of the End User Agreement in order to receive Microbiologics biological materials.

Registration can be completed at [microbiologics.com](http://microbiologics.com). Contact Customer Service at +1.320.253.7400 or [info@microbiologics.com](mailto:info@microbiologics.com) with questions about the End User Agreement.



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

## Microbiologics Product Formats

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

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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

&lt;60&gt;

### 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*

&lt;61&gt;

### 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™\*

See all 40+ EZ-Accu Shot™ strains at [www.microbiologics.com](http://www.microbiologics.com).

## 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.



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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™\*

See all 20+ EZ-CFU™ One Step strains at [www.microbiologics.com](http://www.microbiologics.com).



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## 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™\*

See all 20+ EZ-CFU™ strains at [www.microbiologics.com](http://www.microbiologics.com).

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# METHOD SUITABILITY TESTING

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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.



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 paraaeruginosa* 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™\*

See all 50+ Epower™ strains at [www.microbiologics.com](http://www.microbiologics.com).

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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™\*

See all 40+ EZ-Accu Shot™ strains at [www.microbiologics.com](http://www.microbiologics.com).

## 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.



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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  $1.0 \times 10^5$  to  $1.0 \times 10^6$  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  $1.0 \times 10^5$  to  $1.0 \times 10^6$  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™\*

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# 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™\*

See all 60+ KWIK-STIK™ Plus strains at [www.microbiologics.com](http://www.microbiologics.com).

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# DISINFECTANT EFFICACY TESTING

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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 paraaeruginosa* 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™\*

See all 50+ Epower™ strains at [www.microbiologics.com](http://www.microbiologics.com).

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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™\*

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# MYCOPLASMA TESTING

USP <63> | PH. EUR. 2.6.7

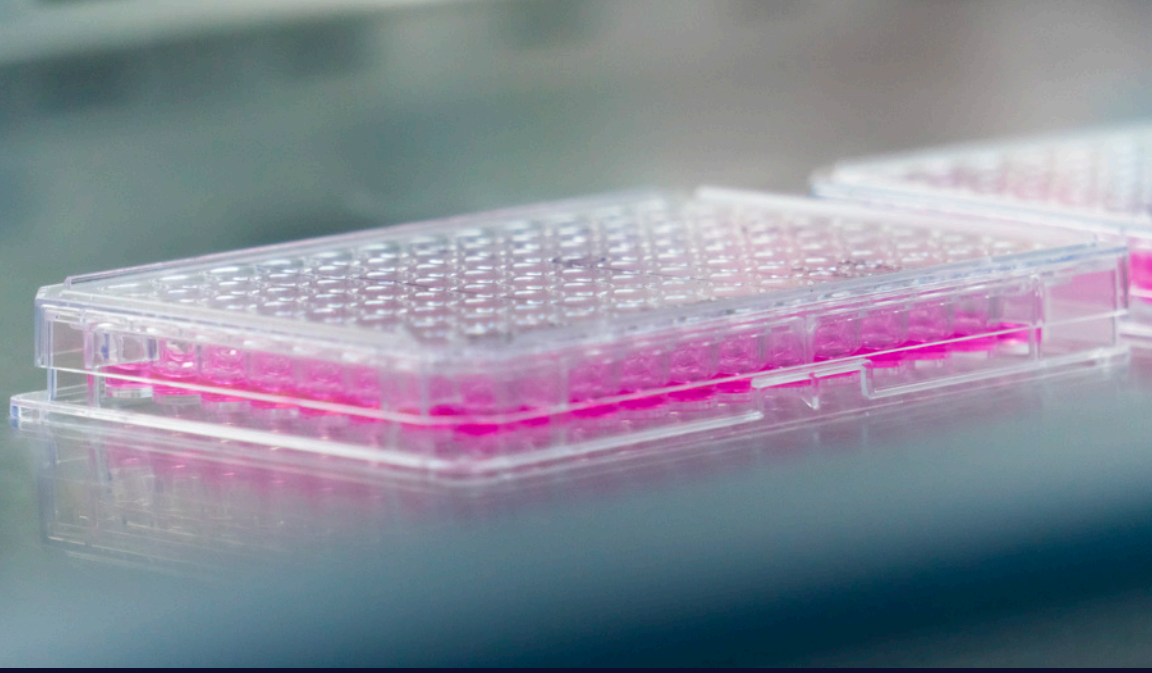
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As the use of cell lines to produce biopharmaceuticals continues to increase, Mycoplasma testing is a growing quality control challenge. Because of its unique properties, Mycoplasma poses many challenges for detection and management. Mycoplasma contamination 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**

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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.









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 paraaeruginosa* 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*

See more examples at [www.microbiologics.com](http://www.microbiologics.com).

# 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.



# PAYMENT AND SHIPPING

## PAYMENT OPTIONS

Microbiologics accepts payment by the following methods:

- ACH
- Check (payable to Microbiologics, Inc.)
- Credit card
- Money order
- Wire transfer

**Important:** To ensure your payment is processed accurately, please note your account number and the invoice number on all correspondence and payments.

## Credit Card Purchases

Microbiologics welcomes the use of VISA®, MasterCard® and American Express®.

## Terms

- All invoices are payable “Net 30 Days” (with the exception of credit card payments)
- Past due accounts are subject to finance charges of 1.5% per month
- All payments are paid in United States Dollars (USD)
- A royalty fee will be charged on behalf of the culture collection.
- If not reflected on an invoice, the purchaser is responsible for all applicable State Sales and Use Taxes
- When paying by wire transfer the customer is responsible to pay all applicable transfer fees. Please email Microbiologics Customer Service at [info@microbiologics.com](mailto:info@microbiologics.com) to review options for wire transfer fee payments.

## SHIPPING AND DELIVERY

Orders are shipped within 48 hours except when a specific shipping date is requested. All shipments are EXW (Ex Works) Saint Cloud, Minnesota, unless prior arrangements are made. Lyophilized microorganisms are identified as Biological Substance Category B or Infectious Substance and are subject to regulated packaging materials, special labeling and special shipping requirements. All shipping and handling charges will be listed as separate line items on the invoice.

Products are shipped at ambient temperature unless otherwise requested. The outside of the shipping container is identified with the notation “refrigerate upon receipt” to assure proper handling and storage upon arrival. Due to the nature of our products, we are unable to accept returns. If any product arrives in a damaged condition, the carrier must note the condition on the delivery receipt. All claims for products damaged during shipment must be made within 30 days of receipt. Microbiologics guarantees the performance of our products at all times. If at any time you are dissatisfied with our products or service, please contact our Customer Service team at 1.320.253.7400 or [info@microbiologics.com](mailto:info@microbiologics.com) for resolution.



[www.microbiologics.com](http://www.microbiologics.com)



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