



EZ-Accu Shot™, EZ-Accu Shot™ *Select* and
The Growth Promotion Test

Accuracy and traceability have never been easier or more affordable.



Licensed, Traceable Growth Promotion Testing.

- Authentic and licensed strains
- Meets the requirements for USP, JP and Ph. Eur.
- Delivers <100 CFU per 0.1mL
- Eight hour stability
- Pellets dissolve instantly
- Traceable to **ATCC Genuine Cultures**[®]
- Four passages or less from Reference Culture
- 10 inocula per 1.2mL



Look for the ATCC Licensed Derivative[®] Emblem for products derived from ATCC[®] cultures.

Features and Benefits

Features:	Benefits:
Instant dissolve, no pre-incubation	Little to no preparation time
One pellet per vial	Eliminates the need for forceps/Reduces risk of contamination
Lower price than competitive products	Cost effective/Economical
Eight hour stability	Extended time & flexibility to perform tests
Increased precision in CFU count	Increased customer confidence
Does not require freezing storage condition	Reduces shipping costs/Easy storage/No dry ice
Peel-off Certificate of Assay Label	Complete and convenient documentation
Online Certificate of Analysis	Documentation of phenotypic, macroscopic and microscopic test results
Authentic ATCC Licensed Derivative® Strains	USP recommended/ Traceable/ Assured quality



Look for the ATCC Licensed Derivative® Emblem for products derived from ATCC® cultures.



Kit Includes:

- 5 vials of a single enumerated microorganism (1 lyophilized pellet per vial)
- 5 vials of hydrating fluid (1.2 mL per vial)
- Peel-off Certificate of Assay



Licensed, Traceable Strains

Cat. No.	Description
0392A	<i>Aspergillus brasiliensis</i> ATCC® 16404™*
0486A	<i>Bacillus subtilis</i> subsp. <i>spizizenii</i> ATCC® 6633™*
0443A	<i>Candida albicans</i> ATCC® 10231™*
0317A	<i>Clostridium sporogenes</i> ATCC® 19404™*
0487A	<i>Clostridium sporogenes</i> ATCC® 11437™*
0483A	<i>Escherichia coli</i> ATCC® 8739™*
0484A	<i>Pseudomonas aeruginosa</i> ATCC® 9027™*
0485A	<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC® 6538™*
0363A	<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Typhimurium</i> ATCC® 14028™*



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accu shot™
GROWTH PROMOTION TESTING

**Five Compendial Strains.
One Convenient Package.**

Select



Kit Includes:

- 5 **different** compendial strains (1 lyophilized pellet per vial)
- 5 vials of hydrating fluid (1.2 mL per vial)
- 5 peel-off labels (1 for **each** strain)

A safer, healthier world.





accu shot™
GROWTH PROMOTION TESTING

**Five Compendial Strains.
One Convenient Package.**

Select

Licensed, Traceable Strains:



Cat. No.	Description
0392A	<i>Aspergillus brasiliensis</i> ATCC® 16404™*
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A safer, healthier world.



The Growth Promotion Test

- Each new batch of medium used in a pharmaceutical laboratory must be tested in order to confirm that the medium will grow organisms such as *Staphylococcus aureus*, *Candida albicans* and *Aspergillus brasiliensis*.
- The new medium must be tested with a small number of microorganisms (≤ 100 CFU).
- The Growth Promotion Test is harmonized in the Ph. Eur., USP and JP.
- Microorganisms must not be more than 5 passages from Reference Culture (master seed lot). Use microorganism strains recommended by harmonized pharmacopeias.

Four Growth Promotion Test Products

EZ-Accu Shot™ <i>Select</i>	EZ-Accu Shot™	EZ-CFU™ One Step	EZ-CFU™
For small volume user	For small volume user	For small volume user	For large volume user
Delivers <100 CFU/0.1mL	Delivers <100 CFU/0.1mL	Delivers <100 CFU/0.1mL	Delivers <100 CFU/0.1mL
No dilution step	No dilution step	No dilution step	One dilution step
10 tests per vial	10 tests per vial	19 tests per vial	>90 tests per vial
Stable for 8 hrs. after hydration, when refrigerated	Stable for 8 hrs. after hydration, when refrigerated	Stable for 8 hrs. after hydration, when refrigerated*	
Quick-dissolve	Quick-dissolve	Pre-warm 30 minutes	Pre-warm 30 minutes
5 different strains per kit	1 strain per kit	1 strain per kit	1 strain per kit

* Exceptions are 0318Z and 0320Z.

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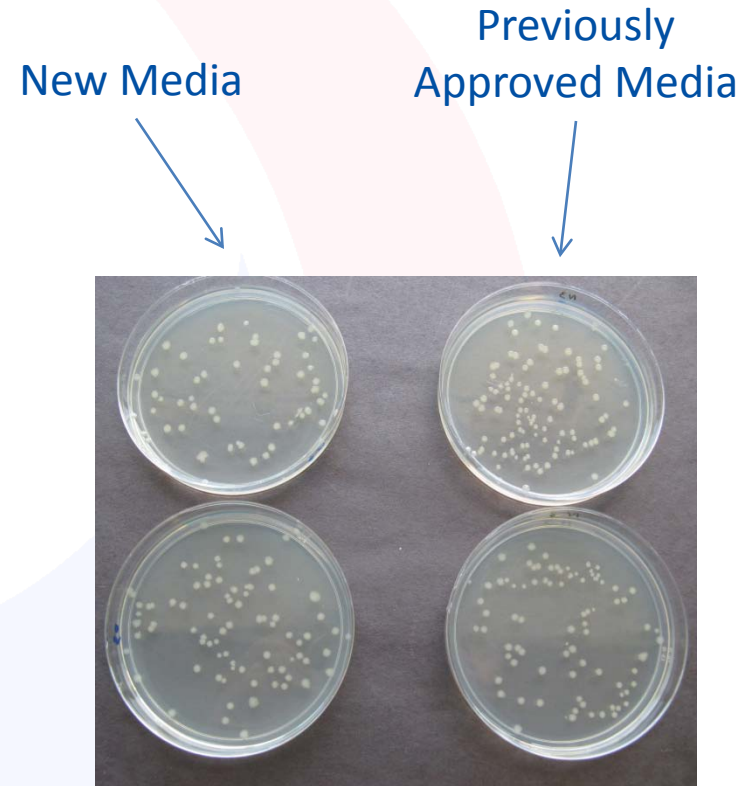


Pharmacopeia Instructions for Testing

- Inoculate medium with 100 CFU or less.
- Incubate medium according to pharmacopeia directions.
- If using agar, count the colonies.
- If the new agar is to be used for microbial enumeration tests, the number of colonies should be within a factor of two from the number of colonies on the previously approved medium. Examples of agar are Soybean Casein Agar and Sabouraud Dextrose Agar.
- If the new agar is to be used in tests for specified microorganisms (for example, *Salmonella*), the number of colonies on the new medium should be “comparable” to the number of colonies on the previously approved medium.

Microbiologics Recommendations for Ensuring Satisfactory Results

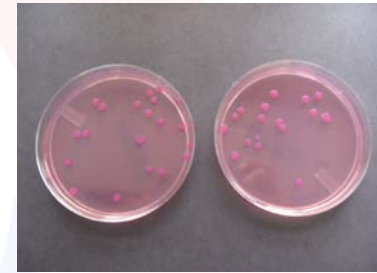
- For best results, use parallel testing instead of historical data for comparing new medium to previously approved medium.
- When using parallel testing, the new media and the previously approved media are inoculated with the same inoculum by the same technician and are subjected to identical incubation conditions.
- The only variable is the media.



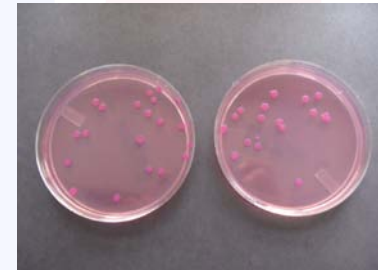
Microbiologics Recommendations for Ensuring Satisfactory Results

- If testing selective media, test nonselective media at the same time because recovery on selective media is not as high as on nonselective media.
- The nonselective agar should grow less than 100 colonies.
- Remember, the count on the new media does not have to be within a factor of 2 from the count of the previously approved media. For **selective** media the count only needs to be “comparable”.

Previously Approved
Selective Media



New Selective Media



Nonselective Media



Microbiologics Recommendations for Ensuring Satisfactory Results

- If using historical data to compare new media to previously approved media, use the same lot of microorganisms for both tests.
- Let the vial of pellets equilibrate to room temperature before opening it.
- Use a spreader to disperse the inoculum over the entire plate.
- Vortex suspensions until they are homogeneous. Remix suspension between inoculations.
- Follow pharmacopeia directions for temperature and incubation time.
- Calibrate pipette routinely and validate thermometers and incubators yearly.

Important Things to Remember

- Microbiologics guarantees that the customer will get <100 colonies per 0.1mL when using EZ-Accu Shot™, EZ-Accu Shot™ Select, EZ-CFU™ One Step or EZ-CFU™ as directed. Customers won't necessarily get the value on the Certificate of Assay because of different methods, different conditions, different techs, etc.
- 21 CFR 211.165 Testing and release for distribution... (b) There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of **objectionable microorganisms**.
 - Not just free from USP specified organisms.

Helpful Resources

- [Microbiologics Support Center - Product Inserts](#)

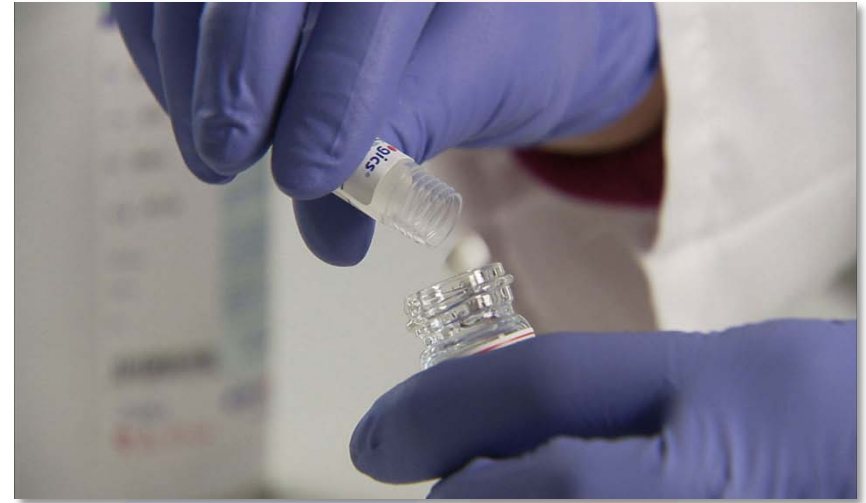
- [EZ-Accu Shot Video Demonstration](#)

- Growth Promotion Test Guide and Verification Protocol Guides for EZ-Accu Shot™ and EZ-CFU™ One Step [Microbiologics Support Center - Technical Information Bulletins](#)

- [Pharmaceutical Microbiology Forum \(PMF\):](#)
 - **PMF Newsletter:** a publication of the Pharmaceutical Microbiology Forum.
 - **PMF List:** provides a forum for the exchange of ideas concerning microbiology ideas and experiences. The list uses email.

- [European Directorate of the Quality of Medicines and HealthCare \(EDQM\):](#) a question and answer list concerning the harmonized chapters and the growth promotion tests. You need to search by number. Enter 2.06.12 or 2.06.13.

Quick and Easy Steps



1. Remove one hydrating fluid vial and one foil pouch containing the lyophilized microorganism pellet from canister. Remove vial from pouch. Allow unopened vials to equilibrate to room temperature.

2. Tip the microorganism pellet into the 1.2mL vial of hydrating fluid. Recap hydrating fluid vial.

Quick and Easy Steps



- 3.** Vortex hydrated material for a few seconds to achieve a homogenous suspension.
Pellet dissolves instantly.

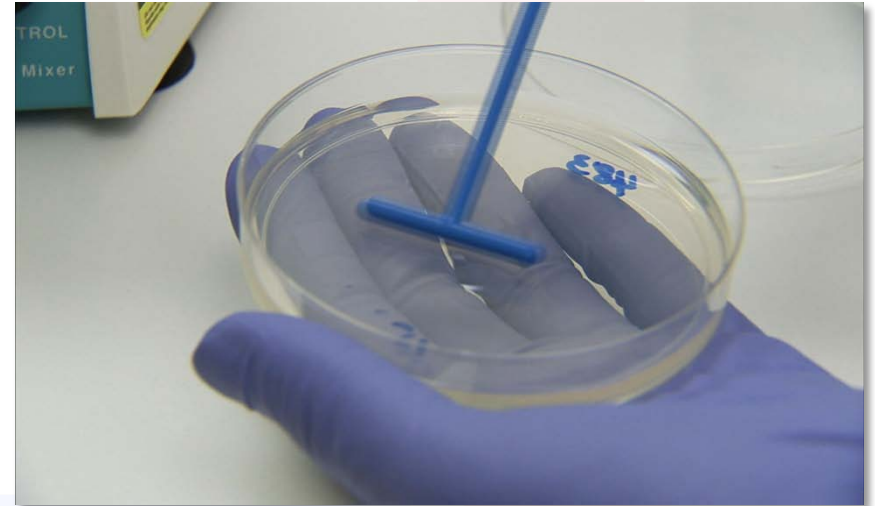


- 4.** Using a sterile pipetter, remove 0.1 mL of the suspension.

Quick and Easy Steps



5. Transfer 0.1 mL suspension to media plate.

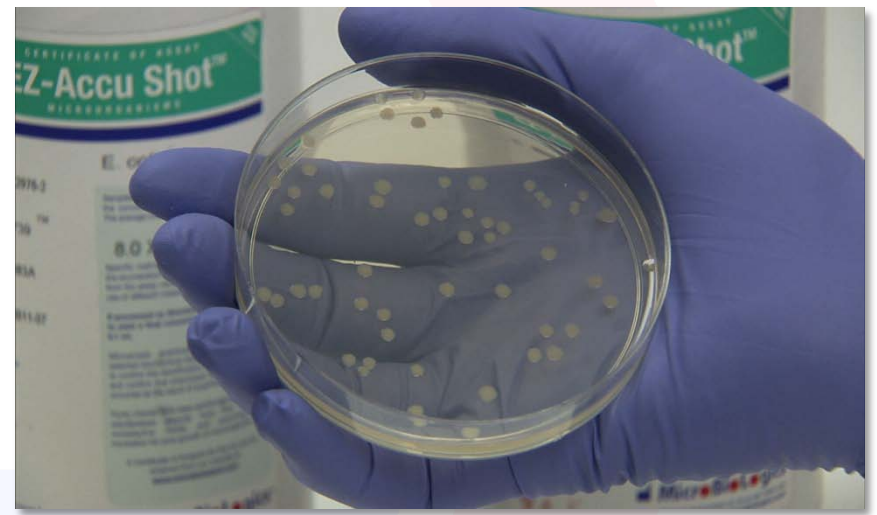


6. Spread inoculum evenly across plate.

Quick and Easy Steps



7. Incubate according to
USP, JP, Ph. Eur. requirements.



8. Count colonies.

To place an order, contact your authorized distributor, or Microbiologics Customer Service.

Customer Service

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Fax: 320.253.6250

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Web: www.microbiologics.com



EZ-Accu Shot™ and EZ-Accu Shot™ Select are not intended for clinical use.

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