

Comparative Evaluation of Microbiologics® EZ-Accu Shot™ and bioMérieux BIOBALL® for Media Qualification Testing

Dustin A. Baird, Alec Shalk, Anna F. Lau

Sterility Testing Service, Department of Laboratory Medicine, Clinical Center, National Institutes of Health, Bethesda, MD



INTRODUCTION

- Commercial availability of quantified organisms has enabled streamlined approaches for growth promotion testing and lot-to-lot comparison testing of microbiological media.
- At the NIH Sterility Lab, incoming quantified organisms are qualified for the first lot and/or shipment each calendar year. After annual qualification, quantified organisms are released based on Certificate of Analysis (COA) by the manufacturer.
- The NIH Sterility Lab has used the Microbiologics® EZ-Accu Shot™ (advertised as providing 10-100 CFU/inoculum) since 2018. A trend in consistently low CFU (≤ 10 CFU) recovery from a single lot of *Candida albicans* and poor recovery of *Aspergillus brasiliensis* from BacT/ALERT® iFA Plus bottles prompted this side-by-side product evaluation.
- This study compares the performance of Microbiologics® EZ-Accu Shot™ and bioMérieux BIOBALL® using 6 USP QC strains.

METHODS

Table 1. Number of Unique Lots Evaluated

Organism	EZ-Accu Shot™	BIOBALL®	Media Evaluated
<i>B. spizizenii</i> ¹	33	3	TSA, TSALT, TSASB
<i>S. aureus</i> ¹	35	2	
<i>P. paraeruginosa</i> ¹	34	4	
<i>C. sporogenes</i> ¹	21	2	
<i>C. albicans</i> ^{2,3}	42	5	TSA, TSALT, TSASB, SDA, SDALT
<i>A. brasiliensis</i> ^{2,3}	39	4	

- Bacteria on TSA, TSALT, and TSASB incubated at 30-35°C for 24-72 hours.
- Fungi on TSA, TSALT, and TSASB incubated 30-35°C for 48-120 hours.
- Fungi on SDA and SDALT incubated 20-25°C for 48-120 hours.

- A total of 2,584 EZ-Accu Shot™ tests were conducted but only 1,792 were used in analysis because 792 had statistical errors in the manufacturer's COA.
- A total of 194 BIOBALL® tests analyzed.

ACKNOWLEDGEMENTS

This work was supported by the Intramural Research Program of the National Institutes of Health. The content is solely our responsibility and does not represent the official views of the National Institutes of Health.

RESULTS

Figure 1. Percentage of tests that fall within 95% confidence interval (CI) as published on the manufacturer's COA. (A) EZ-Accu Shot™ ; (B) EZ-Accu Shot™ adjusted; (C) BIOBALL®

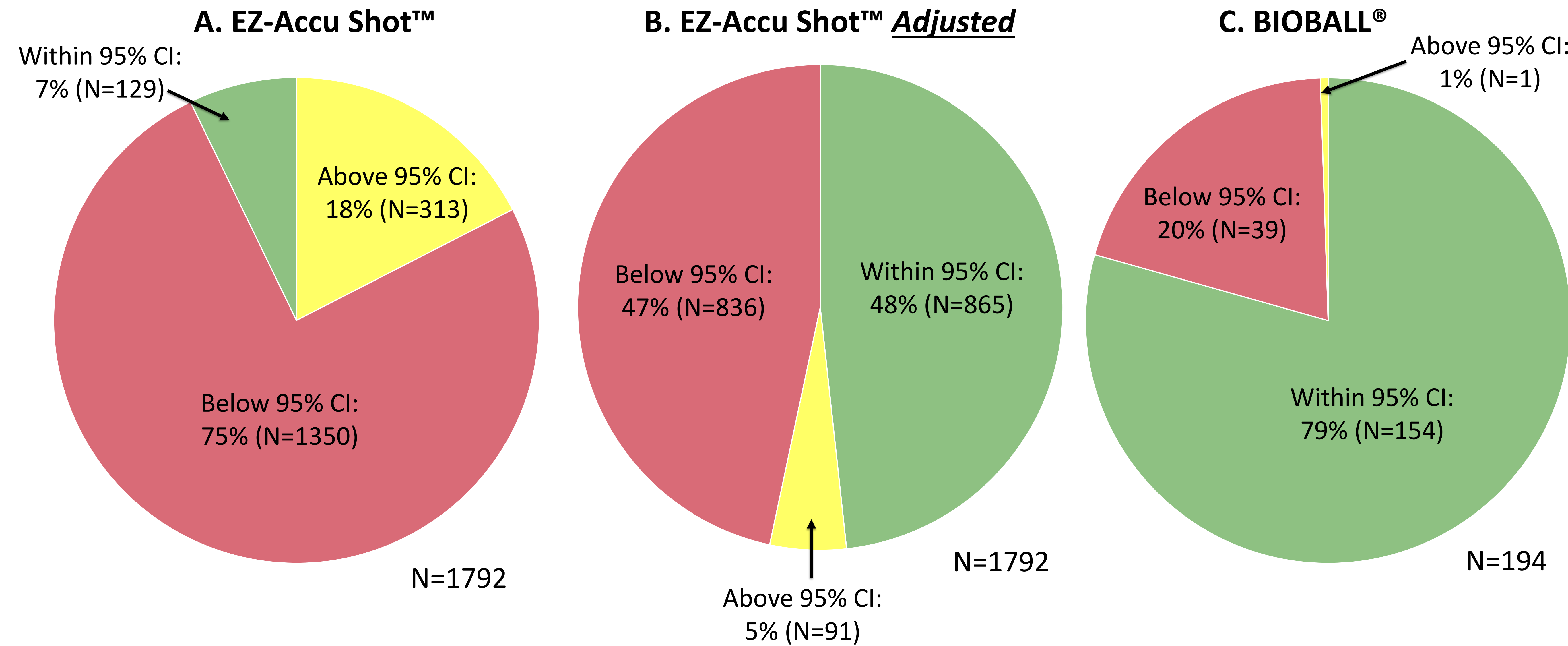
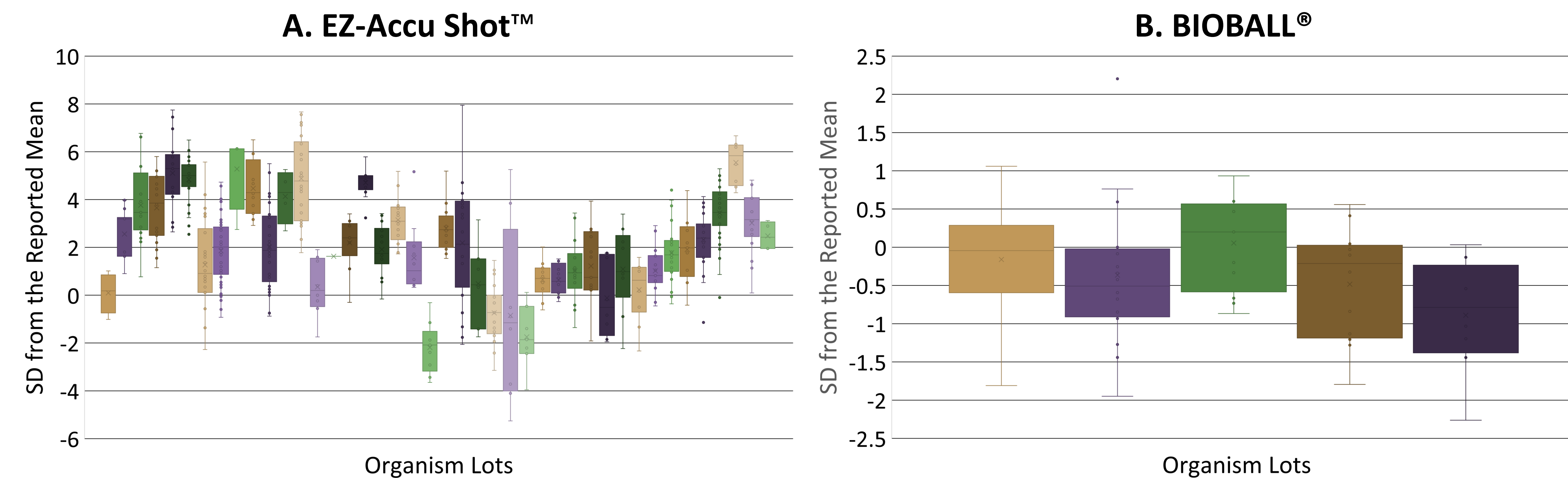


Table 2. Percentage of Tests within 95% CI by Organism

Organism	EZ-Accu Shot™	EZ-Accu Shot adjusted	BIOBALL®
<i>B. spizizenii</i>	4.9%	53.5%	100.0%
<i>S. aureus</i>	12.5%	72.0%	100.0%
<i>P. paraeruginosa</i>	2.9%	26.4%	96.4%
<i>C. sporogenes</i>	0.0%	25.0%	92.9%
<i>C. albicans</i>	8.0%	47.6%	96.8%
<i>A. brasiliensis</i>	7.6%	44.9%	33.3%

- BIOBALL® performed well for all organisms except for *A. brasiliensis* where only 33.3% fell within 95% CI as published in the COA.
- EZ-Accu Shot™ had consistently low results even when 95% CI were adjusted offline using the manufacturer's mean ± 1.96 standard deviation as published in the manufacturer's COA.

Figure 2. *C. albicans* test data across multiple lots compared with manufacturer's published mean in the COA.



- Figure 2A.** *C. albicans* test data from EZ-Accu Shot™ has wide range of standard deviation between 42 lots (-6 to +8).
- Figure 2B.** *C. albicans* test data from BIOBALL® was highly reproducible across 5 different lots.

CONCLUSIONS

- BIOBALL® was highly reproducible across 194 tests for all 6 organisms studied.
- BIOBALL® end user data aligned with manufacturer's published 95% CI in the COA significantly better than EZ-Accu Shot™ ($p < 0.0001$).
- Test condition variations (media, incubation conditions, time to product expiration) did not impact results (data not shown).
- Time to detection on the BacT/ALERT® (iFA Plus and iFN Plus) was faster with BIOBALL® organisms compared with EZ-Accu Shot™ (data not shown).