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Credible leads to Incredible®

Ready-to-use Quantitative Microorganisms for Quality Control Testing

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Abstract

Ready-to-use quantified microbial standards are of significant value for improving end-user workflows and turnaround times in compendial release assays used in the manufacture of biopharmaceutical products and cosmetics. Quantitative preparations of microbial controls are traditionally produced from the dilution of saturated growth culture; however, such techniques demand significant efforts to obtain the desired concentration. Traditional techniques also require revalidation of the cultures at a defined interval to ensure compliance to prescribed standards. While multiple companies have quantitative microbial products on the market that are based on microbial materials sourced from ATCC, they either require longer and more involved assay preparation time or require lower storage temperature (-10°C to -20°C). In order to satisfy the need for quantitative compendial controls that deliver a fast turnaround time with minimal handling, we have developed our best-in-class microbial quality control strains in a novel single-use, ready-to-use, discretely quantitative pellet format. These quantitative controls are directly from a USP-cited strain source-of-origin and demonstrate consistent lot-to-lot quantitation, immediate rehydration at room temperature, and stable storage at refrigeration temperature (2-8°C).

Application of MicroQuant™ high (HQ) and low (LQ) titer pellets

Table 1: Application of MicroQuant™ products

Species	ATCC® No.	Compendial assays*				Other industry uses
		USP <51>	USP <61>	USP <62>	USP <71>	
<i>Aspergillus brasiliensis</i>	16404-HQ-PACK™	✓				Food, media, QC, & pharma testing
	16404-LQ-PACK™		✓		✓	
<i>Bacillus spizizenii</i>	6633-HQ-PACK™					Food, media, QC, & pharma testing
	6633-LQ-PACK™		✓		✓	
<i>Candida albicans</i>	10231-HQ-PACK™	✓				Food, media, QC, & antimicrobial testing
	10231-LQ-PACK™		✓	✓	✓	
<i>Escherichia coli</i>	8739-HQ-PACK™	✓				Water, food, media, QC, & pharma testing
	8739-LQ-PACK™			✓		
<i>Pseudomonas paraeruginosa</i>	9027-HQ-PACK™	✓				Water, media, QC, & pharma testing
	9027-LQ-PACK™		✓	✓	✓	
<i>Staphylococcus aureus</i>	6538-HQ-PACK™	✓				Food, media, QC, & water testing
	6538-LQ-PACK™		✓	✓	✓	

*USP <51>: Antimicrobial Effectiveness Test; USP <61>: Microbial Enumeration Test; USP <62>: Tests for Specified Microorganism; USP <71>: Sterility Testing

Schematic use of MicroQuant™

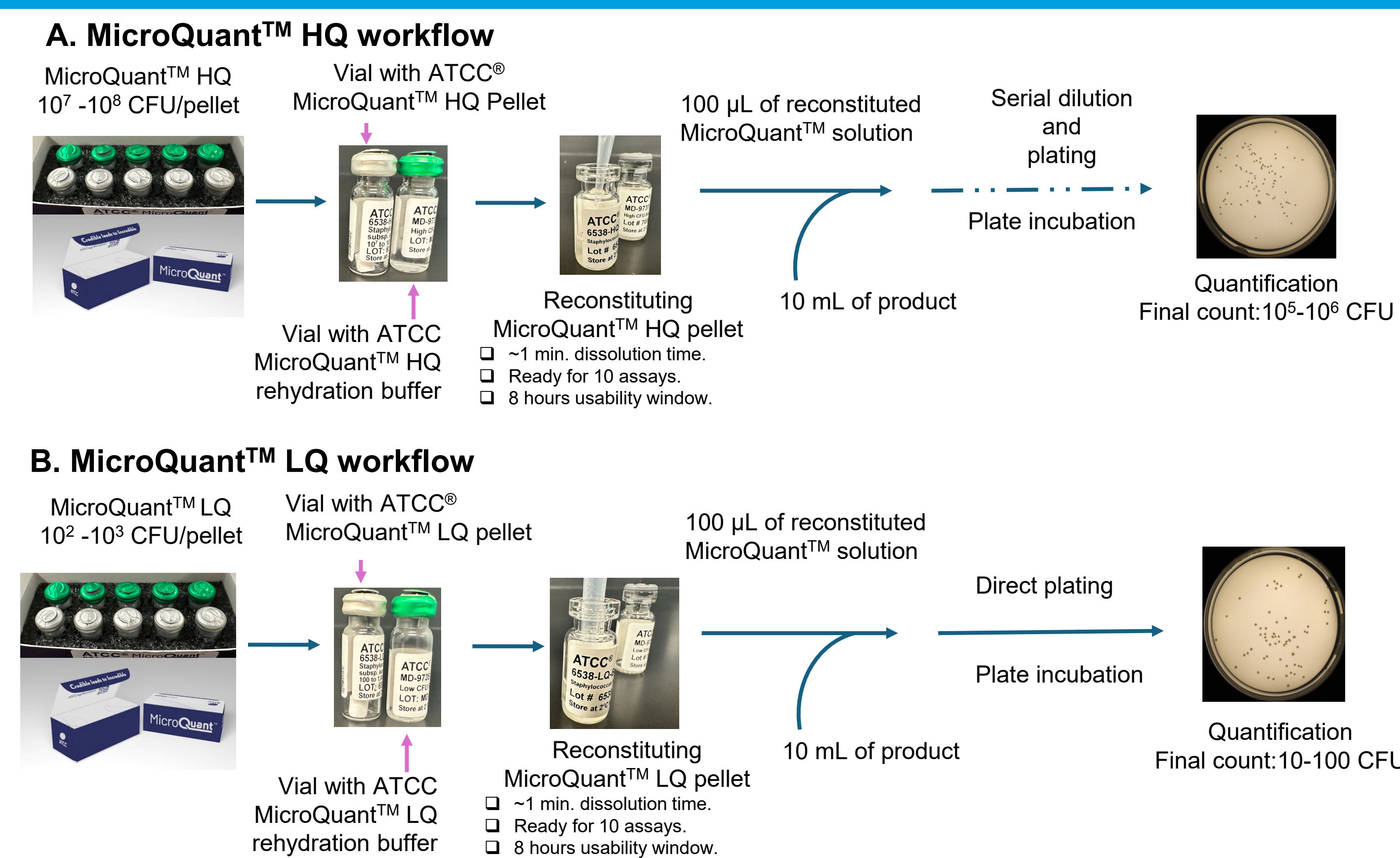


Figure 1: MicroQuant™ assay workflow. (A) MicroQuant™ HQ assay workflow. (B) MicroQuant™ LQ assay workflow. In brief, the MicroQuant™ product is supplied as a kit; each kit contains five pellets of a specific organism (either HQ or LQ) and individual rehydration buffers.

Variation of MicroQuant™ colony forming unit (CFU)

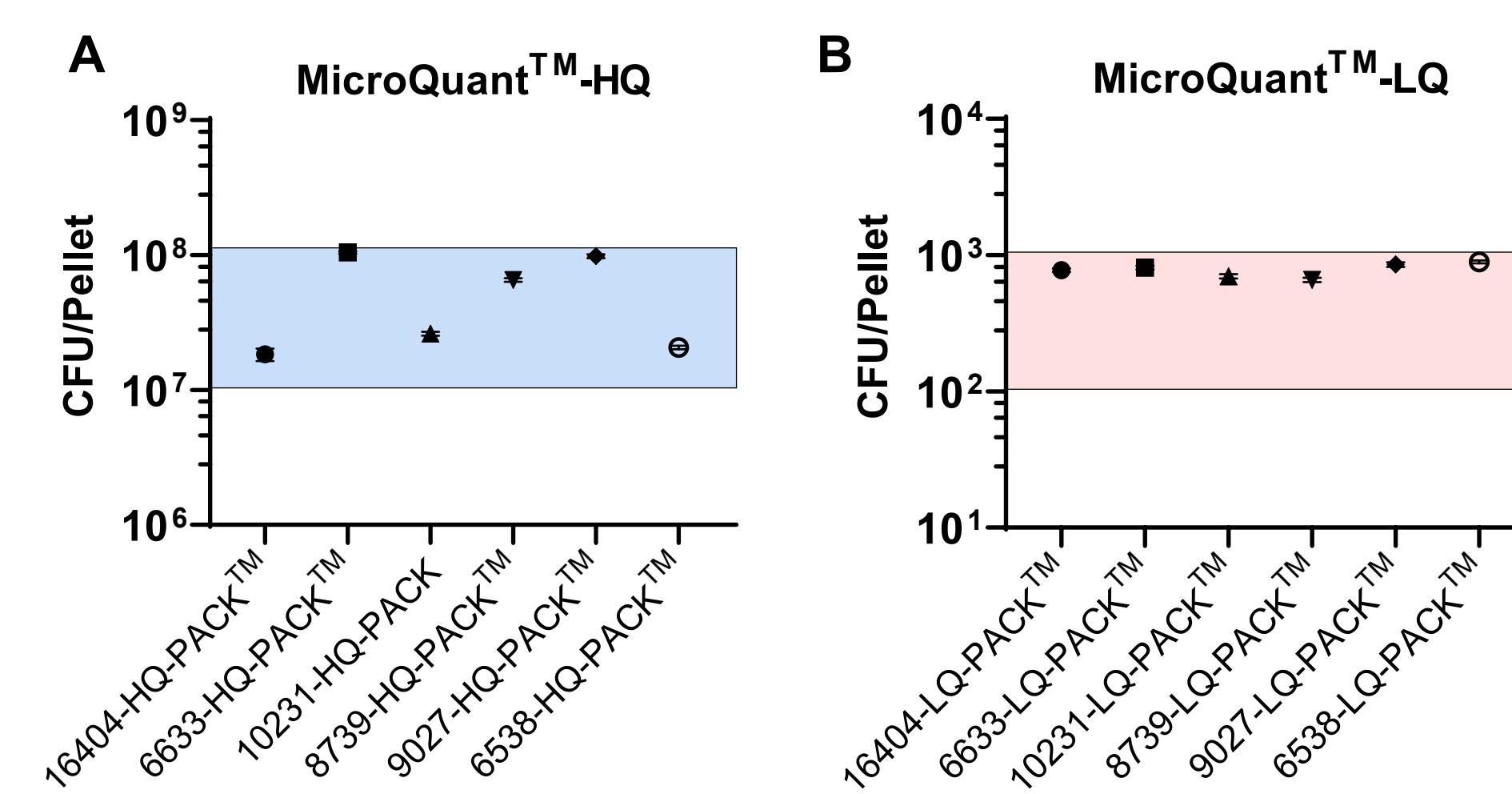


Figure 2: Variation of MicroQuant™ colony forming units (CFU) from three separate batches. Assay property values for the pellets of (A) MicroQuant™ HQ and (B) MicroQuant™ LQ products. The data were obtained from three independent batches, twenty-seven pellets total, two technical replicates each. The assay was performed by three analysts. Mean CFU and SEM for all analyses are shown. The blue and purple box indicates the product specification for the MicroQuant™ HQ and LQ, respectively. CFU of the products was determined as described in Figure 1.

Short-term stability (usability) of ATCC® MicroQuant™

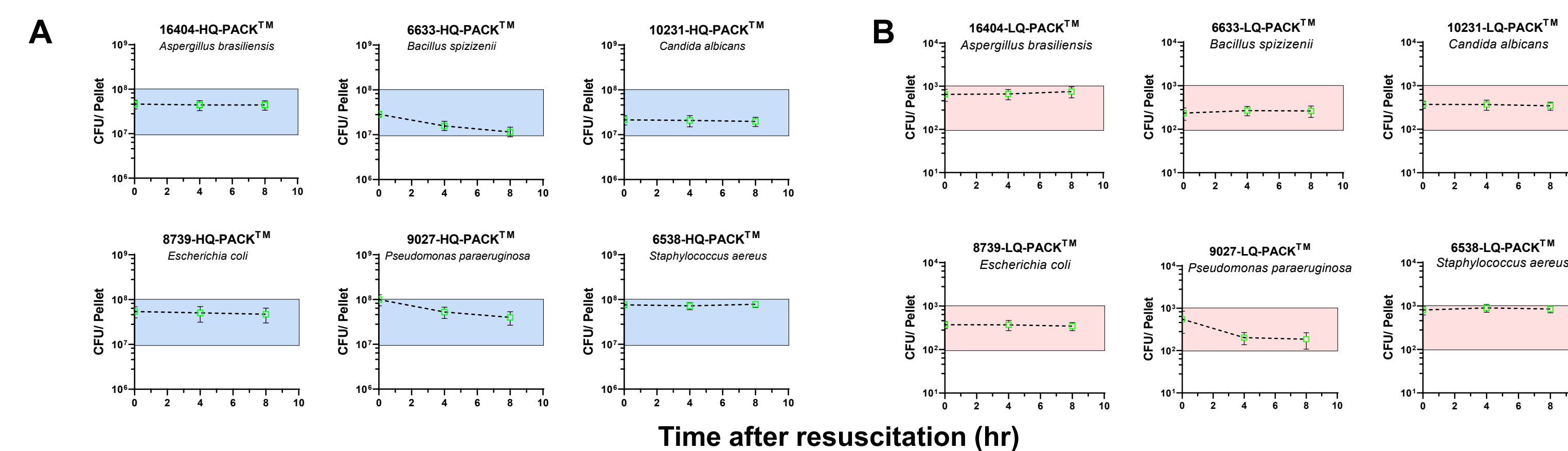


Figure 3: Short-term stability of MicroQuant™ after rehydration. Assay property values for the pellets of (A) MicroQuant™ HQ and (B) MicroQuant™ LQ products were resuscitated in rehydration buffer and then immediately diluted and plated (HQ) or plated (LQ) for "0 hour" reading. The remaining amounts of resuscitated samples were stored at 4°C. Samples were removed from storage at specified intervals and were then diluted and plated (HQ) or directly plated (LQ). Plates were incubated and CFUs were counted following ATCC's guidelines. The blue and purple boxes indicate product specification for the MicroQuant™ HQ and LQ, respectively. Above each panel, product number, and microorganism names are included.

Transportation stability of ATCC® MicroQuant™

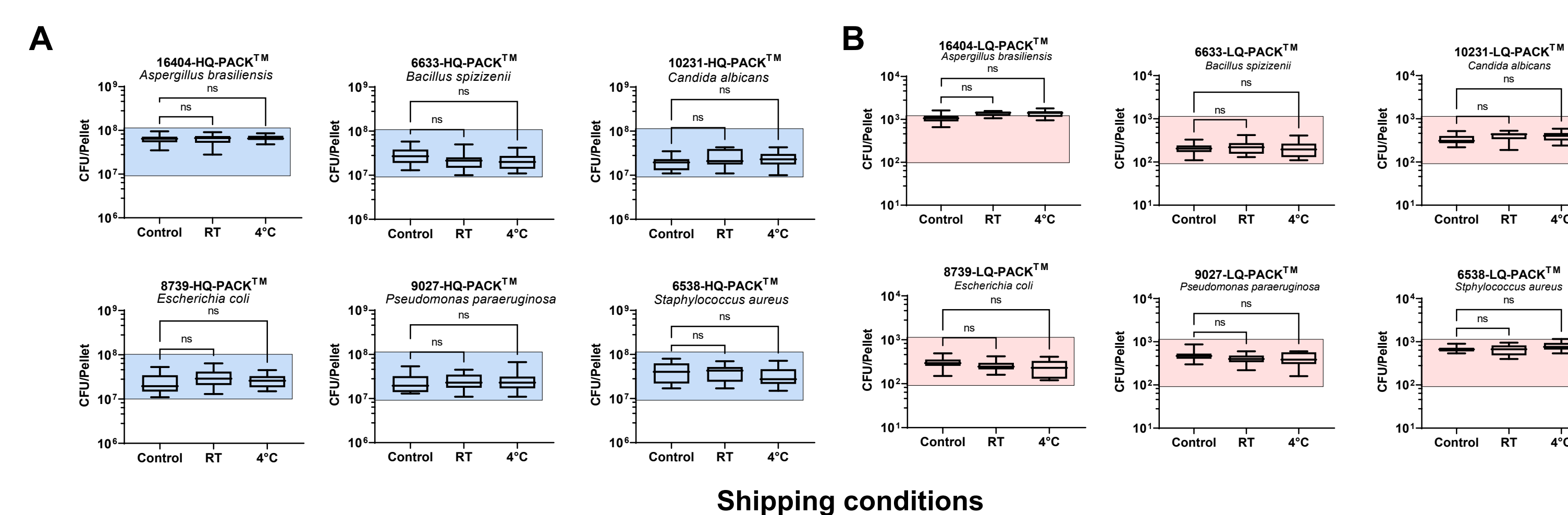


Figure 4: Comparing the stability of MicroQuant™ products before and after transportation. Assay property values for the pellets of (A) MicroQuant™ HQ and (B) MicroQuant™ LQ products. To assess transportation stability, MicroQuant™ kits were shipped at 2-8°C temperatures. Products were assayed to determine CFU/pellet before and after shipping. The average time during transportation was about 4 days. Control: CFU/pellet of MicroQuant™-HQ or LQ pellets before shipping, RT; CFU/pellet of pellets retrieved after room temperature transportation (Average temperature obtained from logger was 24±3°C); 4°C: CFU of pellets retrieved after 4°C transportation (Average temperature obtained from logger was 6±2°C), ns: not significant. Y-axis indicates CFU/pellet values of the product and X-axis indicates shipping conditions. A total of 9 random pellets and two technical replicates were used for CFU/pellet determination. The blue and purple boxes indicate the product specification for the MicroQuant™ HQ and LQ, respectively.

Comparison of processing time and storage condition

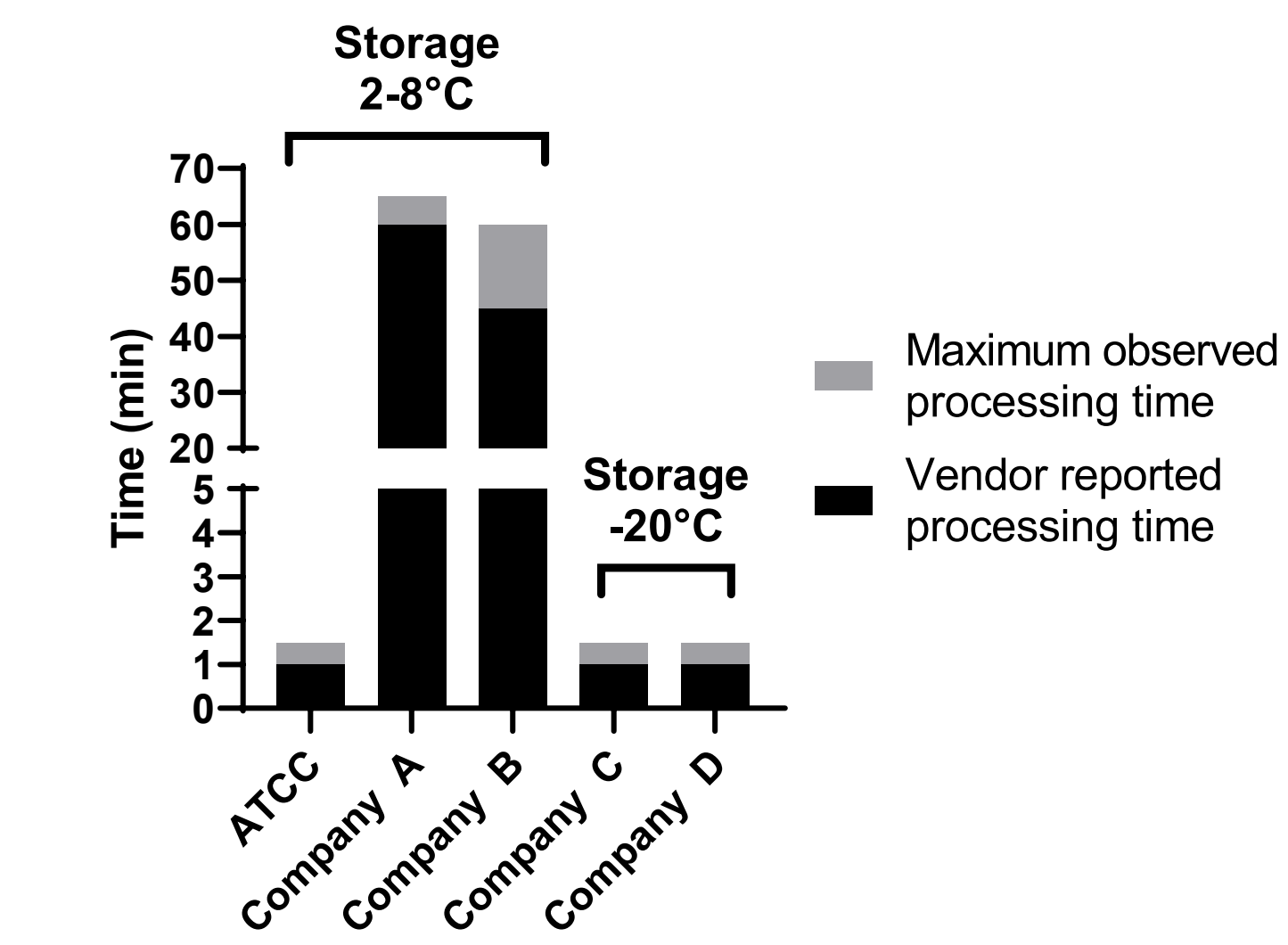


Figure 5: Comparison of processing time and storage temperature among ATCC's MicroQuant™ and other company's product. Processing time for ATCC's MicroQuant™ product is compared with the processing time for the formats available from Company A-D in the market. Storage temperature of ATCC, Company A and B products is 4°C, whereas the storage temperature of Company C and D products is -20°C.

MicroQuant™ stability compared to similar products

Table 2: Shelf-life comparison of MicroQuant™ HQ with products from other companies

Organism	ATCC® No.	Shelf-life of high-titer products (years)				
		ATCC	Company A	Company B	Company C*	Company D*
<i>A. brasiliensis</i>	16404-HQ-PACK™	>2	<2	NA	2	NA
<i>B. spizizenii</i>	6633-HQ-PACK™	>2	<2	NA	NA	<2
<i>C. albicans</i>	10231-HQ-PACK™	>1	<2	NA	2	<2
<i>E. coli</i>	8739-HQ-PACK™	>1	2	NA	2	<2
<i>P. paraeruginosa</i>	9027-HQ-PACK™	1	<2	NA	<2	<2
<i>S. aureus</i>	6538-HQ-PACK™	1	<2	NA	<2	<2
Product storage		4°C			-20°C	

Table 3: Shelf-life comparison of MicroQuant™ LQ with products from other companies

Organism	ATCC® No.	Shelf-life of high-titer products (years)				
		ATCC	Company A	Company B	Company C*	Company D*
<i>A. brasiliensis</i>	16404-LQ-PACK™	>2	<2	>1	<2	<1
<i>B. spizizenii</i>	6633-LQ-PACK™	~2	<2	>1	2	<2
<i>C. albicans</i>	10231-LQ-PACK™	>1	<2	>1	<2	<2
<i>E. coli</i>	8739-LQ-PACK™	1	<2	<1	<2	<2
<i>P. paraeruginosa</i>	9027-LQ-PACK™	1	<2	<1	2	<2
<i>S. aureus</i>	6538-LQ-PACK™	>1	<2	>1	<2	<2
Product storage		4°C			-20°C	

NA – Products were not available from the companies at the time the study was conducted.

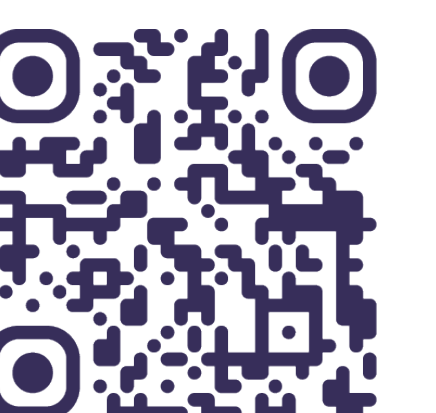
*Equivalent products available from Company C and D, respectively.

Company A-D are products from other companies currently available in the market. ATCC's MicroQuant™ shelf-life is based on a combination of real-time stability studies, accelerated stability studies, and stability modeling.

Conclusions

- ATCC® MicroQuant™ is an innovative product suite designed to streamline microbial quality control testing.
- Precisely quantitated in high-titer (10⁷ to 10⁸ CFU per pellet) and low-titer (100 to 1,000 CFU per pellet) formats.
- Single-use format enables fast assay set up and minimal handling.
- Immediate rehydration at room temperature with 8 hours of usability window.
- Stable storage at 2-8°C.
- Manufactured under an ISO 17034-accredited process.
- Developed from traceable, original source materials.

MicroQuant™



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