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Precisely Quantitated Reference Materials for Microbial Quality Control Testing

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Abstract

MicroQuant™ is ATCC®'s new product line of quantitated microbial reference materials designed for quality control in biopharmaceutical, cosmetic, food safety, and wastewater testing. This novel product suite was developed using an innovative cryopreservation technology to create pre-quantitated microbial strains in a stable pelleted format that delivers consistent and reproducible results, easy workflows, and quick turnaround times. MicroQuant™ meets ISO 17034 standards and supports guidelines from organizations like USP, EP, and JP. Unlike other products, MicroQuant™ controls are made from original ATCC® strains, ensuring better strain identity and authentication. They provide consistent quantitation, instant rehydration at room temperature, and stable storage at 2-8°C. In this study, we highlight the stability of MicroQuant™ products during transport and rehydration, and we showcase how they compare to similar products with regard to processing time, storage, and stability.

Schematic use of MicroQuant™

MicroQuant™ HQ/LQ workflow

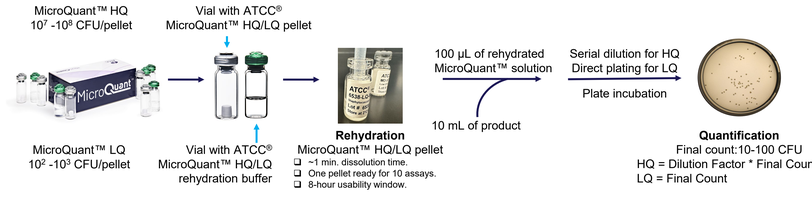

Figure 1: MicroQuant™ assay workflow. MicroQuant™ products are supplied as a kit; each kit contains five pellets of a specific organism (either HQ or LQ titer) and five vials of the respective rehydration buffer.

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

Table 1: Application of MicroQuant™ products

Species	ATCC® No.	Release	Compendial assays*	Other industrial uses
Aspergillus brasiliensis	16404-HQ-PACK™	Available	USP <51>, <1072> | EP5.1.3 | JP19	Food, media, QC, and pharma testing
	16404-LQ-PACK™	Available	USP <61>, <71>, <72>, <2021> | EP2.6.12/13	
Bacillus spizizenii	6633-HQ-PACK™	Available	USP <81> | EP2.7.2	Food, media, QC, and pharma testing
	6633-LQ-PACK™	Available	USP <61>, <71>, <72>, <2021> | EP 2.6.1, 2.6.12, 2.6.27, 2.6.31	
Candida albicans	10231-HQ-PACK™	Available	USP <51>, <1072> | EP5.1.3 | JP19	Food, media, QC, and antimicrobial testing
	10231-LQ-PACK™	Available	USP<61>, <62>, <71>, <72>, <2021> | EP2.6.12/13 | JP4.05	
Escherichia coli	8739-HQ-PACK™	Available	USP <51> | EP5.1.3 | JP19	Water, food, media, QC, and pharma testing
	8739-LQ-PACK™	Available	USP <62>, <2021>	
Pseudomonas paraeruginosa	9027-HQ-PACK™	Available	USP <51> | EP5.1.3 | JP19	Water, media, QC, and pharma testing
	9027-LQ-PACK™	Available	USP <60>, <61>, <62>, <71>, <72>, <2021> | EP2.6.12/13	
Staphylococcus aureus	6538-HQ-PACK™	Available	USP <51>, <1072> | EP5.1.3 | JP19	Food, media, QC, and water testing
	6538-LQ-PACK™	Available	USP <60>, <61>, <62>, <71>, <72>, <2021>	
Burkholderia cepacia	25416-HQ-PACK™	Q3 - 2025		Media, QC, and pharma testing
	25416-LQ-PACK™	Q3 - 2025	USP <60>	
Burkholderia cenocepacia	BAA-245-HQ-PACK™	Q3 - 2025		QC and pharma testing
	BAA-245-LQ-PACK™	Q3 - 2025	USP <60>	
Burkholderia multivorans	BAA-247-HQ-PACK™	Q3 - 2025		QC and pharma testing
	BAA-247-LQ-PACK™	Q3 - 2025	USP <60>	
Clostridium sporogenes	11437-HQ-PACK™	Q3 - 2025		Media, QC, and pharma testing
	11437-LQ-PACK™	Q3 - 2025	USP <62>, <71>, <72> | EP2.6.13 | JP4.05	
Clostridium. sporogenes	19404-HQ-PACK™	Q3 - 2025		Media, QC, and pharma testing
	19404-LQ-PACK™	Q3 - 2025	USP <62>, <71>, <72> | EP2.6.13 | JP4.05	
Salmonella enterica	14028-HQ-PACK™	Q3 - 2025		Food, media, water, QC, and pharma testing
	14028-LQ-PACK™	Q3 - 2025	USP <62> | EP2.6.13 | JP4.05	

*USP- United States Pharmacopoeia; EP- European Pharmacopoeia; JP- Japanese Pharmacopoeia. The numbers after the USP, EP, and JP indicate the chapters of the respective Pharmacopoeia.

Quantitation of MicroQuant™ production batches

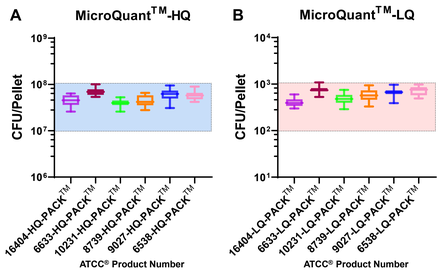

Figure 2: Analysis of MicroQuant™ colony forming units (CFU) per pellet from production batches. Assay property values for (A) MicroQuant™ HQ and (B) MicroQuant™ LQ products. The data were obtained from nine random pellets per product with two technical replicates; the assay was performed by three independent analysts. Mean CFU/pellet and minimum and maximum CFU/pellet values are shown here. The blue and red shaded regions indicate the product specification for the MicroQuant™ HQ and LQ, respectively. CFU of the products was determined as described in Figure 1.

Transportation stability of ATCC® MicroQuant™

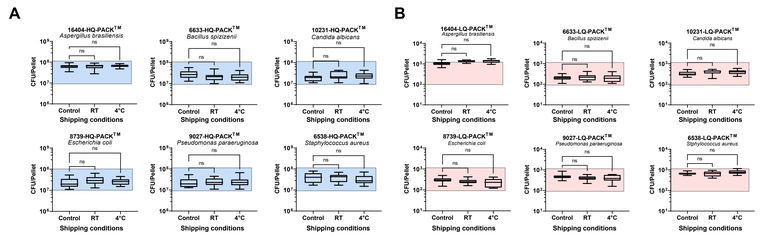

Figure 3: Comparing the stability of MicroQuant™ products before and after transportation. Assay property values for the pellets of (A) MicroQuant™ HQ and (B) MicroQuant™ LQ products. To assess transportation stability, MicroQuant™ kits were shipped at 2-8°C temperatures. Products were assayed to determine 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. The Y-axis indicates the CFU/pellet values of the product, and the X-axis indicates shipping conditions. A total of 9 random pellets and two technical replicates were used for CFU/pellet determination. The blue and red boxes indicate the product specification for the MicroQuant™ HQ and LQ, respectively.

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

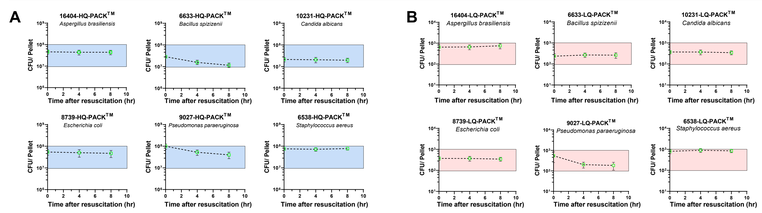

Figure 4: Short-term stability of MicroQuant™ after rehydration. Assay property values for the pellets of (A) MicroQuant™ HQ and (B) MicroQuant™ LQ products were resuscitated in rehydration buffer and then immediately diluted and plated (HQ) or plated (LQ) for "0 hour" reading. The remaining amounts 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 red boxes indicate product specification for the MicroQuant™ HQ and LQ, respectively. Above each panel, product number, and the microorganism names are included.

Comparison of processing time and storage condition

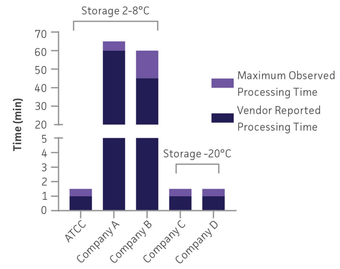

Figure 5: Comparison of processing time and storage temperature of ATCC®'s MicroQuant™ with other products. The processing time for MicroQuant™ was compared with the processing time for the formats available form Company A-D in the market. The storage temperature of ATCC, Company A, and Company B products is 4°C, whereas the storage temperature of Company C and Company 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*
A. brasiliensis	16404-HQ-PACK™	>1	<2	NA	2	NA
B. spizizenii	6633-HQ-PACK™	>1	<2	NA	NA	<2
C. albicans	10231-HQ-PACK™	>1	<2	NA	2	<2
E. coli	8739-HQ-PACK™	>1	2	NA	2	<2
P. paraeruginosa	9027-HQ-PACK™	<1	<2	NA	<2	<2
S. aureus	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*
A. brasiliensis	16404-LQ-PACK™	>1	<2	>1	<2	<1
B. spizizenii	6633-LQ-PACK™	>1	<2	>1	2	<2
C. albicans	10231-LQ-PACK™	>1	<2	>1	<2	<2
E. coli	8739-LQ-PACK™	>1	<2	<1	<2	<2
P. paraeruginosa	9027-LQ-PACK™	<1	<2	<1	2	<2
S. aureus	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 (HQ;10^7 to 10^8 CFU per pellet) and low-titer (LQ;100 to 1,000 CFU per pellet) formats.
- Single-use format enables fast assay setup 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 (**Passage zero**).

Scan the QR code to learn more

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