# Evaluation of ATCC MicroQuant™ Controls as Traceable Microbial Reference Standards for Compendial Quality Control Testing

ATCC®

Credible leads to Incredible®

Jyoti K Jha, PhD; Wan Li Low, PhD; Emmanuel Boafo-Asare, MS; Rahul Tevatia, PhD; Joshua Yeroshefsky, MS; Quinn Osgood, BSE; Fadima Samboal, MS; Aqilah Kermani, MS; Viraj Patel, MS; Nilay Chakraborty, PhD, MBA
ATCC, Manassas, VA 20110

## Abstract

Robust and traceable microbial reference materials are essential for compendial quality control testing across the pharmaceutical, biopharmaceutical, food, and cosmetic industries. Traditional microbial preparations often require labor-intensive workflows, involve multistep dilution schemes, and exhibit variability in colony forming units (CFU), which can impact reproducibility and regulatory compliance. Additionally, constraints related to storage conditions and strain stability can further complicate routine laboratory operations. ATCC® MicroQuant™ controls have been developed as a next-generation platform of precisely quantified microbial reference materials that address these challenges while aligning with pharmacopeial requirements.

## Schematic use of MicroQuant™

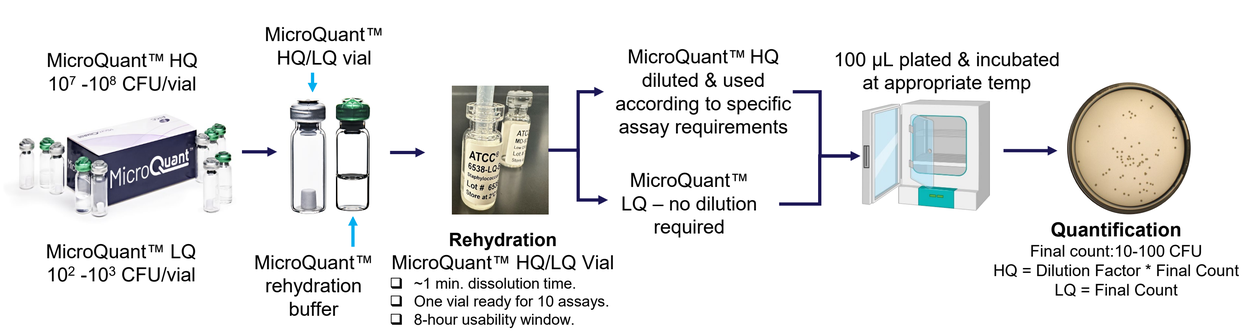


**Figure 1: MicroQuant™ assay workflow**. MicroQuant™ products are supplied as kits containing five vials of a specific organism in a high-titer (HQ:$10^7$ -$10^8$ CFU/vial) or low-titer (LQ:$10^2$ -$10^3$ CFU/vial) format and five vials of the respective rehydration buffer.

## Quantitation of MicroQuant™ production batches

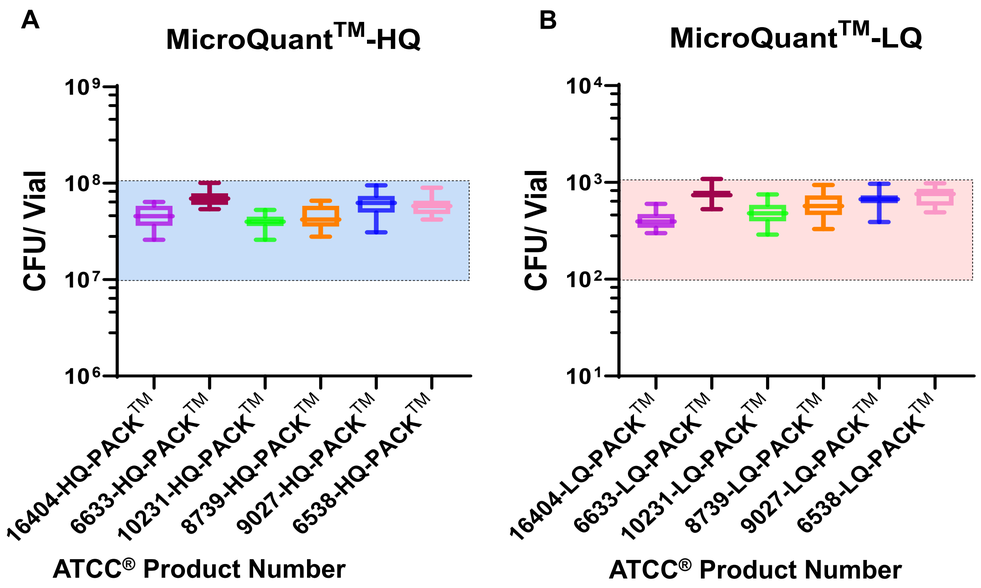


**Figure 2: Analysis of colony forming units (CFU) per vial of representative organisms from production batches of MicroQuant™.** Data were obtained from nine random vials per product for (A) HQ and (B) LQ packs, diluted where appropriate (HQ), and plated in duplicate. The assay was performed by three independent analysts. Mean, minimum, and maximum CFU/vial values are shown. Blue and red shaded regions indicate the specification ranges for MicroQuant™ HQ and LQ, respectively. CFU was determined as described in Figure 1.

## Comparison of processing time and storage condition

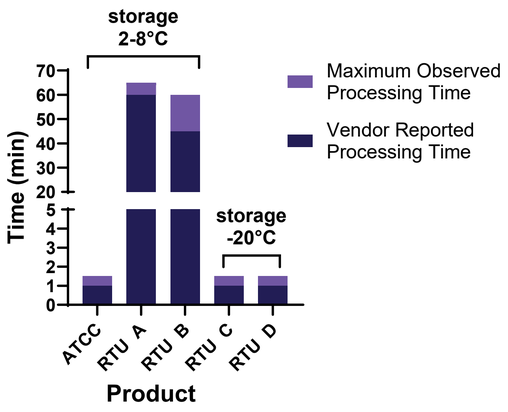


**Figure 3: Comparison of processing time and storage temperature of ATCC® MicroQuant™ with other ready-to-use (RTU) products available in the market.** The storage temperature of MicroQuant™, RTU A, and RTU B products is 2-8°C, whereas the recommended storage temperature for RTU C and RTU D products is -20°C.

## Short-term stability (usability) of MicroQuant™

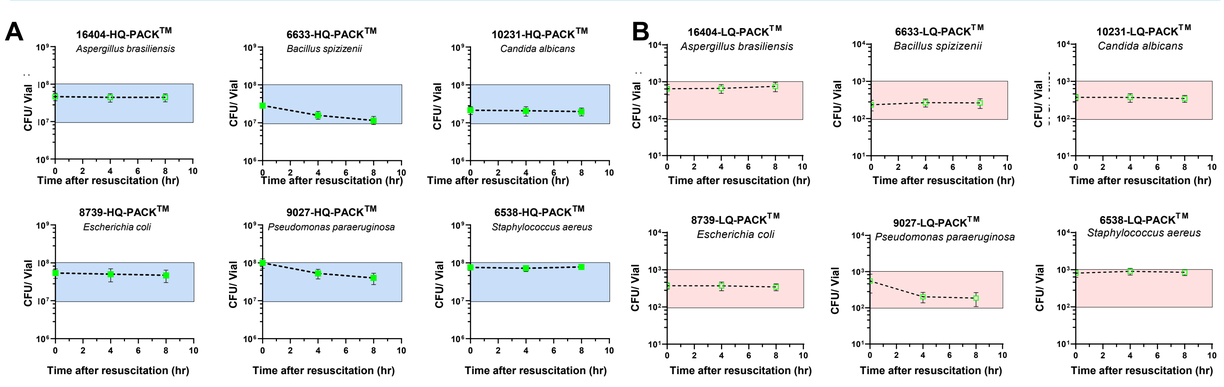


**Figure 4: Short-term stability of MicroQuant™ after rehydration**. Representative organisms from (A) MicroQuant™ HQ and (B) MicroQuant™ LQ were rehydrated using the rehydration buffer and viability counts were obtained immediately after rehydration (0 hours). Samples were stored at 4°C and viability counts were performed again at 4 and 8 hours post-rehydration. Rehydrated LQ samples were directly plated whereas HQ samples were serially diluted before plating. Plates were incubated and CFUs were counted following ATCC's guidelines. The blue and red shared regions indicate product specification for the MicroQuant™ HQ and LQ, respectively.

## Stability of MicroQuant™ post temperature excursion

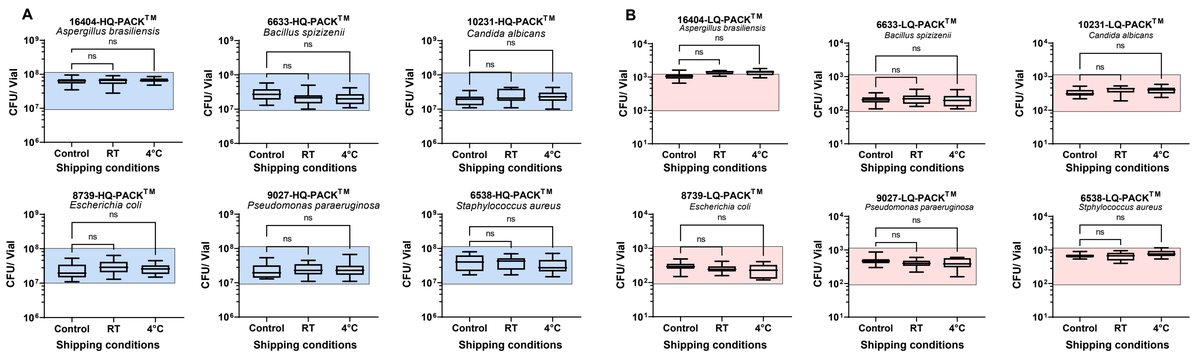


**Figure 5: Comparing the stability of MicroQuant™ products before and after exposure to temperature excursions.** MicroQuant™ kits were exposed to either refrigerated conditions (2-8°C) or ambient temperatures (21-27°C) for 4 days and assayed for CFU/vial. Control: CFU/vial pre-exposure; RT: CFU/Vial post-exposure to ambient temperature (24 ± 3°C average logger temperature); 4°C: CFU/vial post-exposure to refrigerated conditions (6 ± 2°C average logger temperature); ns: not significant. CFU/vial was determined using nine random vials plated in duplicates. Blue and red shaded regions indicate the specification ranges for MicroQuant™ HQ and LQ products, respectively.

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

**Table 1: Application of MicroQuant™ products**

| Species | ATCC® No. | Compendial assays | Shelf life (Months) | Industrial uses |
|---|---|---|---|---|
| ***Aspergillus brasiliensis*** | 16404-HQ-PACK™ | USP <51>, <1072> \| EP5.1.3 \| JP19 | 24 | Food, media, QC, and pharma testing |
| | 16404-LQ-PACK™ | USP <61>, <71>, <72>, <2021> \| EP2.6.12/13 | 24 | |
| ***Bacillus spizizenii*** | 6633-HQ-PACK™; 19659-HQ-PACK™ | USP <81> \| EP2.7.2 | 21<br>24 | Food, media, QC, and pharma testing |
| | 6633-LQ-PACK™; 19659-HQ-PACK™ | USP <61>, <71>, <72>, <2021> \| EP 2.6.1, 2.6.12, 2.6.27, 2.6.31 | 18<br>24 | |
| ***Candida albicans*** | 10231-HQ-PACK™ | USP <51>, <1072> \| EP5.1.3 \| JP19 | 24 | Food, media, QC, & antimicrobial testing |
| | 10231-LQ-PACK™ | USP <61>, <62>, <71>, <72>, <2021> \| EP2.6.12/13 \| JP4.05 | 24 | |
| ***Escherichia coli*** | 8739-HQ-PACK™; 11229-HQ-PACK™ | USP <51>, \| EP5.1.3 \| JP19 | 15<br>24 | Water, food, media, QC, and pharma testing |
| | 8739-LQ-PACK™; 11229-LQ-PACK™ | USP <62>, USP <1072>, <2021> | 15<br>24 | |
| ***Pseudomonas paraeruginosa*** | 9027-HQ-PACK™; 15442-HQ-PACK™ | USP <51> \| EP5.1.3 \| JP19 | 06<br>24 | Water, media, QC,& pharma testing |
| | 9027-LQ-PACK™; 15442-LQ-PACK™ | USP <60>, <61>, <62>, <71>, <72>,<1072> <2021> \| EP2.6.12/13 | 06*<br>24 | |
| ***Staphylococcus aureus*** | 6538-HQ-PACK™ | USP <51>, <1072> \| EP5.1.3 \| JP19 | 24 | Food, media, QC, and water testing |
| | 6538-LQ-PACK™ | USP <60>, <61>, <62>, <71>, <72>, <2021> | 15 | |
| ***Burkholderia cepacia*** | 25416-HQ-PACK™ | | 18 | Media, QC, & pharma testing |
| | 25416-LQ-PACK™ | USP <60> | 12 | |
| ***Burkholderia cenocepacia*** | BAA-245-HQ-PACK™ | | 24 | QC and pharma testing |
| | BAA-245-LQ-PACK™ | USP <60> | 24 | |
| ***Burkholderia multivorans*** | BAA-247-HQ-PACK™ | | 24 | QC and pharma testing |
| | BAA-247-LQ-PACK™ | USP <60> | 15 | |
| ***Clostridium sporogenes*** | 11437-LQ-PACK™ | USP <62>, <71>, <72> \| EP2.6.13 \| JP4.05 | 24 | |
| | 19404-HQ-PACK™ | | 24 | Media, QC, and pharma testing |
| | 19404-LQ-PACK™ | USP <62>, <71>, <72> \| EP2.6.13 \| JP4.05 | 24 | |
| ***Salmonella enterica*** | 14028-HQ-PACK™; 11311-HQ-PACK™ | | 24<br>24 | Food, media, water, QC, & pharma testing |
| | 14028-LQ-PACK™; 11311-LQ-PACK™ | USP <62>, <2021> \| EP2.6.13 \| JP4.05 | 24<br>24 | |
| ***Cutebacterium acnes*** | 11827-LQ-PACK™ | USP <72> | 24 | QC & pharma testing |
| ***Penicillium chrysogenum*** | 10106-HQ-PACK™ | | 24 | QC and pharma testing |
| | 10106-LQ-PACK™ | USP <72> | 24 | |
| ***Penicillium Rubens*** | 11709-HQ-PACK™ | | 12 | QC and pharma testing |
| | 11709-LQ-PACK™ | USP <1072> | 21 | |

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.
* Shelf life is measured from the shipment date where indicated; otherwise, from the manufacturing date.

## MicroQuant™ shelf-life compared to alternative RTU products

**Table 2: Shelf-life comparison of MicroQuant™ with other available Ready To Use (RTU) products**

| Organism | Shelf-life of Products (Years) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | HQ-PACK** | | | | | LQ-PACK*** | | | | |
| | ATCC | RTU A | RTU B | RTU C* | RTU D* | ATCC | RTU A | RTU B | RTU C* | RTU D* |
| ***A. brasiliensis*** (ATCC® 16404™) | 2 | <2 | NA | 2 | <2 | 2 | <2 | >1 | <2 | <1 |
| ***B. spizizenii*** (ATCC® 6633™) | NA | NA | NA | NA | NA | 2 | <2 | >1 | 2 | <2 |
| ***C. albicans*** (ATCC® 10231™) | 2 | <2 | NA | 2 | <2 | 2 | <2 | >1 | <2 | <2 |
| ***E. coli*** (ATCC® 8739™) | 2 | 2 | NA | 2 | 2 | 2 | <2 | <1 | <2 | <2 |
| ***P. paraeruginosa*** (ATCC® 9027™) | <1 | <2 | NA | <1 | <2 | <1 | <2 | <1 | 2 | <2 |
| ***S. aureus*** (ATCC® 6538™) | 2 | <2 | NA | 2 | <2 | 2 | <2 | >1 | <2 | <2 |
| **Product storage** | **4°C** | | | **-20°C** | | **4°C** | | | **-20°C** | |

NA – Products were not available from the companies at the time the study was conducted.
*Equivalent products available from RTU C and D, respectively.
** Products used in USP<51>,EP5.1.3, & JP5.02
***Products used in USP<61>,USP<62>, EP2.6.12, EP2.6.13 & JP4.05
RTU A-D are products from other companies currently available in the market.
ATCC® MicroQuant™ shelf-life is based on real-time stability and accelerated stability studies.

## Conclusions

**ATCC® MicroQuant™ is an innovative products designed to streamline microbial quality control testing.**

- Precisely quantitated in high-titer (HQ;$10^7$ to $10^8$ CFU per vial) & low-titer (LQ;100 to 1,000 CFU per vial) formats.
- Single, ready-to-use format enables simplifies workflow and accelerates testing.
- Stable storage at 2-8°C, saves critical freezer space and potentially contribute to lower carbon footprint.
- Immediate rehydration at room temperature with 8 hours of usability window.
- Maintains viability following refrigerated and ambient temperature excursions.
- Demonstrates favorable stability and shelf life compared with alternative RTU products.
- Produced from authenticated ATCC® passage-zero strains under ISO 17034-accredited manufacturing conditions.
- Provides a reliable, traceable reference material solution for microbiological quality control and method suitability testing.

**ATCC** 10801 University Boulevard, Manassas, Virginia 20110-2209 **Phone:** 800.638.6597 **Email:** sales@atcc.org **Web:** www.atcc.org

© 2026 American Type Culture Collection. ATCC product identifiers marked with the TM symbol are trademarks owned by the American Type Culture Collection.