

WHITE PAPER



MicroQuant™

PRECISION, SPEED, AND COMPLIANCE: THE MICROQUANT™ ADVANTAGE FOR MICROBIAL QUALITY CONTROL TESTING

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Traditional workflows using frozen stocks have long served as the backbone of microbial quality control (QC) testing; however, their legacy is increasingly marked by operational challenges. Beneath the surface of improved assay consistency lies persistent inefficiencies—thawing delays, cumbersome handling procedures, and freezer-dependent logistics—that quietly hinder productivity in QC labs. More critically, the use of non-authenticated strains near the upper passage limit permitted by pharmacopeia guidelines may introduce variability, raising concerns about genetic drift, strain reliability, assay reproducibility, and regulatory compliance. Preparing these controls can take up to two weeks and typically involves multiple steps, including incubations and serial dilutions, which demand both time and expertise. Even single-use formats derived from frozen stocks remain cumbersome, typically requiring freezer storage and up to two hours of preparation, making them less convenient for routine use. In an era demanding precision and agility, can we afford to retain workflows that require weeks of preparation and expert oversight just to maintain consistency?

Enter MicroQuant™—a paradigm shift in microbial QC that challenges the status quo. These fast-dissolving, precisely quantitated pellets do more than streamline workflows; they redefine what readiness means in a regulatory landscape where time, accuracy, and authenticity are non-negotiable. By delivering passage-zero reference material, MicroQuant™ ensures strain fidelity from the outset, eliminating preparation and oversight labor required for traditional methods. In a competitive environment where every minute counts and every assay must stand up to scrutiny, MicroQuant™ doesn't just meet expectations—it reshapes them. Below, we compare MicroQuant™ with traditional methods and other single-use controls to understand why MicroQuant™ is the superior option.

INTRODUCTION TO MICROQUANT™

MicroQuant™ streamlines microbial quality control testing by delivering ATCC's best-in-class microbial control strains in a precisely quantitated, single-use format. Developed under an ISO 17034–accredited lab, MicroQuant™ products are available in both high-titer and low-titer formats to support a wide range of methods such as those described in pharmacopeias. These stable pellets rapidly rehydrate in under a minute and require minimal handling, enabling simplified workflows and quick turnaround times while adhering to strict quality standards.

WHY MICROQUANT™ IS THE PREMIER CHOICE FOR MICROBIAL QC TESTING

For laboratories that may be hesitant to revalidate their processes with a new microbial QC format, it's essential to consider the long-term benefits of using a high-quality product like MicroQuant™. It's not just about getting samples tested for QC—it's about optimizing your QC testing processes with highly authenticated materials that streamline capabilities and save resources compared to other currently used solutions. Here are some reasons why MicroQuant™ is the best choice for your microbial quality control needs:

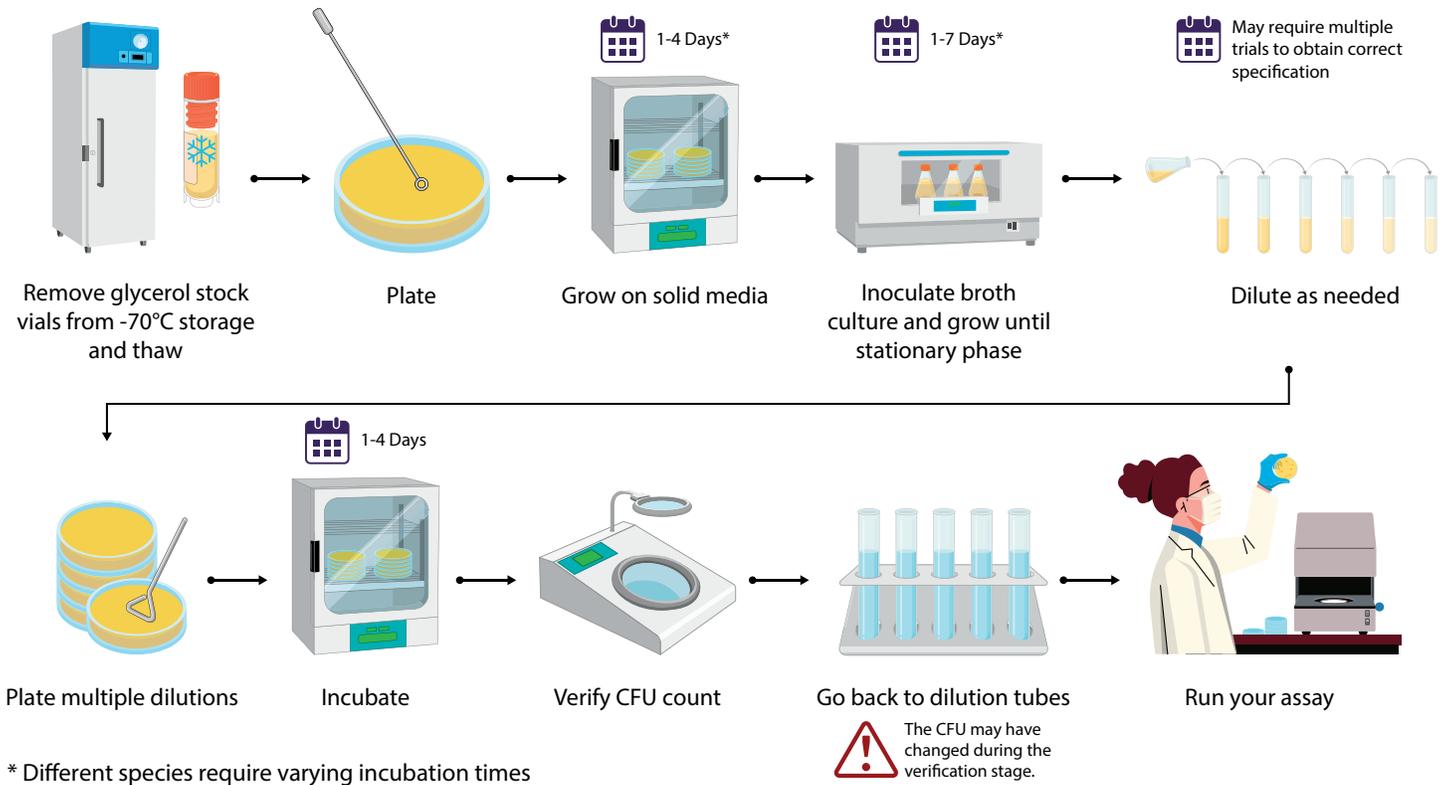
- **Superior ease-of-use & contamination mitigation:** MicroQuant™ simplifies workflows by allowing buffer to be added directly to the pellet—eliminating thawing, dilution steps, and risk of pellet loss or contamination. This ensures greater reliability and consistency in testing.
- **Precisely quantitated microbial controls:** Available in both high-titer (10^7 – 10^8 CFU/vial) and low-titer (100–1,000 CFU/vial) formats, MicroQuant™ supports broader coverage of pharmacopoeia and regulatory specifications. This simplifies inventory management and minimizes training requirements.
- **Rapid, uniform rehydration:** Leveraging ATCC's proprietary cryopreservation technology, MicroQuant™ pellets rehydrate completely in less than a minute at room temperature—saving time and enabling fast assay setup.
- **Ready-to-use, single-use format:** Designed for convenience and speed, MicroQuant™ pellets minimize handling and reduce contamination risk, streamlining QC workflows.
- **Convenient storage & stability:** MicroQuant™ remains stable at 2–8°C for up to 12 months, ensuring consistent availability while reducing waste.
- **Post-rehydration usability:** MicroQuant™ products are stable following rehydration for up to 8 hours at 2–8°C or at room temperature.
- **Passage-zero strains:** Each product is derived directly from the original ATCC culture, minimizing genetic drift and ensuring consistency across batches.
- **Rigorous authentication & whole-genome sequencing:** MicroQuant™ strains undergo phenotypic, functional, and genotypic validation—including whole-genome sequencing—for unmatched accuracy and trustworthiness.
- **ISO 17034 accreditation & full traceability:** Manufactured under strict quality standards, MicroQuant™ offers complete traceability and documentation, giving labs confidence in the origin and integrity of their QC materials.

SKIP THE COMPLEXITY—HERE'S WHY MICROQUANT™ OUTPERFORMS TRADITIONAL QC METHODS

Traditional microbial QC methods—using starter cultures and manually prepared controls—are often laborious, time-consuming, and operationally inefficient. These legacy approaches typically require extensive hands-on time, multiple incubations, and complex dilution steps that can stretch over one to two weeks. In contrast, MicroQuant™ provides a modern, ready-to-use solution featuring passage-zero, authenticated ATCC strains in a precisely quantitated pelleted format. This innovative approach dramatically streamlines operations—saving time, reducing costs, and enhancing reproducibility—while eliminating the risks of genetic drift and variability associated with in-house culture maintenance. Here is how MicroQuant™ provides superior solutions to traditional methods:

1. **Labor time savings:** Using MicroQuant™ can **save end-users more than 80% of labor time** compared to preparing internal controls manually—reducing or eliminating time spent on growth, titration, internal quality oversight, inventory management, and equipment management. This substantial reduction in labor time allows laboratory personnel to focus on other critical tasks, enhancing overall productivity and efficiency.
2. **Cost reduction:** MicroQuant™ achieves an estimated **cost reduction of more than 80%** versus using internally prepared controls. In addition to labor costs, MicroQuant™ consumes fewer overall reagent resources and requires less equipment. These savings make MicroQuant™ an economically advantageous choice for laboratories, reducing operational costs while maintaining high standards of quality and reliability.
3. **Operational time saving:** Using traditional methods for microbial QC can take 1–2 weeks of preparation, involving extensive hands-on time (e.g., media preparation and verification, equipment maintenance), multiple incubations, and numerous dilutions. In contrast, **MicroQuant™ condenses the entire setup process into just minutes**, significantly enhancing efficiency and reducing the complexity of microbial QC testing (Figure 1).
4. **Streamlined handling:** MicroQuant™ simplifies microbial QC workflows with a direct buffer-to-pellet format—no thawing, no dilution, no complex preparation. This intuitive design minimizes handling, reduces contamination risk, and ensures consistent, reproducible results—all while lowering the need for additional lab consumables (e.g., pipette tips, plates, media).

THE TRADITIONAL WORKFLOW



THE MICROQUANT™ WORKFLOW

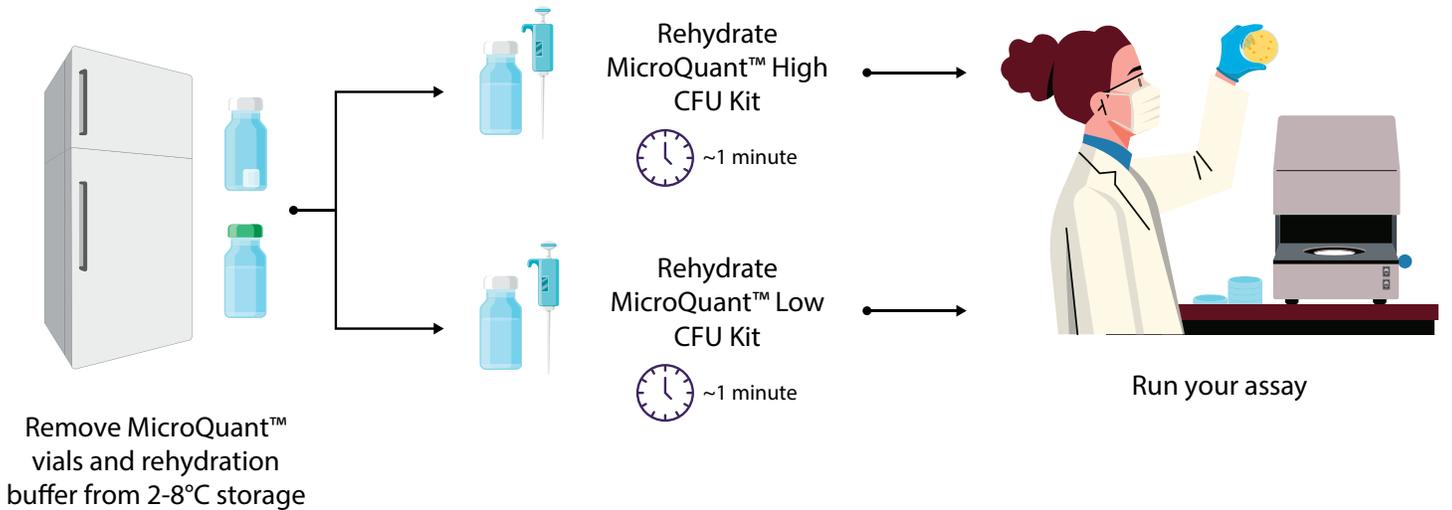


Figure 1: MicroQuant's™ innovative cryopreservation technology enables you to streamline your microbial QC workflow from days to minutes. By adopting MicroQuant™, laboratories can benefit from both time and cost savings, making it a smart investment for improving operational efficiency, while benefiting from use of authenticated, passage zero material.

MICROQUANT™ DELIVERS WHAT OTHER SINGLE-USE PRODUCTS CAN'T

While current single-use microbial QC products on the market aim to simplify workflows as compared to traditional approaches, many have shortcomings (Table 1). MicroQuant™ stands out not only for its exceptional performance but also for its ability to streamline operations compared to challenges with older, less efficient single-use controls:

- 1. Ready in under a minute:** Unlike other single-use controls that require 30–60 minutes of warming and buffer preparation, MicroQuant™ is fully rehydrated and ready for plating in less than a minute—saving valuable time and accelerating your QC workflows.
- 2. Convenient storage:** MicroQuant™ eliminates the need for freezer storage. Its stable format stores easily at 2–8°C, freeing up lab space, reducing equipment costs, and protecting microbial integrity from freeze-thaw damage.
- 3. Original source strains with full traceability:** Unlike other single-use products that rely on strains acquired from culture collections with high-passage number MicroQuant™ uses original source materials authenticated by ATCC. This ensures complete traceability, consistent performance, and confidence in how each strain was handled and validated in an ISO 17034 compliant manufacturing facility.

Table 1: Comparison of MicroQuant™ with single-use controls from other companies.

Features	MicroQuant™	Company A	Company B	Company C	Company D
Processing time ~1 minute	✓			✓	✓
2–8°C refrigeration storage	✓	✓	✓		
Manufactured under ISO 17034	✓	✓	✓	✓	✓
Product kit includes rehydration buffer	✓	✓	✓	✓	
Sourced from ATCC	✓	✓	✓		
Provided as a passage 0 strain	✓				

END-USER ASSESSMENT COMPARING MICROQUANT™ TO OTHER SINGLE-USE MICROBIAL CONTROLS

In our assessment, we asked end-users to score MicroQuant™ and competitive products on a scale of 1 to 5, with 1 being the lowest and 5 being the highest. These scores were collected through side-by-side experiments where users compared the ease of use, accuracy, and overall performance of MicroQuant™ against single-use products offered by other companies (Table 2). The results were overwhelmingly positive for MicroQuant™, with users consistently rating it higher across all categories.

- **Ease of use:** Users found MicroQuant™ to be intuitive and easy to prepare, with the fastest rehydration time compared to competitors.
- **Quantitative accuracy:** MicroQuant™ provided the most accurate CFU results, ensuring reliable and consistent microbial quality control testing.

Table 2: End-user feedback when comparing MicroQuant™ to other single-use controls provided by other companies.

Single-use control	Observation rating	Justification from the end-user
MicroQuant™	★★★★★	“Simple and intuitive preparation.” “No clumping or precipitation.” “Buffer included.”
Company A	★★★☆☆	“Moderate preparation with 1 hour of warming.” “Additional buffer needed for some formats.”
Company B	★★★☆☆	“Simple process but physical risks noted (pellet may miss vial, tipping risk).”
Company C	★★★★☆	“Simple preparation.” “No consumables needed.” “Incubator required.”
Company D	★★★★☆	“Simple preparation.” “No clumping or precipitation noted.” “Additional buffer needed for high CFU quantitation.”

These high ratings underscore the exceptional user experience and reliability of MicroQuant™, making it the preferred choice for laboratories seeking precision, efficiency, and reliability in their microbial QC processes.

MICROQUANT™: BUILT FOR PHARMACOPEIA COMPLIANCE

MicroQuant™ is uniquely positioned to support QC laboratories in meeting global regulatory standards. The microbial strains prepared in our precisely quantitated, ready-to-use MicroQuant™ format are the same authenticated ATCC strains cited in key pharmacopeia chapters, including USP <51>, <60>, <61>, <62>, and <71>, as well as harmonized chapters from the European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) (Table 3). Unlike competitor products that may use strains of higher passage number sourced from other culture collections, MicroQuant™ uses original source materials prepared at passage zero, ensuring full traceability and confidence in strain integrity.

MicroQuant™ strains are also formatted to match the titer specifications outlined in the respective chapters—available in both high-titer and low-titer formats. This alignment allows laboratories to perform microbial quality control testing with precision and consistency, while adhering to the strict requirements of USP, EP, and JP guidelines.

Table 3: MicroQuant™ strains support USP, EP, and JP pharmacopeias.

Species	Pharmacopeial chapters				
	USP <51> EP 5.3.1 JP 4.05 I	USP <61> EP 2.6.12 JP 4.05 I	USP <60>	USP <62> EP 2.6.13 JP 4.05 II	USP <71> EP 2.6.1 JP 4.06
<i>Aspergillus brasiliensis</i> WLRI 034(120)	HQ	LQ			LQ
<i>Bacillus spizizenii</i> NRS 231		LQ			LQ
<i>Burkholderia cenocepacia</i> LMG 16656			LQ		
<i>Burkholderia cepacia</i> UCB 717			LQ		
<i>Burkholderia multivorans</i> LMG 13010			LQ		
<i>Candida albicans</i> 3147	HQ	LQ		LQ	LQ
<i>Clostridium sporogenes</i> L.S. McClung 2006				LQ	LQ
<i>Clostridium sporogenes</i> SR 5				LQ	LQ
<i>Escherichia coli</i> Crooks	HQ			LQ	
<i>Pseudomonas paraeruginosa</i> R. Hugh 813	HQ	LQ	LQ	LQ	LQ
<i>Salmonella enterica</i> CDC 6516-60				LQ	
<i>Staphylococcus aureus</i> FDA 209	HQ	LQ	LQ	LQ	LQ

HQ = High quantitative MicroQuant™ product

LQ = Low quantitative MicroQuant™ product

CONCLUSION

MicroQuant™ represents a transformative advancement in microbial quality control—combining precision, speed, and regulatory confidence in a single-use format that meets the evolving needs of QC laboratories. By addressing the limitations of traditional workflows and older single-use products, MicroQuant™ empowers you to streamline operations, reduce costs, and improve reproducibility. Its use of authenticated, passage-zero ATCC strains cited in global pharmacopeia chapters ensures full traceability and compliance, while its rapid rehydration and intuitive handling simplify even the most demanding workflows.

For laboratories seeking to modernize their microbial QC processes without compromising quality or compliance, MicroQuant™ is more than a product—it's a strategic solution built for today's regulatory landscape and tomorrow's innovation.

For more information and to explore the full range of MicroQuant™ products, visit us online at www.atcc.org/MicroQuant.

Table 4: MicroQuant™ strains available from ATCC.

ATCC® No.	Description	Quantitation (CFU/vial)	Availability
16404-LQ-PACK™	MicroQuant™ <i>Aspergillus brasiliensis</i> , low CFU	100-1,000	Available now
16404-HQ-PACK™	MicroQuant™ <i>Aspergillus brasiliensis</i> , high CFU	10 ⁷ -10 ⁸	Available now
6633-LQ-PACK™	MicroQuant™ <i>Bacillus spizizenii</i> , low CFU	100-1,000	Available now
6633-HQ-PACK™	MicroQuant™ <i>Bacillus spizizenii</i> , high CFU	10 ⁷ -10 ⁸	Available now
19659-LQ-PACK™	MicroQuant™ <i>Bacillus spizizenii</i> , low CFU	100-1,000	Available now
19659-HQ-PACK™	MicroQuant™ <i>Bacillus spizizenii</i> , high CFU	10 ⁷ -10 ⁸	Available now
BAA-245-LQ-PACK™	MicroQuant™ <i>Burkholderia cenocepacia</i> , low CFU	100-1,000	Available now
BAA-245-HQ-PACK™	MicroQuant™ <i>Burkholderia cenocepacia</i> , high CFU	10 ⁷ -10 ⁸	Available now
25416-LQ-PACK™	MicroQuant™ <i>Burkholderia cepacia</i> , low CFU	100-1,000	Available now
25416-HQ-PACK™	MicroQuant™ <i>Burkholderia cepacia</i> , high CFU	10 ⁷ -10 ⁸	Available now
BAA-247-LQ-PACK™	MicroQuant™ <i>Burkholderia multivorans</i> , low CFU	100-1,000	Available now
BAA-247-HQ-PACK™	MicroQuant™ <i>Burkholderia multivorans</i> , high CFU	10 ⁷ -10 ⁸	Available now
10231-LQ-PACK™	MicroQuant™ <i>Candida albicans</i> , low CFU	100-1,000	Available now
10231-HQ-PACK™	MicroQuant™ <i>Candida albicans</i> , high CFU	10 ⁷ -10 ⁸	Available now
11437-LQ-PACK™	MicroQuant™ <i>Clostridium sporogenes</i> , low CFU	100-1,000	Available now
19404-LQ-PACK™	MicroQuant™ <i>Clostridium sporogenes</i> , low CFU	100-1,000	Available now
19404-HQ-PACK™	MicroQuant™ <i>Clostridium sporogenes</i> , high CFU	10 ⁷ -10 ⁸	Available now
11827-LQ-PACK™	MicroQuant™ <i>Cutibacterium acnes</i> , low CFU	100-1,000	Available now
11827-HQ-PACK™	MicroQuant™ <i>Cutibacterium acnes</i> , high CFU	10 ⁷ -10 ⁸	Coming soon
8739-LQ-PACK™	MicroQuant™ <i>Escherichia coli</i> , low CFU	100-1,000	Available now
8739-HQ-PACK™	MicroQuant™ <i>Escherichia coli</i> , high CFU	10 ⁷ -10 ⁸	Available now
11229-LQ-PACK™	MicroQuant™ <i>Escherichia coli</i> , low CFU	100-1,000	Available now
11229-HQ-PACK™	MicroQuant™ <i>Escherichia coli</i> , high CFU	10 ⁷ -10 ⁸	Available now
10106-LQ-PACK™	MicroQuant™ <i>Penicillium chrysogenum</i> , low CFU	100-1,000	Available now
10106-HQ-PACK™	MicroQuant™ <i>Penicillium chrysogenum</i> , high CFU	10 ⁷ -10 ⁸	Available now
11709-LQ-PACK™	MicroQuant™ <i>Penicillium rubens</i> , low CFU	100-1,000	Available now
11709-HQ-PACK™	MicroQuant™ <i>Penicillium rubens</i> , high CFU	10 ⁷ -10 ⁸	Available now
15442-LQ-PACK™	MicroQuant™ <i>Pseudomonas aeruginosa</i> , low CFU	100-1,000	Available now
15442-HQ-PACK™	MicroQuant™ <i>Pseudomonas aeruginosa</i> , high CFU	10 ⁷ -10 ⁸	Available now
9027-LQ-PACK™	MicroQuant™ <i>Pseudomonas paraaeruginosa</i> , low CFU	100-1,000	Available now
9027-HQ-PACK™	MicroQuant™ <i>Pseudomonas paraaeruginosa</i> , high CFU	10 ⁷ -10 ⁸	Available now
14028-LQ-PACK™	MicroQuant™ <i>Salmonella enterica</i> , low CFU	100-1,000	Available now
14028-HQ-PACK™	MicroQuant™ <i>Salmonella enterica</i> , high CFU	10 ⁷ -10 ⁸	Available now
13311-LQ-PACK™	MicroQuant™ <i>Salmonella enterica</i> subsp. <i>enterica</i> , low CFU	100-1,000	Available now
13311-HQ-PACK™	MicroQuant™ <i>Salmonella enterica</i> subsp. <i>enterica</i> , high CFU	10 ⁷ -10 ⁸	Available now
6538-LQ-PACK™	MicroQuant™ <i>Staphylococcus aureus</i> subsp. <i>aureus</i> , low CFU	100-1,000	Available now
6538-HQ-PACK™	MicroQuant™ <i>Staphylococcus aureus</i> subsp. <i>aureus</i> , high CFU	10 ⁷ -10 ⁸	Available now

Table 5: ATCC® MicroQuant™ panels

ATCC® No.	Description
MQ-51™	MicroQuant™ Antimicrobial Effectiveness Panel
MQ-60™	MicroQuant™ Microbial Examination of Nonsterile Products: Tests for <i>Burkholderia cepacia</i> Complex Panel
MQ-61™	MicroQuant™ Microbial Examination of Nonsterile Products Panel
MQ-62™	MicroQuant™ Microbial Examination of Nonsterile Products: Tests for Specified Microorganisms Panel
MQ-71™	MicroQuant™ Sterility Tests Panel

Learn more about MicroQuant™ at www.atcc.org/MicroQuant



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