

INSTRUCTIONS FOR USE

ATCC® MICROQUANT™ HIGH CFU KIT

DESCRIPTION

ATCC® MicroQuant™ strains are precisely quantitated controls provided in a single-use format that rehydrates immediately, requires minimal handling, and is convenient to store. The high CFU kits comprise five vials of an ISO 17034 reference material and five vials of rehydration buffer. Once rehydrated, each cryopreserved pellet provides reference cultures with 10^7 - 10^8 CFU per 1.0 mL.

INTENDED USE

This kit is intended for research use only (RUO). It was developed to support USP General Chapters.

PRECAUTIONS

- Aseptic procedures are recommended while handling this kit.
- The product should be handled under the proper biosafety level conditions (Table 1). ATCC determines the biosafety level of a material based on our risk assessment as guided by the current edition of *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, U.S. Department of Health and Human Services. It is your responsibility to understand the hazards associated with the material per your organization's policies and procedures as well as any other applicable regulations as enforced by your local or national agencies.
- Biohazard disposing procedures must be followed while discarding kit contents.
- The rehydration buffer provided in each of these kits does not contain animal by-products.

RECOMMENDED STORAGE CONDITIONS

ATCC® MicroQuant™ High CFU kits can be stored at 2-8°C for 6-12 months (Verify expiry for individual products).

LIMITED LABEL LICENSE FOR MICROQUANT™

Use of ATCC's MicroQuant™ products are subject to the ATCC Material Transfer Agreement. Notwithstanding, ATCC hereby grants you the further right to use this single-use consumable MicroQuant™ product as a reagent for a single quality control assay in your laboratory only, whether as a commercial service or internally. ATCC's MicroQuant™ products contain trade secrets and intellectual property of ATCC, and you may not reverse engineer, replicate, alter, or tamper with the products or authorize any third party to do any of the foregoing. ATCC's MicroQuant™ products shall not be used for any other use restricted by the ATCC Material Transfer Agreement, including any animal or human therapeutic use, any human or animal consumption, any diagnostic use, or use to manufacture any products.

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INSTRUCTIONS FOR USE

1. Remove the desired number of cryopreserved reference culture vials (gray crimp) and rehydration buffer vials (green crimp) from 2-8°C storage and place into a biosafety cabinet. One vial of rehydration buffer should be used for each vial of reference culture.
2. Uncap each vial. Add 1.0 mL of rehydration buffer to the reference culture vial. Recap the vial and allow the pellet to dissolve for 30 seconds.
3. Vortex on the high setting for 30 seconds to ensure the suspension is well mixed. The suspension is now useable and contains 10^7 - 10^8 CFU per 1.0 mL. The suspension can be used immediately or stored at 2-8°C for up to 8 hours.
4. If this product is used in alignment with USP <51>, add 100 μ L of the above prepared suspension to 900 μ L of the test sample.
5. Add 9.0 mL of the USP recommended diluent (not provided) to the 1.0 mL of sample prepared in step 3. Follow the procedure detailed in USP Chapter <51> for the challenge test.

FOR QUANTITATION

1. Follow steps 1-3 listed above.
2. Add 100 μ L of the prepared suspension to 900 μ L dilution buffer.
3. Repeat the dilution 4 times to achieve a dilution factor of 1.0×10^5 (See Figure below).
4. From the final dilution, pipette 100 μ L directly on to a non-selective media plate. Use a sterile plate spreader for optimal results.
Note: ATCC quantitation results were obtained using 100 mm Tryptic Soy Agar plates with 1.5% Tryptone, 0.5% Soytone, 0.5% Sodium Chloride, and 1.5% Agar (plates were procured from Teknova®).
5. Incubate plates in an incubator at the appropriate temperature and time. If following a specific pharmacopeial chapter, use the incubation conditions specified.
6. Following incubation, read the plate for CFU counts using a standard colony counting procedure.

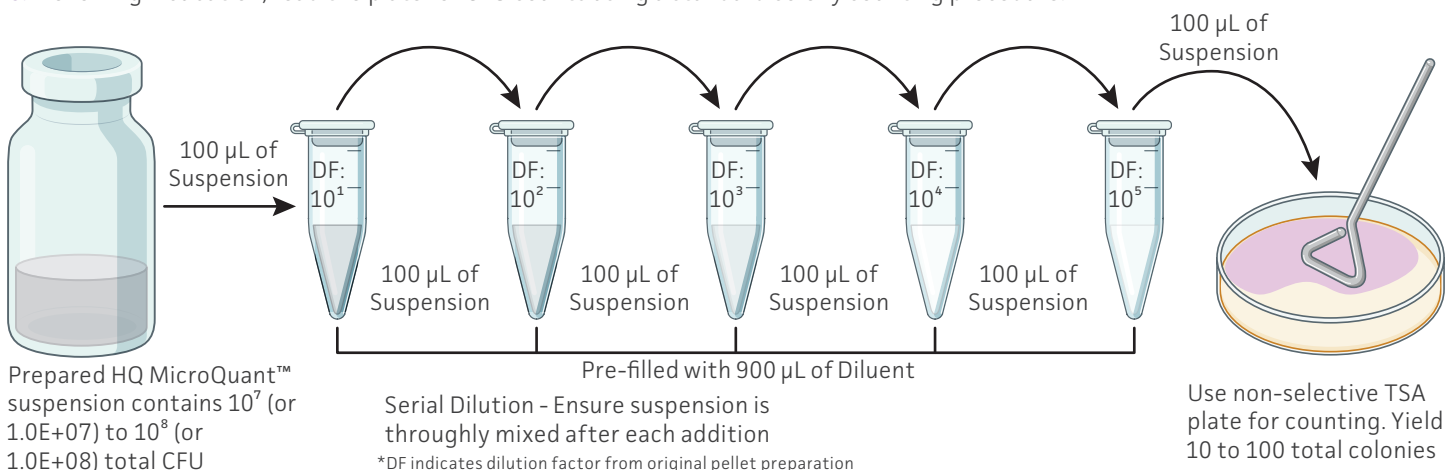


Table 1: MicroQuant™ High CFU Kits available from ATCC

ATCC® No.	Organism	Strain designation	BSL
16404-HQ-PACK™	<i>Aspergillus brasiliensis</i> *	WLRI 034(120)	1
6633-HQ-PACK™	<i>Bacillus spizizenii</i> (Formerly <i>Bacillus subtilis</i>)	NRS 231	1
10231-HQ-PACK™	<i>Candida albicans</i>	3147	1
8739-HQ-PACK™	<i>Escherichia coli</i>	Crooks	1
9027-HQ-PACK™	<i>Pseudomonas paraeruginosa</i> (Formerly <i>Pseudomonas aeruginosa</i>)	R. Hugh 813	2
6538-HQ-PACK™	<i>Staphylococcus aureus</i> subsp. <i>aureus</i>	FDA 209	2

*Please refer to the IFU document specific for *Aspergillus brasiliensis* (16404-HQ-PACK™)

For assistance, please contact ATCC customer support at tech@atcc.org or your local distributor

10801 University Boulevard
Manassas, Virginia 20110-2209

703.365.2700

703.365.2701

sales@atcc.org

www.atcc.org

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