

Certificate of Analysis

Product Name: A. fumigatus KM 8001 PK/5
Lot Number: 132785

Product Number: R4601018
Expiration Date: 2025-12-17
(YYYY-MM-DD)

This product has been manufactured, processed and packaged in accordance with Quality Systems Regulation, 21 CFR Part 820. Representative samples were tested per Remel Inc., a part of Thermo Fisher Scientific Quality Control specifications and were found to meet performance criteria for this product.

Purity:

Standardized aliquots of the rehydrated product are inoculated onto nonselective media and examined for pure growth following the appropriate incubation. Selective and Differential media are also tested where applicable.

Viability And Quantification:

Each organism is recovered from the preserved state within the required time frame and at an acceptable level. Passage number is stated as the current preserved state.

Macroscopic And Microscopic Morphology:

Colony morphology is consistent with documented referenced description. Traditional staining is performed.

Characterization:

Organism exhibits characteristic biochemical, enzymatic, genotypical and/or biochemical reactions. Automated and/or conventional testing was performed and results were within established limits. Antimicrobial testing performed where applicable. Results within expected ranges.

CFU/loop: >10(3) Passage: NA - Clinical Strain Identification Profile: MicroSEQ®

Macroscopic Morphology: Mature within 3-5 days, 25-30°C. Powdery or velvety texture. Surface - White turning blue-green to grey-green. Reverse - Pale, white to yellow-tan.

Microscopic Morphology: Short, smooth-walled conidiophores of variable length; uniseriate phialides cover upper surface of vesicle; rounded conidia in chains with finely roughened walls.

Appearance: Preserved Gel Matrix suspended in inoculating loop
pH: N/A

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Signed



Quality Assurance Manager

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