

Certificate of Quality

Product Name: API20C Clinical Yeasts System QC Set/3
Lot Number: 316700

Product Number: R4653059
Expiration Date: 2026-06-15
(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 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.

Biochemical Analysis:

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

	Strain	Gram Reaction:	Profile:
<i>Candida glabrata</i>	15126	Gram Positive Yeast	Vitek YBC
<i>Cryptococcus laurentii</i>	18803	Gram Positive Yeast	Vitek YBC
<i>Candida guilliermondii</i>	6260	Gram Positive Yeast	Vitek YBC

CFU/1ml: >10(4)

Passage: Kit - All <5

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

Signed

GBh

Senior Quality Assurance Engineer