

IVD

Certificate of Analysis

Filamentous Fungi Pretreatment Reagent		Standard: In-house Standard CP-0519-007	
REF MSA05	LOT 2025021001	2026-02-09	120T

Items	Controls	Result	Acceptable range
Component	/	The kit is complete according to the IFU.	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> The component should be complete.
Appearance	/	The package is complete. Package label and component labels are correct and clear without alterations and easy to identify. No leakage of the liquid.No deformation and damage of the vial and lid.The identification code of the kit is consistent with the Marketable Catalogue of Export Products.	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> The package should be complete. Package label and component labels are correct and clear without alterations and easy to identify. No leakage of the liquid.No deformation and damage of the vial and lid.The identification code of the kit should be consistent with the Marketable Catalogue of Export Products.
Volume	/	1.300mL	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> ≥1.1mL。
Usability	<i>Aspergillus fumigatus</i> (ATCC 16903)	Identify the reference strains <i>Aspergillus fumigatus</i>	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> Identify the reference strains <i>Aspergillus fumigatus</i> ATCC®16903, <i>Rhizopus oryzae</i> ATCC®56536, <i>Aspergillus niger</i> ATCC®16888 and <i>Aspergillus flavus</i> ATCC®22546 separately. The results shall be <i>Aspergillus fumigatus</i> , <i>Rhizopus oryzae</i> , <i>Aspergillus niger</i> , <i>Aspergillus flavus</i> , the identification score should be ≥7.0 and confirmed to the species level.
	<i>Rhizopus oryzae</i> (ATCC 56536)	ATCC®16903, <i>Rhizopus oryzae</i> ATCC®56536, <i>Aspergillus niger</i>	
	<i>Aspergillus niger</i> (ATCC 16888)	ATCC®16888 and <i>Aspergillus flavus</i> ATCC®22546 separately.	
	<i>Aspergillus flavus</i> (ATCC 22546)	The results are <i>Aspergillus fumigatus</i> , <i>Rhizopus oryzae</i> , <i>Aspergillus niger</i> , <i>Aspergillus flavus</i> , the identification score is ≥7.0 and confirm to the species level.	
UDI	/	Use the scanner to scan the QR-code on the label, compare with the clear code on the label of the identified information box, and visually observe the product identification (01) and production date (11) in the clear code. The expiration date (17) and production batch number (10) are consistent	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> QR-code on the label is the same with the clear code on the label of the identified information box, and visually observe the product identification (01) and production date (11) in the clear code. The expiration date (17) and production batch number



		with the corresponding information on the label.		(10) are consistent with the corresponding information on the label.
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Components	LOT		QTY	Components	LOT		QTY
Filamentous Fungi Pretreatment Reagent	2025021001	2026-02-09	4	IFU	/	/	1
Package label and component labels are correct and clear without alterations.							

Conclusion: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
Operator/ Date: Wushuang Jiang/Feb.24,2025
Approved by/ Date: Lijing Liu/Feb.24,2025
Comments: /
All AUTOBIO products are manufactured under ISO 13485:2016 certified quality system.