

IVD

Certificate of Analysis

Positive Blood Cultures Pretreatment Reagent		Standard: In-house Standard CP-0491-007	
REF MSA04	LOT 2024100801	 2025-10-07	 60T

Performance					
Items	Controls	LOT	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. No leakage of the liquid. Pretreatment reagent is clear liquid, and there are no visible flocculent impurities in the bottle. 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. No leakage of the liquid. Pretreatment reagent shall be clear liquid, and there shall be no visible flocculent impurities in the bottle. The identification code of the kit should be consistent with the Marketable Catalogue of Export Products.
Volume	/		3.600mL	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	≥3.5mL
Usability	<i>E.coli</i> (ATCC 43888)	/	Identify the strains <i>E.coli</i> ATCC®43888, <i>Staphylococcus aureus</i> ATCC®BAA-1747, and <i>Candida albicans</i> ATCC®10231 separately. There have more than one correct spot. The results are <i>E.coli</i> , <i>Staphylococcus aureus</i> , <i>Candida albicans</i> and the identification score are ≥6.0. The identification result is negative.	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	Identify the strains <i>E.coli</i> ATCC®43888, <i>Staphylococcus aureus</i> ATCC®BAA-1747, and <i>Candida albicans</i> ATCC®10231 separately. There should have more than one correct spot. The results shall be <i>E.coli</i> , <i>Staphylococcus aureus</i> , <i>Candida albicans</i> and the identification score should be ≥6.0. Treat the mass spectrometry with blood culture microbial pretreatment reagent, and the identification result should be negative.
	<i>Staphylococcus aureus</i> (ATCC BAA-1747)	/			
	<i>Candida albicans</i> (ATCC10231)	/			
	Negative test	/			
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	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



			identification (01) and production date (11) in the clear code. The expiration date (17) and production batch number (10) are consistent with the corresponding information on the label.		production date (11) in the clear code. The expiration date (17) and production batch number (10) are consistent with the corresponding information on the label.
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Components	LOT		QTY	Components	LOT		QTY
Positive Blood Cultures Pretreatment Reagent	2024100801	2025-10-07	4	IFU	/	/	1

Package label and component labels are correct and clear without alterations.

Content of each component is clear and transparent without sediment or flocs.

Conclusion: YES NO

Operator/ Date: Wushuang Jiang/Oct.10,2024-Oct.12,2024

Approved by/ Date:Lijing Liu/Oct.12,2024

Comments: /

All AUTOBIO products are manufactured under ISO 13485:2016 certified quality system.