IVD

Certificate of Analysis

Positive Blood Cultures Pretreatment Reagent		Standard: In-house Standard CP-0491-007	
REF MSA04	LOT 2025100701 Production Date：2025.10.07	2026-10-06	Σ 60

Items	Controls	Result		Acceptable range
Component	/	The kit is complete according to the IFU.	YES【√】 NO 【 】	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【√】 NO 【 】	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	/	3.650mL	YES【√】 NO 【 】	≥3.5mL
Usability	*E.coli*（ATCC 43888） *Staphylococcus aureus*（ATCC BAA-1747） *Candida albicans*（ATCC10231） Negative test	Identify the strains *E.coli* ATCC®43888, *Staphylococcus aureus* ATCC®BAA-1747, and *Candida albicans* ATCC®10231 separately. There have more than one correct spot. The results are *E.coli, Staphylococcus aureus, Candida albicans* and the identification score are ≥6.0. The identification result is negative.	YES【√】 NO 【 】	Identify the strains *E.coli* ATCC®43888, *Staphylococcus aureus* ATCC®BAA-1747, and *Candida albicans* ATCC®10231 separately. There should have more than one correct spot. The results shall be *E.coli, Staphylococcus aureus, Candida albicans* 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.
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	YES 【√】 NO 【 】	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

		product 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.		expiration date (17) and production batch number (10) are consistent with the corresponding information on the label.

Components	LOT	⌛	QTY	Components	LOT	⌛	QTY
Positive Blood Cultures Pretreatment Reagent	2025100701	2026-10-06	4	IFU	/	/	1
Package label and component labels are correct and clear without alterations.							

Conclusion: YES【√】 NO【 】
Operator/ Date: WuShuang JiTang /October 21, 2025
Approved by/ Date: XiaoLi Zhao /October 21, 2025
Comments: /
All AUTOBIO products are manufactured under ISO 13485:2016 certified quality system.