

**IVD**

# Certificate of Analysis

Sample Pretreatment Reagent		Standard: In-house Standard CP-0287-009;	
<b>REF</b> MSA01	<b>LOT</b> 20240726	2025-07-25	100tests

Performance					
Items	Controls	<b>LOT</b>	Result		Acceptable range
Volume	/	/	Lysate 1 : 1.35mL Lysate 2 : 1.45mL Buffer : 0.45mL	YES【 <input checked="" type="checkbox"/> 】 NO【 <input type="checkbox"/> 】	The lysate 1 is not less than 1.0 mL. The lysate 2 is not less than 1.1 mL. The buffer is not less than 0.3 mL.
Dissolubility	/	/	The matrix can be dissolved, the solution is clear and transparent after dissolution.	YES【 <input checked="" type="checkbox"/> 】 NO【 <input type="checkbox"/> 】	The matrix shall be dissolved. The solution shall be clear and transparent after dissolution. It is normal to have trace precipitation at the bottom.
Control tests	Positive control	<i>E. Coli</i> ATCC®DH5α (ATCC® PTA-1977)	Identify the reference strains <i>E. Coli</i> ATCC®DH5α (ATCC® PTA-1977) and <i>Candida albicans</i> ATCC®10231 separately. The results are <i>E. Coli</i> and <i>Candida albicans</i> , and confirmed to the species level.	YES【 <input checked="" type="checkbox"/> 】 NO【 <input type="checkbox"/> 】	Identify the reference strains <i>E. Coli</i> ATCC®DH5α (ATCC® PTA-1977) and <i>Candida albicans</i> ATCC®10231 separately. The results shall be <i>E. Coli</i> and <i>Candida albicans</i> , and confirmed to the species level.
		<i>Candida albicans</i> ATCC®10231			
	Negative control	/	The results of mass spectrometry is negative.	YES【 <input checked="" type="checkbox"/> 】 NO【 <input type="checkbox"/> 】	Identify the reagents of the kit directly. The result shall be negative.

Components	<b>LOT</b>		QTY	Components	<b>LOT</b>		QTY
Lysate 1	20240726	2025-07-25	1	Matrix	20240726	2025-07-25	1
Lysate 2	20240726	2025-07-25	1	Buffer	20240726	2025-07-25	1
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/ Jul.26,2024

**Approved by/ Date:** Xiaoli Zhao/ Jul.26,2024

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