

IVD

Certificate of Analysis

Sample Pretreatment Reagent		Standard: In-house Standard CP-0287-009.	
REF MSA01	LOT 20250911 Production Date: 2025.09.11	2026-09-10	100

Items	Controls	Result		Acceptable range
Composition of kit	/	Complete kit.	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	The kit shall be complete.
Appearance	/	The appearance of the kit is clean, complete and intact; batch number, validity, qualification number and specification information are correct. Each reagent bottle is kept intact without leakage and leakage; lysate 1, lysate 2 and buffer are colorless transparent liquid, and the matrix is light yellow powder solid without agglomeration. The manual and box qualification number are correct.	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	The appearance of the kit shall be clean, complete and intact; batch number, validity, qualification number and specification information are correct. Each reagent bottle shall be kept intact without leakage and leakage; lysate 1, lysate 2 and buffer are colorless transparent liquid, and the matrix is light yellow powder solid without agglomeration. The manual and box qualification number are correct.
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 with the corresponding information on the label.	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 (10) are consistent with the corresponding information on the label.
Volume	/	Lysate 1 : 1.30mL Lysate 2 : 1.40mL Buffer : 0.40mL	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) <i>Candida albicans</i> ATCC®10231	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.
	Negative control	/	The results of mass spectrometry are negative.	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	Identify the reagents of the kit directly. The result shall be negative.

Components	LOT		QTY	Components	LOT		QTY
Lysate 1	20250911	2026-09-10	1	Matrix	20250911	2026-09-10	1
Lysate 2	20250911	2026-09-10	1	Buffer	20250911	2026-09-10	1
IFU	/	/	1	/	/	/	/

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

Conclusion: YES NO

Operator/ Date: Wushuang Jiang /November 05, 2025

Approved by/ Date: Xiaoli Zhao /November 05, 2025

Comments: /

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