

IVD

Certificate of Analysis

CHCA Matrix for use with AUTOF MS		Standard: In-house Standard CP-0326-018	
REF MSA03	LOT 2025102701 Production Date: 2025.10.27	 2026-10-26	 0.5mL*4 Vials

Items	Controls	Result		Acceptable range
Appearance	/	1) The component is complete. 2) The REF on the kit label is the same as the REF on the instructions. 3) Product validity date is consistent with K3 information verification.	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	1) The component should be complete. 2) Check the REF on the kit label should be the same as the REF on the instructions. 3) Product validity date is consistent with K3 information verification.
Volume	/	0.570mL.	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	≥0.5mL/bottle.
Positive Test	<i>E. Coli</i> ATCC®DH5α (ATCC® PTA -1977)	Conduct the pretreatment on <i>E. Coli</i> ATCC®DH5α (ATCC® PTA -1977) and <i>Candida albicans</i> ATCC®10231 separately. The result is <i>E. Coli</i> and <i>Candida albicans</i> , and confirmed to the species level.	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	Conduct the pretreatment on <i>E. Coli</i> ATCC®DH5α (ATCC® PTA -1977) and <i>Candida albicans</i> ATCC®10231 separately. The result should be <i>E. Coli</i> and <i>Candida albicans</i> , and confirmed to the species level.
	<i>Candida albicans</i> ATCC®10231			
Negative Test	CHCA Matrix	Identify the CHCA Matrix directly, the result is negative.	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	Identify the CHCA Matrix directly, the result shall be negative.

Components	LOT		QTY	Components	LOT		QTY
CHCA Matrix for use with AUTOF MS	2025102701	2026-10-26	4	IFU	/	/	1

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

Conclusion: YES NO

Operator/ Date: Wushuang Jiang / October 30, 2025

Approved by/ Date: Xiaohu Zhao / October 30, 2025

Comments: /

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