

IVD

Certificate of Analysis

CHCA Matrix for use with AUTO MS		Standard: In-house Standard CP-0326-009	
REF MSA03	LOT 2025030301	 2026-03-02	 0.5mL*4 Vials

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 kit composition is not damaged. The label is clear and easy to identify; No leakage of liquid components. The matrix solution is light yellow clear transparent liquid, and no yellow crystals at the bottom. The kit identification code is consistent with the Sales Catalogue of Export Products. YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	The composition of the kit shall be free from damage. Labels shall be clear and easy to identify; No leakage of liquid components. The matrix solution is light yellow clear transparent liquid, and it is normal to have a small amount of yellow crystals at the bottom. The kit identification code shall be consistent with the Sales Catalogue of Export Products.
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) <i>Candida albicans</i> ATCC®10231	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.
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.
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.

Components	LOT		QTY	Components	LOT		QTY
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CHCA Matrix for use with AUTOF MS	2025030301	2026-03-02	4	IFU	/	/	1
Package label and component labels are correct and clear without alterations.							
Conclusion: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>							
Operator/ Date: Wushuang Jiang/Mar.12,2025							
Approved by/ Date: Lijing Liu/Mar.12,2025							
Comments: /							
All AUTOBIO products are manufactured under ISO 13485:2016 certified quality system.							