

IVD

## Certificate of Analysis

Calibrator for use with AUTOF MS		Standard: In-house Standard CP-0325-015; TY-0026-006	
<b>REF</b> MSA02	<b>LOT</b> 2025101501 Production Date: 2025.10.15	 2026-10-14	 80

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. 4) The appearance of the kit is undamaged; the label is clear and easily recognizable; the lyophilized component is solid, and the solution is opaque and cloudy with little white precipitate.	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. 4) The appearance of the kit shall be undamaged; the label shall be clear and easily recognizable; the lyophilized component is solid, and the solution is opaque and cloudy with little white precipitate.
accuracy	/	The bias between Calibrator and enterprise calibrator standard value is $\leq 0.1\%$ .	Test the Calibrator with AUTOF MS, the bias between Calibrator and enterprise calibrator standard value should be $\leq 0.1\%$ .
UDI	/	The production date, batch number and expiration date information on the clear code and kit are consistent.	The production date, batch number and expiration date information on the clear code and kit should be consistent.
		The corresponding code information in the coding system is consistent with the clear code information on the kit.	The corresponding code information in the coding system should be consistent with the clear code information on the kit.
Product identification validation	/	The UDI-DI information on the product packaging is consistent with the UDI database or K3 information of the corresponding exporting country.	The UDI-DI information on the product packaging is consistent with the UDI database or K3 information of the corresponding exporting country.

Components	<b>LOT</b>		QTY	Components	<b>LOT</b>		QTY
Calibrator for use with AUTOF MS	2025101501	2026-10-14	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 / October 23, 2025
Approved by/ Date: Xiaoli Zhao / October 23, 2025
Comments: /
All AUTOBIO products are manufactured under ISO 13485:2016 certified quality system.