

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> 2025022601 | 2026-02-25   | 80 |

| Items                             | Controls | Result  | Acceptable range  |
|-----------------------------------|----------|---|---|
| Appearance                        | /        | 1) The component is complete.<br>2) The REF on the kit label is the same as the REF on the instructions.<br>3) Product validity date is consistent with K3 information verification.<br>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.<br>2) Check the REF on the kit label should be the same as the REF on the instructions.<br>3) Product validity date is consistent with K3 information verification.<br>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 | 2025022601 | 2026-02-25 | 4   | IFU        | /          | / | 1   |

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

Conclusion: YES  NO

Operator/ Date: Wushuang Jiang/Mar.07,2025

Approved by/ Date: Lijing Liu/Mar.07,2025

Comments: /

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