

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HBsAb Quantitative EIA Test Kit

PURCHASE NO.: 37740066B

BATCH NO.: 2003706

EXPIRATION DATE: 2021/03/04

QUANTITY: 33kits

| SPECIFICATION                                                                                   |           | STANDARD                                                                          | CONCLUSION |
|-------------------------------------------------------------------------------------------------|-----------|-----------------------------------------------------------------------------------|------------|
| Appearance                                                                                      |           | No obvious sediments or floccules in liquid component and color meets requirement | Complies   |
| Sensitivity Standard                                                                            | 10mIU/mL  | $0.105 < OD < 0.400$                                                              | Complies   |
|                                                                                                 | 100mIU/mL | $0.500 < OD < 1.600$                                                              | Complies   |
|                                                                                                 | 200mIU/mL | $OD > 1.200$ and $OD > 100.0 \text{ mIU/mL}$ OD                                   | Complies   |
| Compliance of Negative Standard                                                                 |           | $OD < \text{Calibrator 2\# } OD$                                                  | Complies   |
| Calibrator 1#                                                                                   |           | $OD < 0.105$                                                                      | Complies   |
| Calibrator 2#                                                                                   |           | $OD > 0.105$                                                                      | Complies   |
| Calibrator 3#                                                                                   |           | $OD > 0.250$                                                                      | Complies   |
| Calibrator 4#                                                                                   |           | $OD > 0.500$                                                                      | Complies   |
| Calibrator 5#                                                                                   |           | $OD > 1.000$                                                                      | Complies   |
| R value                                                                                         |           | $R > 0.98$                                                                        | Complies   |
| Precision                                                                                       |           | $CV < 15\%$                                                                       | Complies   |
| The above results based on evaluation on the whole kit with all components manufactured by ACON |           |                                                                                   |            |

Quality Department: Antony. Hu

Date: Apr. 21, 2020