

## **Certificate of Analysis**

Number: FAPON-FR-T0-017 Edition: B.2

| Product overview              |   |                                  |                        |                  |  |
|-------------------------------|---|----------------------------------|------------------------|------------------|--|
| Product Name                  | HIV-2 gp36 recombinant antigen  | Catalog Number                   | GRCHIVS205             |                  |  |
| Date of Manufacture           | Specific date   | Lot Number                       | Specific lot number    |                  |  |
| Immunogen                     | N/A   |                                  | •                      |                  |  |
| Species                       | N/A   | Expressed Host                   | E.coli                 |                  |  |
| Tag                           | His   | Clone number                     | N/A                    |                  |  |
| Isotype                       | N/A   | Molecular weight                 | 31.4kDa                |                  |  |
| Product buffer solution       | 10mMPB+150mMNaCl+3mMEDTA , pH7.4  | Preservative                     | N/A                    |                  |  |
| Storage Conditions            | 2~8°C   | Date of Expiration               | Shelf life:36 months   |                  |  |
| Applications                  | Capture   | Platforms tested                 | GICA                   |                  |  |
| Parameters tested on each lot |   |                                  |                        |                  |  |
| Product appearance            | Product appearance Liquid   |                                  |                        |                  |  |
| Conc.determined by            | UV absorption   | Concentration /Recommended titer | Specific Concentration |                  |  |
| Purification                  | Ion-exchange chromatography   | Purity                           | ≥90%                   |                  |  |
| Performance:                  |   |                                  |                        |                  |  |
| Items                         | Passing criteria  |                                  |                        | Qualified or not |  |
| Immunoreactivity              | At the same working concentration, the deviation of the activity in the test group from the control group is within $\pm0.5$ C.   |                                  |                        | Yes√ No□         |  |
| Clinical specificity          | <ol> <li>There is no color reaction in negative internal control samples.</li> <li>In testing the internal control samples, the deviation of the colorimetric level in the test group from the control group is within ±0.5.</li> </ol> |                                  |                        | Yes√ No□         |  |
| Product stability             | N/A   |                                  |                        | Yes□ No□         |  |
| Miscellaneous                 | N/A   |                                  |                        | Yes□ No□         |  |
| Remark                        | N/A   |                                  |                        |                  |  |
| Conclusion                    | Pass√ Fail □  |                                  |                        |                  |  |

| Quality signature | N/A | Quality inspection date | N/A |
|-------------------|-----|-------------------------|-----|

管理者代表: 人 人 Management representative

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