

Certificate of Analysis

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

| Product overview | | | | | |
|-------------------------------|--|-------------------------------------|------------------------|---------------------|--|
| Product Name | HIV-1+2 gp41+120+gp36 recombinant antigen | Catalog Number | GRJHIVS306 | | |
| Date of Manufacture | Specific date | Lot Number | Specifi | Specific lot number | |
| Immunogen | N/A | | | | |
| Species | N/A | Expressed Host | E.coli | | |
| Tag | N/A | Clone number | N/A | | |
| Isotype | N/A | Molecular weight | 43kDa | | |
| Product buffer solution | 20mMTris-HCl+5mMEDTA,pH8.5 | Preservative | N/A | | |
| Storage Conditions | 2~8°C | Date of Expiration | Shelf life:36 months | | |
| Applications | Detection | Platforms tested | GICA | | |
| Parameters tested on each lot | | | | | |
| Product appearance | Liquid | | | | |
| Conc.determined by | UV absorption | Concentration /Recommended titer | Specific Concentration | | |
| Purification | Ion-exchange chromatography | Purity | N/A | | |
| 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 ±0.5 C. | | | Yes√ No□ | |
| Clinical specificity | In testing 30 clinical samples, the positivity rate/negativity rate in the test group is the same as the control group. In the blood samples tested positive/negative, the deviation of the colorimetric level in the test group from the control group is within ±0.5C. | | | 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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