

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

| | Produc | t overview | | | | |
|-------------------------|---|-------------------------------------|------------------------|------------------|--|--|
| Product Name | Anti-Dengue NS1 monoclonal antibody | Catalog Number | BRCNS1S114 | | | |
| Date of Manufacture | Specific date | Lot Number | Specific lot number | | | |
| Immunogen | recombinant Dengue NS1 protein | | | | | |
| Species | N/A | Expressed Host | СНО | | | |
| Тад | N/A | Clone number | 30F3 | | | |
| Isotype | lgG1 | Molecular weight | 150kDa | | | |
| Product buffer solution | 10mM PB+150mM NaCl+0.1% ProClin300,pH7.4 | Preservative | ProClin300 | | | |
| Storage Conditions | -20±5°C, Avoid multiple freeze/thaw cycles | Date of Expiration | Shelf life:36 months | | | |
| Applications | Capture | Platforms tested | GICA | | | |
| | Parameters to | ested on each lot | | | | |
| Product appearance | Liquid | | | | | |
| Conc.determined by | UV absorption | Concentration /Recommended titer | Specific Concentration | | | |
| Purification | Affinity 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 ±0.5C. | | | Yes√ No□ | | |
| Clinical specificity | There is no color reaction in negative internal control samples. In testing the internal control samples, the deviation of the colorimetric level in the test group from the control group is within ±0.5. | | | Yes√ No⊓ | | |
| Product stability | N/A | | | Yes□ No□ | | |
| Miscellaneous | N/A | | | Yes□ No□ | | |
| Remark | N/A | | 1 | | | |

| Conclusion | Pass√ | Fail 🗆 | | |
|-------------------|-------|--------|----------------------------|-----|
| Quality signature | N/A | | Quality inspection date | N/A |

管理者代表: 了, 2 · 以子 Management representative

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