

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

| Product overview | | | |
|--------------------------------|---|---|---|
| Product Name | Anti-Malaria HRP II monoclonal antibody | Catalog Number | BRJMALS109 |
| Date of Manufacture | Specific date | Lot Number | Specific lot number |
| Immunogen | Recombinant Plasmodium falciparum HRP-II protein | | |
| Species | Mouse | Expressed Host | N/A |
| Tag | N/A | Clone number | 18F7 |
| Isotype | IgG1 | 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 | Detection | Platforms tested | GICA |
| Parameters tested on each lot | | | |
| Product appearance | Liquid | | |
| Conc.determined by | UV absorption | Concentration /Recommended titer | Specific Concentration |
| Purification | caprylic acid precipitation | 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 <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Clinical specificity | 1. There is no color reaction in negative internal control samples. 2. 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 <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Product stability | N/A | | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Miscellaneous | N/A | | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Remark | N/A | | |

| | | | |
|--------------------------|---|--------------------------------------|-----|
| Conclusion | Pass <input checked="" type="checkbox"/> | Fail <input type="checkbox"/> | |
| Quality signature | N/A | Quality inspection date | N/A |

管理者代表: 
Management representative

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