

## Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

| Product overview               |   |   |   |
|--------------------------------|---|---|---|
| <b>Product Name</b>            | Anti-Malaria PLDH monoclonal antibody   | <b>Catalog Number</b>                   | BRJMALS202  |
| <b>Date of Manufacture</b>     | Specific date   | <b>Lot Number</b>                       | Specific lot number   |
| <b>Immunogen</b>               | N/A   |   |   |
| <b>Species</b>                 | N/A   | <b>Expressed Host</b>                   | N/A   |
| <b>Tag</b>                     | N/A   | <b>Clone number</b>                     | 1A5   |
| <b>Isotype</b>                 | IgG1  | <b>Molecular weight</b>                 | 150kDa  |
| <b>Product buffer solution</b> | 10mM PB+150mM NaCl+0.1% ProClin300,pH7.4  | <b>Preservative</b>                     | ProClin300  |
| <b>Storage Conditions</b>      | -20±5°C, Avoid multiple freeze/thaw cycles  | <b>Date of Expiration</b>               | Shelf life:36 months  |
| <b>Applications</b>            | Detection   | <b>Platforms tested</b>                 | N/A   |
| Parameters tested on each lot  |   |   |   |
| <b>Product appearance</b>      | Liquid  |   |   |
| <b>Conc.determined by</b>      | N/A   | <b>Concentration /Recommended titer</b> | Specific Concentration  |
| <b>Purification</b>            | N/A   | <b>Purity</b>                           | ≥90%  |
| <b>Performance:</b>            |   |   |   |
| Items                          | Passing criteria  |   | Qualified or not  |
| <b>Immunoreactivity</b>        | 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"/> |
| <b>Clinical specificity</b>    | 1. There is no color reaction in negative internal control samples.<br>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"/> |
| <b>Product stability</b>       | N/A   |   | Yes <input type="checkbox"/> No <input type="checkbox"/>            |
| <b>Miscellaneous</b>           | N/A   |   | Yes <input type="checkbox"/> No <input type="checkbox"/>            |
| <b>Remark</b>                  | 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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