

## Certificate of Analysis

Number: FAPON-FR-T0-017

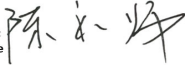
Edition: B.2

| Product overview               |  |   |   |
|--------------------------------|--|---|---|
| <b>Product Name</b>            | Anti-HBe Monoclonal Antibody   | <b>Catalog Number</b>                   | BEJHBVS201  |
| <b>Date of Manufacture</b>     | Specific date  | <b>Lot Number</b>                       | Specific lot number   |
| <b>Immunogen</b>               | Recombinant HBeAg antigen  |   |   |
| <b>Species</b>                 | Mouse  | <b>Expressed Host</b>                   | N/A   |
| <b>Tag</b>                     | N/A  | <b>Clone number</b>                     | 2B4   |
| <b>Isotype</b>                 | IgG1   | <b>Molecular weight</b>                 | 150kDa  |
| <b>Product buffer solution</b> | 10mM PB+150mMNaCl+0.1%<br>ProClin300,pH7.4   | <b>Preservative</b>                     | ProClin300  |
| <b>Storage Conditions</b>      | -20±5°C, Avoid multiple freeze/thaw<br>cycles  | <b>Date of Expiration</b>               | Shelf life:36 months  |
| <b>Applications</b>            | Capture  | <b>Platforms tested</b>                 | ELISA、CLIA  |
| Parameters tested on each lot  |  |   |   |
| <b>Product appearance</b>      | Liquid   |   |   |
| <b>Conc.determined by</b>      | UV absorption  | <b>Concentration /Recommended titer</b> | Specific Concentration  |
| <b>Purification</b>            | Protein A chromatography   | <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 ± 10%.   |   | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| <b>Clinical specificity</b>    | 1. There is no positive result in testing all negative internal control samples.<br>2. In testing internal control samples, the deviation of the specificity in the test group from the control group is not more than 1 sample. |   | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| <b>Product stability</b>       | When accelerated stability testing at 37°C was performed, No change in specificity testing of the internal controls samples was observed and the change in activity was not higher than 10%.                                     |   | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| <b>Miscellaneous</b>           | N/A  |   | Yes <input type="checkbox"/> No <input type="checkbox"/>            |

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

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管理者代表:  
Management representative



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