

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

| Product overview | | | |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|-----------------------------------------------------------------------------------|
| Product Name | Anti TSH recombinant Antibody | Catalog Number | BEJTSHS102 |
| Date of Manufacture | Specific date | Lot Number | Specific lot number |
| Immunogen | N/A | | |
| Species | Mouse | Expressed Host | CHO |
| Tag | N/A | Clone number | 26C5 |
| Isotype | IgG2a | 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 | ELISA、CLIA |
| Parameters tested on each lot | | | |
| Product appearance | Liquid | | |
| Conc.determined by | UV absorption | Concentration /Recommended titer | Specific Concentration |
| Purification | Protein A chromatography+Ion-exchange chromatography | Purity | ≥90% |
| Performance: | | | |
| Items | Passing criteria | | Qualified or not |
| Immunoreactivity | CMIA platform: When the quality control concentration is equivalent, the reading value deviation of the batch to be tested and the control batch for the same quality control is less than ±10%. | | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Clinical specificity | N/A | | Yes <input 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"/> | | |

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|-------------------|-----|-------------------------|-----|
| Quality signature | N/A | Quality inspection date | N/A |
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管理者代表: 
Management representative

广东省东莞市松山湖台湾高科技园花莲路5号
No.5 Hualian Road, Taiwan High-tech industrial park, Songshan Lake, Dongguan, Guangdong, 523808, China
0769-22898885 marketcn@fapon.com (国内/Domestic) market@fapon.com (国际/International) www.faponbiotech.com