

Certificate of Analysis

Number: FAPON-FR-T0-017 Edition: B.2

| Product overview | | | | | | |
|-------------------------------|---|----------------------------------|------------------------|------------------|--|--|
| Product Name | Anti-cTnI monoclonal antibody | Catalog Number | BRNC ⁻ | BRNCTNIN102 | | |
| Date of Manufacture | Specific date | Lot Number | Specific lot number | | | |
| Immunogen | Recombinant human cTnI | | | | | |
| Species | Mouse | Expressed Host CHO | | | | |
| Tag | N/A | Clone number | 26G2 | | | |
| Isotype | lgG1 | Molecular weight | 150 kDa | | | |
| 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 | FIA | | | |
| Parameters tested on each lot | | | | | | |
| Product appearance | Liquid | | | | | |
| Conc.determined by | UV absorption | Concentration /Recommended titer | Specific Concentration | | | |
| Purification | Protein A 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 | | | | | |

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

管理者代表: 人 人 人

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