

Certificate of Analysis

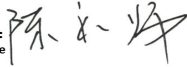
Number: FAPON-FR-T0-017

Edition: B.2

| Product overview | | | |
|--------------------------------|--|---|---|
| Product Name | Anti-CEA Monoclonal Antibody | Catalog Number | BECCEAS104 |
| Date of Manufacture | Specific date | Lot Number | Specific lot number |
| Immunogen | N/A | | |
| Species | N/A | Expressed Host | CHO |
| Tag | N/A | Clone number | N/A |
| Isotype | IgG | 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 | N/A | Platforms tested | N/A |
| 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 | 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"/> |
| Clinical specificity | 1. Internal negative control samples did not show any positivity during testing. 2. The slope was within range of 0.75-1.2 and R ² is not less than 0.85, when the results of the test group and in the 80 positive samples were compared. | | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Product stability | 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 20%. | | Yes <input checked="" 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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