

Certificate of Analysis

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

| Product overview | | | | | | | |
|-------------------------------|---|----------------------------------|------------------------|------------------|--|--|--|
| Product Name | Anti-CEA monoclonal antibody | Catalog Number | BENCEAS101 | | | | |
| Date of Manufacture | Specific date | Lot Number | Specific lot number | | | | |
| Immunogen | N/A | | | | | | |
| Species | Mouse | Expressed Host | N/A | N/A | | | |
| Tag | N/A | Clone number | N/A | | | | |
| Isotype | lgG1 | 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 | N/A | | | | |
| Parameters tested on each lot | | | | | | | |
| Product appearance | Liquid | | | | | | |
| Conc.determined by | N/A | Concentration /Recommended titer | Specific Concentration | | | | |
| Purification | N/A | 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 \pm 10%. | | | Yes√ No□ | | | |
| Clinical specificity | Internal negative control samples did not show any positivity during testing. 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√ No□ | | | |
| Product stability | When accelerated stability testing at 37°C was performend, No change in specificity testing of the internal controls samples was observed and the change in activity was not higher than 20%. | | | Yes√ No□ | | | |

| Miscellaneous | N/A | | | | | Yes□ No□ |
|-------------------|-----|------|--------|-------------------------|-----|----------|
| Remark | N/A | | | | | |
| Conclusion | Pa | ass√ | Fail □ | | | |
| Quality signature | N/A | | | Quality inspection date | N/A | |

| 管理者代表: Management representative | 34 | χ- | X |
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