

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

| Product overview | | | |
|--------------------------------|--|---|---|
| Product Name | HCV recombinant antigen | Catalog Number | GECHCVI301 |
| Date of Manufacture | Specific date | Lot Number | Specific lot number |
| Immunogen | N/A | | |
| Species | N/A | Expressed Host | E.coli |
| Tag | His | Clone number | N/A |
| Isotype | N/A | Molecular weight | 55kDa |
| Product buffer solution | 25mM Tris-HCl+0.1% SDS+5mMEDTA,pH8.0 | Preservative | N/A |
| Storage Conditions | -20±5°C, Avoid multiple freeze/thaw cycles | Date of Expiration | Shelf life:36 months |
| Applications | Capture | 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 | ≥95% |
| 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. There is no positive result in testing all negative internal control samples. 2. In testing internal control samples, the deviation of the specificity in the test group from the control group is not more than 3 sample. | | 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 15%. | | 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 | |

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管理者代表:
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