

Certificate of Analysis

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

| Product overview | | | | | |
|-------------------------------|---|----------------------------------|------------------------|------------------|--|
| Product Name | Anti Methadone antibody | Catalog Number | BRNMTDN101 | | |
| Date of Manufacture | Specific date | Lot Number | Specific lot number | | |
| Immunogen | N/A | | | | |
| Species | N/A | Expressed Host | СНО | | |
| Tag | N/A | Clone number | 30F2 | | |
| 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 | GICA | | |
| Parameters tested on each lot | | | | | |
| Product appearance | Liquid | | | | |
| Conc.determined by | UV absorption | Concentration /Recommended titer | Specific Concentration | | |
| Purification | Protein A chromatography+lon- exchange chromatography | Purity | ≥90% | | |
| Performance: | | | | | |
| Items | Passing criteria | | | Qualified or not | |
| Immunoreactivity | In testing the internal control samples, the deviation of the colorimetric level in the test group from the control group is within ±0.5. | | rimetric | Yes√ No□ | |
| Clinical specificity | The 10 negative urine samples tested true negative. | | | 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 Management representative

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