

K233417 AllTest Fentanyl Urine Test CassetteOct 26, 2023
16 days to decisionK233417 · Product code: **NGL** · Toxicology
Source: <https://www.510kdatabase.net/k233417/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test, Opiates, Over The Counter (NGL) |
| Date received | Oct 10, 2023 |
| Decision date | Oct 26, 2023 |
| Days to decision | 16 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------|
| Company | Hangzhou AllTest Biotech Co., Ltd. |
| Location | Hangzhou, CN |
| Contact | Rosa Wu |
| 510(k) history | 14 submissions · 14 cleared · 2019-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233417/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026