

K250727 AllTest Multi-Drug Rapid Urine Test CupApr 4, 2025
24 days to decisionK250727 · Product code: **NFT** · Toxicology
Source: <https://www.510kdatabase.net/k250727/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test, Amphetamine, Over The Counter (NFT) |
| Date received | Mar 11, 2025 |
| Decision date | Apr 4, 2025 |
| Days to decision | 24 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | AllTest Multi-Drug Urine Test Cup |

APPLICANT

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

REGULATORY CONSULTANT

| | |
|-----------------|--------------------------------|
| Consulting firm | LSI International, Inc. |
| Contact | Jenny Xia |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250727/> 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