

K863127 TESTPACK ACUTE HCG URINGE CONTROLSSep 15, 1986
31 days to decisionK863127 · Product code: **JJW** · Chemistry
Source: <https://www.510kdatabase.net/k863127/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Urinalysis Controls (assayed And Unassayed) (JJW) |
| Date received | Aug 15, 1986 |
| Decision date | Sep 15, 1986 |
| Days to decision | 31 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Abbott Laboratories |
| Location | Abbott Park, IL, US |
| Contact | MATT KLAMRZYNSKI |
| Website | http://www.abbott.com |
| 510(k) history | 883 submissions · 868 cleared · 1976-2026 |

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

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Device record: <https://www.510kdatabase.net/k863127/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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