

K113793 HOMOCYSTEINE TESTJun 5, 2012
165 days to decisionK113793 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k113793/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Urinary Homocystine (nonquantitative) Test System (LPS) |
| Date received | Dec 23, 2011 |
| Decision date | Jun 5, 2012 |
| Days to decision | 165 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Roche |
| Location | Indianapolis, IN, US |
| Contact | Susan Hollandbeck |
| 510(k) history | 2 submissions · 2 cleared · 2011-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113793/> 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 June 14, 2026