

**K103627 ARCHITECT ICARBAMAZEPINE ICARBAMAZEPINE REAGENTS**Oct 14, 2011  
305 days to decisionK103627 · Product code: **KLT** · Toxicology  
Source: <https://www.510kdatabase.net/k103627/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Enzyme Immunoassay, Carbamazepine (KLT) |
| Date received         | Dec 13, 2010                            |
| Decision date         | Oct 14, 2011                            |
| Days to decision      | 305 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |
| Other names           | ARCHITECT ICARBAMAZEPINE CALIBRATORS    |

**APPLICANT**

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|----------------|---|
| Company        | <b>Abbott Laboratories</b>                                |
| Location       | Abbott Park, IL, US                                       |
| Contact        | JUDITH R WALLACH  |
| Website        | <a href="http://www.abbott.com">http://www.abbott.com</a> |
| 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...