

**K990594 INTEGRA REAGENT CASSETTE FOR  
APOLIPOPROTEIN A-1**Apr 14, 1999  
49 days to decisionK990594 · Product code: DER · Chemistry  
Source: <https://www.510kdatabase.net/k990594/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Alpha-1-lipoprotein, Antigen, Antiserum, Control (DER) |
| Date received         | Feb 24, 1999   |
| Decision date         | Apr 14, 1999   |
| Days to decision      | 49 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Roche Diagnostics Corp.</b>            |
| Location       | Indianapolis, IN, US                      |
| Contact        | PRISCILLA A HAMILL                        |
| 510(k) history | 264 submissions · 263 cleared · 1999-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k990594/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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