

**K992528 BIOCHECK IGE ELISA, MODEL BC-1035**Sep 21, 1999  
55 days to decisionK992528 · Product code: **DGC** · Immunology  
Source: <https://www.510kdatabase.net/k992528/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Ige, Antigen, Antiserum, Control (DGC) |
| Date received         | Jul 28, 1999                           |
| Decision date         | Sep 21, 1999                           |
| Days to decision      | 55 days                                |
| Third-party review    | No                                     |
| Summary / Statement   | Statement                              |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biocheck, Inc.</b>                   |
| Location       | Northridge, CA, US                      |
| Contact        | ROBIN J HELLEN                          |
| 510(k) history | 14 submissions · 14 cleared · 1999-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992528/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026