

**K973824 VIRGO PANCO KIT**Nov 13, 1997  
37 days to decisionK973824 · Product code: **MOB** · Immunology  
Source: <https://www.510kdatabase.net/k973824/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                              |
| Submission type       | Traditional   |
| Device classification | Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB) |
| Date received         | Oct 7, 1997   |
| Decision date         | Nov 13, 1997  |
| Days to decision      | 37 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Hemagen Diagnostics, Inc.</b>                              |
| Location       | Waltham, MA, US   |
| Contact        | JOSEPH M CALIFANO   |
| Website        | <a href="http://www.hemagen.com/">http://www.hemagen.com/</a> |
| 510(k) history | 52 submissions · 52 cleared · 1986-2004                       |

Hemagen Diagnostics, Inc. was founded in 1985 by scientists from Boston University School of Medicine. The company provides clinical diagnostic solutions specializing in immunology devices for autoimmune and infectious disease testing. Hemagen offers gold standard IFA products, ELISA, HA, and point-of-care testing formats for human and veterinary diagnostics. Hemagen has received FDA 510(k) clearances from total submissions since its first clearance in 1986. The company's regulatory portfolio focuses on immunology devices, including antibody detection kits, autoimmune scr...

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