

**K140225 ELIA PR3S IMMUNOASSAY, ELIA MPOS
IMMUNOASSAY, ELIA GBM IMMUNOASSAY, ELIA ANCA/GBM
POSITIVE CONTROL 100, ELIA ANCA/GBM PO**Oct 27, 2014
271 days to decisionK140225 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k140225/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB) |
| Date received | Jan 29, 2014 |
| Decision date | Oct 27, 2014 |
| Days to decision | 271 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Phadia US, Inc. |
| Location | Portae, MI, US |
| Contact | MARTIN MANN |
| 510(k) history | 22 submissions · 21 cleared · 2006-2015 |

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