

**K992124 AVANTI POLAR LIPIDS VDRL ANTIGEN SLIDE TEST
KIT WITH 10 X 0.5 ML AMPULES, AVANTI POLAR LIPIDS BULK
BDRL ANTIGEN, AVANTI**Sep 20, 1999
89 days to decisionK992124 · Product code: **GMQ** · Microbiology
Source: <https://www.510kdatabase.net/k992124/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigens, Nontreponemal, All (GMQ) |
| Date received | Jun 23, 1999 |
| Decision date | Sep 20, 1999 |
| Days to decision | 89 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Avanti Polar Lipids, Inc. |
| Location | Alabaster, AL, US |
| Contact | ROWENA SHAW |
| 510(k) history | 1 submissions · 1 cleared · 1999-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992124/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026