

K132010 VIDAS C DIFFICILE GDHOct 9, 2013
100 days to decisionK132010 · Product code: **MCB** · Microbiology
Source: <https://www.510kdatabase.net/k132010/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigen, C. Difficile (MCB) |
| Date received | Jul 1, 2013 |
| Decision date | Oct 9, 2013 |
| Days to decision | 100 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biomerieux S.A. |
| Location | Craponne, FR |
| Contact | CAROLINE KOCH-MATHIAN |
| 510(k) history | 16 submissions · 16 cleared · 2011-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132010/> 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 May 26, 2026