FDA 510(k) Premarket Notification

**CLEARED**

# K242256 QIAstat-Dx Meningitis/Encephalitis (ME) Panel

Oct 29, 2024
90 days to decision

K242256 · Product code: **PLO** · Microbiology
Source: https://www.510kdatabase.net/k242256/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Meningitis/encephalitis Pathogen Multiplex Nucleic Acid Detection System (PLO) |
| Date received | Jul 31, 2024 |
| Decision date | Oct 29, 2024 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **QIAGEN GmbH** |
| Location | Hilden, DE |
| Contact | Autumn Collasius |
| 510(k) history | 13 submissions · 13 cleared · 2012-2026 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **STAT-Dx Life, S.L. (A QIAGEN Company)** |
| Contact | Sonia Pablo Pablo |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov