

K203220 cobas BKVJan 29, 2021
88 days to decisionK203220 · Product code: **QLX** · Microbiology
Source: <https://www.510kdatabase.net/k203220/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nucleic Acid Amplification Test For The Quantitation Of Epstein-barr Virus (ebv) Dna (QLX) |
| Date received | Nov 2, 2020 |
| Decision date | Jan 29, 2021 |
| Days to decision | 88 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Roche Molecular Systems, Inc. |
| Location | Somerville, NJ, US |
| Contact | Raji Grewal |
| 510(k) history | 49 submissions · 46 cleared · 1993-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203220/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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