

**K242613 NxTAG® Respiratory Pathogen Panel**Oct 2, 2024  
29 days to decisionK242613 · Product code: **OCC** · Microbiology  
Source: <https://www.510kdatabase.net/k242613/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Special   |
| Device classification | Respiratory Virus Panel Nucleic Acid Assay System (OCC) |
| Date received         | Sep 3, 2024   |
| Decision date         | Oct 2, 2024   |
| Days to decision      | 29 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|--|
| Company        | <b>Luminex Molecular Diagnostics, Inc.</b> |
| Location       | Toronto, Ontario, CA                       |
| Contact        | Tara Vivian                                |
| 510(k) history | 26 submissions · 22 cleared · 2008-2024    |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242613/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026