

K190302 CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel, Influenza A/B Typing Kit, CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel, Influenza A Subtyping Kit, CDC Human Influenza Virus Real-time RT-PCR, Influenza B Lineage Genotyping Kit, CDC Human Influenza Virus Real-time RT-PCR, Influenza A/HS Subtyping Kit

Mar 27, 2019
43 days to decision

K190302 · Product code: OZE · Microbiology
Source: <https://www.510kdatabase.net/k190302/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Influenza A And Influenza B Multiplex Nucleic Acid Assay (OZE)
Date received	Feb 12, 2019
Decision date	Mar 27, 2019
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Centers For Disease Control and Prevention
Location	Mchenry, IL, US
Contact	Yon Yu
510(k) history	29 submissions · 25 cleared · 1981-2025

Centers For Disease Control and Prevention is the United States federal public health agency under the Department of Health and Human Services. Headquartered in Atlanta, Georgia, the CDC protects public health through disease control and prevention domestically and worldwide. The CDC has received FDA 510(k) clearances from total submissions since 1981. The agency's regulatory portfolio is dominated by Microbiology devices, representing 97% of submissions. Latest clearance activity in 2025 demonstrates continued engagement in FDA regulatory pathways. The CDC's cleared devi...