

**K140857 INFLUENZA B LINEAGE GENOTYPING KIT, CDC
HUMAN INFLUENZA VIRUS REAL-TIME RT-PCR DIAGNOSTIC
PANEL**Apr 25, 2014
22 days to decisionK140857 · Product code: **OZE** · Microbiology
Source: <https://www.510kdatabase.net/k140857/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Influenza A And Influenza B Multiplex Nucleic Acid Assay (OZE)
Date received	Apr 3, 2014
Decision date	Apr 25, 2014
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Centers For Disease Control and Prevention
Location	Mchenry, IL, US
Contact	CDR YON YU, PHARM.D.
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...