

K101564 CDC INFLUENZA 2009 A(H1N1)PDM REAL-TIME RT-PCR PANELJun 22, 2010
18 days to decisionK101564 · Product code: **OQW** · Microbiology
Source: <https://www.510kdatabase.net/k101564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	2009 H1n1 Influenza Virus (swine Origin), Nucleic Acid Or Antigen, Detection And Identification (OQW)
Date received	Jun 4, 2010
Decision date	Jun 22, 2010
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Centers For Disease Control and Prevention
Location	Mchenry, IL, US
Contact	HYE-JOO KIM
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...