

**K252072 Francisella tularensis Real-time PCR assay**Sep 30, 2025  
91 days to decisionK252072 · Product code: **SGA** · Microbiology  
Source: <https://www.510kdatabase.net/k252072/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biothreat Microbial Agent Nucleic Acid Detection Test (SGA)
Date received	Jul 1, 2025
Decision date	Sep 30, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Centers For Disease Control and Prevention</b>
Location	Mchenry, IL, US
Contact	Jasmine Chaitram
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...