

**K100148 SIMPLEXA INFLUENZA A H1N1 (2009) MODEL  
MOL2500**May 24, 2010  
125 days to decisionK100148 · Product code: **OQW** · Microbiology  
Source: <https://www.510kdatabase.net/k100148/>**SUBMISSION DETAILS**

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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	Jan 19, 2010
Decision date	May 24, 2010
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Focus Diagnostics, Inc.</b>
Location	Cypress, CA, US
Contact	TARA VIVIANI
510(k) history	14 submissions · 13 cleared · 2007-2015

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