



# Technical Bulletin

## Notice of Change to the QuickVue® Influenza A+B Test Package Insert: 2009 H1N1 Influenza A Virus Reactivity Information

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Quidel Corporation received Special 510(k) clearance for an update to the Company's QuickVue Influenza A+B test package insert to include reactivity with culture isolates of the 2009 H1N1 Influenza A virus.

Although the QuickVue Influenza A+B test has been shown to detect the 2009 H1N1 virus cultured from a positive human respiratory specimen, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The QuickVue Influenza A+B test can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes.

This clearance supplements the reactivity with 13 other isolates of seasonal H1N1 influenza viruses currently listed in the package insert. In total, 34 different isolates of human Influenza A, 13 different isolates of human Influenza B, and 24 different isolates from birds and mammals have now been shown to be detectable by the QuickVue Influenza A+B test. Please refer to Table 1 for human isolates of influenza A and B and Table 2 for bird and mammal isolates of influenza A. These tables are also included in the revised package insert on Quidel's website at [www.quidel.com](http://www.quidel.com).

Please contact Quidel Technical Support at 800-874-1517 (USA only), 858-552-1100, or [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com) if you have any questions regarding the QuickVue Influenza A+B test or any other Quidel product. Our hours of operation are Monday-Friday, 7:00 am-5:00 pm Pacific Time.

You may also visit our website at [www.quidel.com](http://www.quidel.com) for information on Quidel's line of Rapid Diagnostics, Bone Health and Autoimmune & Complement product lines. Other product information available on our website includes: CPT codes, CLSI Procedure Guidelines, MSDS and package inserts.

**Table 1: Analytical Sensitivity with Human Isolates of Influenza A and B**

<b>Viral Strain</b>	<b>Viral Type</b>	<b>Sub-Type</b>	<b>Minimum Detectable Level</b>	<b>Viral Strain</b>	<b>Viral Type</b>	<b>Sub-Type</b>	<b>Minimum Detectable Level</b>
			<b>TCID50/mL</b>				<b>pfu/mL**</b>
New Caledonia/20/99	A	H1N1	1.63 X 10 <sup>3</sup>	Shangdong	A	H3N2	8.40 x 10 <sup>3</sup>
California/04/09*	A	H1N1	4.4 X 10 <sup>3</sup>	Maryland/91	A	H1N1	1.00 x 10 <sup>4</sup>
			<b>pfu/mL**</b>	Japan/305/57	A	H2N2	1.30 x 10 <sup>4</sup>
Hong Kong	A	H3N2	6.60 x 10 <sup>-1</sup>	Johannesburg/94	A	H3N2	1.44 x 10 <sup>4</sup>
Beijing/32/92	A	H3N2	3.30 x 10 <sup>0</sup>	Brazil	A	H1N1	1.70 x 10 <sup>4</sup>
Shanghai/11	A	H3N2	6.70 x 10 <sup>0</sup>	Sydney	A	H3N2	2.00 x 10 <sup>4</sup>
Shanghai/16	A	H3N2	1.00 x 10 <sup>1</sup>	Bangkok	A	H3N2	3.30 x 10 <sup>4</sup>
Victoria	A	H3N2	3.30 x 10 <sup>1</sup>	Wuhan	A	H3N2	3.30 x 10 <sup>4</sup>
Singapore/1/57	A	H2N2	6.70 x 10 <sup>1</sup>	Beijing/353/89	A	H3N2	3.30 x 10 <sup>5</sup>
Port Chalmers	A	H3N2	1.24 x 10 <sup>2</sup>	Singapore/86	A	H1N1	6.60 x 10 <sup>5</sup>
USSR	A	H1N1	2.00 x 10 <sup>2</sup>	Texas/91	A	H1N1	1.60 x 10 <sup>7</sup>
Puerto Rico/8/34	A	H1N1	2.60 x 10 <sup>2</sup>	Victoria	B		1.40 x 10 <sup>4</sup>
New Jersey	A	H1N1	2.70 x 10 <sup>2</sup>	Taiwan	B		1.10 x 10 <sup>2</sup>
Taiwan	A	H1N1	3.30 x 10 <sup>2</sup>	Panama	B		1.00 x 10 <sup>0</sup>
Tokyo/3/67	A	H2N2	3.40 x 10 <sup>2</sup>	Ann Arbor	B		3.30 x 10 <sup>2</sup>
Bayern	A	H1N1	6.60 x 10 <sup>2</sup>	Singapore	B		3.30 x 10 <sup>2</sup>
Sichuan	A	H3N2	6.60 x 10 <sup>2</sup>	Lee	B		6.60 x 10 <sup>2</sup>
Beijing/352/89	A	H3N2	7.70 x 10 <sup>2</sup>	Hong Kong	B		7.00 x 10 <sup>2</sup>
NWS/33	A	H1N1	1.00 x 10 <sup>3</sup>	Beijing/184/93	B		1.66 x 10 <sup>3</sup>
Fort Warren/1/50	A	H1N1	1.70 x 10 <sup>3</sup>	California	B		3.30 x 10 <sup>3</sup>
Mississippi	A	H3N2	1.70 x 10 <sup>3</sup>	Maryland	B		6.60 x 10 <sup>3</sup>
Texas/77	A	H1N1	3.30 x 10 <sup>3</sup>	Yamagata/16/88	B		6.70 x 10 <sup>3</sup>
Fort Monmouth/1/47	A	H1N1	6.70 x 10 <sup>3</sup>	Harbin	B		1.40 x 10 <sup>4</sup>
Aichi	A	H3N2	3.20 x 10 <sup>3</sup>	Stockholm	B		3.30 x 10 <sup>5</sup>

TCID50/mL = 50% tissue culture infectious dose  
 pfu/mL = plaque-forming unit per milliliter

\*Although this test has been shown to detect the 2009 H1N1 virus cultured from a positive human respiratory specimen, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The QuickVue Influenza A+B test can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes.

\*\*These viral strains were obtained from American Type Culture Collection (ATCC) with titer information, and the titers were not verified by Quidel. The performance characteristics for influenza A virus subtypes emerging as human pathogens have not been established.

**Table 2: Analytical Sensitivity with Bird and Mammal Isolates of Influenza A**

<b>Viral Strain*</b>	<b>Viral Type</b>	<b>Viral Subtype</b>
Duck/Tottori/723/80	A	H1N1
Duck/Alberta	A	H1N1
Duck/Hokkaido/17/01	A	H2N2
Duck/Mongolia/4/03	A	H3N8
Duck/Ukraine/1/63	A	H3N8
Equine/Miami/1/63	A	H3N8
Duck/Czech/56	A	H4N6
Hong Kong/483/97	A	H5N1
Hong Kong/156/97	A	H5N1
Chicken/Yamaguchi/7/04	A	H5N1
A/Chicken/Vietnam/33/04	A	H5N1
A/Vietnam/3028/04	A	H5N1
A/Thailand/MK2/04	A	H5N1
Duck/Pennsylvania/10128/84	A	H5N2
Turkey/Massachusetts/3740/65	A	H6N2
Seal/Massachusetts/1/80	A	H7N7
Turkey/Ontario/67	A	H8N4
Turkey/Wisconsin/66	A	H9N2
Chicken/Germany/N/49	A	H10N7
Duck/England/56	A	H11N6
Duck/Alberta/60/76	A	H12N5
Gull/Maryland/704/77	A	H13N6
Mallard/Astrakhan/263/82	A	H14N5
Duck/Australia/341/83	A	H15N8

\*Performance characteristics for detecting influenza A virus from human specimens when these or other influenza A virus subtypes are emerging as human pathogens have not been established.