

**Table 1. FDA-cleared RT-PCR Assays and Other Molecular Assays for Influenza Viruses**

Products	Manufacturer(s)	Influenza Virus Type Detected	Influenza Virus Subtype(s) Differentiated	Other Respiratory Viruses Differentiated	Acceptable Specimens <sup>1</sup>	Test Time <sup>2</sup> / Complexity <sup>3</sup>
Alere i NAT Flu A/B (CLIA Waived)	Alere	Influenza A and B	None	None	Nasal swabs (Direct)	0.25h/ CLIA Waived
Alere i NAT Flu A/B (Moderate)	Alere	Influenza A and B	None	None	Nasal swabs (in VTM <sup>5</sup> )	0.25 h/ Moderate
CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A/B Typing Kit <sup>4</sup> )	CDC Influenza Division	Influenza A and B	None	None	Nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes, dual nasopharyngeal/ throat swabs  bronchoalveolar lavages, bronchial washes, tracheal aspirates, sputum, lung tissue, and viral culture	~4 h/ High
CDC Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel	CDC Influenza Division	Influenza A	A/H1, A/H3,	None	Nasopharyngeal swabs, nasal swabs (in VTM <sup>5</sup> ), or viral culture	~4 h/ High

CDC Influenza A/H5 (Asian Lineage) Virus Real-Time RT-PCR Primer and Probe Set	CDC Influenza Division	Influenza A	A/H5N1 (Asian lineage)	None	respiratory specimens and viral culture	~4 h/ High
CDC Influenza 2009 A(H1N1)pdm Real-Time RT-PCR Panel	CDC Influenza Division	Influenza A	2009 H1	None	Nasopharyngeal swabs, nasal swabs, nasal aspirates, nasal washes, dual nasopharyngeal/ throat swabs, bronchoalveolar lavages, tracheal aspirates, bronchial washes, and viral culture	~4 h/ High
Cepheid Xpert Flu Assay	Cepheid	Influenza A and B	A/2009 H1	None	Nasopharyngeal swabs (in VTM <sup>5</sup> ), nasal aspirates, and nasal washes,	1.0 h/ Moderate
Cepheid Xpert Flu/RSV XC Assay	Cepheid	Influenza A and B	None	Respiratory Syncytial Virus	Nasopharyngeal swabs and nasal wash and nasal aspirate (in VTM <sup>5</sup> )	<1.0 h/ Moderate
cobas Influenza A/B	Roche Diagnostics	Influenza A and B	A/H1, A/H3 (30 strains)	None	Nasopharyngeal swabs	≤20 minutes CLIA Waived
eSensor® Respiratory Viral Panel (RVP)	GenMark Diagnostics, Inc.	Influenza A and B	A/H1, A/H3, A/2009 H1	Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B, Parainfluenza 1, 2, and 3 virus, Human Metapneumovirus,	Nasopharyngeal swabs (in VTM <sup>5</sup> )	~8 h/ High

				Adenovirus Species B/E, Adenovirus Species C, and Human Rhinovirus		
FilmArray Respiratory Panel	BioFire Diagnostics, LLC	Influenza A and B	A/H1, A/H3, A/2009 H1	Respiratory Syncytial Virus, Parainfluenza 1, 2, 3 and 4 virus, Human Metapneumovirus, Rhinovirus/Enterovirus, Adenovirus, Coronavirus HKU1, Coronavirus NL63	Nasopharyngeal swabs (in VTM <sup>5</sup> )	1.0 h/ Moderate
Ibis PLEX-ID Flu	Ibis/Abbott	Influenza A and B	A/H1, A/H3, A/2009 H1	None	Nasopharyngeal swabs (in VTM <sup>5</sup> )	~8 h/ High
IMDx Flu A/B and RSV for Abbott m2000	IMDx	Influenza A and B	A/H1, A/H3, A/2009 H1	Respiratory Syncytial Virus	Nasopharyngeal swabs (in VTM <sup>5</sup> )	~4 h/ High
Prodesse PROFLU™+	GenProbe/Hologic	Influenza A and B	None	Respiratory Syncytial Virus	Nasopharyngeal swabs (in VTM <sup>5</sup> )	<4h/ High
Prodesse ProFAST™+	GenProbe/Hologic	Influenza A	A/H1, A/H3, A/2009 H1	None	Nasopharyngeal swabs (in VTM <sup>5</sup> )	<4h/ High
Qiagen Artus Influenza A/B Rotor-gene RT-PCR kit	Qiagen	Influenza A and B	None	None	Nasopharyngeal swabs (in VTM <sup>5</sup> )	~4 h/ High

Quidel Molecular Influenza A+B Assay	Quidel	Influenza A and B	None	None	Nasopharyngeal swabs and nasal swabs (in VTM <sup>5</sup> )	~4 h/ High
Simplexa™ Flu A/B & RSV	Focus Diagnostics, 3M	Influenza A and B	None	RSV	Nasopharyngeal swabs (in VTM <sup>5</sup> )	<4h/ High
Simplexa™ Flu A/B & RSV Direct	Focus Diagnostics, 3M	Influenza A and B	None	RSV	Nasopharyngeal swabs (in VTM <sup>5</sup> )	<2h/ Moderate
Simplexa™ Influenza A H1N1 (2009)	Focus Diagnostics, 3M	Influenza A	A/2009 H1	None	Nasopharyngeal swabs, nasal swabs (in VTM <sup>5</sup> ), and nasopharyngeal aspirates	<4h/ High
U.S. Army JBAIDS Influenza A&B Detection Kit <sup>4</sup>	Biofire Defense	Influenza A and B	None	None	Nasopharyngeal swabs (in VTM <sup>5</sup> ) and Nasopharyngeal washes	~4 h/ High
U.S. Army JBAIDS Influenza A Subtyping Kit <sup>4</sup>	Biofire Defense	Influenza A	A/H1, A/H3, A/2009 H1	None	Nasopharyngeal swabs (in VTM <sup>5</sup> ) and Nasopharyngeal washes	~4 h/ High
U.S. Army JBAIDS Influenza A/H5 Kit <sup>4</sup>	Biofire Defense	Influenza A	A/H5N1 (Asian Lineage)	None	Nasopharyngeal and throat swabs (in VTM <sup>5</sup> )	~4 h/ High
Verigene® Respiratory Virus Nucleic Acid Test	Nanosphere, Inc	Influenza A and B	None	Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B	Nasopharyngeal swabs (in VTM <sup>5</sup> )	3.5 h/ Moderate

Verigene® Respiratory Virus Plus Nucleic Acid Test (RV+)	Nanosphere, Inc	Influenza A and B	A/H1, A/H3, A/2009 H1	Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B	Nasopharyngeal swabs (in VTM <sup>5</sup> )	3.5 h/ Moderate
Verigene® Respiratory Pathogen Nucleic Acid Test (RP Flex)	Nanosphere, Inc	Influenza A and B	A/H1 (including H1 and 2009 H1), and A/H3	Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B, Parainfluenza 1, 2 3, and 4 virus, Human Metapneumovirus, Adenovirus, and Rhinovirus	Nasopharyngeal swabs (in VTM <sup>5</sup> )	3.5 h/ Moderate
x-TAG® Respiratory Viral Panel (RVP)	Luminex Molecular Diagnostics Inc.	Influenza A and B	A/H1, A/H3	Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B, Parainfluenza 1, 2, and 3 virus, Human	Nasopharyngeal swabs (in VTM <sup>5</sup> )	~8 h/ High

				Metapneumovirus, Rhinovirus, and Adenovirus		
x-TAG® Respiratory Viral Panel Fast (RVP FAST)	Luminex Molecular Diagnostics Inc.	Influenza A and B	A/H1, A/H3	Respiratory Syncytial Virus Human Metapneumovirus, Rhinovirus, and Adenovirus	Nasopharyngeal swabs (in VTM <sup>5</sup> )	~6 h/ High

1. These specimen types are specified in product package inserts cleared by the U.S. Food and Drug Administration (FDA)
2. Test Time is inclusive of actual test time and is exclusive of transport, handling, laboratory run schedules, and generating results. Timing may vary depending on extraction process used. Contact laboratory for expected turn-around time.
3. Clinical Laboratory Improvement Amendments require categorization of tests as waived, moderate or high complexity. Ref: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>
4. Available only to qualified DoD laboratories, U.S. public health laboratories, and NREVSS collaborating laboratories.
5. VTM = Viral transport media