

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 Specimens¹	Test Time²/ Complexity³
Alere i NAT Flu A/B	Alere	Influenza A and B	None	None	Nasal swabs (Direct)	0.25 h/ CLIA-Waived
CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel Influenza A/B Typing Kit ⁴	CDC Influenza Division	Influenza A and B	None	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
CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel Influenza A Subtyping Kit ⁴	CDC Influenza Division	Influenza A	A/H1, A/H3, 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
CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel Influenza A/H5 (Asian lineage) Kit ⁴	CDC Influenza Division	Influenza A	A/H5N1 (Asian lineage)	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
CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel Influenza B Lineage Genotyping Assay ⁴	CDC Influenza Division	Influenza B	B/Victoria and B/Yamagata lineages	None	Nasopharyngeal swabs, nasal swabs, nasal aspirates, nasal washes, dual nasopharyngeal/throat swabs	~4 h/ High
Cepheid Xpert Flu Assay	Cepheid	Influenza A and B	A/2009 H1	None	Nasopharyngeal swabs, 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)	<1.0 h/ Moderate
eSensor® Respiratory Viral Panel (RVP)	Clinical Micro Sensors, Inc. dba 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, Adenovirus Species B/E, Adenovirus Species C, and Human Rhinovirus	Nasopharyngeal swabs	~8 h/ High

FilmArray Respiratory Panel	Idaho Technologies	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	1.0 h/ Moderate
Ibis PLEX-ID Flu	Ibis/Abbott	Influenza A and B	A/H1, A/H3, A/2009 H1	None	Nasopharyngeal swabs	~8 h/ High
IMDx Flu A/B and RSV for Abbott <i>m2000</i>	IMDx	Influenza A and B	A/H1, A/H3, A/2009 H1	None	Nasopharyngeal swabs	~8 h/ High
IQuum Liat Influenza A/B Assay	IQuum	Influenza A and B	None	None	Nasopharyngeal swabs	0.5 h/ Moderate
Prodesse PROFLU™+	GenProbe	Influenza A and B	None	Respiratory Syncytial Virus	Nasopharyngeal swabs	<4h/ High
Prodesse ProFAST™+	GenProbe	Influenza A	A/H1, A/H3, A/2009 H1	None	Nasopharyngeal swabs	<4h/ High
Quidel Molecular Influenza A+B Assay	Quidel	Influenza A and B	None	None	Nasopharyngeal swabs and nasal swabs	~4 h/ High
Qiagen Artus Influenza A/B Rotor-gene RT-PCR kit	Qiagen	Influenza A and B	None	None	Nasopharyngeal swabs	~4 h/ High
Simplexa™ Flu A/B & RSV	Focus Diagnostics, 3M	Influenza A and B	None	RSV	Nasopharyngeal swabs	<4h/ High
Simplexa™ Flu A/B & RSV Direct	Focus Diagnostics, 3M	Influenza A and B	None	RSV	Nasopharyngeal swabs	<2h/ Moderate
Simplexa™ Influenza A H1N1 (2009)	Focus Diagnostics, 3M	Influenza A	A/2009 H1	None	Nasopharyngeal swabs, nasal swabs, and nasopharyngeal aspirates	<4h/ High
U.S. Army JBAIDS Influenza A&B Detection Kit ⁴	Idaho Technologies	Influenza A and B	None	None	Nasopharyngeal swabs and Nasopharyngeal washes	~4 h/ High
U.S. Army JBAIDS Influenza A Subtyping Kit ⁴	Idaho Technologies	Influenza A	A/H1, A/H3, A/2009 H1	None	Nasopharyngeal swabs and Nasopharyngeal washes	~4 h/ High
U.S. Army JBAIDS Influenza A/H5 Kit ⁴	Idaho Technologies	Influenza A	A/H5N1 (Asian Lineage)	None	Nasopharyngeal and throat swabs	~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	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	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 Metapneumovirus, Rhinovirus, and Adenovirus	Nasopharyngeal swabs	~8 h/ High
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	~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.