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Flu/Respiratory Virus Testing

	Alere	Alere	BioFire Diagnostics LLC
	Waltham, Mass (877) 441-7440; www.alere.com	**Waltham, Mass (877) 441-7440; www.alere.com**	**Salt Lake City (801) 736-6354; www.biofiredx.com**
1) What is the brand name of your company's influenza or respiratory virus assay?	Alere i Influenza A & B test	Alere BinaxNOW *S. pneumoniae* urinary antigen test	FilmArray respiratory panel
2) What year did the assay first appear on the market?	2014	2004	2011
3) What technology platform does the assay use (eg, incubated culture, lateral flow cartridge, instrumented immunoassay, molecular diagnostic)?	Molecular diagnostic test utilizing isothermal nucleic acid amplification technology	Lateral flow	PCR
4) Is the assay FDA cleared or approved?	Yes	Yes	FDA-cleared
5) What pathogen(s) does the assay detect?	Influenza A, B	*S. pneumoniae*	Adenovirus; coronavirus HKU1, NL63, 229E, OC43; human metapneumovirus; human rhinovirus/enterovirus; influenza A, A/H1, A/H1-2009, A/H3; influenza B; parainfluenza virus 1, 2, 3, 4; respiratory syncytial virus; *B. pertussis; C. pneumoniae; M. pneumoniae*
6) Where is the assay used (check all that apply)?	❑ At a community screening event ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
7) If you answered "elsewhere," explain briefly.			
8) What type(s) of specimen/sample is the assay able to use?	Nasal swab	Urine	Nasopharyngeal swabs
9) What is the average preparation time required for the assay?	Less than 1 minute	Less than 1 minute	2 minutes
10) What is the time to first result under ideal conditions?	Less than 15 minutes	15 minutes	About 1 hour
11) What is the sensitivity of the assay?	Flu A, 99.3%; flu B, 98.9%.	86%	Overall sensitivity of 95%
12) What is the specificity of the assay?	Flu A, 98.1%; flu B, 99.6%. (Alere i Influenza A & B performance versus culture-discrepant results resolved by RT-PCR)	94%	Overall specificity of 99%
13) What capabilities, features, or accessories distinguish this product from others on the market?	First influenza test to use molecular technology. Employs proprietary isothermal nucleic acid amplification technology, providing highly sensitive and specific results within 15 minutes.	Employs easy-to-use lateral-flow technology that enables physicians to provide rapid, focused treatment.	Covering 20 viral and bacterial targets, the FilmArray respiratory panel makes it easier to get faster, more accurate results. The panel integrates sample preparation, amplification, detection, and analysis into a single system that requires only 2 minutes of hands-on time and has a total run time of about 1 hour.

Focus Diagnostics Inc Cypress, Calif (562) 240-6500; www.focusdx.com	Focus Diagnostics Inc Cypress, Calif (562) 240-6500; www.focusdx.com	GenMark Diagnostics Carlsbad, Calif (760) 448-4300; www.genmarkdx.com	Nanosphere Northbrook, Ill (888) 837-4436; www.nanosphere.us
Simplexa Flu A/B and RSV Direct	Simplexa Flu A/B and RSV	eSensor respiratory viral panel	Verigene Respiratory Virus Plus nucleic acid test (RV+)
2011	2010	2012	2009
Molecular diagnostic	Molecular diagnostic	Utilizes proprietary technology based on the principles of competitive DNA hybridization and electrochemical detection.	Microarray-based molecular diagnostic platform using gold nanoparticle probe technology combined with automated nucleic acid extraction, PCR amplification, purification, and hybridization.
FDA-cleared	FDA-cleared	FDA-cleared	FDA-cleared
Influenza A, influenza B, and respiratory syncytial virus	Influenza A, influenza B, and respiratory syncytial virus	Adenovirus B, C, E; human metapneumovirus; human rhinovirus; influenza A, A H1, A H3, A 2009 H1N1; influenza B; parainfluenza virus 1, 2, 3; respiratory syncytial virus A, B.	Influenza A, A-H1, A-H3, A-2009 H1N1; influenza B; respiratory syncytial virus A, B.
❑ At a community screening event ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
Nasopharyngeal swabs	Nasopharyngeal swabs	Nasopharyngeal swab obtained from individuals exhibiting signs and symptoms of respiratory infection.	Nasopharyngeal swab from individuals with signs and symptoms of respiratory tract infection.
Less than 1 minute per sample	After extraction, about 30 minutes	Less than 60 minutes of hands-on time, including extraction.	5 minutes
About 1 hour	About 1 hour	A total of 6 hours from initiation to result reporting.	Less than 2.5 hours
Flu A, 97.1%; flu B, 100%; RSV, 97.6%.	Flu A, 100%; flu B, 100%; RSV, 98.0%.	ADV B/E, 100%; ADV C, 100%; flu A, 96.4%; flu A H1, 96.7%; flu A H3, 100%; flu A 2009 H1N1, 100%; flu B, 92.8%; hMPV, 100%; HRV, 89.2%; PIV 1, 100%; PIV 2, 100%; PIV 3, 94.1%; RSV A, 100%; RSV B, 100%.	Flu A, 98.7%; flu A H1, 100%; flu A H3, 100%; flu A 2009 H1N1, 99.5%; flu B, 100%; RSV A, 100%; RSV B, 100%.
Flu A, 97.9%; flu B, 99.9%; RSV, 92.9%.	Flu A, 99.3%; flu B, 99.8%; RSV, 96.9%.	Flu A, 94.8%; flu A H1, 100%; flu A H3, 97.4%; flu A 2009 H1N1, 98.5%; flu B, 98.1%; RSV A, 94.7%; RSV B, 95.9%; PIV 1, 99.9%; PIV 2, 99.8%; PIV 3, 97.7%; hMPV, 99.8%; HRV, 96.1%; ADV B/E, 99.1%; ADV C, 96.6%.	Flu A, 93.2%; flu A-H1, 99.9%; flu A-H3, 100%; flu A-2009 H1N1, 100%; flu B, 99.7%; RSV A, 100%; RSV B, 99.9%.
Test is performed directly from the sample without extraction.	Test can run up to 96 reactions per run on the Integrated Cycler.	Provides sensitive and specific respiratory virus detection and subtyping, including 99.2% agreement with qPCR, and an optimized workflow to maximize laboratory efficiency. The tests are less prone to sample contamination risk than competing multiplexing technologies, and do not require many of their time-consuming washing and preparation steps.	Less than 5 minutes of hands-on time; automated test processing; exceptional sensitivity and specificity; scalable, modular instrumentation.

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	Nanosphere Northbrook, Ill (888) 837-4436; www.nanosphere.us	Quidel San Diego (800) 874-1517; www.quidel.com	Quidel San Diego (800) 874-1517; www.quidel.com
1) What is the brand name of your company's influenza or respiratory virus assay?	Verigene Respiratory Pathogens Flex nucleic acid test (RP Flex)	Lyra Influenza A+B assay	Sofia Influenza A+B FIA
2) What year did the assay first appear on the market?	Available for research use only.	2011	2011
3) What technology platform does the assay use (eg, incubated culture, lateral flow cartridge, instrumented immunoassay, molecular diagnostic)?	Microarray-based molecular diagnostic platform using gold nanoparticle probe technology combined with automated nucleic acid extraction, PCR amplification, purification, and hybridization.	Molecular diagnostic using polymerase chain reaction amplification	Lateral flow immunoassay utilizing immunofluorescence technology
4) Is the assay FDA cleared or approved?	FDA clearance pending	Yes	Yes
5) What pathogen(s) does the assay detect?	Viruses: adenovirus; human metapneumovirus; influenza A, A-H1, A-H3; influenza B; parainfluenza 1, 2, 3, 4; rhinovirus; respiratory syncytial virus A, B. Bacteria: Bordetella group (*B. pertussis*, *B. parapertussis*, *B. bronchiseptica*); *Bordetella holmesii*; *Bordetella pertussis*.	Influenza A and influenza B	Influenza A and influenza B viral nucleoprotein antigens
6) Where is the assay used (check all that apply)?	❑ At a community screening event ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ■ Elsewhere	■ At a community screening event ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ■ Elsewhere
7) If you answered "elsewhere," explain briefly.		Reference lab	Reference lab or pharmacy
8) What type(s) of specimen/sample is the assay able to use?	Nasopharyngeal swab from individuals with signs and symptoms of respiratory tract infection.	Nasal swabs, nasopharyngeal swabs	Nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash
9) What is the average preparation time required for the assay?	5 minutes	75 minutes after extraction	1 to 2 minutes
10) What is the time to first result under ideal conditions?	Less than 2.5 hours	About 2.5 hours	15 minutes
11) What is the sensitivity of the assay?	n/a	Sensitivity provided in terms of positive percent agreement (PPA) and negative percent agreement (NPA) with comparator devices used in clinical trials. Applied Biosystems 7500 Fast DX: flu A PPA 100%, NPA 98.5%; flu B PPA 95.5%, NPA 97.8%. Cepheid SmartCycler II: flu A PPA 100%, NPA 98.7%; flu B PPA 98.4%, NPA 95.5%. QuantStudio Dx: flu A PPA 100%, NPA 92.0%; flu B PPA 99.1%, NPA 98.0%.	Flu A: nasal/nasopharyngeal swab, 93.0%; nasopharyngeal aspirate wash, 99.0%. Flu B: nasal/nasopharyngeal swab, 90.0%; nasopharyngeal aspirate wash, 88.0%.
12) What is the specificity of the assay?	n/a	Specificity provided in terms of positive percent agreement (PPA) and negative percent agreement (NPA) with comparator devices used in clinical trials. Applied Biosystems 7500 Fast DX: flu A PPA 100%, NPA 98.5%; flu B PPA 95.5%, NPA 97.8%. Cepheid SmartCycler II: flu A PPA 100%, NPA 98.7%; flu B PPA 98.4%, NPA 95.5%. QuantStudio Dx: flu A PPA 100%, NPA 92.0%; flu B PPA 99.1%, NPA 98.0%.	Flu A: nasal/nasopharyngeal swab, 95.0%; nasopharyngeal aspirate wash, 96.0%. Flu B: nasal/nasopharyngeal swab, 96.0%; nasopharyngeal aspirate wash, 96.0%.
13) What capabilities, features, or accessories distinguish this product from others on the market?	Ability to mask targets and flexibly report only targets of interest from a comprehensive panel of respiratory pathogens; less than 5 minutes of hands-on time; automated test processing; scalable, modular instrumentation.	Rehydration of the lyophilized master mix is simple, leading to more uniform results and workflow. Room-temperature setup removes the need for wet ice or cooling blocks.	Fluorescent chemistry enhances assay sensitivity. Analyzer optically scans and interprets results, eliminating subjectivity and variability from operator to operator.

Randox	Sekisui Diagnostics LLC	Thermo Fisher Scientific
Kearneysville, Wva (866) 472-6369; www.randox.com	**Lexington, Mass (781) 652-7900; www.sekisuidiagnostics.com**	**Waltham, Mass (800) 255-6730; www.thermoscientific.com**
Randox respiratory multiplex array	OSOM	Thermo Scientific Remel Xpect Flu A&B test kits
2014	2006	2003
Utilizes biochip array technology, a unique multiplexing method based on a combination of multiplex PCR, probe hybridization, and chemiluminescence detection.	Lateral flow	Lateral flow cartridge
FDA approval pending	FDA-cleared	FDA-cleared
Detects 22 viral and bacterial respiratory pathogens of the upper and lower tract, including human adenovirus A, B, C, D, E; human parainfluenza virus 1, 2, 3, 4; human respiratory syncytial virus A, B; influenza A, B; *B. pertussis*; *C. pneumoniae*; *H. influenzae*; *M. pneumoniae*; *S. pneumoniae*, and others.	Influenza A, B	Influenza A and influenza B
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Samples can be taken in all settings, but the assay is laboratory-based. Actual testing will take place in a hospital or clinical setting.	Community health centers, public health clinics, urgent care, ER	
Genomic DNA/RNA is extracted from a bronchoalveolar lavage, sputum, nasopharyngeal swab, throat swab, or nasal swab.	Nasal swab specimens	Human nasal wash, nasal swab, and throat swab
About 1 hour (dependent on extraction methodology and initial sample type)	Less than 1 minute	30 seconds or less
About 6 hours	10 minutes	15 minutes
Verification in process	Flu A, 73.0%; flu B, 65.2%	Flu A, 92.2%; flu B, 97.8%
Verification in process	Flu A, 98.6%; flu B, 92.7%	100%
The most comprehensive screening test for respiratory tract infections, detecting 22 common pathogens. The complete infection profile targets key upper and lower tract infections, identifying both primary and coinfections and aiding in the correct prescription of antibiotics.	Time to result is as fast as any other rapid influenza test available. Extremely simple process can be performed by any operator with minimal training. Kit and all components are completely manufactured and assembled in the USA.	Simple two-step, walk-away procedure, with easy-to-read results in 15 minutes. Meets new FDA performance criteria for rapid flu test devices.

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