<table>
<tr><th colspan="2">Louisiana Office of Public Health Laboratories</th></tr>
<tr><td>Test Name</td><td>BioFire FilmArray® Respiratory Panel</td></tr>
<tr><td>PHL Location</td><td>Office of Public Health Laboratory Baton Rouge</td></tr>
<tr><td>CPT Code</td><td>
<table>
<tr><th>Assay</th><th>Potential CPT Code</th></tr>
<tr><td>Adenovirus
Coronavirus 229E
Coronavirus HKU1
Coronavirus NL63
Coronavirus OC43
Influenza A
Influenza A/H3
Influenza A/2009-H1
Influenza B
Human Metapneumovirus
Human Rhinovirus/Enterovirus
Parainfluenza 1 (PIV1)
Parainfluenza 2 (PIV2)
Parainfluenza 3 (PIV3)
Parainfluenza 4 (PIV4)
Respiratory Syncytial Virus</td><td>87633</td></tr>
<tr><td>Bordetella pertussis</td><td>87798</td></tr>
<tr><td>Chlamydophila pneumoniae</td><td>87486</td></tr>
<tr><td>Mycoplasma pneumoniae</td><td>87581</td></tr>
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</td></tr>
<tr><td>Synonyms</td><td>Biofire, RVP, RP, Respiratory Panel</td></tr>
<tr><td>Brief Description of Test</td><td>Prior authorization required. Contact Infectious Disease Epidemiology at 800-256-2748.

FilmArray Respiratory Panel (RP) is a multiplexed nucleic acid test intended for use with FilmArray systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The following organism types and subtypes are identified using the FilmArray RP: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype H1-2009, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human Rhinovirus/Enterovirus, Respiratory Syncytial Virus, Bordetella pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae.</td></tr>
<tr><td>Possible Results</td><td>For each target tested:
Detected
Not Detected
Equivocal (Influenza A only)
Invalid</td></tr>
</table>

Reference Range	Not Detected
Specimen Type	Nasopharyngeal Swab (NPS) - NPS specimens should be collected according to standard technique and immediately placed in Viral Transport Media (VTM).
Specimen Container(s):	VTM Tubes
Minimum volume accepted:	1mL requested 300 µL of sample is required for testing.
Collection Instructions	Label specimen with Patient Name and a 2nd Unique Identifier such as a chart number or medical record number. DOB is not considered unique. Complete a LAB Form 96 to accompany the sample. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date and time of collection, specimen source, test requested, submitter's name, address, fax and contact number. Additional information regarding patients' address is requested. Transport specimen to laboratory as soon as possible after collection/incubation. Keep submission forms insulated from specimens.
Storage and Transport Instructions	Specimens in VTM should be processed and tested as soon as possible. If storage is required, specimens in VTM can be held at room temperature (18–30 °C) for up to 4 hours, at refrigerator temperature (2-8 °C) for up to 3 days, or at freezer temperature (<-15 °C) for up to 30 days. If a specimen has been frozen, document the date and time the sample was frozen and ship on dry ice.
Causes for Rejection	• Received outside acceptable transport/storage conditions • Improper labeling • Incorrect source
Limitations of the Procedure	• The performance of this test has not been established for immunocompromised individuals. • The performance of this test has not been established for patients without signs and symptoms of respiratory infection. • Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. • Viral and bacterial nucleic acids may persist in vivo independent of organism viability. Detection of organism target(s) does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms. • The detection of viral and bacterial nucleic acid is dependent upon proper specimen collection, handling, transportation, storage and preparation. Failure to observe proper procedures in any one of these

	steps can lead to incorrect results. There is a risk of false positive or false negative values resulting from improperly collected, transported or handled specimens. • A negative FilmArray RP result does not exclude the possibility of viral or bacterial infection. Negative test results may occur from the presence of sequence variants in the region targeted by the assay, the presence of inhibitors, technical error, sample mix-up or an infection caused by an organism not detected by the panel. Test results may also be affected by concurrent antiviral/antibacterial therapy or levels of organism in the specimen that are below the limit of detection for the test. Negative results should not be used as the sole basis for diagnosis, treatment, or other management decisions. Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test or lower respiratory tract infection that is not detected by a nasopharyngeal swab specimen. • Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods when prevalence is moderate to low. • Due to the genetic similarity between Human Rhinovirus and Enterovirus, the FilmArray RP cannot reliably differentiate them. A positive FilmArray RP Rhinovirus/Enterovirus result should be followed-up using an alternate method (e.g. cell culture or sequence analysis). • The Coronavirus OC43 assay may cross-react with Coronavirus HKU1. As a result, when both HKU1 and OC43 are detected in the same patient specimen, the result may be due to assay cross-reactivity. A coinfection with these two viruses is also possible. • The FilmArray RP may not be able to distinguish between existing viral strains and new variants as they emerge. For example, the FilmArray RP can detect Influenza A H3N2v (first recognized in August, 2011), but will not be able to distinguish this variant from Influenza A H3N2 seasonal. • Results of the FilmArray RP B. pertussis assay may not be concordant with the results of commonly used Bordetella PCR assays that target the multi-copy insertion sequence (IS481) due to differences in sensitivity and specificity. IS481 is a multi-copy target and is present in several Bordetella species (B. pertussis, B. holmesii and B. bronchiseptica). The FilmArray RP B. pertussis assay targets the single-copy promoter region of the pertussis toxin gene and is designed to be highly specific for detection of B. pertussis. Although crossreactivity with closely-related Bordetella species was not observed in the clinical study or Analytical Specificity testing of a variety of strains at 1 x 106 CFU/mL, instances of cross-reactivity can occur with high levels (above 1 x 106 CFU/mL) or with rare sequence variants of other Bordetella species, such as B. bronchiseptica and B. parapertussis.

Interfering Substances	The FilmArray RP assays react with the Influenza A H1, Influenza A H3 and Influenza B viral material contained in the FluMist® nasal influenza vaccine. No cross-reactivity was observed with other, non-influenza FilmArray RP assays.
References	FilmArray Respiratory Panel (RP) Instruction Booklet
Additional Information	**Prior authorization required. Contact Infectious Disease Epidemiology at 800-256-2748.**
Release Date	05/16/2018
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