Respiratory Pathogen Nucleic Acid Detection Testing (for Tennessee Only)

Policy Number: CS379TN.B
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Instructions for Use

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Related Policy

- Laboratory Services Policy, Professional

Application

This Medical Policy applies to Medicaid and CoverKids in the state of Tennessee.

Coverage Rationale

Respiratory pathogen panel testing of six or more targets in an outpatient setting is unproven and not medically necessary due to insufficient evidence of efficacy for all indications.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0115U	Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected

CPT Code	Description
0556U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific DNA and RNA by real-time PCR, 12 targets, nasopharyngeal or oropharyngeal swab, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0563U	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 11 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative
0564U	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 10 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative
87632	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets
87633	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets

Description of Services

Molecular assays for detecting respiratory pathogens include reverse transcription–polymerase chain reaction and other nucleic acid amplification tests as well as metagenomic next-generation sequencing. Multiplex reverse transcription–polymerase chain reaction assays identify predefined microbial genetic material such as RNA or nucleic acids in respiratory specimens, if present. Metagenomic next-generation sequencing enables comprehensive detection of all genes from all organisms within a sample. It is intended to identify pathogenic microbes responsible for bacterial, fungal, parasitic, and viral illnesses by comparing nucleic acid sequences extracted from a single tissue or liquid specimen (Zhao et al., 2024). However, detection of a microbe by either method does not confirm a viable virus or ongoing replication (U.S. Centers for Disease Control and Prevention, 2019).

Clinical Evidence

There is insufficient evidence to support the use of respiratory pathogen panel testing of six or more targets in an outpatient setting. The fixed nature of these larger multiplex panels includes pathogens that cause infections different enough that simultaneous testing for these pathogens should be rare. The results must be interpreted in light of prolonged shedding periods, the possibility of multiple positive results or coinfections, and variable accuracy for different agents on the panels. The quality of the evidence is low due to small study populations, short follow-up, and lack of randomization with appropriate control groups. Further studies are needed to demonstrate clinical utility, including improvements in individual outcomes.

Hayes (2025) published a Molecular Test Assessment addressing the use of the Karius Spectrum test in the diagnosis of respiratory and other infections in immunocompromised individuals. They identified limited cases in which the Karius Spectrum test led to an earlier diagnosis or impacted treatment decisions, with no evidence indicating that the test led to improved clinical outcomes. Of note, this assessment was based on an earlier version of the test. The Karius Spectrum test now includes assessment of antimicrobial resistance biomarkers. Hayes advised that recent evidence may prompt a change in their assessment of the clinical utility of this test.

The Liu et al. (2024) systematic review and meta-analysis evaluated the diagnostic accuracy of metagenomic next-generation sequencing (mNGS) for infectious diseases. The authors searched PubMed, Embase, the Cochrane Library, and ClinicalTrials.gov through September 2022 and included 85 studies published between 2017 and 2022, encompassing 9,414 individuals with infections across multiple sites, including the lungs, brain, bloodstream, bones, joints, and abdominal cavity. Pulmonary and lower respiratory tract infections were common, with bronchoalveolar lavage (BAL) fluid and sputum as frequent specimen types. Both prospective and retrospective designs were represented, and diagnostic performance was compared against clinical comprehensive diagnosis and conventional microbiological tests. Across all studies, the area under the curve (AUC) was 0.88 (95% CI, 0.85-0.90), and for conventional tests, the AUC was lower at 0.82 (95% CI, 0.78-0.85). mNGS showed high value for ruling out infection in immunocompromised individuals (negative likelihood ratio, 0.08; 95% CI, 0.01-0.62). A subgroup analysis for pulmonary infections across 12 studies

showed a pooled sensitivity of 0.90 (95% CI, 0.77-0.96), specificity of 0.79 (95% CI, 0.58-0.91), and AUC of 0.92 (95% CI, 0.89-0.94). The positive likelihood ratio was 4.27 (95% CI, 1.94-9.39), negative likelihood ratio was 0.12 (95% CI, 0.05-0.33), and diagnostic odds ratio (OR) was 35.03 (95% CI, 7.80-157.32). Limitations include the substantial heterogeneity of the included studies, lack of stratification by care setting, variability in infection sites and specimen types, lack of antimicrobial susceptibility data, and technical differences across sequencing platforms. Based on these results, mNGS appears promising for evaluating respiratory infections, particularly when conventional tests fail or when rapid pathogen identification is needed. Further evidence of the clinical utility of mNGS in outpatient settings is required.

The Meltzer et al. (2024) multicenter, unblinded randomized controlled trial evaluated whether point-of-care syndromic assessment using multiplex polymerase chain reaction (PCR) improved self-reported outcomes compared with standard testing in urgent care centers for participants presenting with acute respiratory illness. Conducted at two urban facilities between May and November 2022, the study enrolled 360 clinically stable participants aged 7 years or older who had at least one respiratory symptom. Participants were randomized to either standard care (n = 155), which included antigen testing for SARS-CoV-2, influenza A/B, or group A streptococci with confirmatory send-out tests, or syndromic assessment (n = 205) using the BioFire RP-EZ 2.1 multiplex PCR device performed on site by trained research staff. Baseline characteristics between the two groups were not significantly different. The results were communicated on the day of enrollment, and follow-up occurred at 7 and 30 days. The primary outcome was individual satisfaction with time to results; the secondary outcomes included confidence in diagnosis, isolation plans, and antibiotic use. Participants in the syndromic assessment group reported significantly higher satisfaction with time to results (98.4% vs 42.4%; $p < 0.001$) and greater confidence in illness cause (60.7% vs 29.6%; $p < 0.001$). They were also less likely to report that delayed results interfered with normal activities at day 7 (16.7% vs 30.6%; $p = 0.039$). Plans not to isolate were more common in the syndromic group (53.6% vs 36.0%; $p < 0.001$). Antibiotic prescribing did not differ significantly between groups (33.5% vs 26.0%; $p = 1.0$). Practitioner surveys mirrored these findings, with higher diagnostic confidence and satisfaction in the syndromic group. Limitations included the lack of blinding, potential influence of practitioner decision-making before results were available, and imbalance in group sizes due to a programming error in the automated randomization module of the survey instrument. The study was funded by bioMérieux; one author disclosed prior financial relationships with the sponsor. These findings suggest that point-of-care syndromic assessment improves satisfaction and diagnostic confidence but does not reduce antibiotic use.

The Sánchez Códez et al. (2024) retrospective study evaluated 1,899 children and adolescents aged ≤ 21 years with rhinovirus-associated acute respiratory infection identified through inpatient [n = 1,596 (84%)] and outpatient [n = 303 (16%)] multiplex PCR testing at a single pediatric hospital between July 2011 and December 2013. The study excluded asymptomatic cases and those with incomplete records. Multiplex PCR panels were used year-round to detect rhinoviruses, along with respiratory syncytial virus (RSV), parainfluenza virus, human metapneumovirus, influenza A/B, and adenovirus, enabling classification into single rhinovirus infections or rhinovirus/viral coinfections. Coinfections occurred in 24% of cases overall, most frequently adenovirus (46%) and RSV (31%). Rhinoviral loads, expressed as cycle threshold values, were categorized as high (≤ 25), intermediate (26-32), or low (> 32). The median cycle threshold values were lower in single rhinovirus infections than in coinfections (24.74 vs 26.62; $p = 0.001$), and coinfection frequency was inversely related to rhinoviral load (32% in low-load cases vs 19% in high-load cases; $p = 0.0001$). Multiplex testing identified coinfections in nearly one-quarter of rhinovirus-positive cases, which influenced the interpretation of viral load and seasonality patterns. Coinfections were more common in winter months, while single rhinovirus infections peaked in summer ($p < 0.001$ for trend). Although coinfections were associated with younger age (median, 9.5 vs 14.9 months; $p = 0.0001$), they did not consistently predict worse outcomes after adjustment. In multivariable models, underlying comorbidities were the strongest predictors of hospitalization, oxygen use, and pediatric intensive care unit admission risk (ORs, 1.61-3.35; all $p \leq 0.001$), while high rhinoviral load increased pediatric intensive care unit admission risk (OR, 1.49; 95% CI, 1.09-2.05; $p = 0.012$). Isolated rhinovirus infection increased hospitalization odds (OR, 1.84; 95% CI, 1.23-2.76; $p = 0.003$). Outpatient cases represented a clinically distinct cohort, but the study did not report separate severity outcomes for this group beyond inclusion in the overall analysis. Other limitations include the retrospective design, use of convenience sampling, and single-center setting. Author disclosures included advisory roles and research funding from multiple pharmaceutical companies.

Gripp et al. (2023) conducted a retrospective chart review of multiplex respiratory pathogen panel testing of symptomatic patients seen in the outpatient oncology setting from April 2020 to November 2021 (n = 183). Antibiotics had been prescribed to 52 patients (28.4%) before testing, and no antiviral medications had been started. The panel detected at least one respiratory virus in 31 cases (16.9%). Of these, 18 tests (54.5%) were positive for a human rhinovirus or enterovirus; nine (27.2%) for parainfluenza virus type 3; two (6.1%) for parainfluenza virus type 4; and one each (3.0%) for RSV subtype A, RSV subtype B, human coronavirus OC43, and human metapneumovirus. The multiplex panel detected two viruses in two cases. Despite this, only three patients (1.6%) had changes in their medication based on these results, including one who began antiviral therapy. These findings suggest that targeted testing for influenza, RSV, and SARS-CoV-2 may be more appropriate. Study limitations include the retrospective design, with variation in

documentation of symptoms, examination findings, and follow-up care; small sample size; lack of a comparison group (i.e., patients who presented with similar symptoms but a multiplex panel was not ordered); and minimal influenza activity in the 2020 to 2021 season. Further studies are needed to validate the clinical utility of multiplex respiratory pathogen panel testing in outpatient settings.

A Hayes Molecular Test Assessment evaluated the FilmArray Respiratory Panel (RP) 2 for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs obtained from individuals suspected of having respiratory tract infections to aid in the diagnosis of respiratory infection, if used in conjunction with other clinical and epidemiological information. However, there was insufficient evidence to support its use, primarily due to limited data on its effectiveness.

A Hayes Molecular Test Assessment (2020a; updated 2023) evaluated the FilmArray RP and assessed its analytical and clinical validity as well as its clinical utility for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs obtained from individuals suspected of having respiratory tract infections, with the aim of aiding in the diagnosis of respiratory infection, if used in conjunction with other clinical and epidemiological information. The review included 16 studies: nine on performance, eight on run and turnaround times, and one on detection limits. Four studies focused on nasopharyngeal swabs, showing good agreement with other nucleic acid amplification tests and good sensitivity and specificity for certain pathogens; however, some cross-reactivity was noted.

The Beal et al. (2020) study evaluated the impact of the BioFire FilmArray RP-EZ panel in two outpatient pediatric clinics between January 2018 and January 2019. All individuals presenting with respiratory symptoms were eligible. Clinic A (n = 298) was assigned to use RP-EZ testing in real time, while clinic B (n = 132) was to rely on influenza and RSV antigen tests, with residual samples later tested by RP-EZ for pathogen identification. However, for those tested at clinic A, clinicians could order RP-EZ and/or antigen tests; RP-EZ was encouraged when diagnostic testing was warranted. Among 430 individuals ultimately tested with RP-EZ, 70.2% had at least one organism detected, most commonly human rhinovirus/enterovirus (n = 111), influenza A (n = 43), and RSV (n = 42). Mixed infections occurred in 6.0% of cases. Statistically significant differences in the distribution of organisms between clinics were observed for influenza A (4.7% vs 22.0%; $p < 0.0001$), parainfluenza (9.7% vs 3.0%; $p = 0.0173$), RSV (12.8% vs 3.0%; $p = 0.0013$), and human rhinovirus/enterovirus (29.5% vs 17.4%; $p = 0.0081$), with clinic A consistently reporting the higher percentage of positive results. Appropriate treatment based on prescriptions was documented in 93.6% of individuals at clinic A vs 87.9% at clinic B ($p = 0.0445$). Antibiotic prescribing was rare, with no evidence of a difference between clinics (1.8% at clinic A vs 2.0% at clinic B for noninfluenza viruses or negative results, $p = 1.000$). For influenza-positive individuals, oseltamivir was prescribed for 31.6% at clinic A and 75.0% at clinic B ($p = 0.0018$). The appointment duration was shorter with RP-EZ testing (48.0 minutes) than with antigen testing alone (54.9 minutes; $p = 0.0009$). The study's design introduced potential selection bias due to the provider choice between tests at clinic A. Other limitations include reliance on prescription presence as a proxy for appropriate care and the lack of a full evaluation of health records to identify confounding variables such as health condition or demographic differences between the two unmatched cohorts. Funding was provided by BioFire Diagnostics.

The Murphy et al. (2020) multicenter study evaluated the performance of the BioFire FilmArray Pneumonia Panel (PN panel) and Pneumonia Plus Panel (PNplus panel) in detecting viruses, bacteria, and antimicrobial resistance genes from sputum samples (n = 846) and BAL fluid (n = 836). The majority of specimens (80%) were collected in an inpatient hospital setting [666/846 (79%) BAL and 682/836 (82%) sputum], with outpatient and emergency department (ED) collections accounting for 19% of BAL specimens [159/845 outpatient (19%) and 21/845 ED (2.5%)] and 18% of sputum specimens [73/836 outpatient (8.5%) and 81/836 ED (10%)]. The BioFire panels were evaluated against traditional methods, quantitative reference culture, and molecular analysis and evaluated for improvements in individual outcomes and antimicrobial stewardship. The PN panel demonstrated 100% sensitivity for 15 of 22 targets in BAL specimens and 10 of 24 targets in sputum specimens. Other targets had sensitivities of at least 75% or could not be calculated due to low prevalence. The specificity for all targets was ≥ 87.2%, with many false positives confirmed by alternative molecular methods. The authors determined that the clinical and analytical limitations of the BioFire panels include the panels' high sensitivity and specificity, which do not always align perfectly with traditional culture methods; semiquantitative nature of the results, which complicates the interpretation of the clinical significance of detected pathogens; complex decision-making required when detection of a pathogen may not always indicate an active infection; and risk of a poor-quality specimen potentially giving inconclusive or difficult-to-interpret results. These findings suggest that the PN panels require careful consideration for use in specific individual populations and have the potential to significantly aid in individual management decisions. Further research is needed to fully establish the clinical utility of these panel tests.

Echavarría et al. (2018) conducted a prospective, randomized, nonblinded study that assessed the impact of multiplex panel testing and how the timely etiologic identification would have an impact on the use of antibiotic and antiviral

therapies as well as complementary studies (chest x-ray; computerized tomography; complete blood cell count; urinary antigen for *Streptococcus pneumoniae* or *Legionella pneumoniae;* and bacterial cultures of blood, urine, or sputum). During the 2016 and 2017 respiratory disease seasons, 432 participants (156 children and 276 adults) who presented to a single-center ED with signs and symptoms of an acute lower respiratory infection had testing performed via the FilmArray assay (n = 289) or immunofluorescence assay (IFA) (n = 143). High-risk participants, such as those with cancer, HIV, immunosuppression, or organ transplants, were excluded from the study. The results showed that any change in medical management was significantly more likely in the FilmArray assay group than in the IFA group in children (OR, 8.07; 95% CI, 3.03-21.47; p < 0.001) and adults (OR, 2.67; 95% CI, 1.32-5.40; p = 0.006). A change in the antibiotic treatment plan was significantly more likely in children (OR, 12.23; 95% CI, 1.56-96.09; p = 0.017) and adults (OR, 15.52; 95% CI, 1.99-120.83; p = 0.009) in the FilmArray assay group than in the IFA group. While there were changes in antiviral prescriptions for significantly more adults who tested positive for influenza A or B (p = 0.091) and adults who tested positive for influenza A or B (p = 0.042), there was no significant difference in antiviral prescriptions between the two pediatric study groups. As for complementary studies, there was a significant decrease in usage noted in children between the two groups (p = 0.001). However, a significant change was not distinguished in adults. Limitations of the study are its single-center design and failure to maintain a 1:1 randomized enrollment during the second portion of 2016. Additional studies are needed to validate these results in the average-risk population.

The Kaku et al. (2018) prospective observational study evaluated the ability of the FilmArray RP to decrease inappropriate prescriptions of antibiotics during an influenza epidemic. The study population was adults with respiratory tract infection symptoms in a hospital outpatient setting (n = 50). Bacteria were isolated from sputum culture in 12 participants, including three participants who went on to receive positive FilmArray results for a viral pathogen as well. The most commonly detected viruses were the influenza A virus (14 cases), RSV (six cases), and human rhinovirus (six cases). In total, the FilmArray RP identified pathogens in 28 participants, but the FilmArray results were not reported to the treating physicians. Among the participants with positive FilmArray RP results, nine received antibiotic treatment, including six without a positive sputum culture. Study limitations include the small sample size, which limited the generalizability of the results, and the concurrent influenza epidemic, potentially confounding results interpretation and altering physician practice patterns. Additional research is needed on the FilmArray RP to determine its efficiency and reliability as well as its clinical utility in diagnosing respiratory infections and improving individuals' care. Study funding was provided by Sysmex bioMérieux Co., Ltd.

Green et al. (2016) conducted a retrospective chart review to evaluate the effect of the FilmArray RP on outcome measures among adult outpatients at a large Veterans Administration medical center between December 2014 and April 2015 (n = 408), with a focus on changes in antibiotic and oseltamivir prescription rates. Of 408 patients tested, 113 (27.7%) were ultimately admitted. Among the 295 who continued as outpatients, 105 (35.6%) tested positive for influenza, and 109 (36.9%) tested positive for a noninfluenza virus. The remaining 81 patients (27.5%) had no respiratory pathogen detected. There were significant differences in oseltamivir and antibiotic prescription rates among these three groups [chi-square values of 167.6 (p < 0.0001) and 10.48 (p = 0.005), respectively]. However, there was no significant difference in antibiotic prescription rates between the noninfluenza virus group and those who tested negative (chi-square value, 0; p = 1.0). Study limitations include the single-center design and inability of multiplex tests to test all pathogens, while positive results may not always be clinically relevant. The authors concluded that testing positive for influenza virus was associated with a lower likelihood of receiving an antibiotic prescription, but no such effect was seen for those who tested positive for a noninfluenza virus. These data suggest that testing for influenza viruses alone may be sufficient. The additional benefit of performing multiplex virus testing instead of targeted influenza virus testing in outpatients is questionable, and additional studies are needed.

Clinical Practice Guidelines

American Society for Microbiology (ASM)

In 2019, the ASM published a guideline that addressed the clinical utility of multiplex tests for respiratory and gastrointestinal pathogens. The guideline states that multiplex molecular panel tests provide the ability to test a single sample for multiple pathogens quickly and with high accuracy. Further noted is the lack of outcome-based evidence that supports the direct benefit to clinical care. Despite this evidence, the ASM guideline asserts that these tests improve patient care by providing accurate results in a timeline that allows actions that positively impact the care of affected patients, such as the timely initiation of appropriate therapies, which may lead to less transmission of disease, shortened duration of symptoms, and a decrease in the need for additional testing. Nonmedical interventions (e.g., isolation) can also be impacted by the detection of pathogens, and for those patients with infections that do not require an intervention, multiplex tests assist providers in determining when antibiotics should not be administered.

An ASM-sponsored Practical Guidance for Clinical Microbiology document (Charlton et al., 2018) identifies the best practices for diagnosis and characterization of viruses that cause acute respiratory infections. The guidelines identify

patient groups suitable for multiplex respiratory viral panel testing. Testing needs can differ based on the patient environment and available resources, given the high costs of multiplex assays. The ideal candidates for testing may vary by health care setting, as some research questions the benefit of testing adult outpatients for viruses other than influenza.

- Hematology and oncology patients may be appropriate patient populations for testing.
- Transplant patients may also be an appropriate patient population for multiplex testing.
- Intensive care unit patients may be another appropriate patient population for respiratory viral multiplex panel testing.
- Pediatric patients with an underlying illness may also be an appropriate patient population for respiratory viral panel testing.

American Thoracic Society (ATS)

The ATS clinical practice guidelines for nucleic acid-based testing for noninfluenza viral pathogens in adults with suspected community-acquired pneumonia (Evans et al., 2021) suggest not performing routine outpatient nucleic acid–based testing of respiratory samples for viral pathogens other than influenza (conditional recommendation; very low-quality evidence).

Association for Molecular Pathology (AMP)/American Society for Microbiology (ASM)/Infectious Diseases Society of America (IDSA)/Pan American Society for Clinical Virology (PASCV)

In a 2023 joint report on consensus opinions of the AMP, ASM, IDSA, and PASCV, Lewinski et al. addressed the detection of atypical or fastidious organisms that require nucleic acid amplification tests or specialized media, rather than culture-based methods. While nucleic acid amplification tests have improved detection rates for pathogens associated with community-acquired and atypical pneumonia, concerns about distinguishing colonization from infection and a lack of standardization have hindered widespread adoption. Several U.S. Food and Drug Administration–cleared multiplex assays for upper respiratory specimens have been adapted for lower respiratory samples, which detect multiple bacteria, fungi, and resistance markers within 5 hours, with recent advances allowing near-patient testing and results in under 30 minutes, compared with 24 to 72 hours for culture. Performance varies by target and specimen type, with studies reporting positive agreement ranging from 16.7% to 100% and negative agreement exceeding 90%. While molecular panels may enable earlier antimicrobial adjustments in hospitalized patients, their limited sensitivity and incomplete pathogen coverage mean that negative results cannot reliably guide treatment changes. Diagnostic stewardship is a consideration for limiting use for relatively healthy patients in the outpatient setting.

Infectious Diseases Society of America (IDSA)

The clinical and diagnostic recommendations from the IDSA's Diagnostics Committee (Hanson et al., 2020) provided comprehensive recommendations for the diagnosis of respiratory infections. These guidelines emphasize the importance of using nucleic acid amplification tests for accurate detection of pathogens in respiratory specimens. When used appropriately, multiplex molecular pneumonia syndromic panels can offer a more timely opportunity for optimizing treatment compared with traditional culture methods.

- For hospitalized patients, especially those in intensive care units, the guidelines suggest comprehensive RP testing to guide appropriate antimicrobial therapy.
- In outpatient settings, testing is recommended for patients with severe symptoms or those at high risk for complications, such as older patients or immunocompromised patients.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has approved a number of devices for use in respiratory viral panel multiplex nucleic acid assay testing. Refer to the following website for more information (use product codes OCC, QDS, QDP, and QOF): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 21, 2025)

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Policy History/Revision Information

Date	Summary of Changes
05/01/2026	**Related Policies** • Added reference link to the Reimbursement Policy titled *Laboratory Services Policy, Professional*

Date	Summary of Changes
	Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version CS379TN.A

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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