

April 28, 2020

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201  
Seema.Verma@cms.hhs.gov

Dear Administrator Verma:

The undersigned organizations are writing to request immediate national coverage for multiplex polymerase chain reaction (PCR) respiratory viral panel (RVP) tests. As a critical component of triage protocols, these tests are critical for ruling in / ruling out COVID-19 patients with other viral respiratory conditions, and helping to guide immediate appropriate treatment during this public health emergency. Unfortunately, laboratories are currently absorbing the cost of performing these tests, which are critical to preventing transmission and speeding recovery during this national emergency.

Laboratories are experiencing an exponential increase in the number of requests for RVPs by clinicians during this COVID-19 outbreak. Multiplex PCR is a highly sensitive, highly specific test for the detection of viral and bacterial infections, including influenza, parainfluenza, respiratory syncytial virus, metapneumovirus, adenovirus, and several common coronaviruses. Utilization of RVPs during this pandemic provides important clinical information such as providing fast turnaround times for persons under investigation, preserving person protective equipment (PPE); and rapid triaging to assign appropriate levels of care and minimize disease transmission to patients, healthcare personnel, and others, while reducing adverse impacts on emergency department and hospital bed capacity. Routine testing using RVPs is especially important where COVID-19 tests and supplies are either limited or not rapidly available to laboratories. Additionally, RVPs are necessary for understanding the likelihood of co-infection: emerging data suggest that patients with COVID-19 may be co-infected with other viruses and/or bacteria, and the risk of co-infections is pressuring clinicians and hospitals to broaden their patient testing portfolios to address new mortality risks.

There are several RVP tests currently available as frontline tests for patients with signs and symptoms of respiratory infection, and, the BioFire® respiratory 2.1 panel, expected to become available in July, will include SARS-CoV-2 as well as 21 other common respiratory pathogens. However, at present coverage of RVPs is severely limited. Current Local coverage determinations (LCDs) for respiratory viral panels restrict coverage to only 3-5 pathogens (CPT 87631) and only in patients who are immunocompromised,<sup>1</sup> based on clinical assumptions that are superseded by the clinical circumstances of the public health emergency. For example, the Centers for Disease Control and Prevention (CDC) now strongly encourages clinicians to test for other causes of respiratory illness.<sup>2</sup> In response to these recommendations, the Centers for Medicare & Medicaid Services (CMS) has clarified in its frequently asked questions released on April 11 that testing for alternative diagnoses should be covered because it helps determine the need for COVID-19 diagnostic testing.<sup>3</sup>

<sup>1</sup> MoIDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37713), available at [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37713&ContrlD=376&ver=9&ContrVer=1&CntrctrSelected=376\\*1&Cntrctr=376&DocType=2%7c3%7c4&bc=AQABAAIAAAAA&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37713&ContrlD=376&ver=9&ContrVer=1&CntrctrSelected=376*1&Cntrctr=376&DocType=2%7c3%7c4&bc=AQABAAIAAAAA&)

<sup>2</sup> Centers for Disease Control and Prevention, Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19), available at <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>.

<sup>3</sup> Centers for Medicare & Medicaid Services FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42, available at <https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf>.

Besides this guidance from your agency and from the CDC, the Society for Post-Acute and Long-Term Care Medicine, and State health departments have also strongly encouraged the use of molecular RVP same-day testing for other causes of respiratory illness, including infections such as influenza and pneumonia. To provide this service, coverage is necessary for respiratory panel tests that target a broader range of pathogens (e.g., CPT codes 87362 and 87363, and proprietary laboratory analyses codes such as codes 0098U, 0099U, 0100U, or 0115U, 0151U).

There is growing concern among epidemiologists that COVID-19 may reemerge, as other viruses have done after their initial outbreaks. Thus, it is critical that laboratories be well equipped with an appropriately comprehensive laboratory test menu and for this to be feasible they must be reimbursed commensurate with the resources required to provide such testing. The very limited Medicare coverage in the face of the critical demand for tests are contributing to the significant financial burden on laboratories and pathologists as a result of the COVID-19 pandemic.

In closing, we appreciate CMS' flexibility in arming clinicians to fight COVID-19, and we strongly urge Medicare to provide the corresponding coverage to laboratories and pathologists for RVPs which their clinical colleagues need to rapidly and effectively diagnose and manage patients with acute respiratory illness. We welcome the opportunity to meet with you as soon as possible to discuss the critical role that RVPs play in the ongoing public health response to COVID-19 and to answer any questions that you may have. We will contact you in the next few days to request a meeting time.

American College of Emergency Physicians  
Association for Molecular Pathology  
Association of Public Health Laboratories  
College of American Pathologists  
Infectious Diseases Society of America  
Pan American Society for Clinical Virology

cc: Tamara Syrek Jensen, JD, Director  
Coverage and Analysis Group  
Centers for Medicare & Medicaid Services

Joseph Chin, M.D., MS, Deputy Director  
Coverage and Analysis Group  
Centers for Medicare & Medicaid Services

Lori Ashby, MA, Deputy Director  
Division of Policy and Evidence Review, Coverage and Analysis Group  
Centers for Medicare & Medicaid Services

Harry Feliciano, M.D., MPH,  
Senior Medical Director  
Palmetto GBA

Antonietta Sculimbrenne, M.D., MHA  
Lead Contractor Medical Director  
Palmetto GBA

Gabriel Alejandro Bien-Willner, M.D., Ph.D  
Director, MolDX Program  
Palmetto GBA