



January 28, 2021

Norris Cochran  
Secretary of Health and Human Services (Acting)  
Office of the Secretary  
United States Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Room 120F  
Washington, DC 20201

Subject: Amended CMS-2020-1-R2

Dear Acting Secretary Cochran,

The American Association for Clinical Chemistry (AACC) urges you to review a previous action by the Centers for Medicare and Medicaid Services (CMS), which reduced Medicare payments for molecular pathology high throughput COVID-19 diagnostic tests that are not completed within two days of the specimen being collected. As of January 1, 2021, laboratories that fail to meet this requirement are reimbursed at \$75 per test rather than the previous fee of \$100.

AACC agrees that timely testing is vital to diagnosing, isolating, and treating patients with the coronavirus and performing much needed contact tracing. Clinical laboratories are committed to providing high quality, timely, accurate tests. Many laboratories are completing their testing within the timeframe specified by CMS. For those laboratories not meeting this timeframe, it is often for reasons outside of their control.

For example, many testing facilities cannot obtain the supplies, particularly the test kits and reagents, needed to continue to rapidly perform the high volume of COVID-19 tests that they receive. Another reason is that staffing is increasingly becoming an issue as the volume of testing continues to rise and the number of highly trained laboratory professionals needed to perform these tests is limited. Finally, laboratories sometimes receive COVID-19 samples days after they were collected making it impossible for them to achieve a two-day turn-around time.

AACC does not think that cutting payments to laboratories, which are already incurring significant costs to perform these tests (e.g., purchasing new equipment, using additional personal protective equipment, and meeting new data reporting requirements) will improve the testing situation. In fact, we are concerned that reducing payments may force some laboratories to outsource COVID-19 tests, which will most certainly delay the reporting of timely, actionable results. We believe a national strategy to increase testing supplies and laboratory workforce will bring more efficiency to laboratory testing than imposing penalties.

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AACC requests that you put this recent payment reduction on hold and include it as part of your regulatory review of recent policy decisions proposed or adopted by the previous administration. We believe that once you review the pertinent information you will agree that this action needs to be reversed. Thank you for your immediate attention to this matter.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

We look forward to working with you on this important issue. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at [vstine@aacc.org](mailto:vstine@aacc.org).

Sincerely,

A handwritten signature in black ink that reads "David G. Grenache". The signature is written in a cursive style with a large, stylized initial "D".

David G. Grenache, PhD, D(ABCC)  
President, AACC