

October 29, 2020

The Honorable Robert R. Neall
Secretary
Maryland Department of Health
201 West Preston Street
Baltimore, Maryland 21215

RE: Accepted Test Status

Dear Secretary Neall:

On behalf of MedChi, the Maryland State Medical Society, we are requesting the Lab Advisory Committee grant accepted test status for Cepheid 4-1 Multi-Target COVID-19 Test, SARSCoV-2, Flu A, Flu B and RSV Combination Test.

Cepheid announced it has received Emergency Use Authorization (EUA) from the U.S. Food & Drug Administration (FDA) for Xpert® Xpress **SARS-CoV-2/Flu/RSV**, a rapid molecular diagnostic test for qualitative detection of the viruses causing COVID-19, Flu A, Flu B, and RSV infections from a single patient sample. The new EUA combination test is expected to begin shipping to US customers this week, with expected CE-IVD availability in November and we believe this could be a useful tool in diagnosing, differentiating and fighting against COVID-19.

Please feel free to reach out with any questions, comments and or concerns.

We appreciate your consideration on this matter and look forward to hearing from you.

Sincerely,

Gene M. Ransom III
CEO MedChi, The Maryland State Medical Society