



## Minutes of Meeting – May 13, 2021

The Laboratory Advisory Committee (LAC) meeting took place by conference call at 10:30 a.m.

**Members Attending:** John G. Newby, Chair, American College of Pathology  
Piyush K. Patel, Vice Chair, American College of Physicians  
Barbara S. Caldwell, American Society of Clinical Pathology  
Melissa Day, Consumer Member  
Lindsey Howard, Jr., Industry  
Gattu Rao, Maryland Academy of Family Physicians  
Thomas J. Remsberg, Pharmacist

**Other Attendees:** Robert A. Myers, Director, Laboratories Administration  
Rodney Hargraves, Deputy Director, Administrative and Support Services  
Renee Scurry, Administrator, Regulatory and Administrative Services  
Hope Miller, Paralegal II, Regulatory and Administrative Services

**Members Absent:** Gail McGucken, Laboratory Surveyor Scientist II, OHCQ

Dr. Newby called the meeting to order at 10:30 a.m.

I. Review and approval of December 11, 2020 meeting minutes.

The Laboratory Advisory Committee (“LAC”) minutes from the December 11, 2020 meeting were previously distributed via email. Dr. Newby asked for a motion to accept the December 11th minutes as drafted. The motion was made by Mr. Thomas Remsberg and seconded by Ms. Barbara Caldwell. The minutes were thereafter accepted with no objections.

II. 2021 Maryland Legislative Session Re-Cap from Renee Scurry.

The Maryland General Assembly legislative session began on January 13<sup>th</sup> and ended on April 12<sup>th</sup>, 2021. This year 1,380 house bills and 967 senate bills were assessed. Thereafter, 817 bills were passed. The topical areas of the bills subject to review included: pharmacists regarding prescription drugs; public safety on limitations on emergency powers; prohibitions and requirements on PFAS chemicals; single use plastics; standards, reporting and penalties following mold inspections; catastrophic health emergencies; legalization and regulation of cannabis; mental health and emotional disorders; memory care units within assisted living programs; criminal procedures concerning registered sex offenders, police training and medical emergencies; health occupation licensing; telehealth; use of force and body cameras for law enforcement officers; access to records and required denials regarding the Public Information Act; State finance and procurement; and COVID-19 testing, contact tracing and vaccinations. Other significant issues included coronavirus pandemic relief, health disparities in minority communities, state funding for historically black colleges, life without parole for juvenile offenders; home detention monitoring; telehealth options and voting by mail expanded options. None of the bills this session required review by the LAC.

### III. Follow-up on request from MedChi (on behalf of Cepheid) for a Letter of Exception.

On November 20, 2020, the Laboratory Advisory Committee held an emergency meeting to review and assess a request by MedChi (The Maryland State Medical Society), on behalf of Cepheid, for a letter of Exception for their COVID-19 SARS CoV-2, Flu A, Flu B and RSV combination test. After approval by the LAC for the Letter of Exception, a letter was forwarded to Secretary Schrader requesting review of the request and a decision to adopt or reject the LAC's recommendation. Thereafter, via memo, Secretary Schrader approved the request for a Letter of Exception from MedChi. Renee Scurry will follow-up with the Deputy Secretary's Office to confirm that they are aware that they need to communicate their decision back to MedChi in letter form.

### IV. Open Forum.

Ms. Renee Scurry stated that the State Lab has received several calls from manufactures who are interested in submitting requests for a Letter of Exception to the Secretary. As a result, the State Lab may be receiving more requests for the LAC to review. Dr. Newby replied that there are essentially many tests currently in the market place that are specifically for point-of-care testing. He then requested Ms. Scurry to notify the LAC of any inquiries concerning requests for a Letter of Exception in an effort to give the LAC committee members time to review the laboratories/companies ahead of any potential formal requests.

Mr. Lindsey Howard thereafter stated that he would like to relay the proper protocols and procedures for submitting a request for a Letter of Exception to Qiagen. He also wanted to know if there was a script or process information available on the internet. Ms. Scurry replied that the proper protocols are in the State regulations and she would assemble information that could be provided for all inquiries.

Dr. Myers further inquired whether the LAC provided guidelines to requestors on how to interact with MedChi. Ms. Scurry replied that laboratories/companies interested in obtaining a Letter of Exception are often not aware that their requests must be forwarded through MedChi or a Maryland chapter of a specialty medical society before being reviewed by the LAC. However, upon contacting the Laboratories Administration to be added to the next LAC meeting agenda, the laboratories/companies are informed of the regulatory protocols and procedures for requesting a Letter of Exception.

Dr. Myers thereafter inquired about the individuals/entities that are making these requests. Specifically, he inquired whether clinicians are sending requests to MedChi. Dr. Newby responded that generally a clinician will not forward a request for a Letter of Exception directly to MedChi. However, MedChi or a Maryland chapter of a specialty medical society will recognize that a test is valuable for clinical practice and will provide the appropriate protocols to clinicians for submitting a formal request to the LAC.

Lastly, Lindsey Howard is retiring this year. Therefore, he will no longer be considered as an LAC Industry member. Lindsey Howard will notify Ms. Scurry to further discuss his future with the LAC.

The meeting was adjourned at 10:50 a.m.

Respectfully submitted,

Renee Scurry and Hope Miller  
MDH Laboratories Administration  
Office of Regulatory and Administrative Services