Maryland
DEPARTMENT OF HEALTH

Minutes of Meeting – December 4, 2019

The Laboratory Advisory Committee (LAC) meeting took place at the Maryland Public Health Laboratory, Conference Room 128E, located at 1770 Ashland Avenue Baltimore, Maryland 21205. Dr. John G. Newby called the meeting to order at 9:08 AM.

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
Lindsey Howard, Jr., Industry (via teleconference)
Gail McGucken, Laboratory Surveyor Scientist II, OHCQ
Gattu Rao, Maryland Academy of Family Physicians
Thomas J. Remsberg, Pharmacist
Malcolm R. Rubinstein, Consumer Member
Robert Yim, American Academy of Pediatricians (via teleconference)

Other Attendees: Dr. Robert Myers, Director, Laboratories Administration
Rodney Hargraves, Deputy Director, Administrative and Support Services
Renee Scurry, Administration, Regulatory and Administrative Services
Hope Miller, Paralegal II, Regulatory and Administrative Services
Paul Celli, Public Health Administrator, OHCQ (via teleconference)

Members Absent: None

Public Attending: Meghan Lawson, Government Affairs, Cepheid

All attendees went around the table and introduced themselves and their representation.

I. Approval of Minutes

The Laboratory Advisory Committee minutes from the May 4, 2019 meeting were distributed via email and also during the December 4, 2019 meeting. Dr. Newby asked for a motion to accept the minutes as drafted. The motion was made and all members accepted.

II. Review of the new MDH Attendance Policy

Renee Scurry reviewed Secretary Robert Neall's new Maryland Department of Health (MDH) Attendance Policy for Appointments. Copies of the new policy were provided to all of the LAC members. In an accompanying memo to all MDH Board Liaisons, Secretary Neall stated that he was in the process of implementing a system to track the attendance of all Boards, Commissions, Committees, Workgroups, Task Forces, Councils, etc.

According to the policy, members are required to attend 50% of all meetings in a consecutive 12 month period. Any member failing to attend at least 50% of all scheduled meetings will be considered to have resigned. However, a waiver letter outlining an exceptional reason for non-compliance can be submitted (at the discretion of the Chair) along with the end of the year attendance report. The Office of Appointments and Executive Nominations (OAEN)

will thereafter review the waiver letter and notify the Chair of their decision. Any member submitting a waiver letter may remain active while they are waiting for OAEN to render a decision.

Dr. Newby thereafter inquired whether attending meetings electronically was acceptable. After consulting with Kathleen Ellis, Principal Counsel for MDH, video/electronic conferencing was deemed an acceptable form of attendance.

III. Review of LAC membership

All but two (2) LAC members sought re-appointment at the end of their term in 2019. Dr. Malcolm Rubinstein and Dr. Robert Yim decided not to seek re-appointment. However, they are both willing to remain with the LAC until new members from the organizations they represent are appointed. Dr. Newby also thanked Dr. Rubinstein and Dr. Yim for their commitment and service to the LAC.

IV. Discussion of the new LAC By-laws

The newly created by-laws provide the mission, duties and responsibilities of the Laboratory Advisory Committee. The by-laws contain ten (10) articles that include the name of the Committee, the mission, duties and responsibilities, membership, meeting schedule, officers, staffing, standards of conduct, procedures for amending the by-laws and other general information. After a brief discussion, Dr. Newby requested a motion to accept the by-laws as drafted. A motion was made and all members accepted.

V. Requirements for Requesting Excepted Test Status

Pursuant to COMAR 10.10.01.03E, the Laboratory Advisory Committee may consider a test for excepted test status and make recommendations to the Secretary if the LAC receives a request in writing from the Secretary, a Maryland chapter of a specialty medical society or the Medical and Chirugical Faculty of Maryland (MedChi). Once an official request is received by the Secretary and forwarded to the LAC, the LAC will review the request and provide a recommendation to the Secretary on whether the test should be placed on the excepted test list.

Maryland also touts a level of stringency above that of the Clinical Laboratory Improvement Advisory Committee (CLIAC). Maryland has maintained stringency in terms of what type of testing manipulations need to be done because even the most basic test can go awry. For example, a test as simple as a Group A Strep test had a practice where the person performing the test used the controls to help enhance positive results. Due to this type of testing manipulation, Maryland maintains a higher level of stringency with tests on the excepted list. The only time the level of stringency was changed, however, was for PT/INR where Maryland insisted on proficiency testing (which was over and above that which was required).

It is also worthwhile to note that since the LAC has a Pharmacist member, the LAC has recommended testing that would allow pharmacists to conduct certain tests based on pharmacy education.

VI. CAP Today Article – "New Requirements for Molecular Micro Waived Testing"

The CAP Today article provided new requirements for molecular micro waived testing. The article indicates that there are four new checklist requirements for waived molecular-based microbiology tests that have been added to the CAP point-of-care testing, limited service laboratory, and immunology accreditation checklists.

The first new checklist requirement, POC.08675 – Quality Monitoring Statistics, requires written procedures to monitor for the presence of false-positive results for all molecular microbiology tests. This may include (1) review of summary statistics, (2) performance of wipe (environmental) testing, (3) review and investigation of physician inquiries and (4) use of process controls to minimize risk of contamination.

The second new checklist requirement, POC.08690 – Specimen Handling Procedures, calls for written procedures to prevent specimen lost, alteration, or contamination during collection, transport, processing and storage. Collection, processing and storage must follow the manufacturer's instruction and point-of-care labs should have procedures in place to prevent loss, alteration and contamination.

The third new checklist requirement, POC.08715 – Safe Specimen Handling/Processing requires written policies for safely handling and processing samples from patients with suspected infection due to avian influenza, SARS, Ebola or similar emerging pathogens. The policies may be a part of an institution's plan and must address point-of-care specifically.

The fourth and final new checklist requirement, POC.08730 – Final Report, requires the report to include a summary of the test method and information regarding clinical interpretation, if appropriate. The report must also include a brief description of the method if the methodology is not explicit in the test name. Therefore, any laboratory (including limited service labs) using waived molecular-based microbiology tests in a CAP-accredited laboratory will have to comply with the above requirements.

This article primarily warns that with molecular testing, there are certain stringencies that need to be followed. Also, laboratories that are accredited by the College of American Pathologists to perform molecular testing must ensure that the testing environment is not contaminated; because contamination causes molecular test results to be unreliable. Dr. Myers provided that specimen contamination is also an issue for single target assay testing. Thus, the new checklist requirements will assist with preventing amplicon contamination and reduce the opportunity for false positive results. Maryland will additionally be able to better monitor those performing molecular-based microbiology tests with the new checklist requirements in place.

Dr. Newby thereafter inquired whether Ms. Gail McGucken or Mr. Paul Celli had any information to add. Ms. McGucken and Mr. Celli did not have any additional information, but they did provide that the local health departments are required to perform proficiency testing which is another level of stringency. Dr. Newby then inquired what type of testing Dr. Patel (Internist) and Dr. Yim (Pediatrics) perform. Drs. Patel and Yim replied that they both perform CLIA waived testing in their individual practices. Dr. Newby thereafter encouraged manufacturer methodology, ease of use and increased stringency.

VII. Q & A and Final Thoughts

Ms. Meghan Lawson (public attendee) from Cepheid attended the LAC meeting in an effort to determine the process to apply for a letter of exception to conduct testing for the flu. After reiterating the requirements from Section V. above (and mentioning that the LAC should be copied on all requests), Dr. Newby provided that upon receiving a letter requesting excepted status, a decision will be made to determine if the request is appropriate for the LAC to review. If the request falls under the purview of the LAC, a determination will thereafter be made based on (1) how much sample manipulation has to occur, (2) the testing strategy needed, (3) the impact of a false positive or a false negative, (4) access to care and (5) whether there is a need for proficiency testing (stringency consideration). Also, in an effort to ensure receipt of a proper request, it would be beneficial to write a letter to MedChi and other

qualifying medical societies in Maryland to articulate the requirements to apply for a letter of exception.

Dr. Newby subsequently inquired whether there was any proposed legislation for the upcoming Legislative Session that would impact laboratories and/or the LAC. Ms. Renee Scurry replied that the Legislative Session was scheduled to begin on January 8th and that the LAC should be available should any bill be presented that would require input from the LAC. Dr. Myers also added that there is a potential bill that will require hospitals to perform paternity testing. However, since paternity testing is actually a legal/court issue, this type of testing should not be considered as a healthcare issue.

Ms. Barbara Caldwell thereafter spoke on the shortage of staff, i.e. trained laboratory scientists, in the laboratory field. According to the American Society for Clinical Pathology (ASCP) workforce report to CLIA, the workforce regarding laboratory scientists is in dire straits. Some of the issues concerning the workforce shortage include, (1) a huge increase in retirement, (2) salary that is not compatible to nurses, (3) the need for more outreach and (4) the lack of sufficient medical laboratory technology programs available in the State of Maryland. As such, it would be beneficial for all State colleges to have laboratory testing programs. In addition, State legislation should not restrict funding (since this would cause a loss of programs and reduced funding will further exacerbate the workforce crisis). For additional information, Barbara Caldwell emailed the American Society for Clinical Pathology's 2017 and 2018 Wage and Vacancy surveys and a copy of her ASCLS presentation on behalf the ASCP wage and vacancy survey will be forthcoming.

Dr. Myers and Deputy Director Rodney Hargraves additionally provided that 30% of the State Public Health Lab's scientists are eligible to retire in the next five (5) years. This will further reduce the State Lab's scientific workforce. Even Ms. Caldwell, with 40 years of experience had her position cut and was replaced with a lower paying managerial position. Dr. Newby therefore concluded that these concerns regarding workforce issues should be brought to the attention of Secretary Robert Neall.

VIII. Adjournment

Tasks to be accomplished before the next meeting:

- 2019 Attendance Reports due by January 15, 2020

The meeting was adjourned at 10:10 AM.

Respectfully submitted,

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