Maryland
DEPARTMENT OF HEALTH

Minutes of Meeting – May 28, 2020

The Laboratory Advisory Committee (LAC) meeting took place by conference call at 2:00 p.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
Lindsey Howard, Jr., Industry
Gail McGucken, Laboratory Surveyor Scientist II, OHCQ
Gattu Rao, Maryland Academy of Family Physicians
Thomas J. Remsberg, Pharmacist
Malcolm R. Rubinstein, Consumer Member

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

Members Absent: None

I. Approval of Minutes

The Laboratory Advisory Committee minutes from the December 4, 2019 meeting were distributed via email and also during the May 28, 2020 meeting. Dr. Newby asked for a motion to accept the minutes as drafted. The motion was made and all members accepted.

II. COVID – 19 Testing Information – Paul Celli, OHCQ

Mr. Celli provided that an emergency use authorization (EUA) was given to LabCorp along with a swab collection kit for PCR testing. Everlywell was also granted a EUA. Questions subsequently arose concerning direct-to-consumer collections. However, since Health General § 17-215 was modified, these services are offered in Maryland by purchasing the pixel kits.

Note, alternatively, that rapid tests have accuracy issues. As a result, all EUA tests must be done in a non-waived setting or in a waived Point-of-Care (POC) setting on a case by case basis to include the following provisions:

- For EUA tests authorized for use in a POC patient care setting, perform quality control following the manufacturer's instructions, at minimum. The FDA deems these tests to be CLIA waived tests. No Individualized Quality Control Plan (IQCP) is required.

- For EUA tests authorized for use by moderate or high complexity laboratories only, perform quality control following the manufacturer's instructions, at minimum. These tests are considered to be nonwaived tests; however, no IQCP is required unless the

manufacturer does not define conditions for reduced external QC frequency in its instructions for use.

- If the manufacturer does not define conditions for reduced external quality control in its instructions for use (e.g., states to perform external QC in accordance with applicable federal, state, or local accreditation requirements), the laboratory must:

- Perform external QC following the default CLIA frequency (e.g., two levels of QC each day of testing) or implement an IQCP if it wishes to reduce the frequency of external QC. Written QC plans must be approved by the laboratory director prior to implementation.

Also OHCQ is requiring CLIA waived labs using either the EUA POC PCR test or Quidel Serology:

- Testing is performed in contained and dedicated laboratory spaces isolated from patients at each site;

- Bench shields or a Biosafety Cabinet (BSC) set up, and all manipulation of specimens is performed behind the protective barrier;

- Testing Staff are wearing full personal protective equipment (PPE) while in the lab, including N-95 respirators, gowns, eye protection, and gloves;

- Training on continuous cleaning of the environment and instrument to prevent contamination should be conducted, and disinfection performed every three hours, or as needed.

- Monitoring of positivity rates maintained to assess for contamination of instruments;

- Enrollment in Proficiency Testing or plan to provide unknown (blind) proficiency testing samples to the testing locations on 6 month intervals as part of competency and testing assessment;

- Each operator has documented competency for all steps of the testing process, assessment of all operators at 6 months and at 12 months; all training and competency documents are reviewed and signed by the lab director;

- Laboratories using an unmodified EUA test kit must verify the test method performance specifications (accuracy, precision, reportable range, and reference intervals), as applicable at their own laboratory prior to beginning patient testing. The laboratory may use information published in the manufacturer's package insert and other published literature for some aspects of the study (e.g., interferences). While the ultimate objective is to fully verify the method performance of the assay, the pandemic crisis, urgent need for patient testing, and possible lack of reagents and supplies make it difficult to fully evaluate the accuracy, precision, and reportable range. The laboratory director should determine the depth of verification needed to begin testing and must approve the verification study prior to testing. The test kits may have quality control materials for checking performance of the test kit. For accuracy verification, laboratories may use known positive and negative patient specimens, positive and negative QC materials, and other commercially purchased materials. Patient specimens can be altered (e.g., spiked with control materials).

The U.S. Department of Health and Human Services supplied the Laboratories Administration with 15 Abbott NOW devices that can perform 1200 tests per week. Dr. Myers is planning on distributing them to rural hospitals soon. The devices though have come under some scrutiny for accuracy and the FDA has alerted the public. There have also been several national news articles regarding the ID NOW devices. As

for laboratory licensing, the Office of Health Care Quality (OHCQ) has licensed a myriad of laboratories.

CMS has also decided that Research Facilities can help with RNA Extraction for the PCR testing. As long as the facility is only extracting specimens, it does not require its own CLIA certificate. Once the facility starts performing the tests which are under CLIA oversight, it would need to obtain a CLIA certificate.

The Labcorp Pixel home collection EUA kit for PCR testing is listed as not available in Maryland on Labcorp's website. It is being discussed with Labcorp attorney Kathryn Kyle and MDH attorney Kathleen Ellis. Mr. Celli has not heard of any decision made on its use in Maryland.

There are currently no "at home" FDA EUA test devices for Covid-19. There are many serology antibody test kits that the FDA has allowed to flood the market, but has not reviewed. The FDA is allowing use of these tests with disclaimers and they default to CLIA high complexity.

Finally, Maryland is one of seven states that has notified the FDA that it is willing to authorize labs to develop and perform their own test, but to date OHCQ has not had any request to do so. All of the testing for Maryland is being done with a EUA Kit or LDT that the FDA has granted.

III. CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated With Coronavirus Disease 2019 (COVID-19)

Clinical Specimen Testing

The CDC devised respiratory guidance for COVID-19 testing which included information on the use of splash shields and proper PPE.

The CDC stressed that precautions should be taken when handling specimens suspected or confirmed for COVID-19. There should be continuous communication between clinical staff to minimize risks associated with handling these specimens. Specimens should also be properly labeled and the laboratory conducting testing should also ensure proper handling of specimens.

The CDC also provided that all laboratories should perform site and activity specific risk assessments to identify and mitigate risks. Risk assessments and mitigation measures depend on: (1) the procedures performed; (2) identification of the hazards involved in the process and/or procedures; (3) the competency level of the personnel who perform the procedures; (4) the laboratory equipment and facility; (5) the resources available. Standard precautions such as hand washing, use of personal protective equipment and adhering to procedures for decontamination of work surfaces should also be strictly followed. As for routine vial testing, specimens can be handled in a BSL-2 laboratory using standard precautions.

For additional information, please use the link below to further review these guidelines: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

IV. Adjournment

The meeting was adjourned at 2:30 p.m.

Respectfully submitted,

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