

Special Review

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**Review of Procurement of Certain COVID Tests**

March 2021

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**OFFICE OF LEGISLATIVE AUDITS**  
DEPARTMENT OF LEGISLATIVE SERVICES  
MARYLAND GENERAL ASSEMBLY

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Victoria L. Gruber  
Executive Director

DEPARTMENT OF LEGISLATIVE SERVICES  
OFFICE OF LEGISLATIVE AUDITS  
MARYLAND GENERAL ASSEMBLY

Gregory A. Hook, CPA  
Legislative Auditor

March 31, 2021

Senator Clarence K. Lam, M.D., Senate Chair, Joint Audit and Evaluation Committee  
Delegate Carol L. Krimm, House Chair, Joint Audit and Evaluation Committee  
Members of Joint Audit and Evaluation Committee  
Annapolis, Maryland

Ladies and Gentlemen:

We have conducted a special review of the procurement and related use of COVID tests from LabGenomics, a foreign-based healthcare company. We also reviewed the circumstances surrounding the termination of two State employees after they had raised concerns related to the COVID tests. Our review was initiated based on a joint request from the chairs of the Senate Education, Health, and Environmental Affairs and the House Health and Government Operations Committees for a review of two COVID-related emergency procurements. This report is limited to the results of our review of one of those procurements and the two State employee terminations.

We conducted our review during the period from September 11, 2020 through January 29, 2021 and the results herein are based on information obtained during this period. As will be expanded upon later, we were unable to obtain written documentation on various aspects of the subject matter, but other information relevant to our review may exist and could be provided to us in the future. Any additional developments, which may come to our attention, will be addressed in a subsequent report along with results of our review of other emergency procurements made during the COVID pandemic state of emergency and the related recommendations.

Our review disclosed a pervasive lack of written documentation to support the key aspects of the procurement, use, and validity of the tests and the aforementioned terminations. Consequently, the results of our review are based primarily on interviews with current and former State employees and

other personnel including members of senior management at the Department of General Services (DGS), Maryland Department of Health (MDH), the Governor's Office, and Towson University (TU). The procurement of the tests occurred during the onset of the formal state of emergency declared by the Governor. While there was an expressed urgency to procure the tests, such conditions would not mitigate the need to properly document and comply with State regulations specifically tailored to emergency procurements.

We concluded that the tests were not procured in accordance with State procurement regulations. For example, the payments made for the COVID tests were not supported by formal written contracts or agreements containing any of the critical provisions required by State procurement regulations. Instead, we were provided with a letter of intent for the initial purchase; however, this document was not a contract as required by regulations. The lack of a comprehensive written contract precluded effective monitoring. We also were not provided with comprehensive written documentation of the extent to which other vendors were considered, or of the specific parties involved in the evaluation and selection of LabGenomics. Finally, there was no support of the basis for the \$11.5 million ultimately paid for the tests or the decision to charter a flight for the shipment of the first tests at a cost of \$464,369 when the second tests were shipped for a cost of \$14,265.

We also found that the first tests obtained from LabGenomics had not been authorized by the Federal Food and Drug Administration and one study conducted by a laboratory in Maryland concluded the tests were likely to have an increased number of false-negatives and inconclusive results. In addition, while concerns were raised with the reliability of test results reported by the University of Maryland Pathology Associates (UMPA) laboratory using the second tests obtained from LabGenomics, we were unable to obtain documentation of test results from UMPA to corroborate the concerns with the reliability of test results. As discussed below, our requests for these records were initially denied. Subsequently, legal counsel to the Maryland General Assembly confirmed that we were entitled to these records, but we have not yet obtained and analyzed the records. We also determined that MDH looked into concerns with the test results and noted deficiencies with the lab procedures, but it did not determine if there were any issues with the tests.

Finally, our review of the circumstances surrounding the termination of two State employees after they had raised concerns related to the COVID tests, found that the verbal representations made to us by the agencies' management as the basis for the terminations were not supported by available written

documentation. For example, one of these employees was terminated approximately one month after questioning a large spike in positive COVID cases, which we were advised were processed by UMPA, and among the tests used by UMPA at the time were the second LabGenomics tests. In this regard, supervisory officials advised us that the termination was due solely to unrelated performance issues; however, this was not supported by written documentation in the employee's personnel file.

The responses to this review from the Governor's Office, the Departments of General Services and Health (combined), and Towson University are included in Appendices B, C, and D, respectively. In accordance with State law, we have reviewed the responses, and identified numerous statements that conflict or disagree with statements and findings in our report. In each instance, we re-examined and reassessed our documentation, and reaffirmed the validity of our work and the related findings. In accordance with our policy, we have redacted certain names and other information from the agencies' responses.

Appendix A includes auditor's comments, on what we deemed to be the significant disagreements. Perhaps most troubling for OLA, is that we had discussed each of these issues with senior management at the respective agencies. As noted in the report, our conclusions reached were based on their answers to specific questions, and our review of often limited documentation made available by them or their staff to us. Nevertheless, we have concluded that these responses, while generally disagreeing with our findings, have either confirmed the correctness of our findings (such as the lack of a comprehensive contract) or do not answer key questions posed by the review (such as the identity of the individual who was ultimately responsible for making the decision to purchase the test kits).

In addition to the aforementioned auditor's comments included to address certain disagreements in the agencies' responses, we also want to address two general statements included in the combined DGS and MDH response. The first is the perception that this review "gives the appearance that OLA produced a rushed and politically-driven report", which is a characterization unsupported by the facts. The field work underlying this report's conclusions was conducted over a four-and-half-month period, which is an unprecedented amount of time for such a focused review, and demonstrates OLA's level of care and detail taken to ensure the comprehensiveness and correctness of our conclusions. In addition, as State government agencies are well aware, OLA provides nonpartisan services to the General Assembly, and prides itself on presenting objective results in an unbiased manner. Second, we wish to acknowledge the "full and frank working relationship" that OLA has with both departments. These longstanding

relationships are much valued by OLA and are based on mutual respect and trust, and driven by a shared goal to establish proper accountability and good governance. We believe that the conclusions in this report demonstrate OLA's commitment to that shared goal.

Respectfully submitted,

A handwritten signature in black ink that reads "Gregory A. Hook". The signature is written in a cursive style with a prominent initial 'G'.

Gregory A. Hook, CPA  
Legislative Auditor

## **Background Information**

### **Legislative Request and Allegations**

In June 2020, the chairs of the Senate Education, Health, and Environmental Affairs and the House Health and Government Operations Committees requested that the Office of Legislative Audits conduct a review of the emergency procurements awarded to:

- LabGenomics for COVID tests used by laboratories to analyze samples collected from patients at testing sites, and
- Blue Flame Medical for medical supplies

The legislators asked that the review include an evaluation of the procurement process and accountability over the items purchased. We initially intended to conduct the review in conjunction with our fiscal compliance audit of the Department of General Services (DGS) – Office of the Secretary. However, our preliminary inquiries disclosed that multiple State agencies were involved in the procurement, accountability, and use of the items purchased from these vendors. In addition, we identified numerous other material emergency procurements made by the State associated with the ongoing COVID-19 pandemic. Consequently, we decided to expand the scope of our review and we will issue a separate report on emergency procurements made by the State during the COVID state of emergency, rather than as a component of the DGS audit.

Our initial focus was on the LabGenomics tests due to the ongoing concerns with the procurement and use of the related tests. In addition, our review included the review of the termination of two employees associated with the LabGenomics tests. Specifically, we received an allegation through our fraud, waste, and abuse hotline regarding concerns raised with COVID test results by an employee at Towson University (TU) who was subsequently terminated. In addition, during the December 8, 2020 Joint Audit and Evaluation Committee hearing, we were also asked to review the circumstances of the termination of the former Director of Procurement at the Maryland Department of Health (MDH) who had raised concerns with the process used to procure the COVID tests from LabGenomics.

In order to provide timely results on our efforts, this report includes the results of our review of the procurement and accountability of the LabGenomics tests and the aforementioned terminations based on information we obtained as of January 29, 2021. Our review of other emergency procurements, including the award to Blue Flame Medical, will be included in a subsequent report.

## **COVID-19 Pandemic**

COVID-19 (Coronavirus disease 2019) is a disease that was first identified in China in December 2019. It quickly spread worldwide and was characterized as a pandemic on March 11, 2020 by the World Health Organization.

On March 5, 2020, the Governor of Maryland announced the State's first positive cases of COVID-19 and declared a state of emergency to mobilize all of the State's available resources. The COVID-19 pandemic created a worldwide demand for COVID tests, and increased demand for personal protective equipment (PPE) and other supplies. While the identification of these items was a coordinated effort of multiple State agencies, DGS was primarily responsible for conducting the related emergency procurements with technical assistance from MDH.

## **Overview**

DGS purchased the first 500,000 tests from LabGenomics in April 2020. We were advised by MDH that all of these tests (except for the limited number used by certain laboratories) were returned to LabGenomics on June 23, 2020. DGS purchased the second 500,000 tests from LabGenomics in May 2020. The combined costs of these purchases (including shipping charges) for the 500,000 tests ultimately received by the State totaled approximately \$12 million.



## **Scope, Objectives, and Methodology**

### **Scope**

We conducted a review of the emergency procurements performed by the Department of General Services (DGS) to purchase COVID tests from LabGenomics. We also reviewed the circumstances surrounding the terminations of the former Director of Student Health Services (SHS) at Towson University (TU) and the former Director of Procurement at the Maryland Department of Health (MDH).

This review was initiated based on requests from members of the Maryland General Assembly; and after its commencement, we received an allegation of a related matter through our fraud, waste, and abuse hotline. Our review was conducted during the period from September 11, 2020 through January 29, 2021 and the results herein reflect information we were able to obtain during this period. Other information relevant to our review may exist and could be provided to us in the future. Any additional developments, which may come to our attention, as well as the results of our review of other emergency procurements and any related recommendations will be addressed in a subsequent report.

We conducted our review under the authority of State Government Article, Section 2-1220 of the Annotated Code of Maryland. Our review did not constitute an audit conducted in accordance with generally accepted government auditing standards.

### **OLA Access to Information**

During our review, we requested documentation of test results from the laboratories that used the LabGenomics tests, specifically from the University of Maryland, Baltimore's Institute of Genome Sciences and University of Maryland Pathology Associates, the MDH Maryland Public Health Laboratory, and CIAN Diagnostics. The reason that we asked for this documentation was to verify certain assertions made by the individuals that we interviewed. These assertions included statements about the reliability or unreliability of the tests as well as their disposition. The laboratories initially denied our request for these records. Legal counsel to the Maryland General Assembly confirmed that we were entitled to these records; however, we were unable to obtain and analyze the records prior to issuing this report. Accordingly, the results of our review of those records will be subject to inclusion in a subsequent report.

## **Objectives and Methodology**

Our review included the following three objectives:

1. To evaluate the following areas related to the first 500,000 tests purchased from LabGenomics.
  - Procurement of Tests
  - Receipt of Tests
  - Disposition of Tests
  
2. To evaluate the following areas related to the second 500,000 tests purchased from LabGenomics.
  - Procurement of Tests
  - Receipt of Tests
  - Disposition of Tests
  - Concerns with Test Results
  
3. To review the circumstances of the terminations of the former Director of SHS at TU and the former Director of Procurement at MDH after they had raised concerns related to the COVID tests.

Our review included tests, analyses, observations, and discussions with current and former State personnel and others, as we deemed necessary to accomplish our objectives. We reviewed numerous documents, including available procurement records, invoices, laboratory studies and procedures, COVID test specifications, and other related records. We interviewed 36 current and former State employees and other personnel including members of senior management at DGS, MDH, the Governor's Office, TU, and the aforementioned laboratories (see Exhibit for a listing). Finally, we conducted certain physical inspections of COVID tests located at State and private facilities.

Due to a pervasive lack of written documentation to support the objectives in our review, the majority of our results are based on verbal representations of the State employees and other personnel we interviewed. To ensure that information obtained by these interviews was properly recorded and was not subject to misinterpretation, at least two OLA employees were present during substantially all of the interviews and physical inspections we conducted.

## OLA Observations

### Objective 1

Initial Tests				
Vendors	Number Purchased	Purchase Price	Shipping Cost	Total Cost
JKICT/LabGenomics Samsung SDS	500,000	\$9,000,000	\$464,369	\$9,464,369
Disposition of Tests				
<b>MDH advised us that almost all of the tests were returned unused on June 23, 2020.</b>				
OLA Conclusions as of January 29, 2021				
<ul style="list-style-type: none"> <li>• <b>Tests were not procured in accordance with State procurement regulations, including the lack of a written contract.<sup>1</sup></b></li> <li>• <b>While there was certain documentation that other vendors were contacted, we could not determine the extent to which they were actually considered to provide the tests.<sup>1</sup></b></li> <li>• <b>We found no records documenting the formal evaluation of the vendors, the basis for the selection of LabGenomics, or whether LabGenomics was the best qualified vendor.<sup>1</sup></b></li> <li>• <b>We were unable to identify the specific parties ultimately responsible for the evaluation and selection of LabGenomics.<sup>1</sup></b></li> <li>• <b>A review of available records indicates the State did not ensure that the tests received on April 18 and 22, 2020, were authorized by the Federal Food and Drug Administration prior to them being shipped by LabGenomics.</b></li> <li>• <b>A study of the tests by one laboratory indicated the tests were likely to have an increased number of false-negatives and inconclusive results, and increased test processing times.</b></li> <li>• <b>We were advised by MDH that certain tests used by one laboratory were found to produce inconclusive results.</b></li> <li>• <b>MDH did not acknowledge the aforementioned issues in its decision to return the tests.</b></li> </ul>				

### **Procurement of Tests:**

The COVID tests were procured by the Department of General Services (DGS) as an emergency procurement authorized in State procurement regulations. These regulations include several requirements for emergency procurements including

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<sup>1</sup> Condition described is a violation or potential violation of requirements found in State procurement regulations.

(a) a formal written contract; (b) obtaining as much competition as practicable; (c) submitting the procurement to the Board of Public Works; (d) publicizing the award on *eMaryland Marketplace (eMM)*<sup>2</sup>; and (e) documenting the details of the procurement, including justification for the use of the emergency procurement and the basis for selecting the vendor. In regard to the written contract, the regulations require the contract to include critical provisions such as conformance of specifications, delivery and acceptance, dispute resolution, indemnification, liquidated damages, compliance with laws, cost and price certifications, political contribution disclosures, anti-bribery statements, and requirements for registration of the business in the State.

**a. Was the procurement in accordance with State procurement regulations?**

Our review disclosed that DGS did not have a formal written contract with LabGenomics, a South Korean company, containing the critical provisions required by State procurement regulations. Rather, DGS provided us with a Letter of Intent (LOI) dated April 2, 2020 it issued to a Virginia firm (JKICT) representing LabGenomics. The LOI included the following information:

*We are writing to provide a letter of intent from the Maryland Department of General Services (DGS) with respect to a transaction with your firm for Covid19 PCR Assay Kit (100T), quantity 5,000<sup>3</sup>, responsive to your Proforma Invoice PIL20-0402, dated April 2, 2020. The total cost of the transaction is \$9,000,000. The terms are 100% upon placement of order, via wire transfer. This wire is scheduled for transmittal on April 3, 2020.*

As such, the LOI did not contain any of the aforementioned critical provisions required by State procurement regulations or any specifications or requirements for the tests to ensure they would work as intended and complied with Federal Food and Drug Administration (FDA) Emergency Use Authorization (EUA)<sup>4</sup>. Furthermore, we determined that neither LabGenomics nor JKICT were registered with the State Department of Assessments and Taxation (SDAT), as required, to do business in the State

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<sup>2</sup> Although DGS replaced *eMM* with *eMaryland Marketplace Advantage (eMMA)* effective July 2019, the same publishing requirements exist.

<sup>3</sup> 5,000 refers to the number of test kits (1 test kit = 100 tests), which totals 500,000 tests.

<sup>4</sup> EUAs are issued by the FDA to permit the emergency use of an unapproved medical product during a period of a public health emergency.

prior to the purchase. JKICT subsequently registered with the SDAT three months after the purchase.

In relation to the selection of LabGenomics as the vendor to provide the tests, as further described below, we found there was documentation that other vendors were contacted regarding the procurement, but we could not determine the extent to which they were actually considered to provide the tests or whether the selected vendor was the best qualified. DGS did notify the Board of Public Works (BPW) of the procurement and publish the award in *eMaryland Marketplace* as required. However, BPW staff advised us that due to the lack of the required written contract, the purchase may now need to be submitted for ratification by BPW.

In addition, we found certain assertions made by State employees regarding the selection of LabGenomics could not be supported. Specifically, DGS prepared an undated procurement checklist, which included the following statement:

*On behalf of the Maryland Department of Health (MDH), DGS Office of State Procurement (OSP) tendered payment to JKICT/LabGenomics for 500,000 COVID-19 tests. Due to the emerging details about the virus and testing, OSP has little to no market research around this commodity. Accordingly, DGS OSP relies upon the expert opinions of clinicians and others within MDH who have made the determination that these tests will meet the needs of the State and that costs are fair and reasonable. DGS OSP is unable to find comparable products within current contracts or its normal supply chain sources.*

Regarding this statement, neither DGS nor MDH staff could provide us with written documentation to support the evaluation of potential vendors as further described below in Question c. “Why was LabGenomics selected?”

Finally, DGS chartered two special flights from South Korea to deliver the tests for which it paid an additional \$464,369 to another company (Samsung SDS) without any written contract. DGS’s undated written justification for the charter stated that

*Samsung has provided a fair and reasonable cost for charters. DGS OSP notes lack of availability of flights and, when available, prices have been significantly higher than the cost presented by this vendor. Due to the volatile environment of*

*overseas air freight, as well as the need for this transaction to be finalized immediately, seeking competition was not practical. Further, due to the need for upfront payment for the flights, a direct voucher wire payment has been initiated.*

DGS senior staff we interviewed could not provide us with any documentation to support these assertions made in DGS' written justification. Moreover, as noted below, the shipping cost for the second 500,000 tests was \$14,265. DGS did not document its rationale for chartering the flights and incurring the additional cost for the first tests.

**b. Were other vendors considered?**

While there was certain documentation that other vendors were contacted, we could not determine the extent to which they were actually considered to provide the tests. Specifically, the Governor's Office provided us with a spreadsheet containing the names of 23 vendors that it claimed were contacted prior to and after the tests from LabGenomics were purchased including 8 from the United States, 13 from South Korea, and 2 from China. We were advised that one employee from the Governor's Office and one employee from MDH were primarily responsible for contacting and obtaining information from these companies related to their tests. The results of these inquiries such as the status of the vendor's application for FDA EUA, types of equipment that may be used with the tests, technical specifications for the tests, and number of tests available were included on the spreadsheet for certain vendors.

However, the information for certain attributes was not completed for 20 of the vendors on the spreadsheet (including for LabGenomics), and no documentation was provided to support any of the information on the spreadsheet for 12 vendors. For the remaining 11 vendors, we were provided with certain written documentation such as performance data and EUA acknowledgment letters for their respective tests, which appears to substantiate that they had been in contact with the State.

**c. Why was LabGenomics selected?**

Neither DGS nor MDH could provide us written documentation to support or otherwise justify the selection of LabGenomics as the vendor to provide the tests. Rather, we were advised by the Secretary of DGS that MDH selected LabGenomics because it had the ability to provide the desired quantity of COVID tests within the State's timeframe, which can be characterized as "as soon as possible". As noted above, we were advised by Governor's Office personnel that numerous vendors were contacted and the

selection was based on an evaluation of specifications (for example, the type of equipment required to process the tests). Senior management officials at DGS and the Governor's Office advised us that pricing was considered, but the State's priority was to obtain a large volume of tests that met the State's requirements within a minimal amount of time.

We were advised that the State requested specifications on each vendor's tests, the status of their EUA application, estimated volumes of production, and whether there were any issues with timely delivery. We were further advised that the Maryland Public Health Laboratory (MPHL), which is a unit within MDH – Laboratories Administration, was responsible for reviewing the technical qualifications. While we sighted certain correspondence related to the qualifications of the tests, there was no formal document (such as selection committee evaluations and rankings) summarizing the evaluation of the vendors for these key attributes with a corresponding recommendation for which vendor was best suited to meet the State's needs.

In addition, the officials we interviewed could not identify the individual or individuals ultimately responsible for deciding to procure the tests from LabGenomics. The following is our understanding of the events surrounding the procurement of the tests from LabGenomics based on our review of existing documents and interviews of appropriate officials. The former DGS Director of Procurement advised us that he prepared and signed the LOI at the direction of the DGS Secretary. The Secretary of DGS said we would have to speak with MDH for details regarding this decision and could not identify the specific individual responsible for making the decision. The former Secretary and current Acting Secretary of MDH both advised us that they were not involved in the process and did not know who decided to select LabGenomics. A senior MDH official said that the Governor's Office (including the First Lady's staff), worked with DGS on acquiring the initial tests. However, the Governor's former chief of staff acknowledged that he was involved in logistics, such as facilitating calls, but did not know who made the decision to purchase the tests from LabGenomics, and the First Lady's current chief of staff advised us that she was just involved as a translator.

As of January 29, 2021, we have been unable to locate any documentation or reach a conclusion as to the identity of the party or parties who authorized the purchase of the tests from LabGenomics. Ultimately, it is possible that a paper trail identifying the employee responsible for approving the LabGenomics purchase does not exist.

## Receipt of Tests

### a. When and how many tests were received?

We received shipping records indicating the receipt of two shipments of tests on April 18, 2020 and April 22, 2020 at the Baltimore/Washington International Thurgood Marshall Airport containing 350,000 tests and 150,000 tests, respectively. MDH advised us in writing that the 350,000 tests were transported to MDH's warehouse and the 150,000 tests were transported to the Maryland Department of State Police's Pikesville lab. We were provided with a tracking sheet maintained by MDH documenting the location and disposition of the tests. However, we have not been able to trace the information from the tracking sheet to any supporting documentation (receiving reports or independently maintained inventory records identifying the specific number of tests received and transported to other locations), and we were unable to sight any of these physical tests because, as described below, the tests were returned prior to our review.

Based on the tracking sheet, it appears that MDH retained most of the tests until they were returned (see below for discussion of the return process) and the remainder of the tests were distributed as follows:

- **Maryland Department of State Police** received 150,000 tests.
- **CIAN Diagnostics** received 10,100 tests (7,200 were returned to MDH. The 2,900 remaining tests were used for laboratory studies and patient testing.)
- **University of Maryland Medical System** received 500 tests.
- **Integrated Cellular & Molecular Diagnostics (ICMD)** received 100 tests.

### b. Did the State verify the tests worked as intended?

The CIAN Diagnostics and ICMD laboratories performed studies to verify the efficacy of the tests by conducting analyses and comparing the results to an FDA authorized test from another manufacturer. We obtained the results of the studies, which disclosed that CIAN Diagnostics did not have any concerns with the reliability and processing time of the tests. However, ICMD's study identified several concerns<sup>5</sup> including:

- The LabGenomics' test is less sensitive than the other manufacturer's test.

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<sup>5</sup> As of January 29, 2021, we are waiting on a response from the Maryland Public Health Laboratory regarding the reasonableness of comparing the bridging studies between CIAN and ICMD.



- The LabGenomics’ test processing times (6-8 hours) was almost twice as long as the other manufacturer’s test (3-4 hours) which limits the number of samples that can be processed in a given day.
- The design of the LabGenomics’ test is likely to increase the number of false-negative and inconclusive results.

Due to the concerns raised by ICMD, MDH requested that MPHL conduct an independent study. MPHL noted that the tests did not contain the same internal control reagent material and procedures that were referenced in the FDA’s EUA granted to LabGenomics. Our review of available documentation disclosed the following timeline and relevant facts related to the EUA application submitted by LabGenomics and the shipment of the tests to the State.

<b>March 26, 2020</b>	LabGenomics submitted the EUA application to the FDA.
<b>March 30, 2020</b>	The FDA requested that LabGenomics change the internal control reagent material included in the test.
<b>April 2, 2020</b>	DGS issued the LOI to LabGenomics for the order of 500,000 tests.
<b>April 3, 2020</b>	LabGenomics revised its EUA application to reflect the new internal control reagent material and resubmitted it to the FDA.
<b>April 18, 2020</b>	350,000 tests were shipped from South Korea and delivered to the State.
<b>April 22, 2020</b>	150,000 tests were shipped from South Korea and delivered to the State.
<b>April 29, 2020</b>	The FDA issued the EUA to LabGenomics; however, the 500,000 tests previously shipped to the State did not contain the new internal control reagent material and, therefore, did not conform to the EUA ultimately issued by the FDA.

So, the tests received on April 18, 2020 and April 22, 2020 were not in conformity with the EUA issued to LabGenomics. This means that although MDH had verified that LabGenomics submitted its EUA application to the FDA prior to purchasing the tests, there was no written requirement that LabGenomics had to provide tests that conformed to the EUA.

In addition, we were advised by MDH management (including the prior Deputy Secretary for Public Health) that “up to a couple thousand” tests were used by CIAN Diagnostics for patient testing in early May 2020 and that some of the specimens had to be retested using a different manufacturer’s test because the LabGenomics’ test results were

inconclusive. In this regard, CIAN Diagnostics management initially denied using any of the tests but subsequently acknowledged using some of them but denied having any concerns with the results. We were unable to validate these assertions because documentation of these test results has not been provided by CIAN Diagnostics as of January 29, 2021.

## **Disposition of Tests**

### **a. Why were the tests returned?**

MDH did not acknowledge the aforementioned problems (the ICMD concerns and EUA issues) as the reason(s) for returning the tests when responding to our inquiries in its written response dated November 16, 2020. Rather, MDH stated that the reason the tests were returned (to obtain the newer tests) was because, after delivery of the first tests, MDH learned that LabGenomics had an upgraded test that had better controls for extraction of the RNA process. MDH further asserted that it understood that the original tests could still have been used with a custom lab process (as permitted by the federal government) but this process would have taken longer than purchasing the upgraded tests.

### **b. What happened to the unused tests?**

We were advised by MDH that all of the original tests (except for the limited number used by the laboratories) were returned to LabGenomics on June 23, 2020. Our review of shipping documents provided by MDH disclosed that 26 boxes of tests were picked up from the Maryland Department of State Police on June 23, 2020, for shipment to an address in Ridgefield, New Jersey. MDH did not provide us with the specific number of tests included in the 26 boxes.

## Objective 2

<b>Second Tests</b>				
<b>Vendor</b>	<b>Number Purchased</b>	<b>Purchase Price</b>	<b>Shipping Cost</b>	<b>Total Cost</b>
LabGenomics	500,000	\$11,500,000 (original payment of \$9 million for initial tests and an additional payment of \$2.5 million)	\$14,265	\$11,514,265
<b>Disposition of Tests</b>				
<b>The Governor announced that all of the tests were used as of December 15, 2020.</b>				
<b>OLA Conclusions as of January 29, 2021</b>				
<ul style="list-style-type: none"> <li>• Tests were not procured in accordance with State procurement regulations, including the lack of a written contract.<sup>6</sup></li> <li>• We were provided no documentation of the extent to which other vendors were considered.<sup>6</sup></li> <li>• We were provided no documentation to support the basis for the selection of LabGenomics.<sup>6</sup></li> <li>• We were unable to identify the specific parties involved in the decision to purchase the second tests from LabGenomics.<sup>6</sup></li> <li>• We were provided no documentation supporting negotiations for the additional \$2.5 million paid for second tests that were received May 21, 2020 and June 17, 2020.</li> <li>• We were unable to obtain documentation of test results from laboratories to substantiate the disposition of the tests.</li> <li>• Towson University and certain nursing homes raised concerns with the reliability of test results reported by the University of Maryland Pathology Associates (UMPA) laboratory; among the tests used by UMPA at the time were the second tests from LabGenomics.</li> <li>• MDH Maryland Public Health Laboratory (MPHL) and the MDH Office of Health Care Quality (OHCQ) looked into concerns with the test results and noted deficiencies with the UMPA procedures but did not determine if there were any issues with the tests themselves.</li> <li>• We were unable to obtain documentation of test results from laboratories to corroborate the concerns with the reliability of test results.</li> </ul>				

<sup>6</sup> Condition described is a violation or potential violation of requirements found in State procurement regulations.

## Procurement of Tests:

DGS purchased the second COVID tests directly from LabGenomics in May 2020 and returned the first tests as previously discussed. The purchase of the second tests was also conducted as an emergency procurement authorized by State procurement regulations and was subject to the same requirements we noted for the initial tests. We were advised that the State returned the initial tests after the two shipments of the second tests were received in May and June 2020.

**a. Was the procurement consistent with State procurement regulations?**

Although the purchases of the initial and second tests were separate transactions, we could not determine if they were considered one combined emergency procurement or two separate procurements. Specifically, while we were advised by BPW staff that both purchases could be considered one large emergency procurement, the first purchase agreement was with a Virginia-based company (JKCIT) and the second purchase was made directly from LabGenomics. In this regard, there was no written contract or LOI for the second test purchase, and there was no amendment to the original LOI issued for the initial test purchase to account for the second purchase. This lack of a contract is significant given the issues previously noted with the initial tests.

DGS notified BPW of the second purchase and published the award on *eMaryland Marketplace* as required. However, BPW staff advised us that due to the lack of the required written contract, the purchase may need to be submitted for ratification by BPW.

We found that documentation for the procurement of the second tests from LabGenomics was lacking, such as, support for the basis of selecting the particular vendor, and for certain assertions made regarding the negotiation, competition, and pricing. Rather, DGS prepared an undated procurement checklist, which included the following statement:

*For greater reliability, productivity and efficiency in laboratory settings, DGS received a request to purchase upgrades to previously acquired COVID-19 test kits. These upgrades were negotiated directly with the manufacturer, LabGenomics. Citing the compatibility needs, competition would not be practicable. Pricing is fair and reasonable both by comparing to the costs of the original tests, as well as examining the extremely limited available data regarding the costs to acquire tests. The air freight charge is far below market value and is also considered fair and reasonable. Due to the payment being made via wire transfer, a BPO has*

*been created for tracking purposes only. Payment to be made upon final delivery of all 500,000 upgraded tests.*

However, neither DGS nor MDH could provide us with documentation to support the negotiation with LabGenomics and the determination that competition was not practicable and pricing was fair and reasonable.<sup>7</sup> In regard to the shipping of the tests, the invoice from LabGenomics included a shipping charge of \$14,265.

**b. Were other vendors considered?**

We could not determine if any other vendors, in lieu of LabGenomics, were considered at the time the second tests were acquired. The Secretary of DGS did not know if other vendors were considered at the time of this purchase and referred us to MDH. The former Deputy Secretary for Public Health advised us that other vendors were consistently being pursued but could not provide us with documentation to support this assertion. A former Chief of Staff to the Governor advised us that he believed other vendors were considered because he was personally engaged in conversations with at least three test suppliers. However, he could not provide us with any documentation related to these conversations. The current Deputy Legislative Officer at the Governor's Office, although not providing us with written information regarding the consideration of vendors during the decision to procure the second tests, did advise us that other vendors were considered at the end of summer 2020, which was several months after the purchase of the second tests. Specifically, the State was researching Multiplex tests (that is, tests that could detect both flu and COVID), and he believed MPHL ultimately purchased COVID tests from another vendor, in addition to those purchased from LabGenomics.

**c. Why was LabGenomics selected?**

Neither DGS, MDH, nor the Governor's Office could provide us with documentation to support the decision or the specific parties responsible for the decision to procure the second tests from LabGenomics. The former Director of Procurement at DGS who processed the transaction advised us that the Secretary of DGS directed him to process the purchase of the new tests. The Secretary of DGS directed us to MDH for the reason that the purchase was made from LabGenomics, and the former Secretary of MDH advised us that it was the Secretary of DGS or the Governor who made the decision. The current Chief of Staff to the First Lady advised us that someone determined LabGenomics was the only option available at the time of the second purchase, but could not specify who made the determination. A former Chief

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<sup>7</sup> We were unable to obtain clarity if the second tests were deemed a new procurement or upgrades to the original existing purchase.

of Staff to the Governor advised us that the decision was made in consultation with multiple agencies, but also could not specifically identify who ultimately made the decision. The current Deputy Legislative Officer at the Governor's Office said the former Deputy Secretary of Public Health at MDH and a former Chief of Staff at the Governor's Office participated in the discussions regarding the new tests; however, both of these individuals denied any direct involvement in the decision.

As of January 29, 2021, we have been unable to locate any documentation as to why LabGenomics was selected and the identity of the party or parties who authorized the purchase of the second tests, and it is possible that a paper trail does not exist.

**d. How was the additional amount paid to LabGenomics determined?**

We could not obtain any documentation to support how the price of the second tests was determined. The current Chief of Staff to the First Lady advised us that LabGenomics required the additional \$2.5 million to offset the costs of manufacturing and raw materials used to produce the tests. However, there was no documentation to support this assertion. A former Chief of Staff to the Governor advised us that the cost was always a concern; however, the State was more focused on increasing testing capacity (that is, purchasing as many tests as possible) in the interest of saving lives. In addition, the former Chief of Staff stated that negotiations with LabGenomics occurred with a combination of people from DGS and MDH but we spoke to the DGS Secretary and the current Deputy Legislative Officer at the Governor's Office who was the former Deputy Director of Governmental Affairs at MDH, and they could not provide us with the specific parties involved. The current Deputy Legislative Officer at the Governor's Office also advised that he participated in a few of the initial phone calls between the State and LabGenomics, during which LabGenomics was notified that the State wanted the new tests at no additional cost to the State. He could not explain or document how the payment of the additional \$2.5 million was ultimately determined.

## **Receipt of Tests**

**a. When and how many tests were received?**

We reviewed shipping records and other documentation indicating the receipt of two shipments of the second tests on May 21, 2020 and June 17, 2020 at the University of Maryland, Baltimore's (UMB) Health and Science Facility containing 100,000 tests and 400,000 tests, respectively. According to available records, 344,800 of these tests were subsequently distributed to

CIAN Diagnostics and 30,200 were distributed to MPHL. The remaining 125,000 were retained by the laboratories at the UMB's Institute of Genome Sciences (IGS) and UMPA.

**b. Did the State verify the tests worked as intended?**

We obtained documentation of studies performed on the second tests by MPHL and CIAN Diagnostics. MPHL's study concluded that the tests demonstrated a slightly narrower range of detection compared to the federal Centers for Disease Control and Prevention's test, but concluded that the tests did consistently detect the virus. CIAN Diagnostic's study did not identify any concerns with the tests.

## **Disposition of Tests**

On December 15, 2020, the Governor announced that all of the tests from LabGenomics had been used, but, as of January 29, 2021, we were unable to obtain documentation supporting this assertion. No centralized records of tests distributed and/or used was maintained by MDH, and we are unaware of the existence of any such records. Consequently, we requested documentation of test results from the laboratories that used the second tests (specifically from MPHL, CIAN Diagnostics, and UMB for IGS and UMPA) in part to aid us in accounting for the number of tests used. However, the laboratories initially denied our request for these records. Legal counsel to the Maryland General Assembly confirmed we were entitled to these records. However, we were unable to obtain and analyze the records from the laboratories prior to issuing this report. The results of our review of those records will be subject to inclusion in a subsequent OLA report.

## **Concerns with Test Results**

We received an allegation on our fraud, waste, and abuse hotline in September 2020 regarding concerns with the accuracy of test results received for samples collected at Towson University (TU) and the response to these concerns by TU administration. Subsequent to the receipt of this allegation, the local news reported on similar concerns with the accuracy of test results identified by at least one nursing home in the State. The samples collected at TU and the nursing home during this period of time were sent to the laboratory at UMPA for processing and analysis, and among the tests used by UMPA at the time were the second tests from LabGenomics.

**a. When were the concerns first identified?**

The individual who submitted the allegation to our fraud, waste, and abuse hotline advised us that 66 individuals whose test samples were collected by TU in August 2020 and sent to UMPA for analysis were positive; however, we were further advised that many of these individuals challenged the validity of their test results for a variety of reasons (such as having no symptoms or known exposures since an earlier test). As a result, the individual who submitted the allegation stated that certain of these individuals immediately retested at other laboratories and received negative test results.

In September 2020, OHCQ received a complaint from a nursing home regarding staff members and residents whose test results came back positive from UMPA. The Director of OHCQ provided us a redacted copy of the nursing home complaint, which noted that nursing home staff members and residents, who were asymptomatic, received positive test results. The nursing home contacted MDH, which had MPHL retest staff members. Per the complaint, all the retests for staff members were negative.

The Director of the MDH Laboratories Administration advised us that the State Epidemiologist contacted him in September 2020 about concerns with clusters of positive test results at several nursing homes that had their samples tested by UMPA. Specifically, the Epidemiologist indicated that a large number of asymptomatic staff members from a nursing home tested positive and many of these individuals were subsequently retested by other laboratories, including MPHL, and received negative test results. The Epidemiologist was concerned that the results reported by UMPA using the second LabGenomics tests could be falsely positive and requested a review of the data by MPHL. The results of this review will be discussed in the section below.

**b. What actions were taken to address the concerns?**

We were advised by the individual who submitted the allegation to our fraud, waste, and abuse hotline that the former Director of Student Health Services at TU who was responsible for obtaining and monitoring COVID test results on campus raised concerns with the test results at TU. The individual who made the allegation further advised us that these concerns were shared with TU's senior management, including the President of TU, the Baltimore County Health Department, and the State Epidemiologist. However, the individual who submitted the allegation did not believe that adequate action was taken by TU, the Baltimore County Health Department, or the State Epidemiologist to address the concerns with the accuracy of the test results.



We attempted to contact the President of TU to discuss these concerns and were directed to the Vice President of Administration who was a member of TU's COVID response leadership team. The Vice President denied that there were any concerns with the accuracy of the test results. This response was not consistent with assertions made to us by the individual who submitted the allegation and documentation we obtained, which indicated concerns with the test results were communicated to TU's senior management, the Baltimore County Health Department, and MDH. In addition, this response was not consistent with information we received from medical personnel at TU.

Specifically, TU's Medical Staff Supervisor advised us that TU became aware of similar concerns raised with positive test results from nursing homes that used UMPA during this same period of time as TU and contacted UMPA to determine if the samples from TU were processed using the second LabGenomics tests and if the tests were repeated. The Supervisor advised us that UMPA refused to provide any information. We were advised by the individual who submitted the allegation that 44 of the 66 individuals who tested positive were retested, but we were unable to obtain documentation of the results as of January 29, 2021.

We also contacted the Supervisor of Disease Control at the Baltimore County Health Department who acknowledged that concerns were raised about a large number of positive test results at TU. He further advised that the Baltimore County Health Department continued to monitor the test results at TU, but did not take any actions to investigate the accuracy of the results.

In regard to the nursing home's concerns, OHCQ initiated a review of the UMPA laboratory after it received the September 2020 complaint to evaluate UMPA's compliance with federal and State regulations. The Director of OHCQ advised us that the review did not include an evaluation of the functionality or reliability of the specific LabGenomics tests used by UMPA because it is beyond the scope of OHCQ's authority. The Director advised us that UMPA was found to be non-compliant with federal and State regulations, for which OHCQ issued a statement of deficiencies on September 30, 2020. For example, OHCQ reported that UMPA failed to establish and follow written procedures to ensure patient samples were only tested within the allowable timeframe after collection.

As noted above, the State Epidemiologist requested that MPHL conduct a review of the nursing home tests that had questionable results. The Director of the MDH Laboratories Administration advised us that the original samples processed by UMPA were not available to perform retesting to determine

whether the specific results were accurate. However, new samples were collected several days later from 27 individuals who had tested positive. The Director advised us that the new samples from all of these individuals, which were processed by MPHL using the CDC's test, had negative test results. MPHL also conducted antibody testing on 58 individuals who had tested positive from nursing homes and found that 51 individuals (88 percent) likely had not been exposed to the virus.

Ultimately, we were advised by the Director that MPHL was unable to determine if the questionable results were due to 1) inherent performance issues with the LabGenomics tests, 2) modifications of the LabGenomics tests made by UMPA, 3) cross contamination from specimen collection errors, or 4) breakdowns in testing practices or procedures at UMPA.

We were unable to obtain documentation of test results to corroborate these concerns and the related statements. As noted above, the laboratories had initially denied our request for these records. Legal counsel to the Maryland General Assembly confirmed that we were entitled to these records. However, we were unable to obtain and analyze the records from the laboratories prior to issuing this report, and will include any findings in a subsequent OLA report.

## **Objective 3**

<b>Employee Terminations</b>
<b>OLA Conclusions as of January 29, 2021</b>
<b>Our review of the circumstances surrounding the termination of two State employees after they had raised concerns related to the COVID tests found that the verbal representations made to us by Towson University (TU) and the Maryland Department of Health (MDH) as the basis for the terminations were not supported by available written documentation.</b>

### **Employee Terminations**

We received an allegation on our fraud, waste, and abuse hotline in September 2020 regarding concerns raised with COVID test results by an employee at TU who was subsequently terminated. Specifically, the former Director of Student Health Services (SHS) at TU was terminated approximately one month after pointing out potential inaccuracies with the LabGenomics test results. This related to 66 samples collected from individuals at TU in August 2020 which came back positive. During the December 8, 2020 Joint Audit and Evaluation Committee meeting, we were asked to review the circumstances of the termination of the former Director of Procurement at MDH who had raised concerns with the process used to procure the LabGenomics tests.

#### **a. What circumstances led to the termination of the Director of SHS at TU?**

##### **Allegation**

We were advised during the follow up of our allegation that the former Director of SHS was terminated on October 1, 2020, after a disagreement with TU management regarding the cause of a spike in positive COVID test results at TU in August 2020. Specifically, the former Director of SHS disagreed with the view of the President of TU and leadership personnel from other USM institutions who attributed the spike to the irresponsible behavior of the individuals (primarily students), such as attending social events.

We interviewed the former Director of SHS who stated that he shared his opinion with TU administration officials and other USM officials that the spike was attributable to problems with the UMPA laboratory that processed the tests. In this regard, the former Director of SHS advised us that many of the TU individuals who initially tested positive for COVID approached the then Director, challenging the validity of their test results for a variety of reasons, such as having no symptoms, and certain of them were immediately

retested at other laboratories and received negative test results. Specifically, the former Director further advised us that TU collected new samples from 44 of the individuals two days after the initial results were received and sent them to UMPA for retesting. The former Director of SHS further advised us that, upon being retested, 20 of these samples were negative, 16 were positive, and 8 were lost. These results combined with reports of increased positivity rates at nursing homes and other institutions resulted in the former Director of SHS' conclusion that the initial results from UMPA were not accurate. As previously noted, we were unable to obtain and analyze test results from UMPA.

The former Director was terminated approximately one month after voicing his concerns about the LabGenomics test results.

### **TU Administration's Comments on the Substance of the Allegation**

The Associate Vice President of Student Affairs (the former Director of SHS's direct supervisor), the Vice President of Student Affairs, the Associate Vice President of Human Resources, and TU's General Counsel all advised us that the former Director of SHS was terminated because of performance issues and not the disagreement regarding the increase in positive COVID cases.

The Associate Vice President of Student Affairs stated that the former Director of SHS was good at working with students and had a "strong bedside manner", but had difficulty with administrative tasks, such as, creating spreadsheets and reports and automating certain practices, which led to a lack of trust in his abilities. In addition, TU's General Counsel stated the former Director of SHS expressed reluctance to embrace TU leadership's directives, such as establishing an external medical advisory committee, which was a source of tension. The Vice President of Human Resources stated that the termination was not the result of a singular event, but a pattern of behavior that was being addressed from a performance perspective, which extended prior to the COVID pandemic situation.

### **Personnel File**

We reviewed the former Director's four most recent performance evaluations on file. While we were advised there is no requirement to document the reason for termination, all of the evaluations indicated that the Director of SHS met or exceeded expectations and had no areas of deficiencies. For example, the performance evaluation prepared by the Associate Vice President of Student Affairs and signed by the Director of SHS on July 1, 2020, included the following comments (former Director of SHS authorized for disclosure):

*Administratively [the former Director] has met all deadlines, continued to maintain an open line of communication, kept me apprised of new developments, and brings potential solutions to problems and situations.*

*Based on my observations, I do not have any immediate areas of professional improvement or areas that that I would define as deficient.*

Ultimately, TU could not provide any further documentation related to the former Director's termination.

**b. What circumstances led to the termination<sup>8</sup> of the Director of Procurement at MDH?**

**Allegation**

We interviewed the former Director of Procurement at MDH who advised us that he was terminated and his last day at work was November 23, 2020. We were further advised that this termination may have been related to the former Director's planned attendance at an upcoming Board of Public Works' meeting during which the COVID tests were to be a subject of discussion.

Specifically, the former Director of Procurement advised us that his termination may have been because the Governor's Office did not want him in attendance at the BPW meeting to avoid the risk of the former Director speaking in a direction that was not aligned with the public position of MDH and the Governor's Office. This BPW meeting occurred approximately one week after the former Director's termination, during which the Acting Secretary of MDH stated that the original LabGenomics tests were "clunky." The former Director of Procurement advised us that due to the nature of his position, he rarely missed BPW meetings and would have attended this meeting if not for the termination.

The former Director of Procurement further advised us that he had expressed concerns with the first tests from LabGenomics on two occasions. Specifically, he was contacted, via conference call, one evening prior to the purchase of the first tests by the current Deputy Secretary of Operations at MDH and the current Deputy Legislative Officer at the Governor's Office (who was the former Deputy Director of MDH's Office of Governmental

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<sup>8</sup> Although the former Director officially resigned from State service, he advised us that he would characterize his separation from service as a termination, based on his discussions with MDH officials. Consequentially, we used "termination" throughout this discussion to be consistent with his interpretation of events and MDH's stated position.

Affairs) and was asked to wire millions of dollars to a South Korean COVID test company. The former Director of Procurement refused to process the payment and explained that the transaction had to follow the proper procurement process (previous sections in this report describe the lack of compliance with State procurement regulations in the test purchases). Additionally, after the original tests were received, the former Director of Procurement stated that he contacted his supervisor, the former Deputy Secretary of Operations, and suggested that the tests' be verified by MPHL for reliability. According to the former Director of Procurement, he was told to not ask questions of this nature.

### **MDH's Position on the Allegation**

The former Secretary advised us that the termination was unrelated to the LabGenomics tests and the BPW meeting. Rather, the former Secretary and current Chief of Staff asserted that the former Director of Procurement was terminated because he was only working part-time and MDH needed a strong, full-time leader for procurement.<sup>9</sup> We were advised by the Director for the Office of Human Resources that she did not recall other terminations for a similar reason, but it was unusual for the director of a unit to only work part-time.

In addition, the current Deputy Legislative Officer at the Governor's Office acknowledged that he participated in a call to the former Director of Procurement prior to the purchase of the first tests, but denied that the former Director of Procurement was asked to process a wire transfer to a South Korean COVID test company. The current Deputy Legislative Officer advised us that the call was to inquire about expediting the procurement process if MDH could identify a COVID test company. The current Deputy Legislative Officer could not remember if LabGenomics was discussed during the call.

### **Personnel File**

The concern with the former Director of Procurement only working part-time was not reflected in his personnel file. While we were advised there is no requirement to document the reason for termination, we found no mention of this concern in the performance evaluations that the former Director of Procurement received or on any other written document. In this regard, our review of the eight performance evaluations issued to the former Director of Procurement covering the period from January 2016 to June 2020, disclosed

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<sup>9</sup> Based on the understanding that MDH needed a strong full-time procurement leader, we reached out to MDH to determine if a new full time Director of Procurement has been hired. As of February 25, 2021, we were advised by MDH that the position had not been filled.

that his performance was evaluated as “outstanding” on five of the evaluations including his most recent evaluation for the period ending June 2020 and “satisfactory” on three of the evaluations. Although the majority of these evaluations had no written comments on the performance of the former Director of Procurement, we noted that the evaluation dated July 3, 2018 stated that he had “done an excellent job of preparing MDH for BPW meetings.” The former Director of Procurement authorized disclosure of information from the personnel file.

Finally, our review of payroll records for calendar years 2019 and 2020 did substantiate MDH’s assertion that the former Director of Procurement only worked part-time during periods of those years. For example, the Director worked an average of 58 hours per pay period during the last 12 pay periods of calendar year 2019.

Ultimately, MDH could not provide any further documentation related to the former Director’s termination.

## Exhibit

<b>Schedule of Individuals Interviewed</b>	
<b>Maryland Department of Health (MDH)</b>	
Thomas C. Andrews	Chief of Staff
Corey Carpenter	Director of Policy, Office of Governmental Affairs
Dr. Jinlene Chan	Acting Deputy Secretary of Public Health Services; prior Assistant Secretary and Chief Medical Officer
Atif T. Chaudhry	Deputy Secretary of Operations (replaced Gregg Todd); prior Director of Facilities Management and Development
Dana L. Dembrow	Former Director of Procurement (resigned November 2020)
Rodney E. Hargraves	Deputy Director of Administrative and Support Services, Laboratories Administration
Jennifer E. McMahan	Director of Office of Human Resources
Dr. Robert A. Myers	Director of Laboratories Administration
Dr. Patricia T. Nay	Director of the Office of Health Care Quality, Public Health Services
Robert R. Neall	Former Secretary (retired November 2020)
Frances B. Phillips, R.N.	Former Deputy Secretary of Public Health Services (retired August 2020)
Dennis R. Schrader	Acting Secretary (since December 2020); prior Deputy Secretary of Health Care Financing and Chief Operating Officer
Gregg Todd	Former Deputy Secretary of Operations (resigned in July 2020)
Webster Ye	Assistant Secretary of Health Policy, Office of Governmental Affairs
<b>Department of General Services (DGS)</b>	
Ellington E. Churchill, Jr.	Secretary
Michael F. Haifley	Deputy Chief Procurement Officer
Daniel J. Mays	Former Director of Procurement Bureau, Office of State Procurement (resigned December 2020 to become Director of Procurement at Judiciary)
<b>Institute for Genome Sciences (IGS) at the University of Maryland School of Medicine (UMB laboratory contracted by the State)</b>	
Mike Humphrys	Director of Microbiome Service Laboratory at IGS
Dr. Jacques Ravel	Associate Director for Genomics



<b>Towson University</b>	
Dr. Matthias Goldstein	Former Director of Student Health Services (terminated October 2020)
Dr. Vernon J. Hurte	Vice President of Student Affairs
Steve Jones	Associate Vice President of Human Resources
Benjamin Lowenthal	Vice President of Administration and Finance and Chief Fiscal Officer; member of the University COVID Response Leadership Team
Dr. Lisa Murray	Medical Staff Supervisor
Anthony Skevakis	Associate Vice President of Student Affairs and Dean of Students
Sara Slaff	Vice President of Legal Affairs and General Counsel
<b>Baltimore County Department of Health and Human Services</b>	
Sabrina Chase	Assistant County Attorney, Baltimore County Office of Law
George Elder	Public Health Investigator, Supervisor of Disease Control; COVID liaison for colleges
<b>Governor's Office</b>	
Matthew A. Clark	Former Chief of Staff to Governor Hogan (effective August 2017, resigned June 2020 to become Senior Vice President for Marketing and Communications at the University of Maryland Medical System)
Soo Koo	Chief of Staff to the First Lady of Maryland; Prior Communications Director of the Governor's Office of Community Initiatives
Roy C. McGrath	Former Chief of Staff to Governor Hogan (effective June 2020, resigned August 2020)
Jake A. Whitaker	Deputy Legislative Officer (effective December 2020); former Deputy Director of Office of Governmental Affairs at MDH (started December 2017, resigned December 2020)
<b>Others Interviewed or that Contributed to Our Review</b>	
Sherry B. Adams	Director of Office of Preparedness and Response, Operations, MDH
Dr. Manoj Adusumilli	Medical Director, CIAN Diagnostics
Harrison Brown	Planning Unit Supervisor, Maryland Emergency Management Agency (MEMA)
Diane M. Croghan	Deputy Chief of Staff, Governor's Office
Marcia S. Deppen	Director of Consequence Management Directorate, MEMA
Charles A. Eby	Deputy Executive Director, MEMA
Robert E. Gleason	Chief Procurement Officer, DGS
Kristen Jones-Bryce	Chief External Affairs Officer, University of Maryland Medical System

Dr. Adnan Khan	Medical Director, Integrated Cellular and Molecular Diagnostics, LLC
Kyle Koeppler	Chief Executive Officer, CIAN Diagnostics
Walter F. Landon	Deputy Chief of Staff and Director of Office of Homeland Security
Jennifer Leatherman	General Counsel, CIAN Diagnostics
Dr. Sombabu Mallapudi	Principal/owner, CIAN Diagnostics
Russell J. Strickland	Director, MEMA
Jon Weinstein	Director, COVID-19 Testing Task Force, MDH

## APPENDIX A

### **Auditor's Comments on Agencies' Responses**

The agencies subject to this review disagreed with many of OLA's statements and conclusions in their written responses (see Appendices B – D). After reviewing these responses, we re-examined our work and reaffirmed that our published findings are appropriate, clearly presented, and properly supported by the results of interviews and our examination of the limited documentation provided to us both during the review and in the attached responses. Thus, we continue to believe that OLA's statements and conclusions in the report are valid and were not disproved by any of the unsupported assertions included in the responses. Although we reviewed each response in its entirety, we did not deem it necessary to provide a point-by-point rebuttal, but rather provided the Auditor's Comments below to certain significant disagreements in each of the agencies' responses.

#### Auditor's Comments regarding the Governor's Office response (Appendix B):

The Governor's Office disagreed with the statements made in our report regarding its failure to provide documentation. Specifically, the Governor's Office stated in its response that its Senior Deputy Legal Counsel had advised us that he was the point of contact for document requests, but our requests were made solely to two current Governor's Office employees for documents from their former positions with the State.

The Governor's Office had sufficient opportunities to provide the documentation we requested, and contrary to its response, OLA did request documentation from the Senior Deputy Legal Counsel. For example, in emails to the Senior Deputy Legal Counsel dated January 14, 2020, we requested "a list of manufacturers (and related documentation, such as proposals from the companies) that were contacted for COVID test kits and any other correspondence" and "Any documentation and correspondence that would be helpful for us to understand the process of acquiring the COVID test kits." Such requests were intentionally broad in scope, given a lack of specific information obtained from interviews on existing records, and were intended to obtain any documentation potentially or remotely relevant to the subject under investigation.

In addition, as is typical during our examinations, we requested documentation from the employees who were directly involved in the matters under review, and to support assertions made during the interviews. Consequently, during our

interviews, the aforementioned two employees agreed to look for and provide relevant documentation, as requested. Although these individuals provided us with some records, upon our examination the records were generally deemed to be insufficient to address the questions we were attempting to answer. Finally, although given two weeks to review our draft report and understand our concerns and findings, the Governor's Office's response did not include any additional documentation to address the questions, providing further evidence as to the validity of the conclusions reached in our report.

Auditor's Comments regarding the Department of General Services (DGS)/Maryland Department of Health (MDH) combined response (Appendix C):

The combined response from DGS and MDH included certain disagreements with the content of our report. After reviewing this response and our related work, we believe the content and conclusions of our report are appropriate, clearly presented, and properly supported. For example, we noted the following:

- I. **Lack of Written Contract** – It is troubling to us that the response considers the letter of intent (see Attachment 1 to Appendix A) sufficient to document a \$9 million procurement from a foreign vendor that had not previously conducted business with the State. Our report acknowledged that there was a letter of intent, but indicated that it did not include all of the required contract provisions, including language to address the following key elements intended to protect the State:
  - a. conformance of specifications,
  - b. indemnification,
  - c. cost and price certifications, and
  - d. requirements for registration of the business in the State.

The response stated that the letter of intent satisfied the requirement of a legally valid contract. However, as noted above, it did not include all the required elements and accordingly did not comply with State procurement regulations. Furthermore, we were advised by Board of Public Works staff that, while the letter of intent may be evidence of an agreement between the vendor and the State, without further documentation incorporating the State's required contract provisions, including those noted above, this agreement may be "void" under State law.

In addition, although the response stated that the procurement of the second tests was completed with a purchase order, we noted that the procurement checklist prepared by DGS for the second tests indicated that

the purchase order was created for tracking purposes only. This was confirmed during an interview with the former Director of Procurement at DGS who stated that the purchase order was created to track the receipt of the tests prior to payment of the invoices.

- II. **Board of Public Works (BPW) Notification** – The response implies that the contract was compliant since it was submitted to the BPW and no concerns were raised with the form of the contract. However, in accordance with BPW Advisory 2009-2, when reporting emergency procurements to the BPW, agencies are required to only submit an Action Agenda item and a copy of the Procurement Officer’s Determination of the Emergency. We were advised by BPW staff that the Labgenomics award was initially presented to the BPW on the June 3, 2020 Agenda in a compilation report with numerous other DGS emergency commodity awards. That report was remanded back to DGS so that actual documented invoices could be provided to the BPW office for review and verification. According to the BPW staff, DGS provided purchase orders (which as noted above were only used for tracking purposes), invoices, payment transmittal documents and verifications of payment disbursements, but BPW staff did not believe the actual contract(s) were provided. Consequently, the BPW would not have reviewed the actual “contract” document submitted and therefore, would not be in a position to, nor have been required to, comment on whether it was compliant with State regulations.
- III. **Documentation of Test Results** – MDH acknowledged in its response that patient identifiers were redacted in the records initially provided to us in response to our inquiries. However, these records were deemed by us to be incomplete (which we previously conveyed to MDH) as the records only included results from certain periods of time and not all of the results produced using the LabGenomics tests. The missing/redacted information was critical to our review for multiple reasons. For example, the redaction and omission of certain patient information precluded us from conducting planned analyses and from verifying the accuracy and completeness of the records. While the legal concerns regarding this issue were ultimately resolved, we were unable to obtain and review the unredacted versions of the records prior to issuing this report (as prominently disclosed in our report).
- IV. **Concerns with Selective Utilization of Statements** – The response raises concerns that we did not include all information obtained during interviews, which negatively impacts the validity of our work and

contributes an element of bias in our report. Frankly, this assertion confounds us as both departments know from longstanding practice and professional standards that OLA reports do not and are not intended to include all information obtained from an examination or review, verbatim. Rather, OLA condenses the results from numerous audit processes (for example, interviews, tests, observations, etc.) into a readable report of practical length.

We believe that we have included all information obtained relevant to the questions we attempted to answer for each of our objectives; and that the selection and presentation of that information was done consistent with our past practices. Finally, much of the lengthy response from DGS/MDH includes explanations and not answers to the questions we were tasked with answering and accordingly we did not include the information in the body of our report. However, consistent with OLA's report policy, we have included these explanatory agency comments, which were submitted with the combined response, in their entirety as an appendix to our report.

Auditor's Comments regarding Towson University's (TU) response (Appendix D):

The response from TU included certain disagreements with the content of our report. For example, TU disagreed with any implied or expressed assertion that it took inadequate action after receiving a spike in positive COVID test results in August 2020 and that the former Director of Student Health Services (SHS) was terminated because he raised concerns regarding this spike in positive test results.

In response to these disagreements, we note the following:

- I. We did not opine on the adequacy of action taken by TU in response to the spike in positive tests or the reason for the termination of the former Director of SHS; rather, our report reflects the information that was communicated to us by the individuals involved in matters under review.
- II. We acknowledged in our report that documentation was not required to justify the termination. Our report simply disclosed that the assertions made by TU regarding the reason for the termination were not supported with documentation and was not consistent with employee performance evaluations included in the former Director's personnel file.

We agree with TU's response that neither TU nor any of its employees had a role related to the procurement and use of the COVID tests from LabGenomics, and our report does not make such a statement. Rather, our reference to TU in this

report is limited to its role as a user of the LabGenomics tests and its termination of an employee.

APPENDIX A - Attachment 1

Larry Hogan  
Governor

Boyd K. Rutherford  
Lt. Governor



Ellington E. Churchill, Jr.  
Secretary

MARYLAND DEPARTMENT OF GENERAL SERVICES

ADMINISTRATION • FACILITIES OPERATIONS & MAINTENANCE • FACILITIES PLANNING, DESIGN, CONSTRUCTION & ENERGY  
PROCUREMENT & LOGISTICS • REAL ESTATE

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**Date:** April 2, 2020

**Subject:** Letter of Intent- LabGenomics/JKICT., INC

Mr. Kim,

We are writing to provide a letter of intent from the Maryland Department of General Services (DGS) with respect to a transaction with your firm for Covid19 PCR Assay Kit (100T), quantity 5,000, responsive to your Proforma Invoice PI-L20-0402, dated April 2, 2020.

The total cost of the transaction is \$9,000,000. The terms are 100% upon placement of order, via wire transfer. This wire is scheduled for transmittal on April 3, 2020.

If you need any additional information from me, please feel free to reach out.

Sincerely,

A handwritten signature in black ink, appearing to read "Danny Mays".

Danny Mays  
Director of Procurement  
Office of State Procurement  
Maryland Department of General Services  
[REDACTED]  
[Danny.Mays@maryland.gov](mailto:Danny.Mays@maryland.gov)



## APPENDIX B



LARRY HOGAN  
GOVERNOR

### STATE OF MARYLAND OFFICE OF THE GOVERNOR

See Appendix A for  
Auditor's Comments  
regarding response

March 26, 2021

Gregory A. Hook, CPA  
Legislative Auditor  
Office of Legislative Audits  
Department of Legislative Services  
301 West Preston Street, Room 1202  
Baltimore Maryland 21201  
*Submitted electronically to [response@ola.state.md.us](mailto:response@ola.state.md.us)*

Dear Mr. Hook:

We have received and reviewed the Office of Legislative Audits' special Review of the Procurement of Certain COVID Tests (the "Review"). Your thorough and comprehensive examination of these important matters is appropriate and welcomed. However, we concur with the response of the Department of General Services and the Department of Health, which conveys our shared concerns and disappointment with various aspects of this hastily completed Review.

We have been, and remain, eager to assist and comply with the Office of Legislative Audits' examination of emergency procurements. As such, we are particularly puzzled by the allegations in the Review that the Office of the Governor failed to provide documentation in numerous respects. Our senior deputy legal counsel, Christopher Mincher, recalls that, in a phone conversation with the Office of Legislative Audits on January 14, he explained that he was the point of contact for document requests to the Office of the Governor. Yet requests were made solely to two current Governor's Office employees for documents from their former positions with the State.

In emails on January 19 and February 4, auditor [REDACTED] wrote to Mr. Mincher that she would review the documentation provided and let him know of any follow-up questions. Mr. Mincher did not receive auditor requests for documents from the Governor's Office more generally or any related follow-up questions. In short, the Review appears to fault the Governor's Office for failing to provide documents that were not requested.

We want to additionally reiterate and highlight the dire need for COVID-19 tests that Maryland and all states across the nation faced in the early days of the pandemic. The decisions made to procure 500,000 tests - a resource unimaginable in many states at the time - from LabGenomics reflected the best information available at the time and the most creative thinking to solve a very real problem. The procedures that were followed matched the reality of the rapidly developing public health emergency, and the resulting emergency procurements were unanimously accepted by the Board of Public Works on September 2, 2020. The purposes of the State's procurement law were fulfilled, and the tests acquired ultimately saved the lives of countless Marylanders. On December 15, 2020, the State announced that 500,000 LabGenomics tests were utilized, and an additional 1 million tests were acquired by a private clinical laboratory based in Maryland.

We respectfully request that the Office of Legislative Audits revisit the Review's conclusions in light of the departments' response and with fuller appreciation of the exigent circumstances in which the procurements were made.

Please do not hesitate to contact me if you have further questions that I can assist you with.

Sincerely,

A handwritten signature in blue ink, appearing to read "Amelia Chasse Alcivar".

Amelia Chasse Alcivar  
Chief of Staff, Office of the Governor

## APPENDIX C



**DEPARTMENT OF HEALTH**  
*Dennis R. Schrader, Acting Secretary*

**DEPARTMENT OF GENERAL SERVICES**  
*Ellington E. Churchill, Jr., Secretary*

See Appendix A for Auditor's Comments regarding response

March 26, 2021

Gregory A. Hook, CPA  
Legislative Auditor  
Office of Legislative Audits  
Department of Legislative Services  
301 West Preston Street, Room 1202  
Baltimore Maryland 21201  
*Submitted electronically to [response@ola.state.md.us](mailto:response@ola.state.md.us)*

Dear Mr. Hook:

The Maryland Departments of General Services (DGS) and Health (MDH) appreciate the opportunity to respond to the Office of Legislative Audits' (OLA) Review of Procurement of Certain COVID Tests (Review), received on March 12, 2021. We thank the OLA auditors for our ongoing conversations regarding these matters. DGS and MDH collaborated on this response.

We highlight the Review's cautionary note: "[OLA's] review did not constitute an audit conducted in accordance with generally accepted government auditing standards" (Review at page 9). Unfortunately, the Review has a number of factual and other inaccuracies, which we respectfully raise below.

We have five principal areas of concerns about the Review and respectfully disagree with:

1. OLA Review Objective 2: "We were unable to obtain documentation of test results from laboratories to substantiate the disposition of the tests" and "We were unable to obtain documentation of test results from laboratories to corroborate the concerns with the reliability of the test results." ;
2. OLA Review Objective 3: "Our review of the circumstances surrounding the termination of two State employees after they had raised concerns related to the COVID tests found that the verbal representations made to us by Towson University (TU) and the Maryland Department of Health (MDH) as the basis for the terminations were not supported by available written documentation."
3. OLA Review Objective 1: "Tests were not procured in accordance with state procurement regulations, including the lack of a written contract."
4. OLA Review Objective 1: "A review of available records indicates the State did not ensure that the tests received on April 18 and 22, 2020, were authorized by

the Federal Food and Drug Administration prior to them being shipped by LabGenomics.”

## 5. Additional Concerns and Conclusions

### 1. **OLA Review Objective 2: “We were unable to obtain documentation of test results from laboratories to substantiate the disposition of the tests” and “We were unable to obtain documentation of test results from laboratories to corroborate the concerns with the reliability of the test results.”**

Both DGS and MDH have fully complied with all requests for documentation made by OLA. The Review contains several inaccuracies and omissions related to document requests and productions, all seemingly intended to portray MDH and its public health laboratory in a suspicious light.

On page 17, the Review claims that it could not “obtain documentation of test results from laboratories to substantiate the disposition of tests” and that it was “unable to obtain documentation of test results from laboratories to corroborate the concerns with the reliability of test results.” Those assertions ignore the documents that the MDH lab provided on November 24, 2020 as attachments 4, 9, 12, 12, 16, 22, 23, 25, and 27 to Dr. Myers’ response via the OLA portal; see **Attachment A**. These attachments contain the results from tests run by the MDH lab as well as the results of the tests run by UMPA that were questioned. Only patient identifiers were redacted.

On page 21, the Review asserts that “[n]o centralized records of tests distributed and/or used was maintained by MDH, and we are unaware of the existence of any such records.” That assertion ignores the documentation provided as attachments 17-19 of Dr. Myers’ response.

Also on page 21, the Review claims that the MDH lab denied OLA's requests for documentation of test results. As the attachments listed above show, that assertion is inaccurate. In response to the November request for documents, the MDH lab gave OLA documents with patient identifiers redacted. In one case, in response to a request for a report by source of test, patient names were not requested. See attachment 16 of Dr. Myers’ response.

Regarding the so-called denial of record requests and the related question of whether OLA was entitled to the unredacted versions of the attachments listed above, at some point after MDH provided those attachments, MDH counsel learned that UMPA and UMB were questioning whether OLA was entitled to unredacted records without at least an explanation of the need for patient specific information like name, DOB, SSN, etc. The assistance of the OAG's Opinions and Advice counsel was requested in resolving this matter. Accordingly, the MDH lab did not provide unredacted documents showing test results until that legal issue was resolved.

**2. OLA Review Objective 3: “Our review of the circumstances surrounding the termination of two State employees after they had raised concerns related to the COVID tests found that the verbal representations made to us by Towson University (TU) and the Maryland Department of Health (MDH) as the basis for the terminations were not supported by available written documentation.”**

Regarding the individual in question with the Towson University personnel action, no one in the Administration, DGS, or MDH was aware of this employee, the complaint, or the termination prior to reading the Review. As such, we reject any implication or allegation that the Towson University personnel action had any nexus to the procurement of COVID-19 tests as inaccurate and not based in fact.

MDH rejects the implication that the former employee mentioned in Review resigned for any reason other than 1) MDH needed new leadership to manage a proposed redesigned procurement and contract management office, and 2) that leadership could not be provided by a part-time employee.

These circumstances were discussed with the former employee who acknowledged during the course of the conversation that indeed, the part-time nature of his employment was a limitation on the overall performance of the Office of Procurement and Support Services. These were the only topics discussed during the meeting on November 23, 2020. However, at the conclusion of the meeting, the former employee referenced a letter he intended to respond to from DGS recommending that a major MDH procurement unrelated to COVID be terminated due to questionable procedures. The former employee was thanked for his good service during his tenure, which as stated in the Review, is reflected in the former employee’s personnel file.

The former employee’s part-time status was due to the earning limitation placed on a retired state employee who returns to work for a state agency; i.e., the returned employee’s salary cannot exceed the difference between the employee’s salary prior to retirement and the employee’s pension amount. The earnings limitation provision resulted in the former employee having to work less than 40 hours per week, as the Legislative Auditor acknowledged. This was explained to the Legislative Auditor as well as to why other MDH employees in similar circumstances were not subject to the same treatment as the former employee; that is, they were not the head of a major MDH program averaging more than \$600 million in procurements each year.

If the former employee had any concerns about the procurements addressed in the Review for which he was not responsible, those concerns were not brought to the attention of senior MDH leadership at any time before, during, or after the November 23, 2020 meeting when the former employee’s status with the department was discussed.

The Review asserts as does the former employee that he was terminated to keep him from appearing at an upcoming Board of Public Works (BPW) meeting. The former employee resigned on November 23, 2020. The next BPW meeting was held on December 2, 2020. There were no test kit procurements on that agenda. Furthermore, reports of the LabGenomics emergency procurements were accepted by the BPW at its September 2, 2020 meeting, nearly three months prior to the former employee’s

resignation. These facts directly contradict the assertion in the Review that the employee was terminated to prevent him from attending the upcoming BPW meeting where the test kits would be discussed.

MDH respectfully suggests that the only pertinent documentation related to the former employee's "termination" is his letter of resignation.

The footnote on page 28 of the Review implies that the MDH was disingenuous in asserting that a change in procurement leadership needed to occur because the position had not been filled as of February 25, 2021. In order to demonstrate MDH's commitment to re-defining and revamping its procurement operations, the following actions are currently underway to improve and redesign procurement and contract management processes:

- MDH has been working with the DGS Office of State Procurement (OSP) regarding the need to redesign the overall methodology for procurement and contract management within MDH. MDH is coordinating extensively with DGS OSP to perform an end-to-end review and analysis of the procurement policies and procedures across MDH.
  - The DGS Agency Procurement Review program (APR) team is currently assessing MDH's procurement processes and procedures to provide recommendations for improvement.
    - The initial kick off meeting for this review occurred on January 4, 2021.
    - This involves evaluating all aspects of procurement operations, including: Organizational standards; Compliance; Program standards; Staffing standards; and Professional standards.
    - MDH is working closely with DGS APR throughout this review process and is beginning to implement recommendations prior to completion of the assessment and finalization of the report.
- MDH worked with DGS OSP to develop a proposed expanded organizational structure for the MDH Office of Procurement and Support Services, which includes:
  - Adding additional permanent positions to more than double the number of staff in this unit
  - Restructuring the department with an additional layer of oversight by procurement managers
    - Previously, all procurement managers reported directly to the Deputy Director who oversaw all procurements directly
  - Restructuring the workflows within the department by creating structured service delivery lines that are segregated based on common procurement disciplines
- MDH is also working with DGS OSP to expand the capacity of the MDH Office of Procurement and Support Services to provide additional services that were not previously provided by this office. These additional services include:
  - Comprehensive end-to-end contract management for all agreements
  - A consolidated agency-wide unit for Memoranda of Understanding and Interagency Agreements

- A consolidated agency-wide unit for grants management
- MDH is reviewing the existing Contract Tracking System and evaluating the need for an advanced contract management system, in order to:
  - Enhance visibility into the performance of the contracting process
  - Better track contracts and agreements across all MDH departments

MDH and DGS OSP developed a job posting that will be utilized to fill both the MDH and DGS vacant Procurement Director positions. A job posting was published on January 4, 2021 and closed on January 25, 2021 to fill both of these positions. Subsequent to the closing of the job posting, MDH coordinated with DGS OSP to upgrade the job classifications for both the MDH and DGS Procurement Director positions. This has delayed the hiring for these positions; however, MDH and DGS began conducting joint interviews the week of March 22nd.

**3. OLA Review Objective 1: “Tests were not procured in accordance with state procurement regulations, including the lack of a written contract.”**

The Review faults the lack of a “formal written contract” to evidence the transactions. In the regulations referenced in the Review, a “contract” is defined as a written agreement entered into by a procurement agency for the acquisition of supplies. Additionally, the statutory definition of a procurement contract is an agreement **in any form** entered into by the unit for a procurement. By either legal definition, the original letter of intent between the State of Maryland and JKICT/LabGenomics (the “LOI”), provided upon request to the OLA, was indeed a legally valid contract at the time that the State wired payment.

Moreover, the procurement of the upgraded tests was completed with a purchase order, a copy of which was provided to OLA. The regulations referenced by the Review specifically state that, upon acceptance, a purchase order “becomes a contract.” The accepted purchase order here was also a legally valid contract.

In its review of these emergency procurements, the BPW -- which can also waive any of its regulations when appropriate -- did not express any concern that the form of the contracts violated its regulations. As described in BPW Advisory 2009-2, the regulations referenced by the Review provide that, after reviewing an emergency procurement, the BPW “may require the agency to take preventive or corrective future action.” After reviewing these contracts, however, BPW did not state that any corrective future action was needed. The Review’s conclusions about the contractual requirements are legally questionable and to date unsupported by the unit that promulgated them.

In any case, the contracts did embody several of the regulatory clauses, such as those accounting for the parties, scope, price, terms, and payment method. In the end, valid contracts occurred with goods delivered at the prices stipulated and in the provided delivery timeframes.

The OLA’s Review also finds fault with what it claims is a lack of evidence documenting the extent to which research was conducted into other sources of tests, and the

subsequent evaluation process. The regulations require that for an emergency procurement, the agency's procurement officer obtain such competition as is possible and practicable to acquire the needed items or services in time to meet the emergency.

In the instant case, alternative vendors were sought and considered. A chart naming the companies and noting important aspects for consideration when selecting a vendor was created as part of this due diligence. The OLA received a copy of this chart. There is no legal requirement for emergency procurements that there be records documenting a "formal evaluation" of vendors, or a determination by the procurement officer that the vendor selected is the "best qualified," as would occur in a procurement conducted under normal circumstances.

The regulations referenced by OLA state that an emergency procurement occurs when there is a "sudden or unexpected occurrence or condition which agency management could not foresee" and items must be "procured in time to meet the emergency." These are not the circumstances, as suggested by the Review, when a "selection committee" should be organized to deliberate and compile rankings.

It is important to remember the context during which this procurement occurred. During the early stages of the pandemic, there was unprecedented global competition for scarce resources to mitigate the threats posed by the pandemic and allow the State to care for the health and safety of the citizens of Maryland. After a needed resource was identified as being available, and an offer was made to the State with acceptable terms given the circumstances, if the State were to hesitate for too long to undertake standard due diligence, more often than not, the offer was no longer available. The need for caution and due diligence had to be viewed in light of the unprecedented crisis the State, the nation and the world were facing at the time, and the risk inherent in any transaction had to be balanced with the risk to the lives of Marylanders.

During the early stages of the pandemic, the sources for most of the high-demand items (masks, ventilators, test kits, etc.) were almost non-existent domestically. South Korea was well-positioned to offer these desperately needed supplies.

Subsequent to the procurement, DGS reported the emergency procurements to the BPW. DGS worked with BPW staff to determine how best to report these items, after which BPW provided DGS with emergency procurement forms and agreed to accept a chart with the required information. (Copies of the chart and completed reporting forms were provided to the OLA upon request.) Members of the BPW submitted numerous follow-up questions about the procurement.

**4. OLA Review Objective 1: “A review of available records indicates the State did not ensure that the tests received on April 18 and 22, 2020, were authorized by the Federal Food and Drug Administration prior to them being shipped by LabGenomics.”**

OLA further faults the State for procuring test kits that had not yet received an EUA. At the time the LabGenomics’ COVID-19 test kits were purchased, the EUA was pending with the FDA. The Review also fails to explain that the FDA allowed manufacturers to sell a COVID test as soon as they had validated the test and with the understanding that an EUA application would be submitted within 15 days. See [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff \(fda.gov\)](#) (Mar. 25, 2020).

The unprecedented nature of the emergency required adapting existing practices to assure that Maryland was able to meet the needs of this emergency and was not restrained by practices that had never been tested in such an extraordinary way. The simple truth is that the demand was so high in America and around the globe for test kits, that practically instant decisions had to be made with the best information available in an effort to ensure the State could properly respond to the ongoing threats to the health and safety of Maryland’s citizens.

Given the existence of a catastrophic health emergency and a worldwide pandemic, and given the scarcity of tests for COVID in April 2020, it was a reasonable decision to purchase the tests before LabGenomics’ receipt of the EUA.

Lastly, the Review suggests impropriety in, as part of the initial procurement of COVID-19 tests, incurring costs for charter freight instead of commercial shipping. These payments to Samsung SDS were accepted by BPW on September 2, 2020. See line 51, page 63, BPW Agenda: <https://bpw.maryland.gov/MeetingDocs/2020-Sept-02-Agenda.pdf>.

Commercial passenger air transport is a critical component of the freight supply chain. Under normal times it is more economical to place freight in the cargo area of a passenger plane. Worldwide passenger flights experienced an unprecedented decline in 2020. Per the International Civil Aviation Organization (ICAO) international and domestic air passengers experienced an overall reduction of 60% in 2020 compared to 2019. In April 2020, international commercial air traffic had essentially ceased, and for the flights that were still in operation, it was sporadic at best. There was an enormous amount of competition for the limited cargo transport space available.

Additionally, at the time of the charter, numerous health care officials and state leaders had reported instances in which federal authorities had intervened and, in some cases diverted the delivery of medical supplies related to the COVID pandemic regardless of contracts between State and local governments and vendors. In several cases, state officials reported that the Federal Emergency Management Agency confiscated supplies



with no explanation, while others reported that the agency had outbid them for the equipment. A sampling of news reports in March and April 2020 is included as **Attachment B**.

In order to ensure the timely and safe delivery of the test kits, and to avoid having the cargo confiscated or diverted by the federal government upon arrival, chartering a flight directly into Maryland's State- owned airport was deemed essential. Baltimore/ Washington International Thurgood Marshall Airport provided the safest, most reliable and expedient transport option to allow the State of Maryland greater control of the cargo. DGS consulted its logistics specialist to consider alternate direct charter pricing. Initial estimates far exceeded the transport cost offered through Korean Air.

## **5. Additional Concerns and Conclusions**

MDH and DGS strenuously object to the Review's practice throughout of selectively utilizing statements and reflections gleaned from the interviews conducted by the auditors without mentioning certain information and explanations that were also provided during the interviews. For example, it was explicitly stated during one of the MDH interviews that the former employee who was allegedly terminated for disagreeing with the test kit procurements had absolutely nothing to do with those procurements. That information is absent from the Review. For the Review to fail to present all of the information given to OLA, both through in-person interviews and the voluminous amounts of documentation provided, casts serious doubt as to whether the Review completely and accurately presents a factual set of findings and any subsequent inferences were properly drawn.

In conclusion, for both DGS and MDH, compliance with audits and the underlying statutes and regulations is of the highest priority. As a matter of professional pride, we have ensured that we typically have a full and frank working relationship with OLA. Unfortunately, the Review and the manner in which it was conducted, gives the appearance that OLA produced a rushed and politically-driven report implying dubious conclusions reached without regard to the actual circumstances surrounding the subjects of the Review.

Please do not hesitate to let us know if you have any questions in this regard.

Sincerely,



Eric T. Lomboy  
Chief of Staff, DGS



Thomas C. Andrews  
Chief of Staff, MDH



# ATTACHMENT A

Robert Myers -MDH- <robert.myers-phd@maryland.gov>

## Re: Concerns about UMPA

1 message

**David Blythe -MDH-** <david.blythe@maryland.gov>  
 To: Robert Myers -MDH- <robert.myers-phd@maryland.gov>  
 Cc: Monique Duwell -MDH- <monique.duwell@maryland.gov>

Wed, Sep 9, 2020 at 6:04 PM

I do have the total positives for each day but they're in separate emails each day - don't have those put together in a summary.

And no, have the Ct values for only one of the outbreak-associated clusters. Have attached that to this email

On Wed, Sep 9, 2020 at 5:58 PM Robert Myers -MDH- <robert.myers-phd@maryland.gov> wrote:  
 David,

Do you have the total number of positives reported for each day because I noticed large differences in the number of tests reported on certain days (<500 to 6500/day) ? I am assuming the red line is the percent positive ? Their overall positivity rate 2.84% is not much higher than ours. For the month of August MDH Lab's positivity rate was 2.46% but they do report larger numbers and therefore more positives. Can you obtain a line list of their positives with the Ct. values for the SARS-CoV-2 gene targets? I would be more concerned if there are clusters of weak positives in their runs.

Best regards,

Bob  
**Robert A. Myers PhD**  
 Director  
 Maryland Department of Health Laboratories Administration  
 1770 Ashland Avenue  
 Baltimore, Maryland 21205

Phone: 443-681-3800 Fax: 443-681-4501



DHMH is committed to customer service. [Click here](#) to take the Customer Satisfaction Survey.

On Wed, Sep 9, 2020 at 5:06 PM David Blythe -MDH- <david.blythe@maryland.gov> wrote:  
 Hi Monique and Bob - see the attached graph Ryan put together of % positivity for UMPA. Might be missing something but I don't see anything here that suggests some sort of specific event that led to a bunch of false positives. You guys?

--  
 David Blythe, MD, MPH  
 State Epidemiologist and Director  
 Infectious Disease Epidemiology and Outbreak Response Bureau  
 Maryland Department of Health  
 ph: 410-767-6685  
 fax: 410-669-4215

Attachment 4

Maryland Department of Health is committed to customer service. [Click here](#) to take the Customer Satisfaction Survey.

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--  
David Blythe, MD, MPH  
State Epidemiologist and Director  
Infectious Disease Epidemiology and Outbreak Response Bureau  
Maryland Department of Health  
ph: 410-767-6685  
fax: 410-669-4215

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ct values sep 1 positives (1).xlsx

10K

UMPA Lab Gun PCR ct values  
outbreak associated patients

name	accession	e gene	RdRP	MMS2 E	Ms2
	7340	37.4	39.95	28.5	28.7
	7290	36.9	37.3	29.6	29.7
	7160	36.4	38.3	29.1	29.2
	7664	32.1	31.5	29	29
	7643	30.1	30.1	28.8	28.8
	7611	36	35.2	20.6	20.7
	7597	36.3	35.6	28.8	28.6
	7570	36.9	36.9	28.6	28.7
	7559	38.6	37	28.5	28.5
	7551 n/a		39.9	29.5	29.5
	7475	36.8	35.2	28.5	28.5
	7462	39	37.3	28.8	29
	7449	29.5	29.6	27.7	27.7
	7439	36.7	36	27.6	28
	7424	35.6	35.1	28.4	28.3
	7415	35.3	34.7	28.6	28.4
	7408	35.9	35.2	28.5	28.5
	7402	36.9	35.5	28	28
	7392	37.8	36.6	28.7	28.9
	7382	35.7	35.4	28.1	28
	7372	37.2	38.6	28.6	28.7
	7363	36.3	35.7	28.8	28.8
	7354	35.8	35.1	27.9	27.7
	7348	40.7	38	29.4	29.6
	7334	37.2	36.8	30.8	30.7
	7170	42.3	39.5	28.8	28.6
	7152	37.6	38.6	28.6	28.8
	7157	39.9	39.4	28.4	28.3
	8152 n/a		39.8	29.7	29.7
	8112	39.2	39.2	29.4	29.3



Robert Myers -MDH- <robert.myers-phd@maryland.gov>

## Ct Values from UMPA Testing

1 message

David Blythe -MDH- <david.blythe@maryland.gov>

Thu, Sep 17, 2020 at 8:26 AM

To: Jake Whitaker -MDH- <jake.whitaker1@maryland.gov>

Cc: Brian Bachaus <brian.bachaus@maryland.gov>, Monique Duwell -MDH- <monique.duwell@maryland.gov>, Robert Myers -MDH- <robert.myers-phd@maryland.gov>

Hi Jake - As discussed previously, we are still trying to resolve whether some people who had "positive" PCRs at UMPA are really cases. It's important for us to sort this out because we're trying to determine whether these locations are really having "outbreaks" and therefore having to impose all the associated restrictions and restrict their ability to move through reopening phases, etc.

To help, we're looking at several additional types of information: prior and subsequent PCR tests; serologic tests; and the Ct values and specific test used for the UMPA testing.

Can you help us get the Ct values from UMPA?

We have the Ct values for one of the outbreaks (██████████ - Outbreak 2020-250). We do NOT have the Ct values for 2 other situations

██████████ (2020-1567)

Summary of results: 17 positive out of 227 tested (all staff)

Date of test: 9/8/2020 (not 100% sure of date of collection)

██████████  
Date of collection 8/28: 6 positive staff, 25 pending.

Date of collection 9/4: 49 +residents, 3+staff. None symptomatic.

We also have questions about results from at least two universities - and given the numbers, might be hard to get all the Cts. If available, great. If not, would at least be helpful to know what test was used for those specimens.

### Salisbury University

333 (6.1%) of 5479 tests positive between 9/5-9/11.

### Towson University

260 (18%) of 1434 tests positive between 8/29-9/9.

Brian or Bob - anything to add?

Thanks. - David

--

David Blythe, MD, MPH  
State Epidemiologist and Director  
Infectious Disease Epidemiology and Outbreak Response Bureau  
Maryland Department of Health  
ph: 410-767-6685  
fax: 410-669-4215

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Attachment 9



Robert Myers -MDH- <robert.myers-phd@maryland.gov>

**Fwd: Ct Values from UMPA Testing**

1 message

**David Blythe -MDH-** <david.blythe@maryland.gov> Thu, Sep 17, 2020 at 11:21 AM  
To: Brian Bachaus <brian.bachaus@maryland.gov>, Robert Myers -MDH- <robert.myers-phd@maryland.gov>, Jake Whitaker -MDH- <jake.whitaker1@maryland.gov>

Do you all want to be on this call?

----- Forwarded message -----  
From: **Baehr, Nicole** <NBaehr@som.umaryland.edu>  
Date: Thu, Sep 17, 2020 at 11:19 AM  
Subject: Re: Ct Values from UMPA Testing  
To: David Blythe -MDH- <david.blythe@maryland.gov>

That works, I have sent out an appointment invite to you and our team.

Thanks!  
Nicki

Nicole E. Baehr, MHA  
Emergency Medicine Population Health Project Supervisor  
University of Maryland Department of Emergency Medicine  
110 South Paca St. 6th Floor Suite 200  
Baltimore, MD 21201  
Nbaehr@som.umaryland.edu  
[Redacted]

Attachment 9

**From:** David Blythe -MDH- <david.blythe@maryland.gov>  
**Sent:** Thursday, September 17, 2020 11:16 AM  
**To:** Baehr, Nicole <NBaehr@som.umaryland.edu>  
**Subject:** Re: Ct Values from UMPA Testing

How about 2:15?

On Thu, Sep 17, 2020 at 9:37 AM Baehr, Nicole <NBaehr@som.umaryland.edu> wrote:  
We can be flexible to your schedule so whatever works best for you.

Thanks,  
Nicki

Nicole E. Baehr, MHA  
Emergency Medicine Population Health Project Supervisor  
University of Maryland Department of Emergency Medicine  
110 South Paca St. 6th Floor Suite 200  
Baltimore, MD 21201  
[Redacted]

---

**From:** David Blythe -MDH- <[david.blythe@maryland.gov](mailto:david.blythe@maryland.gov)>  
**Sent:** Thursday, September 17, 2020 9:34 AM  
**To:** Baehr, Nicole <[NBaehr@som.umaryland.edu](mailto:NBaehr@som.umaryland.edu)>  
**Subject:** Re: Ct Values from UMPA Testing

Sure - but mainly want to see the Ct values. I understand the issues related to Cts but as one element of several, they help us with decision-making.

What times this afternoon might work?

On Thu, Sep 17, 2020 at 9:28 AM Baehr, Nicole <[NBaehr@som.umaryland.edu](mailto:NBaehr@som.umaryland.edu)> wrote:  
Good Morning, Dr. Blythe

I spoke with the UMPA/UMB team on the below information request, they suggested to set up a call to further discuss the information.

Can you let me know if you have any availability today for a brief call?

Thank you,  
Nicki

Nicole E. Baehr, MHA  
Emergency Medicine Population Health Project Supervisor  
University of Maryland Department of Emergency Medicine  
110 South Paca St. 6th Floor Suite 200  
Baltimore, MD 21201  
[Nbaehr@som.umaryland.edu](mailto:Nbaehr@som.umaryland.edu)  
[REDACTED]

Attachment 9

---

**From:** Jake Whitaker -MDH- <[jake.whitaker1@maryland.gov](mailto:jake.whitaker1@maryland.gov)>  
**Sent:** Thursday, September 17, 2020 8:30 AM  
**To:** David Blythe -MDH- <[david.blythe@maryland.gov](mailto:david.blythe@maryland.gov)>  
**Cc:** Brian Bachaus <[brian.bachaus@maryland.gov](mailto:brian.bachaus@maryland.gov)>; Monique Duwell -MDH- <[monique.duwell@maryland.gov](mailto:monique.duwell@maryland.gov)>; Robert Myers -MDH- <[robert.myers-phd@maryland.gov](mailto:robert.myers-phd@maryland.gov)>; Baehr, Nicole <[NBaehr@som.umaryland.edu](mailto:NBaehr@som.umaryland.edu)>  
**Subject:** Re: Ct Values from UMPA Testing

Dr. Blythe,

I'm looping in Nicole Baehr who will be able to assist with getting this information.

Nicole - can you please work with the UMPA/UMB team to get the information requested by Dr. Blythe?

Thanks,  
Jake

On Thu, Sep 17, 2020 at 8:25 AM David Blythe -MDH- <[david.blythe@maryland.gov](mailto:david.blythe@maryland.gov)> wrote:

Hi Jake - As discussed previously, we are still trying to resolve whether some people who had "positive" PCRs at UMPA are really cases. It's important for us to sort this out because we're trying to determine whether these locations are really having "outbreaks" and therefore having to impose all the associated restrictions and restrict their ability to move through reopening phases, etc.

To help, we're looking at several additional types of information: prior and subsequent PCR tests; serologic tests; and the Ct values and specific test used for the UMPA testing.

Can you help us get the Ct values from UMPA?

We have the Ct values for one of the outbreaks ( [REDACTED] - Outbreak 2020-250). We do NOT have the Ct values for 2 other situations

[REDACTED] (2020-1567)  
Summary of results: 17 positive out of 227 tested (all staff)  
Date of test: 9/8/2020 (not 100% sure of date of collection)

[REDACTED]  
Date of collection 8/28: 6 positive staff, 25 pending.  
Date of collection 9/4: 49 +residents, 3+staff. None symptomatic.

We also have questions about results from at least two universities - and given the numbers, might be hard to get all the Cts. If available, great. If not, would at least be helpful to know what test was used for those specimens.

Salisbury University  
333 (6.1%) of 5479 tests positive between 9/5-9/11.

Towson University  
260 (18%) of 1434 tests positive between 8/29-9/9.

Brian or Bob - anything to add?

Thanks. - David

--  
David Blythe, MD, MPH  
State Epidemiologist and Director  
Infectious Disease Epidemiology and Outbreak Response Bureau  
Maryland Department of Health  
ph: 410-767-6685  
fax: 410-669-4215

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Jake Whitaker, JD  
Deputy Director,  
Office of Governmental Affairs  
Maryland Department of Health  
201 West Preston Street  
Baltimore, Maryland 21201  
[jake.whitaker1@maryland.gov](mailto:jake.whitaker1@maryland.gov)  
[REDACTED]

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Attachment 9



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State Epidemiologist and Director  
Infectious Disease Epidemiology and Outbreak Response Bureau  
Maryland Department of Health  
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--

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--

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Robert Myers -MDH- <robert.myers-phd@maryland.gov>

**UMPA Ct Values**

1 message

**David Blythe -MDH-** <david.blythe@maryland.gov> Wed, Sep 23, 2020 at 7:47 AM  
To: Brian Bachaus <brian.bachaus@maryland.gov>, Monique Duwell -MDH- <monique.duwell@maryland.gov>, Robert Myers -MDH- <robert.myers-phd@maryland.gov>, Jake Whitaker -MDH- <jake.whitaker1@maryland.gov>




Received last night from UMPA. I haven't looked through carefully yet.

--  
David Blythe, MD, MPH  
State Epidemiologist and Director  
Infectious Disease Epidemiology and Outbreak Response Bureau  
Maryland Department of Health  
ph: 410-767-6685  
fax: 410-669-4215

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**3 attachments**

-  **CtResultsSalisburyPositives-09-05-to-09-11-2020.xlsx**  
46K
-  **[REDACTED] LabGun at IGS with CT counts\_detected only.xlsx**  
28K
-  **Towson University LabGun at IGS with CT counts\_detected only.xlsx**  
117K

Attachment 9

UMPA Lab Gun COVID-19 PCR results  
 Towson University  
 Rec'd 09/23/20  
 1 of 10

Person Name	Class/Room	Room	Person #	Cur Prct Loc	Fac. N	Class Prct Loc	Class Program	Emp/Prct Loc	Result	Result	Result	Result	Result	Result	Result	Date	Order	Date	Date	Complete	
300678900	PA Towson Faculty		300678900	PA Towson Faculty		300678900	300678900	300678900	300678900	300678900	300678900	300678900	300678900	300678900	300678900	300678900	300678900	300678900	300678900	300678900	300678900













300079131 PA Town-Student	300079132 PA Town-Student	300079133 PA Town-Student	300079134 PA Town-Student	300079135 PA Town-Student	300079136 PA Town-Student	300079137 PA Town-Student	300079138 PA Town-Student	300079139 PA Town-Student	300079140 PA Town-Student	300079141 PA Town-Student	300079142 PA Town-Student	300079143 PA Town-Student	300079144 PA Town-Student	300079145 PA Town-Student	300079146 PA Town-Student	300079147 PA Town-Student	300079148 PA Town-Student	300079149 PA Town-Student	300079150 PA Town-Student	300079151 PA Town-Student	300079152 PA Town-Student	300079153 PA Town-Student	300079154 PA Town-Student	300079155 PA Town-Student	300079156 PA Town-Student	300079157 PA Town-Student	300079158 PA Town-Student	300079159 PA Town-Student	300079160 PA Town-Student	300079161 PA Town-Student	300079162 PA Town-Student	300079163 PA Town-Student	300079164 PA Town-Student	300079165 PA Town-Student	300079166 PA Town-Student	300079167 PA Town-Student	300079168 PA Town-Student	300079169 PA Town-Student	300079170 PA Town-Student	300079171 PA Town-Student	300079172 PA Town-Student	300079173 PA Town-Student	300079174 PA Town-Student	300079175 PA Town-Student	300079176 PA Town-Student	300079177 PA Town-Student	300079178 PA Town-Student	300079179 PA Town-Student	300079180 PA Town-Student	300079181 PA Town-Student	300079182 PA Town-Student	300079183 PA Town-Student	300079184 PA Town-Student	300079185 PA Town-Student	300079186 PA Town-Student	300079187 PA Town-Student	300079188 PA Town-Student	300079189 PA Town-Student	300079190 PA Town-Student	300079191 PA Town-Student	300079192 PA Town-Student	300079193 PA Town-Student	300079194 PA Town-Student	300079195 PA Town-Student	300079196 PA Town-Student	300079197 PA Town-Student	300079198 PA Town-Student	300079199 PA Town-Student	300079200 PA Town-Student
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Robert Myers -MDH- <robert.myers-phd@maryland.gov>

### Specimens for COVID serology testing 2020-250

1 message

Emily Luckman -MDH- <emily.luckman@maryland.gov> Fri, Sep 11, 2020 at 2:04 PM  
 To: "Myers, Robert" <Robert.myers-phd@maryland.gov>, "Ami A. Patel -MDH-" <Amia.patel@maryland.gov>, "Venkata R. Vepachedu -MDH-" <Venkata.vepachedu@maryland.gov>, Sarah Langtry -DHMH- <Sarah.langtry@maryland.gov>, "Keith A. Perkins Jr. (DHMH)" <Keith.perkins@maryland.gov>, "Liore H. Klein -MDH-" <Liore.klein@maryland.gov>  
 Cc: David Blythe -MDH- <david.blythe@maryland.gov>, Brian Bachaus -MDH- <brian.bachaus@maryland.gov>

Good afternoon,  
 Please see the attached list of staff members of [REDACTED] who submitted had blood drawn today for serology testing. I requested a few specimens, but they collected 18.  
 These individuals tested positive on 9/1 at the UM Pathology lab, but they subsequently tested negative or have tests pending.  
 Thank you,  
 Emily

Emily Luckman, MPH, BSN, CIC  
 Epidemiologist  
 Maryland Department of Health  
 Division of Outbreak Investigation  
 Infectious Disease Epidemiology and Outbreak Response Bureau  
 201 West Preston Street, 3rd Floor  
 Baltimore, MD 21201  
 phone: 410-767-5778  
 fax: 410-669-4215  
 email: [Emily.Luckman@maryland.gov](mailto:Emily.Luckman@maryland.gov)

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 **Staff from [REDACTED] with positive test result from 9.docx**  
 14K

Attachment 12

Patient Identifiers  
Redacted [Signature]

Staff from [Redacted] with positive test result on 9/1/2020 from UMPA who retested with Maryland Department of Health

Name	DOB	Date MDH Retest	Result	COVID-19 Serology	Result
		9/10/20	9/11 pending	9/11/20	
		9/10/20	9/11 pending		
		9/10/20	9/11 pending	9/11/20	
		9/10/20	9/11 pending		
		9/8/20	Neg	9/11/20	
		9/9/20	Neg	9/11/20	
		9/8/20	Neg	9/11/20	
		9/8/20	Neg		
		9/8/20	Neg	9/11/20	
		9/8/20	Neg		
		9/8/20	Neg		
		9/9/20	Neg		
		9/8/20	Neg	9/11/20	
		9/8/20	Neg	9/11/20	
		9/8/20	Neg	9/11/20	
		9/9/20	Neg	9/11/20	
		9/9/20	Neg	9/11/20	
		9/9/20	Neg	9/11/20	
		9/9/20	Neg	9/11/20	
		9/9/20	Neg	9/11/20	
		9/8/20	Neg	9/11/20	
		9/9/20	Neg		
		9/9/20	Neg		
		9/9/20	Neg		
		9/8/20	Neg	9/11/20	
		9/9/20	Neg	9/11/20	
		9/8/20	Neg	9/11/20	

Staff from [Redacted] with positive test result from 9/1/2020 who retested elsewhere:

- Patient A received negative result from 9/6/2020 test with Lab Corp
- Patient B results pending
- Patient C results pending

Patient Identifiers  
Redacted [Signature]



Robert Myers -MDH- <robert.myers-phd@maryland.gov>

**Re: Time Sensitive SARS-COV-2 Serology Testing Event Tomorrow (09/11)**

1 message

**Yvette C. Washington -MDH-** <yvette.washington@maryland.gov>

Wed, Sep 16, 2020 at 1:16 PM

To: Robert Myers -MDH- <robert.myers-phd@maryland.gov>

Cc: Jake Whitaker -MDH- <jake.whitaker1@maryland.gov>, "Venkata R. Vepachedu -MDH-" <venkata.vepachedu@maryland.gov>, David Blythe -MDH- <david.blythe@maryland.gov>

Dr. Myers,

I had outfit's [redacted] the supplies to [redacted] [redacted]. They will coordinate with Howard County Health Department to get the specimens to central lab next week.

Yvette Washington, M.S.  
Public Health Laboratory Scientist Supervisor  
Division of Virology and Immunology  
Maryland Department of Health, Laboratories Administration  
[1770 Ashland Avenue](#)  
[Baltimore, MD 21205](#)

443-681-3931

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On Wed, Sep 16, 2020 at 12:54 PM Robert Myers -MDH- <[robert.myers-phd@maryland.gov](mailto:robert.myers-phd@maryland.gov)> wrote:

Jake,

Please see the forwarded email from Yvette . We are planning to re-test the staff from [redacted] [redacted] in Columbia that received the weak SARS-CoV-2 RNA positive results from the UMPA lab for SARS-CoV-2 IgG antibodies again. Can your group assist with this? We are also scheduling to test another group of nursing home ([redacted]) patients for SARS-CoV-2 IgG antibodies that received similar results from the UMPA Lab .

Best regards,

Bob

**Robert A. Myers PhD**  
**Director**  
**Maryland Department of Health Laboratories Administration**  
[1770 Ashland Avenue](#)  
[Baltimore, Maryland 21205](#)

Phone: 443-681-3800 Fax: 443-681-4501



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Attachment 12

On Wed, Sep 16, 2020 at 11:25 AM Yvette C. Washington -MDH- <yvette.washington@maryland.gov> wrote:  
I was contacted this morning by [REDACTED] stating she needs to coordinate serological re-testing of the 18 people who were tested from [REDACTED]. Was advised to re-test after 2 weeks. Would like to arrange the delivery of supplies and arrangement of a courier that Jake set up last week. Please advise.

Yvette Washington, M.S.  
Public Health Laboratory Scientist Supervisor  
Division of Virology and Immunology  
Maryland Department of Health, Laboratories Administration  
[1770 Ashland Avenue](#)  
[Baltimore, MD 21205](#)

443-681-3931

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On Thu, Sep 10, 2020 at 7:57 PM Robert Myers -MDH- <robert.myers-phd@maryland.gov> wrote:  
Everyone,

We were called upon to support a request by the Department to quickly perform SARS-CoV-2 Serology testing for the staff of a Howard County nursing home. Per Jake's request I have placed 30 red-top tubes, 30 biobags and 30 MDH Lab Serology test request forms on the loading dock for pick-up early on Friday(09/11) morning by a courier assigned by Jake. The box of collection supplies and accompanying cooler with cold packs is labeled "Howard County SARS-CoV-2 Serology testing".

Yvette, Jake is planning to have collected specimens for SARS-CoV-2 serology testing to be delivered back to us by a special courier by midday tomorrow (09/11). Please do what is necessary to expedite the testing of these specimens tomorrow if possible .

Closely coordinate the logistical details of this event with Jake or his designees and contact me if you have any additional questions or concerns. and thank you for your cooperation in this matter.

Best regards,

Bob

**Robert A. Myers PhD**  
**Director**  
**Maryland Department of Health Laboratories Administration**  
[1770 Ashland Avenue](#)  
[Baltimore, Maryland 21205](#)

**Phone: 443-681-3800 Fax: 443-681-4501**



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Robert Myers -MDH- &lt;robert.myers-phd@maryland.gov&gt;

**Re: Asymptomatic COVID-19 Cluster Investigations**

1 message

David Blythe -MDH- &lt;david.blythe@maryland.gov&gt;

Fri, Sep 18, 2020 at 6:29 PM

To: Robert Myers -MDH- &lt;robert.myers-phd@maryland.gov&gt;

Cc: Brian Bachaus -MDH- &lt;brian.bachaus@maryland.gov&gt;, "Liore H. Klein -MDH-" &lt;liore.klein@maryland.gov&gt;

Super helpful - thanks. I think all the collection dates were September 1, but we will confirm.

Have not received anything back from UMPA. Will let you know as soon as we do.

On Fri, Sep 18, 2020 at 6:21 PM Robert Myers -MDH- <robert.myers-phd@maryland.gov> wrote:

David and Brian,

Attached is the data table we created for the [REDACTED] asymptomatic COVID-19 cluster investigation. Can your group fill in the collection dates for the UMP specimens? We would like to use a standard data table format for the investigations for this and the other asymptomatic COVID-19 Cluster investigations. Will this format work? Revise and edit as needed.

Has UMPA Lab provided you with the COVID-19 PCR Ct values for the asymptomatic COVID-19 infections associated with the other clusters under investigation?

Please let us when we need to perform serology testing and/ or repeat PCR testing for the patients associated with these cluster investigations

Best regards,

Bob

**Robert A. Myers PhD**

**Director**

**Maryland Department of Health Laboratories Administration**

**1770 Ashland Avenue**

**Baltimore, Maryland 21205**

**Phone: 443-681-3800 Fax: 443-681-4501**



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--

David Blythe, MD, MPH  
State Epidemiologist and Director

Attachment 12



Infectious Disease Epidemiology and Outbreak Response Bureau  
Maryland Department of Health  
ph: 410-767-6685  
fax: 410-669-4215

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Initial MDH Lab Findings

09/16/20

redacted  
 ↓ Patient identifiers

Asymptomatic COVID-19 Cluster Investigation									
UMPA Lab SARS-CoV-2 PCR Results					Lab Genomics				
PCR Swab Collection date	accession	e gene	RdRP	MMS2 E	Ms2	Lab			
Gun COVID-19 PCR Kit						Genomics			
Unknown	7340	37.4	39.95	28.5	28.7	PCR Swab Collection date	MDH Lab Results (Hologic COVID-19 TMA)	Serology Collection Date	09/11/20 SARS-CoV-2 Antibody Results
Unknown	7290	36.9	37.3	29.6	29.7	09/08/2020	Neg.	9/11/2020	Neg.
Unknown	7160	36.4	38.3	29.1	29.2	09/08/2020	Neg.	9/11/2020	Neg.
Unknown	7664	32.1	31.5	29	29	09/09/2020	Neg.	9/11/2020	Pos.(+)
Unknown	7643	30.1	30.1	28.8	28.8	09/09/2020	Neg.	9/11/2020	Neg.
Unknown	7611	36	35.2	20.6	20.7	09/09/2020	Not received		Not received?
Unknown	7597	36.3	35.6	28.8	28.6	09/08/2020	Neg.	9/11/2020	Not received?
Unknown	7570	36.9	36.9	28.6	28.7	09/08/2020	Neg.	9/11/2020	Not received?
Unknown	7559	38.6	37	28.5	28.5	09/08/2020	Neg.	9/11/2020	Neg.
Unknown	7551	n/a	39.9	29.5	29.5	09/10/2020	Neg.	9/11/2020	Not received?
Unknown	7475	36.8	35.2	28.5	28.5	09/09/2020	Neg.	9/11/2020	Neg.
Unknown	7462	39	37.3	28.8	29	09/10/2020	Neg.	9/11/2020	Neg.
Unknown	7449	29.5	29.6	27.7	27.7	09/08/2020	Neg.	9/11/2020	Neg.
Unknown	7439	36.7	36	27.6	28	09/08/2020	Neg.	9/11/2020	Neg.
Unknown	7424	35.6	35.1	28.4	28.3	09/08/2020	Neg.	9/11/2020	Neg.
Unknown	7415	35.3	34.7	28.6	28.4	09/08/2020	Neg.	9/11/2020	Neg.
Unknown	7408	35.9	35.2	28.5	28.5	09/08/2020	Neg.	9/11/2020	Neg.
Unknown	7402	36.9	35.5	28	28	09/09/2020	Neg.	9/11/2020	Neg.
Unknown	7392	37.8	36.6	28.7	28.9	09/09/2020	Not received	9/11/2020	Not received?
Unknown	7382	35.7	35.4	28.1	28	09/09/2020	Not received	9/11/2020	Not received?
Unknown	7372	37.2	38.6	28.6	28.7	09/09/2020	Neg.	9/11/2020	Not received?
Unknown	7363	36.3	35.7	28.8	28.8	09/09/2020	Neg.	9/11/2020	Not received?
Unknown	7354	35.8	35.1	27.9	27.7	09/08/2020	Neg.	9/11/2020	Not received?
Unknown	7348	40.7	38	29.4	29.6	09/09/2020	Neg.	9/11/2020	Neg.
Unknown	7334	37.2	36.8	30.8	30.7	09/09/2020	Neg.	9/11/2020	Neg.
Unknown	7170	42.3	39.5	28.8	28.6	09/09/2020	Not received	9/11/2020	Not received?
Unknown	7152	37.6	38.6	28.6	28.8	09/09/2020	Neg.	9/11/2020	Not received?
Unknown	7157	39.9	39.4	28.4	28.3	09/08/2020	Neg.	9/11/2020	Pos.(+)
Unknown	8152	n/a	39.8	29.7	29.7	09/10/2020	Neg.	9/11/2020	Not received?
Unknown	8112	39.2	39.2	29.4	29.3	09/10/2020	Neg.	9/11/2020	Neg.

**MDH Laboratories Administration 2019 LabGun COVID-19 RT-PCR Kit - RESULTS (10/23/20 to 11/11/20)**

SUBMITTER_NAME	FOLDERNO	ORDNO	DATE_RECEIVED	DATE_REPORTED	RESULT
	A20201364	A20201364002	10/22/2020	10/23/2020	Not Detected
	A20201365	A20201365002	10/22/2020	10/23/2020	Not Detected
	A20201366	A20201366002	10/22/2020	10/23/2020	Not Detected
	A20201367	A20201367002	10/22/2020	10/23/2020	Not Detected
	A20201371	A20201371002	10/22/2020	10/23/2020	Not Detected
	A20201372	A20201372002	10/22/2020	10/23/2020	Not Detected
	A20201373	A20201373002	10/22/2020	10/23/2020	Not Detected
	A20201374	A20201374002	10/22/2020	10/23/2020	Not Detected
	A20201375	A20201375002	10/22/2020	10/23/2020	Not Detected
	A20201376	A20201376002	10/22/2020	10/23/2020	Not Detected
	A20201377	A20201377002	10/22/2020	10/23/2020	Not Detected
	A20201378	A20201378002	10/22/2020	10/23/2020	Not Detected
	A20201379	A20201379002	10/22/2020	10/23/2020	Not Detected
	A20201380	A20201380002	10/22/2020	10/23/2020	Not Detected
	A20201381	A20201381002	10/22/2020	10/23/2020	Not Detected
	A20201382	A20201382002	10/22/2020	10/23/2020	Not Detected
	A20201383	A20201383002	10/22/2020	10/23/2020	Not Detected
	A20201384	A20201384002	10/22/2020	10/23/2020	Not Detected
	A20201385	A20201385002	10/22/2020	10/23/2020	Not Detected
	A20201386	A20201386002	10/22/2020	10/23/2020	Not Detected
	A20201387	A20201387002	10/22/2020	10/23/2020	Not Detected
	A20201388	A20201388002	10/22/2020	10/23/2020	Not Detected
	A20201389	A20201389002	10/22/2020	10/23/2020	Not Detected
	A20201390	A20201390002	10/22/2020	10/23/2020	Not Detected
	A20201391	A20201391002	10/22/2020	10/23/2020	Not Detected
	A20201392	A20201392002	10/22/2020	10/23/2020	Not Detected
	A20201393	A20201393002	10/22/2020	10/23/2020	Not Detected
	A20201394	A20201394002	10/22/2020	10/23/2020	Not Detected
	A20201395	A20201395002	10/22/2020	10/23/2020	Not Detected
	A20201396	A20201396002	10/22/2020	10/23/2020	Not Detected
	A20201397	A20201397002	10/22/2020	10/23/2020	Not Detected
	A20201398	A20201398002	10/22/2020	10/23/2020	Not Detected
	A20201399	A20201399002	10/22/2020	10/23/2020	Not Detected
	A20201400	A20201400002	10/22/2020	10/23/2020	Not Detected
	A20201401	A20201401002	10/22/2020	10/23/2020	Not Detected
	A20201402	A20201402002	10/22/2020	10/23/2020	Not Detected
	A20201403	A20201403002	10/22/2020	10/23/2020	Not Detected
	A20201404	A20201404002	10/22/2020	10/23/2020	Not Detected
	A20201405	A20201405002	10/22/2020	10/23/2020	Not Detected
	A20201406	A20201406002	10/22/2020	10/23/2020	Not Detected
	A20203416	A20203416002	10/26/2020	10/27/2020	Not Detected
	A20203417	A20203417002	10/26/2020	10/27/2020	Not Detected
	A20203418	A20203418002	10/26/2020	10/27/2020	Not Detected
	A20203486	A20203486002	10/26/2020	10/27/2020	Not Detected
	A20203914	A20203914002	10/26/2020	10/27/2020	Not Detected
	A20203915	A20203915002	10/26/2020	10/27/2020	Not Detected
	A20203916	A20203916002	10/26/2020	10/27/2020	Not Detected
	A20203917	A20203917002	10/26/2020	10/27/2020	Not Detected
	A20203918	A20203918002	10/26/2020	10/27/2020	Not Detected
	A20203919	A20203919002	10/26/2020	10/27/2020	Not Detected
	A20203920	A20203920002	10/26/2020	10/27/2020	Not Detected
	A20203921	A20203921002	10/26/2020	10/27/2020	Not Detected
	A20203922	A20203922002	10/26/2020	10/27/2020	Not Detected
	A20203923	A20203923002	10/26/2020	10/27/2020	Not Detected
	A20203924	A20203924002	10/26/2020	10/27/2020	Not Detected
	A20203925	A20203925002	10/26/2020	10/27/2020	Not Detected
	A20203926	A20203926002	10/26/2020	10/27/2020	Not Detected
	A20203927	A20203927002	10/26/2020	10/27/2020	Not Detected
	A20203928	A20203928002	10/26/2020	10/27/2020	Not Detected
	A20203929	A20203929002	10/26/2020	10/27/2020	Not Detected
	A20203930	A20203930002	10/26/2020	10/27/2020	Not Detected
	A20203931	A20203931002	10/26/2020	10/27/2020	Not Detected







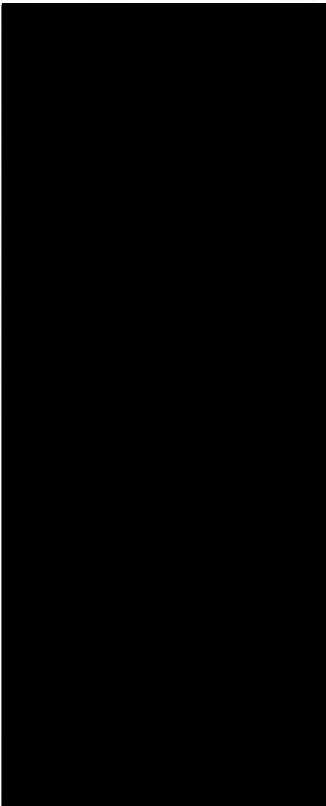












A20220292	A20220292002	11/9/2020	11/11/2020 Not Detected
A20220293	A20220293002	11/9/2020	11/11/2020 Not Detected
A20220294	A20220294002	11/9/2020	11/11/2020 Not Detected
A20220295	A20220295002	11/9/2020	11/11/2020 Not Detected
A20220296	A20220296002	11/9/2020	11/11/2020 Not Detected
A20220297	A20220297002	11/9/2020	11/11/2020 Not Detected
A20220298	A20220298002	11/9/2020	11/11/2020 Not Detected
A20220299	A20220299002	11/9/2020	11/11/2020 Not Detected
A20220300	A20220300002	11/9/2020	11/11/2020 Not Detected
A20220301	A20220301002	11/9/2020	11/11/2020 Not Detected
A20220302	A20220302002	11/9/2020	11/11/2020 Not Detected
A20220303	A20220303002	11/9/2020	11/11/2020 Not Detected
A20220304	A20220304002	11/9/2020	11/11/2020 Not Detected
A20220305	A20220305002	11/9/2020	11/11/2020 Not Detected
A20220306	A20220306002	11/9/2020	11/11/2020 Not Detected
A20220307	A20220307002	11/9/2020	11/11/2020 Not Detected
A20220308	A20220308002	11/9/2020	11/11/2020 Not Detected
A20220309	A20220309002	11/9/2020	11/11/2020 Not Detected
A20220310	A20220310002	11/9/2020	11/11/2020 Not Detected
A20220311	A20220311002	11/9/2020	11/11/2020 Not Detected
A20220312	A20220312002	11/9/2020	11/11/2020 Not Detected
A20220313	A20220313002	11/9/2020	11/11/2020 Not Detected
A20220314	A20220314002	11/9/2020	11/11/2020 Not Detected
A20220315	A20220315002	11/9/2020	11/11/2020 Not Detected
A20220316	A20220316002	11/9/2020	11/11/2020 Not Detected
A20220317	A20220317002	11/9/2020	11/11/2020 Not Detected
A20220318	A20220318002	11/9/2020	11/11/2020 Not Detected
A20220319	A20220319002	11/9/2020	11/11/2020 Not Detected
A20220320	A20220320002	11/9/2020	11/11/2020 Not Detected

Re: [REDACTED] UMPA PCR Serology Spreadsheet

Liore H. Klein -MDH- <liore.klein@maryland.gov>  
to me

Sep 30, 2020, 3:51 PM

Malagasy      English      [Translate message](#)

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See attached for updates and notes from CRISP.

**[UMPA SARS-CoV-2 PCRNursing Home Inv... .tdf \(28.8 Kb\)](#)**

On Wed, Sep 30, 2020 at 3:08 PM Liore H. Klein -MDH- <[liore.klein@maryland.gov](mailto:liore.klein@maryland.gov)> wrote:

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--  
Liore Klein, MSPH (she/her/hers)  
*Sr. Epidemiologist*  
*Lab-Epidemiology Coordinator, ARLN Program*  
Maryland Department of Health Laboratories Administration  
1770 Ashland Avenue  
Baltimore, MD 21205  
Phone: [443-681-3945](tel:443-681-3945)  
Email: [liore.klein@maryland.gov](mailto:liore.klein@maryland.gov)

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Attachment 22

Name	UMPA Lab SARS-CoV-2 PCR Results Lab Generated						MDH Lab SARS-CoV-2 NAAT (Hologic TMA) and Abbott (Diasorin) IgG Scrolog, Results									
	PCR Swab Collection date	Accession #	E-gene	rdRP	MM52 E_M22	PCR Swab Collection date	MDH NAAT Accession # (MDH)	MDH Lab SARS-CoV-2 NAAT Results	MDH Serology Accession #	Serology Collection Date	09/29/20 SARS-CoV-2 Antibody Results	Notes				
	9/1/2020	01-20-248-07240	33.76	33.05	29.24	06/01, 06/23/07/14, 8/23/2020	No MDH NAAT Results (MDH)	N/A	A20162457	9/23/2020	Positive/Positive	No previous positives in CRISP				
	9/4/2020	01-20-248-07252	37.72	34.36	29.84	05/01, 06/23/07/14, 8/23/2020	No MDH NAAT Results (MDH)	N/A	A20162458	9/23/2020	Negative					
	9/4/2020	01-20-248-07282	37.72	38.10	29.09	04/17, 04/30, 05/10, 06/13/20	MDH NAAT Results (MDH)	Not Detected (PK)	A20162459	9/23/2020	Inconclusive					
	9/4/2020	01-20-248-07293	33.61	33.95	29.73	06/13/20	MDH NAAT Results (MDH)	Not Detected (PK)	A20162460	9/23/2020	Negative					
	9/4/2020	01-20-248-07307	36.05	36.36	29.61		MDH NAAT Results (MDH)	N/A	A20162461	9/23/2020	Negative					
	9/4/2020	01-20-248-07316	37.39	36.61	33.76		MDH NAAT Results (MDH)	N/A	A20162462	9/23/2020	Negative					
	9/4/2020	01-20-248-07357	34.78	34.55	29.53	7/15/07, 08/15/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162463	9/23/2020	Inconclusive					
	9/4/2020	01-20-248-07416	38.72	37.73	29.30		MDH NAAT Results (MDH)	N/A	A20162464	9/23/2020	Negative	UMPA Detected collected on 08/31 and released 09/03. Last name spelled in CRISP. Several other negative results in CRISP				
	9/4/2020	01-20-248-07515	31.83	31.84	28.37	06/10, 07/15, 8/24/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162465	9/23/2020	Negative					
	9/4/2020	01-20-248-07516	36.69	36.99	29.20	05/14, 08/31/20, 09/11, 09/15/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162466	9/23/2020	Negative					
	9/4/2020	01-20-248-07517	37.80	39.13	28.65		MDH NAAT Results (MDH)	Not Detected (PK)	A20162467	9/23/2020	Negative					
	9/4/2020	01-20-248-07529	38.11	38.52	28.51		MDH NAAT Results (MDH)	Not Detected (PK)	A20162468	9/23/2020	Negative					
	9/4/2020	01-20-248-07537	37.43	37.43	29.49		MDH NAAT Results (MDH)	Not Detected (PK)	A20162469	9/23/2020	Negative					
	9/4/2020	01-20-248-07538	37.43	37.43	30.02		MDH NAAT Results (MDH)	Not Detected (PK)	A20162470	9/23/2020	Negative					
	9/4/2020	01-20-248-07705	37.80	36.41	29.36	7/09/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162471	9/23/2020	Negative					
	9/4/2020	01-20-248-05646	35.06	36.87	31.12	5/13/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162472	9/23/2020	Negative					
	9/4/2020	01-20-248-07116	37.69	37.18	32.08	04/03, 08/10, 08/23/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162473	9/23/2020	Positive/Positive					
	9/4/2020	01-20-248-07229	38.60	36.70	30.52		MDH NAAT Results (MDH)	Not Detected (PK)	A20162474	9/23/2020	Negative					
	9/4/2020	01-20-248-07216	35.64	36.78	28.91		MDH NAAT Results (MDH)	Not Detected (PK)	A20162475	9/23/2020	Negative					
	9/4/2020	01-20-248-05662	36.00	36.04	29.21		MDH NAAT Results (MDH)	Not Detected (PK)	A20162476	9/23/2020	Negative					
	9/4/2020	01-20-248-03156	35.60	35.64	29.70	04/03, 08/10, 05/16/06, 8/23/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162477	9/23/2020	Negative					
	9/4/2020	01-20-248-07374	38.65	38.11	31.23	03/31/20 (CDC), 08/05, 9/4/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162478	9/23/2020	Positive/Positive	UMPA Detected collected on 08/31 and released 09/03				
	9/4/2020	01-20-248-07105	38.21	36.25	30.76	07/11, 8/4/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162479	9/23/2020	Negative					
	9/4/2020	01-20-248-07103	35.22	35.84	29.85	8/23/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162480	9/23/2020	Negative					
	9/4/2020	01-20-248-07504	37.67	37.74	29.07	8/4/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162481	9/23/2020	Negative					
	9/4/2020	01-20-248-07200	35.18	35.10	30.75	06/10, 8/23/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162482	9/23/2020	Negative					
	9/4/2020	01-20-248-07259	37.26	36.63	29.35	5/11/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162483	9/23/2020	Negative					
	9/4/2020	01-20-248-06958	37.51	38.88	28.47	9/3/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162484	9/23/2020	Negative					
	9/4/2020	01-20-248-06958	37.28	38.83	29.80		MDH NAAT Results (MDH)	Not Detected (PK)	A20162485	9/23/2020	Negative					
	9/4/2020	01-20-248-07204	36.35	36.07	31.35	5/27, 06/10, 07/16, 08/03, 08/13/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162486	9/23/2020	Negative					
	9/4/2020	01-20-248-07205	36.05	35.63	30.51	08/03, 08/13/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162487	9/23/2020	Negative					
	9/4/2020	01-20-248-07223	36.72	36.04	30.16	8/29/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162488	9/23/2020	Positive/Negative					
	9/4/2020	01-20-248-05652	35.45	35.16	28.80	5/15/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162489	9/23/2020	Negative					
	9/4/2020	01-20-248-07341	38.08	37.85	29.87		MDH NAAT Results (MDH)	Not Detected (PK)	A20162490	9/23/2020	Positive/Positive	Note: has second positive collected 09/21 and tested by UMPA CDC relay				
	9/4/2020	01-20-248-01137	37.53	38.41	29.87	06/25, 8/23/2020	MDH NAAT Results (MDH)	Not Detected (PK)	A20162491	9/23/2020	Inconclusive					



Robert Myers -MDH- &lt;robert.myers-phd@maryland.gov&gt;

---

**UMPA Case clusters Investigations**

1 message

---

**Yvette C. Washington -MDH-** <yvette.washington@maryland.gov>

Fri, Oct 2, 2020 at 8:59 AM

To: Robert Myers -MDH- &lt;robert.myers-phd@maryland.gov&gt;

Dr. Myers,

I tested all recent negative samples (collected 9/22-9/23) from [REDACTED] & [REDACTED] for SARS-CoV-2 IgG antibodies on the DiaSorin assay. All specimens tested negative except A20164524 ([REDACTED] from [REDACTED]). There is no previous testing in StarLIMS.

Yvette Washington, M.S.  
Public Health Laboratory Scientist Supervisor  
Division of Virology and Immunology  
Maryland Department of Health, Laboratories Administration  
[1770 Ashland Avenue](#)  
[Baltimore, MD 21205](#)

443-681-3931

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Attachment 22

Robert Myers -MDH- <[robert.myers-phd@maryland.gov](mailto:robert.myers-phd@maryland.gov)>**Re: Updated [REDACTED] SARSCoV Serology Spreadsheet**

1 message

Liore H. Klein -MDH- <[liore.klein@maryland.gov](mailto:liore.klein@maryland.gov)>  
To: Robert Myers -MDH- <[robert.myers-phd@maryland.gov](mailto:robert.myers-phd@maryland.gov)>

Wed, Sep 30, 2020 at 5:05 PM

Here you go!

On Wed, Sep 30, 2020 at 4:05 PM Robert Myers -MDH- <[robert.myers-phd@maryland.gov](mailto:robert.myers-phd@maryland.gov)> wrote:  
Everyone,

I up-dated the [REDACTED]/UMPA Lab PCR (+) SARS-CoV-2 IgG serology spreadsheet with additional serology results that Yvette provided late last week. It appears that we have serology tested 24 of 30 PCR (+) patients from the facility and found only 2 of the 24 to be IgG positive. David can someone from your group fill in the dates of collection for the UMPA PCR specimens? Also I noticed 4 new names on the second list of serology results that Yvette provided last week( see non-highlighted name on the smaller table). Can someone confirm who they are and if UPMA PCR results are available for those individuals ?

Best regards,

Bob

**Robert A. Myers PhD**  
**Director**  
**Maryland Department of Health Laboratories Administration**  
**1770 Ashland Avenue**  
**Baltimore, Maryland 21205**

**Phone: 443-681-3800 Fax: 443-681-4501**



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--  
Liore Klein, MSPH (she/her/hers)  
Sr. Epidemiologist  
Lab-Epidemiology Coordinator, ARLN Program  
Maryland Department of Health Laboratories Administration  
[1770 Ashland Avenue](http://1770AshlandAvenue.com)  
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Phone: 443-681-3945  
Email: [liore.klein@maryland.gov](mailto:liore.klein@maryland.gov)

Attachment 23

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[REDACTED] UMPA SARS-CoV-2 PCR (+) Serolgy Results (09-30-20).xlsx

18K





Robert Myers -MDH- <robert.myers-phd@maryland.gov>

Updated [REDACTED] SARSCoV Serology Spreadsheet

1 message

Robert Myers -MDH- <robert.myers-phd@maryland.gov>

Wed, Sep 30, 2020 at 4:06 PM

To: "Liore H. Klein -MDH-" <liore.klein@maryland.gov>, David Blythe -MDH- <david.blythe@maryland.gov>, "Yvette C. Washington -MDH-" <yvette.washington@maryland.gov>

Everyone,

I up-dated the [REDACTED] /UMPA Lab PCR (+) SARS-CoV-2 IgG serology spreadsheet with additional serology results that Yvette provided late last week. It appears that we have serology tested 24 of 30 PCR (+) patients from the facility and found only 2 of the 24 to be IgG positive . David can someone from your group fill in the dates of collection for the UMPA PCR specimens? Also I noticed 4 new names on the second list of serology results that Yvette provided last week( see non-highlighted name on the smaller table). Can someone confirm who they and if UPMA PCR results are available for those individuals ?

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Bob

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[REDACTED] UMPA SARS-CoV-2 PCR (+) Serolgy Results (09-30-20).xlsx  
18K

Attachment 2/3

**Asymptomatic COVID-19 Cluster Investigation**

UMPA Lab SARS-CoV-2 PCR Results		Lab Genomics		Lab		MDH Lab SARS-CoV-2 NAAT(Hologic TMA) and Abbott(Diasorin) IgG Serology Results					
PCR Swab Collection date	accession	e gene	RdRP	MMS2 E	Ms2	PCR Swab Collection date	MDH Lab Results (Hologic COVID-19 TMA )	Serology Collection Date	09/11/20 SARS-CoV-2 Antibody Results	Serology Collection Date	09/23/20 SARS-CoV-2 Antibody Results
Unknown	7340	37.4	39.95	28.5	28.7	09/08/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7290	36.9	37.3	29.6	29.7	09/08/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7160	36.4	38.3	29.1	29.2	09/09/2020	Neg.	9/11/2020	Pos (+)		
Unknown	7664	32.1	31.5	29.0	29.0	09/09/2020	Neg.	9/11/2020	Negative		
Unknown	7643	30.1	30.1	28.8	28.8	09/09/2020	Neg.		Not received?		
Unknown	7611	36.0	35.2	20.6	20.7				Not received?		
Unknown	7597	36.3	35.6	28.8	28.6	09/08/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7570	36.9	36.9	28.6	28.7	09/08/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7559	38.6	37	28.5	28.5	09/08/2020	Neg.		Not received?		
Unknown	7551	n/a	39.9	29.5	29.5	09/10/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7475	36.8	35.2	28.5	28.5	09/09/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7462	39.0	37.3	28.8	29	09/10/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7449	29.5	29.6	27.7	27.7	09/08/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7439	36.7	36	27.6	28	09/08/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7424	35.6	35.1	28.4	28.3	09/08/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7415	35.3	34.7	28.6	28.4	09/08/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7408	35.9	35.2	28.5	28.5	09/08/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7402	36.9	35.5	28	28	09/09/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7392	37.8	36.6	28.7	28.9		Not received		Not received?		
Unknown	7382	35.7	35.4	28.1	28		Not received		Not received?		
Unknown	7372	37.2	38.6	28.6	28.7	09/09/2020	Neg.		Not received?	9/22/2020	Negative
Unknown	7363	35.7	35.7	28.8	28.8	09/09/2020	Neg.		Not received?	9/22/2020	Negative
Unknown	7354	35.8	35.1	27.9	27.7	09/08/2020	Neg.		Not received?	9/22/2020	Negative
Unknown	7348	40.7	38.0	29.4	29.6	09/09/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7334	37.2	36.8	30.8	30.7	09/09/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative
Unknown	7170	42.3	39.5	28.8	28.6		Not received		Not received?		
Unknown	7152	37.6	38.6	28.6	28.8	09/09/2020	Neg.		Not received?		
Unknown	7157	39.9	39.4	28.4	28.3	09/08/2020	Neg.	9/11/2020	Pos (+)	9/22/2020	Negative
Unknown	8152	n/a	39.8	29.7	29.7	09/10/2020	Neg.		Not received?		
Unknown	8112	39.2	39.2	29.4	29.3	09/10/2020	Neg.	9/11/2020	Negative	9/22/2020	Negative

Patient Name	Serology Collection Date	SARS-CoV-2 Antibody Results
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative
	9/22/2020	Negative

Only CDC-ish pos 09/09 by UMPA, reported 09/21

LabGun pos 09/01

Only CDC-ish pos 09/09 by UMPA, reported 09/21  
 LabGun pos 09/01



Robert Myers -MDH- &lt;robert.myers-phd@maryland.gov&gt;

## MDH Lab: LabGenomics LabGun™ PCR Kit Verification Study

1 message

Robert Myers -MDH- <robert.myers-phd@maryland.gov>  
 To: Jake Whitaker -MDH- <jake.whitaker1@maryland.gov>

Mon, Jun 8, 2020 at 7:19 PM

Jake,

Attached verification study was performed MDH Laboratory to evaluate the limit of detection, accuracy, precision, reproducibility, and clinical sensitivity/specificity of FDA Emergency Use Authorized (EUA) LabGenomics LabGun™ COVID-19 RT-PCR Kit (LabGun PCR) in direct comparison to the CDC FDA EUA 2019 -Novel Coronavirus (2019-n-CoV) Real-time RT-PCR(CDC PCR) that has been routinely performed at the MDH Laboratory. Both assays were performed per procedures specified in FDA EUA “The Instructions Use” for each assay using manual nucleic acid extraction methods per the manufacturer’s instructions.

Our study indicated that the performance of LabGun PCR was nearly comparable to that of CDC PCR assay. The LabGun™ COVID-19 RT-PCR assay demonstrated a slightly narrower range ( $2 \times 10^6 - 2,070$  genome copies/mL) of detection compared to the CDC PCR ( $2 \times 10^6 - 207$  genome copies/mL). The LabGun PCR assay consistently detected 2,070 SARS CoV-2 genomes per ml vs. 207 SARS CoV-2 genomes per ml with the CDC PCR assay. The LabGun™ COVID-19 RT-PCR showed to be both reproducible and precise. When testing the 53 clinical specimens, LabGun™ COVID-19 RT-PCR Assay testing method displayed 95.5 % clinical sensitivity and 100% specificity in comparison to CDC Coronavirus (2019-n-CoV) Real-time RT -PCR

No attempts were made to perform bridging studies from the specified manual extractions method to higher throughput automated nucleic acid extraction platforms.

Please contact me if you have any questions or concerns about this performance verification study.

Best regards,

Bob

**Robert A. Myers PhD**  
**Director**  
**Maryland Department of Health Laboratories Administration**  
**1770 Ashland Avenue**  
**Baltimore, Maryland 21205**

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**MDH Laboratory LabGun Performance Verification (06-2020).pdf**

11/10/2020

State of Maryland Mail - MDH Lab: LabGenomics LabGun™ PCR Kit Verification Study

 539K

Attachment 25

# Verification of LabGun™ COVID-19 RT-PCR Assay for the testing of 2019 Novel Coronavirus (2019-nCoV)

## Background:

An outbreak of respiratory disease now designated “Coronavirus Disease 2019” (COVID-19) caused by a newly discovered novel coronavirus (SARS-CoV-2) was first detected in Wuhan City, Hubei Province, China in December of 2019. Cases of COVID-19 were soon identified globally, resulting in significant impacts on healthcare systems and subsequent societal disruptions. The World Health Organization (WHO) has designated COVID-19 as a pandemic public health threat. Nucleic acid amplification tests that can quickly and accurately detect SARS-CoV-2 viral RNA gene targets in symptomatic COVID-19 patients are vitally important tools needed to manage the COVID-19 pandemic effectively. Accurate results generated by these tests are used to promptly identify acutely infected patients, guiding appropriate clinical management and infection control practices for healthcare providers. Results of SARS-CoV-2 RNA testing can also provide epidemiologists with valuable insights into the dynamics of COVID-19 disease transmissions during case/contact and outbreak investigations leading to the implementation of appropriate community mitigation efforts.

The LabGun™ COVID-19 RT-PCR Kit is a real-time reverse transcription-polymerase chain reaction (rRT-PCR) test. The test was designed to amplify and detect nucleotide sequences encoding RNA dependent RNA polymerase and Envelope (E-Sarbecovirus specific) genes of the SARS-CoV-2 in respiratory tract specimens collected from infected symptomatic COVID-19 patients. A verification study was performed at Maryland Department of Health (MDH) Laboratory to evaluate the limit of detection, accuracy, precision, reproducibility, and clinical sensitivity/specificity of FDA Emergency Use Authorized (EUA) LabGun™ COVID-19 RT-PCR Kit (LabGun PCR) as a testing platform for the detection of SARS-CoV-2 RNA and to assess the performance of the LabGun assay in direct comparison to the CDC FDA EUA 2019 - Novel Coronavirus (2019-n-CoV) Real-time RT-PCR(CDC PCR) that has been routinely performed at the MDH Laboratory. Both assays were performed per procedures specified in FDA EUA “The Instructions Use” for each assay using manual nucleic acid extraction methods per the manufacturer’s instructions (LabGun PCR: QIAamp Viral RNA Mini kit QIAGEN cat. No. 52904 and CDC PCR: QIAmp DSP Viral RNA MiniKit DSP kit QIAGEN cat. No. 61904). The PCR reactions were performed per the manufacturer’s thermocycling conditions using Thermo Fisher ABI 7500 Dx instruments run in the Standard mode, and results were analyzed using available ABI software (version 1.4) and interpreted per the manufacturer’s FDA approved procedure.

## Validation/Verification Summary

### Limit of Detection (Analytical Sensitivity) and PCR Efficiency

A quantitated preparation ( $2.07 \times 10^9$  genomes/mL or  $2.08 \times 10^5$  TCID<sub>50</sub>/mL) of the SARS CoV-2 virus was obtained from the National Institutes of Health (NIH) via Biodefense and Emerging Infections Research Resources Repository (BEI). This virus stock was serially diluted in pooled SARS-CoV-2 RNA negative remnant clinical specimens (Nasopharyngeal [NP] swabs collected in Viral Transport Media [VTM])) to produce concentrations of the virus that ranged from  $2 \times 10^6$  to 2 genomes/ml.

To determine and compare each assay's limit of detection (LOD) and PCR efficiency, each dilution was extracted with both the QIAamp DSP Viral RNA Mini Kit (QIAGEN, cat#61904; for CDC-PCR) and the QIAamp Viral RNA Mini kit (QIAGEN, cat# 17013794; for LabGun-PCR). RNA isolations were analyzed once using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay (CDC PCR) and three or more times using the LabGun™ COVID-19 RT-PCR Assay (LabGun PCR). The resulting Ct values or Ct value averages were plotted against the sample starting concentration (SARS-CoV-2 genomes/mL), in a log scale, to generate a standard curve for each gene target. The slope of each curve was then used to calculate PCR Efficiency (E) for each assay using the equation  $E = -1 + 10^{(-1/\text{slope})}$ .

**Table: 1 The Ct values of Limit of Detection (LOD) assay**

SARS-CoV-2 Particles spiked into VTM Negative NP Swab Matrix (genomes/mL)	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (Ct values)		LabGun™ COVID-19 RT-PCR (Ct values)	
	N1 Gene Target	N2 Gene Target	RdRP Gene Target (Avg.)	E Gene Target (Avg.)
2070000	21.3	21.3	22.5	22.8
207000	24.8	25.8	26.9	25.3
20700	27.7	28.8	31.7	30.5
2070	31.1	32.2	35.9	34.8
207	35.3	36.6	40.4	38.5
20.7	Undetected	Undetected	41.2	42.0
2.07	Undetected	Undetected	Undetected	Undetected
0	Undetected	Undetected	Undetected	Undetected

Limit of detection, or dilution with the lowest concentration to consistently produce a positive result, was 2,070 genomes/ml for LabGun PCR. Although 2 of 3 PCR replicates produced positive results ( $Ct \leq 40.0$ ) at 207 genomes for the E gene target of the LabGun assay, positive results ( $Ct \leq 40.0$ ) for RdRP gene target of this assay were only detected in one of PCR replicates at this dilution.

**Table 2: The Ct values of Limit of Detection (LOD) Replicate Testing**

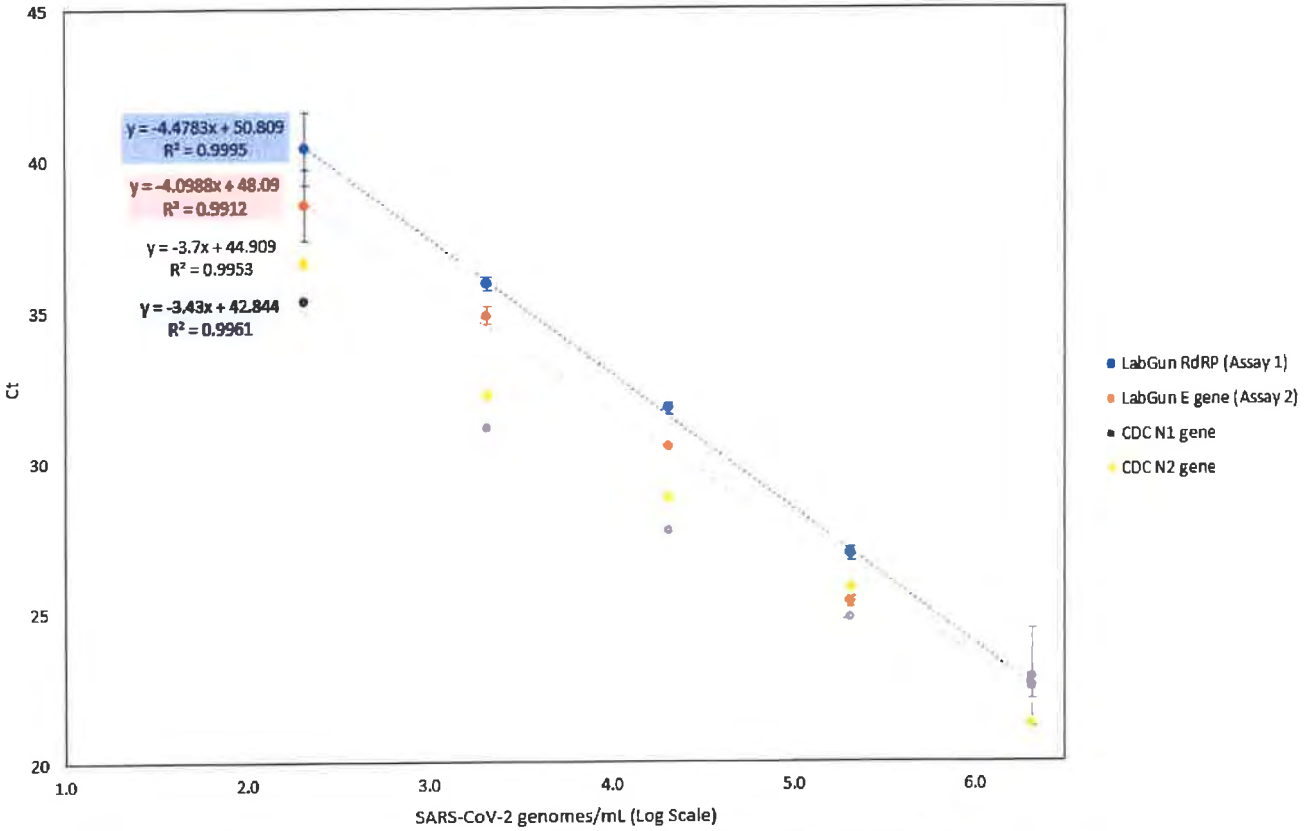
SARS-CoV-2 cells in a VTM Negative NP Swab Matrix (genomes/mL)	LabGun™ COVID-19 RT-PCR	
	RdRP Gene Target (Ct)	E Gene Target (Ct)
2.1E+03	35.7, 35.8, 35.8	34.5, 35.0, 35.2
2.1E+02	42.1, 40.2, 38.5	Undet., 39.5, 37.6
2.1E+01	40.4, 43.1, 42.3	42.6, Undet., Undet.
2.1E+00	Undetected	Undetected
0.0E+00	Undetected	Undetected

In comparison, when limit of detection experiments were previously performed using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay (CDC PCR) with the same quantitated virus stock it consistently demonstrated reactivity for both the N1 and N2 targets at 207 genome copies/ml and occasional reactivity of the N1 primer/probe set at 20.7 genome copies/ml indicating that the CDC PCR assay has slightly better analytical sensitivity than the Lab Gun PCR.



## PCR Efficiencies:

Chart1: LabGun PCR and CDC PCR Primer Probe Set Efficiencies



Assay	Slope	Efficiency
CDC N1 Gene	-3.4	96.84%
CDC N2 Gene	-3.7	86.32%
Lab Gun RdRp Gene	-4.5	66.81%
Lab Gun E Gene	-4.1	75.35%

The LabGun RdRP gene assay and the LabGun E gene assay displayed a 66.81% and 75.35% PCR efficiency, respectively. While the CDC PCR produced an efficiency of 95.68% for the N1 assay and an efficiency of 86.32% for the N2 assay.

We speculate that LabGun PCR is less efficient when analyzing dilutions with lower SARS-CoV-2 concentrations due to competition between the much more abundant internal control molecules and the lesser number of SARS-CoV-2 RNA molecules. Lowering the concentration of the internal control, that is spiked in during extraction, or further optimizing primer concentrations during PCR analysis, could increase the PCR efficiency in samples with lower concentrations of SARS-CoV-2, to ultimately increasing assay sensitivity. The specimen input volume per PCR reaction is higher in the Lab Gun Assay (11.6µl/reaction) in comparison to the

input volume in the CDC PCR assay (5.0µl/reaction) which could help compensate for the reduced analytical sensitivity of the LabGun assay when testing specimens containing lower viral loads of SARSCoV-2 (See below: Clinical Sensitivity). The LabGun PCR uses this internal control (MS2 Bacteriophage) in each PCR reaction to control for the quality of nucleic acid extraction and for possible inhibitors of the PCR reactions present in the patient specimens that could lead to false negative results. In contrast the CDC PCR assay use an additional primer/probe set to control to identify a human “house-keeping gene” (RNase P gene-RP) that is present in every human cell to control for the extraction quality and possible PCR inhibitors. Testing for this house-keeping gene (RP) also assures that a specimen has been collected from the patient and a tube of VTM without a collected swab has not be submitted which could result in a false negative result.

### Reproducibility & Precision (Inter-run and Intra-run)

**Table 3: Intra-Run Reproducibility:**

Intra-Run Reproducibility: Replicate SARSCoV-2 RNA Positive and Negative Clinical Specimens						
Lab Gun SARS-CoV-2 gene target	Run#1 Scientist (A) 05/20/20		Run# 2 Scientist (B) 05/19/20		Run#3 Scientist (C) 05/20/20	
	Positive Sample	Negative Sample	Positive Sample	Negative Sample	Positive Sample	Negative Sample
<b>RdRP</b>	22.5	Und.	22.9	Und.	23.1	Und.
	22.5	Und.	22.1	Und.	22.7	Und.*
	<i>Intra-assay mean</i>					
<i>Intra-assay range</i>	22.5	N/A	22.5 (22.9- 22.1)	N/A	22.9 (23.1-22.7)	N/A
<b>E</b>	21.8	Und.	22.1	Und.	22.0	Und.
	21.8	Und.	22.1	Und.*	22.0	Und.*
	<i>Intra-assay mean</i>					
<i>Intra-assay range</i>	21.8	N/A	22.1	N/A	22.0	N/A

Und. - Undetectable

*\*Note: The result of this samples during the original extraction was suggestive of a potential cross-contamination of SARS-CoV-2 RNA with weak signals. However, when the same sample was re-extracted and re-tested showed non-reactive (05/29/2020).*

The Intra-run (within run) reproducibility of the assay LabGun™ COVID-19 RT-PCR was assessed by two replicates of a previously identified SARSCoV-2 RNA positive and negative clinical samples within the same run by 3 different scientists. The results were 100% reproducible and highly precise (< 1 Ct variations) when the replicates of a positive specimen were tested.

**Table 4: Inter-Run Reproducibility**

<b>Inter-Run Reproducibility at the limit of detection (2070 genomic RNA copies/ml)</b>						
<b>Lab Gun SARS-CoV-2 gene target</b>	<b>Run#1 Scientist (A) 05/20/20</b>	<b>Run# 2 Scientist (B) 05/19/20</b>	<b>Run# 3 Scientist (C) 05/21/20</b>	<b>Inter Assay Mean</b>	<b>Std. Deviation</b>	<b>Range</b>
RdRP	35.8	35.7	35.8	35.77	0.06	(35.7-35.8)
E	35.2	34.5	35.2	34.96	0.40	(35.2-34.5)
<b>Inter-Run Reproducibility of a SARS-CoV-2 RNA (+) and SARS-CoV-2 RNA (-) Clinical specimens</b>						
<b>Specimen type/Lab Gun SARS-CoV-2 gene target</b>	<b>Run #1 Scientist :(A) 05/20/20</b>	<b>Run # 2 Scientist :(B) 05/19/20</b>	<b>Run #3 Scientist :(C) 05/20/20</b>	<b>Inter Assay Mean</b>	<b>Std. Deviation</b>	<b>Range</b>
Positive Specimen: RdRP	22.5	22.9	23.1	22.8	0.31	(22.5-23.1)
	22.5	22.1	22.7	22.4		
Positive Specimen: E	21.8	22.1	22	22	0.15	(21.8-22.1)
	21.8	22.1	22	22		
Negative Specimen: RdRP	Und.	Und.	Und.	N/A	N/A	N/A
Negative Specimen: E	Und.	Und.	Und.	N/A	N/A	N/A
	Und.	Und.*	Und.			

*Und. - Undetectable*

*\*Note: The negative specimen initially demonstrated a negative but weak signal (Ct 42.1). retesting of this specimen resulted in an undetected (Und.) >45 0 Ct finding*

The Inter-run (between runs) reproducibility of the assay LabGun™ COVID-19 RT-PCR was assessed by repeatedly testing three replicates of one spiked NP/VTM sample containing 2,070 genomes copies/mL of SARS-CoV-2 virus and a positive and a negative clinical specimen by three scientists on three separate days. The results were 100% reproducible and highly precise (<1 Ct variations) when the replicates were tested.

## Clinical Sensitivity and Clinical Specificity

A panel of 53 remnant frozen (-80°C) nasopharyngeal swab specimens collected in VTM that had been previously submitted to MDH Laboratory for SARSCoV-2 RNA testing were tested again in parallel in the CDC FDA EUA 2019-Novel Coronavirus (2019-n-CoV) Real-time RT-PCR (CDC PCR) assay and the LabGun™ COVID-19 RT-PCR (LabGun PCR) to determine clinical sensitivity/specificity of the LabGun PCR assay. These specimens were previously determined to be either SARS-CoV-2 RNA positive or SARS-CoV-2 RNA negative using the CDC PCR assay. Results of clinical specimens on the LabGun PCR were then classified as true positive, true negative (TN), false positive (FP), or false negative (FN) when benchmarked to the standard CDC PCR method (Table 5). The assay sensitivity was estimated by dividing the number of true-positives by the sum of true-positives and false-negatives (TPs/(TPs+FNs)). The assay specificity was estimated by dividing the number of true negatives by the sum of true-negatives and false-positives (TNs/(TNs+FPs)).

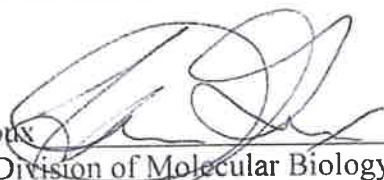
The LabGun™ COVID-19 RT-PCR displayed a 95.5% sensitivity and 100% specificity when identifying 42 true panel positives, 2 false panel negatives, and 9 true panel negatives (See attached data table Appendix A).

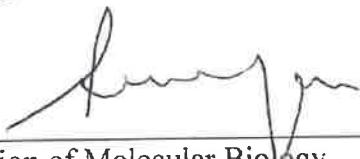
**Table 5: LabGun™ COVID-19 RT-PCR Clinical Sensitivity and Specificity**

LabGun PCR	CDC PCR	
	Positive	Negative
Positive	42	0
Negative	2	9
<b>Clinical Sensitivity</b>	<b>95.50%</b>	
<b>Clinical Specificity</b>	<b>100%</b>	

**Conclusion:**

In this initial study performed at the MDH Laboratory we characterized the performance of LabGun™ COVID-19 RT-PCR Assay for the detection of nCoV-19 from nasopharyngeal swabs. The LabGun™ COVID-19 RT-PCR Assay demonstrated a slightly narrower range ( $2 \times 10^6 - 2,070$  genome copies/mL) of detection compared to the CDC Coronavirus (2019-nCoV) Real-time RT-PCR ( $2 \times 10^6 - 207$  genome copies/mL). The LabGun PCR assay consistently detected 2,070 SARS CoV-2 genomes per ml vs. 207 SARS CoV-2 genomes per ml with the CDC PCR assay. The LabGun™ COVID-19 RT-PCR showed to be both reproducible and precise. When testing the 53 clinical specimens, LabGun™ COVID-19 RT-PCR Assay testing method displayed a 95.5 % clinical sensitivity and a 100% specificity in comparison to CDC Coronavirus (2019-n-CoV) Real-time RT-PCR.

Prepared by Dr. Heather Gony  Date 6/5/2020  
Developmental Scientist I, Division of Molecular Biology

Reviewed by Dr. Murugan Subbiah  Date 6/5/2020  
Principal Developmental Scientist, Division of Molecular Biology

Approved by Robert Myers, PhD  Date 06/05/2020  
Director, Laboratories Administration

Attachment 25

# Appendix A:

## MDH Laboratories: LabGun™ COVID-19 RT-PCR(LabGun PCR) Performance Verification (Clinical Specificity and Sensitivity Study)

Study Sample#	Tech	Date of PCR	LabGun COVID-19 Real-time PCR Results			CDC 2019 nCoV Real-time PCR Results			Original CDC 2019nCoV PCR Results	
			RdRP:Ct Value (< 40 positive)	E: Ct Value (<40 positive)	Test Interpretation	N1: Ct Value (< 40 positive)	N2: Value (<40 positive)	Test Interpretation	N1- Ct Value (<40 positive)	N2- Ct Value (<40 positive)
1	A	5/20/2020	16.7	16.0	Positive	17.7	17.9	Positive	16.9	17
2	B	5/27/2020	18.6	18.5	Positive	18.2	18.3	Positive	19.5	20
3	B	5/19/2020	18.1	17.1	Positive	16.5	17.7	Positive	19.9	20.2
4	C	5/28/2020	20.3	20.7	Positive	20	20.1	Positive	20.3	20.2
5	C	5/28/2020	22.4	22.9	Positive	23.0	23.0	Positive	22.2	22.2
6	A	5/20/2020	21.8	21.3	Positive	22.2	23.1	Positive	22.5	22.7
7	C	5/28/2020	20.7	20.5	Positive	23.4	23.5	Positive	23.1	21.9
8	C	5/28/2020	23.1	23.3	Positive	22.5	23.3	Positive	23.3	23.4
9	B	5/19/2020	24.0	23.0	Positive	21.4	23.0	Positive	24.1	24.4
10	A	5/20/2020	25.3	24.1	Positive	23.5	24.5	Positive	24.4	23.8
11	B	5/19/2020	24.6	23.1	Positive	22.7	22.2	Positive	25.0	24.6
12	C	5/28/2020	31.7	29.7	Positive	26.1	27.3	Positive	26.2	26.9
13	B	5/19/2020	28.1	26.9	Positive	24.9	22.9	Positive	26.4	26.6
14	B	5/19/2020	25.7	24.3	Positive	23.4	24.1	Positive	26.8	27.3
15	C	5/28/2020	26.6	26.2	Positive	27.4	27.8	Positive	27.1	27.1
16	B	5/27/2020	26.0	25.3	Positive	25.0	25.1	Positive	27.2	26.5
17	B	5/27/2020	29.3	28.5	Positive	26.2	27.0	Positive	27.4	26.3
18	A	5/20/2020	30.3	29.5	Positive	27.2	27.9	Positive	27.4	27.6
19	C	5/28/2020	28.8	28.1	Positive	27.7	28.7	Positive	27.5	26.7
20	C	5/28/2020	30.3	29.2	Positive	26.6	27.3	Positive	27.9	28.4
21	C	5/28/2020	26.5	26.0	Positive	25.7	26.4	Positive	28.6	28.7
22	A	5/20/2020	32.7	31.5	Positive	29.6	29.8	Positive	28.7	29
23	A	5/20/2020	29.8	29.3	Positive	28.4	29.1	Positive	28.8	29.2
24	B	5/27/2020	30.0	29.0	Positive	27.3	27.7	Positive	28.8	29.9
25	B	5/27/2020	30.9	30.2	Positive	27.1	28.2	Positive	29	28.5
26	B	5/19/2020	28.9	27.3	Positive	25.4	26.3	Positive	29.4	29.7
27	B	5/19/2020	32.3	30.8	Positive	28.2	28.9	Positive	30.9	32.3
28	B	5/27/2020	34.4	33.4	Positive	30.1	30.9	Positive	31.0	31.9
29	B	5/19/2020	34.4	32.7	Positive	31.1	33.3	Positive	31.2	32.6
30	A	5/20/2020	34.6	35.0	Positive	31.2	33.7	Positive	31.9	33.3
31	C	5/28/2020	32.3	31.4	Positive	32.4	33.1	Positive	32.3	31.4
32	C	5/28/2020	34.3	33.1	Positive	29.6	30.6	Positive	32.5	33.1
33	B	5/19/2020	33.7	31.8	Positive	29.6	30.3	Positive	33.2	34.4
34	C	5/28/2020	39.3	38.2	Positive	36.3	37.5	Positive	33.3	32.2
35	B	5/27/2020	35.2	34.0	Positive	31.8	32.2	Positive	33.9	33.1
36	B	5/27/2020	38.5	37.8	Positive	33.9	34.6	Positive	34.5	35.5
37	B	5/27/2020	36.2	34.4	Positive	31.1	32.4	Positive	34.7	34.5
38	C	5/28/2020	40.7	40.4	Negative	35	36.6	Positive	36.4	36.5
39	A/C	5/28/29/2020	38.1	38.8	Positive	37.1	36.2	Positive	35.7	35.8
40	C	5/28/2020	38.6	37.0	Positive	36.3	35.4	Positive	35.8	38
41	B	5/29/2020	36.9	36.5	Positive	35.0	39.97	Positive	35.9	38.3
42	A	5/20/2020	39.1	37.5	Positive	34.0	36.6	Positive	36.1	36.3
43	C	5/28/2020	38.0	37.0	Positive	36.3	37.0	Positive	37.2	38.2
44	C	5/28/2020	41.0	40.1	Negative	36.1	39.0	Positive	37.8	39.6
45	B	5/19/2020	Undetected	Undetected	Negative	Undetected	Undetected	Negative	Undetected	Undetected
46	B	5/19/2020	Undetected	Undetected	Negative	Undetected	Undetected	Negative	Undetected	Undetected
47	B	5/27/2020	Undetected	Undetected	Negative	Undetected	Undetected	Negative	Undetected	Undetected
48	B	5/27/2020	Undetected	Undetected	Negative	Undetected	Undetected	Negative	Undetected	Undetected
49	C	5/28/2020	Undetected	Undetected	Negative	Undetected	Undetected	Negative	Undetected	Undetected
50	C	5/28/2020	Undetected	Undetected	Negative	Undetected	Undetected	Negative	Undetected	Undetected
51	C	5/28/2020	Undetected	Undetected	Negative	Undetected	Undetected	Negative	Undetected	Undetected
52	A	5/20/2020	Undetected	Undetected	Negative	Undetected	Undetected	Negative	Undetected	Undetected
53	A	5/20/2020	Undetected	Undetected	Negative	Undetected	Undetected	Negative	Undetected	Undetected

Original CDC 2019 NCoV PCR Results	
Key:	Strong PCR Positive ( Ct<30.0)
	Moderate PCR Positive ( Ct >30 to ≤35)
	Weak PCR Positive ( Ct >35 to ≤40)
	PCR: Negative



Rodney E. Hargraves -MDH- <rodney.hargraves@maryland.gov>

## LABGun COVID Test Kit

5 messages

**Rodney E. Hargraves -MDH-** <rodney.hargraves@maryland.gov> Tue, May 26, 2020 at 10:30 AM  
 To: "Humphrys, Mike" <MHumphrys@som.umaryland.edu>  
 Cc: Heather Goux -MDH- <heather.goux@maryland.gov>, Robert Myers -DHMH- <robert.myers-phd@maryland.gov>

Mike: Good Morning, would you have an additional kit we could use for some high priority testing today? We would arrange to pick up today, if available.

Regards, Rod

**Rodney E. Hargraves, MBA**  
 Deputy Director of Administrative and Support Services

Maryland Department of Health- Laboratories Administration  
 1770 Ashland Ave.  
 Baltimore, MD 21205  
 office ph: 443-681-3802  
 fax: 443-681-4501  
 email: [rodney.hargraves@maryland.gov](mailto:rodney.hargraves@maryland.gov)

*DHMH is committed to customer service. [Click here](#) to take the Customer Satisfaction Survey.*

**Humphrys, Mike** <MHumphrys@som.umaryland.edu> Tue, May 26, 2020 at 11:02 AM  
 To: "Rodney E. Hargraves -MDH-" <rodney.hargraves@maryland.gov>  
 Cc: Heather Goux -MDH- <heather.goux@maryland.gov>, Robert Myers -DHMH- <robert.myers-phd@maryland.gov>

Absolutely, just let me know how many kits you need and you can pick them up any time.

Mike

On May 26, 2020, 10:31 AM -0400, Rodney E. Hargraves -MDH- <[rodney.hargraves@maryland.gov](mailto:rodney.hargraves@maryland.gov)>, wrote:

**CAUTION:** This message originated from a non UMB, UMSOM, FPI, or UMMS email system. Whether the sender is known or not known, hover over any links before clicking and use caution opening attachments.

[Quoted text hidden]

NOTICE: This message and the accompanying documents are intended only for the use of the individual or entity to which they are addressed and may contain information that is privileged, or exempt from disclosure under applicable law. If the reader of this email is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, disseminating, distributing, or copying this communication. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

**Rodney E. Hargraves -MDH-** <rodney.hargraves@maryland.gov> Tue, May 26, 2020 at 11:14 AM  
 To: "Humphrys, Mike" <MHumphrys@som.umaryland.edu>

is 12:00 ok?

[Quoted text hidden]

**Humphrys, Mike** <MHumphrys@som.umaryland.edu> Tue, May 26, 2020 at 11:15 AM  
 To: "Rodney E. Hargraves -MDH-" <rodney.hargraves@maryland.gov>

Sure, just one kit of 100 reactions?

Mike

Attachment 27

[Quoted text hidden]

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**Rodney E. Hargraves -MDH-** <rodney.hargraves@maryland.gov>  
To: "Humphrys, Mike" <MHumphrys@som.umaryland.edu>

Tue, May 26, 2020 at 11:26 AM

2 if you can spare.

[Quoted text hidden]

Attachment 27



## ATTACHMENT B

- [Warren to feds: Why did you take Massachusetts' medical supplies?](#)
  - The Boston Globe, Matt Stout Globe Staff, Updated March 31, 2020
- [Hospitals say feds are seizing masks and other coronavirus supplies without a word](#)
  - Los Angeles Times, APRIL 7, 2020 2:07 PM PT
- ["Either be in or out": Feds swooped in on Colorado's ventilator order, Polis says.](#)
  - The Denver Post, By SAM TABACHNIK, PUBLISHED: April 4, 2020 at 12:12 p.m
- [A 'War' For Medical Supplies: States Say FEMA Wins By Poaching Orders](#)
  - NPR, April 15, 2020 4:18 PM ET, Heard on All Things Considered
- [Officials in at least 6 states are accusing the federal government of quietly diverting their orders for coronavirus medical equipment](#)
  - Business Insider, Mia Jankowicz Apr 8, 2020, 7:58 AM

## APPENDIX D

TOWSON.EDU



Office of the  
General Counsel  
8000 York Road  
Towson, MD 21252

March 26, 2021

See Appendix A for  
Auditor's Comments  
regarding response

Mr. Gregory A. Hook, CPA  
Legislative Auditor  
Department of Legislative Services  
Office of Legislative Audits  
301 West Preston Street, Room 1202  
Baltimore, MD 21201  
Via: email at [Response@ola.state.md.us](mailto:Response@ola.state.md.us)

Re: Response to Special Review of Procurement of Certain of COVID Tests

Dear Mr. Hook:

On behalf of Towson University, I would like to thank you for this opportunity to review and comment on the March 2021 draft Report of the Office of Legislative Audits ("OLA"), Department of Legislative Services ("DLS") entitled "Review of Procurement of Certain COVID Tests."

For purposes of clarity and context, the University respectfully requests that it be noted in the final Report that neither Towson University nor any of its employees had any role related to the procurement and use of any COVID-19 ("COVID") tests from LabGenomics, or any other COVID test manufacturer. As part of its COVID testing program for students, faculty, and staff, the University, like many other Universities within the University System of Maryland ("USM"), contracted with University of Maryland Pathology Associates ("UMPA"),<sup>1</sup> a not-for-profit entity, to provide COVID testing services.

The University's Agreement with UMPA, which is attached hereto, sets forth the specific duties performed by UMPA as well as the scope of the contractual relationship. This Agreement was not requested from the University by DLS during its investigation. As set forth in the Agreement, the University's role regarding COVID testing is generally limited to specimen collection on swabs (collection kits) received from UMPA, and receipt of final testing results from UMPA after UMPA had analyzed the collected specimens. (See Attachment A to the contract for the list of services provided by UMPA.) Any questions regarding the procurement or use of the specific test kits used should have been directed to UMPA, not the University.

With respect to references in the draft Report surrounding concerns raised with COVID testing results by the former Director of the University Health Center (UHC), the University strongly disagrees with any implied or express assertion in

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<sup>1</sup> UMPA is clinical practice group that is not a part of USM, or the University, but is a separate legal entity.

the draft Report that it took inadequate action after receiving a spike in positive COVID test results in August 2020. When the batch of positive test results were received in August 2020 from UMPA, the University did not discourage the former Director from expressing his concerns, but instead encouraged communication and discourse both internally and externally.

As acknowledged in the draft Report, the former Director raised his concerns with not only the University and USM, but also with the Baltimore County Health Department and the State Epidemiologist. Such collaboration with University and USM leadership and with outside state and local health agencies was (and still is) encouraged by the University as proper analysis of testing results is critical in assessing the safety of returning students, faculty and staff to campus, and determining the safest and most scientifically sound next steps.<sup>2</sup> The former Director engaged in such discourse. Moreover, as noted in the draft Report, the University's Medical Staff Supervisor reported that UHC contacted UMPA to determine if the samples from the University during this time period were processed by UMPA using the LabGenomics' tests and was unable to obtain such information from UMPA. There was no indication from UMPA that the batch of positive test results were, in fact, false positives. In light of the testing results received and in consultation with scientific experts, the University made the difficult, but safest decision to move in-person student instruction for the Fall of 2020 to remote learning.

The University also disagrees with the implied or express assertion in the draft Report that the former Director was terminated because he raised concerns regarding the cause of a spike in positive COVID test results at the University in August 2020. As reflected in the draft Report, the Associate Vice President of Human Resources/Chief HR Officer stated that the termination was not the result of a singular event, but a pattern of behavior that was addressed from a performance perspective. Additionally, the former Director's direct supervisor (the Associate Vice President for Student Affairs/Dean of Students) and the Vice President for Student Affairs (who made the ultimate termination decision) reported that the former Director was terminated on October 1, 2020 due to significant performance issues related to a pattern of behaviors that had a direct impact on his overall management of the COVID testing program during the

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<sup>2</sup> The University disagrees with the characterization in the draft Report that the Vice President for Administration and Finance (A&F) denied that there were any concerns with the accuracy of the test results. In his interview with DLS staff, he indicated that he was not aware of such complaints and had no reason to believe the tests were inaccurate. The University also disagrees with the characterization that President Schatzel refused to meet with DLS. DLS sent an inquiry for information concerning procurement of certain COVID Tests. The President referred the investigator to our Vice President for A&F and CFO who oversees procurements. The University has made every effort to respond to all DLS requests for documents and interviews.

July-September 2020 timeframe, and not any alleged disagreement regarding the reasons behind the positive COVID cases the University received in August 2020.

The former Director was responsible for overseeing the collection of specimens, aggregation of the collected material, and reporting the test results received from UMPA. As stated above, neither he nor the University had any role in procurement of the type of test used, analyzing the actual specimens utilizing the COVID test kits in question, or making the actual determination of the accuracy of the test results. Thus, the former Director's termination could not have been, and was not, associated with the procurement and use of the COVID tests that are the focus of the DLS investigation.

For additional clarity and context, it is important to note that the draft Report does not fully explain or discuss the employment status of this "at-will" position, the policies covering the position, or the process for notice termination. As a Regular Exempt Employee, the former Director was subject to both University Policy 07-01.22, and USM Policy VII-1.22. Pursuant to these policies, the University may terminate the employment relationship at any time in accordance with the provisions of the policies. (A copy of both of these policies is attached.)

The performance issues that ultimately led the Vice President of Student Affairs to terminate the former Director took place in July-September of 2020, which occurred after his last written performance evaluation. These performance issues were shared by University leadership in interviews with DLS during its investigation, and provide appropriate justification for the notice termination decision. Pursuant to University policy, the documentation required for a notice termination is a separation form accompanied by a letter of termination, both of which were present in the former Director's personnel file and provided to DLS. While the University can include written performance plans or other documentation in a personnel file should such documentation exist, notice termination requires no such documentation. It is also noteworthy that USM policy does not require written documentation providing the reason for termination of an "at will" employee who was terminated by a period of notice.

The University maintains that it fully complied with both University and USM policy regarding (a) the decision to notice terminate the former Director, and (b) the maintenance of the required documentation of that decision. The University respectfully requests that the final Report reflect that appropriate documentation as required by policy was in the former Director's personnel file and was provided to DLS.

Thank you again for the opportunity to respond to the draft Report. Please feel free to contact me if you have any questions.

Sincerely,

*Sara Slaff*

Sara Slaff  
Vice President of Legal Affairs and General Counsel, Towson University

**Enclosures**

**UNIVERSITY OF MARYLAND PATHOLOGY ASSOCIATES, P.A.  
LABORATORY SERVICES AGREEMENT  
FOR COVID-19 TESTING SERVICES**

**THIS LABORATORY SERVICES AGREEMENT** (“Agreement”) made as of the date of the last signature set forth on the signature page below (the “Effective Date”), between the University of Maryland Pathology Associates, P.A. (“UMPA”) and Towson University (“Referring Entity” or “TU”) (referred to as each a “Party” and collectively the “Parties”).

**BACKGROUND**

WHEREAS, UMPA is the not-for-profit corporation that operates as a clinical practice group for the Department of Pathology at the University of Maryland School of Medicine and provides, among other services, diagnostic laboratory services. UMPA is a separate legal entity from the University of Maryland School of Medicine.

WHEREAS, Referring Entity is a public agency and instrumentality of the State of Maryland requiring certain COVID-19 related diagnostic laboratory services for its students, faculty, staff and TU affiliates.

WHEREAS, UMPA is qualified and willing to provide such services, as further defined herein, to Referring Entity on the terms and conditions of this Agreement.

WHEREAS, UMPA is a covered entity as defined by the Health Insurance Portability and Accountability Act (“HIPAA”) and its implementing regulations.

WHEREAS, Referring Entity is a HIPAA hybrid entity under which Referring Entity partners with the TU Institute for Well-Being (IWB), a HIPAA covered entity when providing services to non-students and operates pursuant to the Family Educational Rights and Privacy Act (“FERPA”) when providing services to students, and where all other units and divisions of the Referring Entity are not HIPAA covered entities.

In consideration of the foregoing premises and mutual promises contained herein, and intending to be bound legally hereby, Referring Entity and UMPA agree as follows:

**1. SERVICES.**

- a.** UMPA shall provide laboratory services as described in **Attachment A** (the “Services”).
- b.** Referring Entity shall perform those duties described in **Attachment B** which are necessary for the provision of Services.

**2. TERM AND TERMINATION.** This Agreement shall commence on the Effective Date and shall continue for a period of one (1) year unless terminated earlier as set forth in this Agreement (the “Initial Term”). This Agreement shall be renewed automatically for additional, successive one-year terms (each a “Renewal Term”), upon the expiration of the Initial Term, subject to the termination provisions herein.

The Parties may voluntarily terminate this Agreement at any time by mutual written agreement. Either Party may voluntarily terminate this Agreement by providing written notice of termination to the other

Party at least sixty (60) days prior notice to the effective date of termination. In the event that either Party breaches a material term of this Agreement or a material representation or warranty, the non-breaching Party will issue a notice of breach; if the breaching Party does not cure its breach within thirty (30) days, the non-breaching Party may terminate the Agreement.

The Parties shall continue to fulfill their obligations under this Agreement relating to the Services requested and/or performed prior to the effective date of termination, including, without limitation, Referring Entity's payment for Services provided up and until the date of termination. Notwithstanding anything to the contrary, upon expiration or termination of this Agreement, neither Party shall have any further rights or obligations hereunder except for rights and obligations accruing prior to the date of expiration or termination or arising as a result of any breach or expiration or termination of this Agreement.

3. **PAYMENT.** In consideration for the Services, Referring Entity agrees to pay UMPA the fees specified on **Attachment A**. UMPA will generate an invoice for services rendered the previous month at rates indicated in **Attachment A**. The invoice summary will include a summary of tests and associated volume, charges per test and total charges. Upon request, a list of patient's tests performed by patient, charges per test and total charges will be available. The invoice shall be paid by the Referring Entity within 30 days of receipt of proper invoice. UMPA and Referring Entity will review the scope of laboratory operations at least quarterly to determine the level of service and financial funding for the agreed upon services.

For the avoidance of any doubt, the Parties acknowledge and agree that UMPA will not bill patients or patient's insurance for Services performed hereunder.

4. **CONFIDENTIALITY.** Unless inconsistent with the Maryland Public Information Act, Maryland Code Annotated, State Government, Title 10, Subtitle 6, as amended from time to time, each Party agrees to treat confidentially all of the information marked or designated as confidential at the time of disclosure and provided to such Party by the other Party in connection with this Agreement and to return such information to the providing Party upon termination of this Agreement.
5. **MEDICAL RECORDS.** To any extent applicable, the Parties will comply with the privacy, security and confidentiality requirements of the Health Insurance Portability and Accountability Act, as amended, ("HIPAA") and Maryland law governing the confidentiality of patient information and medical records. Without limiting the generality of the foregoing, each Party will only disclose laboratory test results or other information generated in connection with providing the Services as required by these or other applicable laws. Both Parties agree to comply, and cause each of their respective employees and contractors to comply, with applicable provisions of HIPAA, as amended, any regulations promulgated thereunder, and any applicable state laws protecting the privacy of patient information.

6. **INSURANCE.**

- a. UMPA agrees to procure and maintain in effect during the Term adequate professional liability insurance in the amounts of at least One Million (\$1,000,000) Dollars per occurrence and Three Million (\$3,000,000) Dollars in the aggregate for all negligent acts or omissions of its employees and agents providing services pursuant to this Agreement. In furtherance of the foregoing, the Parties agree to procure and maintain during the Term professional liability insurance covering their employees in the performance of professional services while acting within the scope of this Agreement. These insurance requirements may be satisfied with a policy of commercial insurance from an insurance carrier registered to write insurance policies in Maryland, or a self-insurance trust fund or captive insurance company which is consistent with Medicare self-insurance

requirements. This insurance shall apply to claims asserted for contribution and indemnification, contractual, statutory or under common law, as well as claims by or on behalf of patients. In the event any insurance described in this Section is purchased on a claims-made basis, tail coverage for prior acts shall be obtained so as to continue coverage for a minimum of three (3) years following expiration or termination of this Agreement under any circumstance.

- b. Referring Entity is self-insured pursuant to the State of Maryland self-insurance plan.
  - c. Each Party shall provide the other with at least thirty (30) days' advance written notice of any adverse change in its total program of liability insurance coverage. The Parties agree to provide prompt notice to each other of any potential claim or suit relating to the provision of services under this Agreement as soon as possible and to cooperate with each other in the investigation and settlement of such claims or suits. Each Party further agrees to provide prompt notice of any such claim or suit to its carrier and to provide evidence of such notice to the other Party upon request.
  - d. Each Party is responsible for covering its own employees.
  - e. Each Party shall furnish the other, upon request, a current and valid Certificate of Insurance or verification of the existence and relevant terms of its program for self-insurance satisfying the requirements set forth in this Article.
7. **HEALTH CARE REGULATORY COMPLIANCE.** To any extent applicable, each Party hereby represents to the other that, to the best of its actual knowledge, neither it nor any employee, contractor, or agent now or hereafter engaged by such Party to provide services under this Agreement (collectively, a "Representative") is, or at any time has been, excluded from participation in any federally funded health care program, including the Medicare and Medicaid programs. Each Party hereby agrees to promptly notify the other of any threatened, proposed, or actual exclusion of such Party or any of its Representatives from any federally funded health care program, including the Medicare and Medicaid programs. In the event that a Party or any of its Representatives is excluded from participation in any federally funded health care program during the term of this Agreement, or if at any time after the Effective Date it is determined that a Party or any of its Representatives is in breach of this Section, this Agreement shall automatically terminate as of the date of such exclusion or breach unless the breaching Party cures its breach by removing any Representative who is so excluded or has otherwise breached the provisions of this Section from the performance of services under this Agreement.
8. **COMPLIANCE WITH APPLICABLE LICENSING, CERTIFICATION STANDARDS AND LAW.** UMPA and its personnel shall perform the Services in accordance with all applicable regulatory, licensure, and accreditation requirements including those of The Joint Commission, the Maryland Department of Health, the Federal Drug Administration, College of American Pathologists, CLIA, and the AABB. Further, UMPA shall maintain all applicable licenses, certifications and accreditations in good standing.

To any extent applicable, both Parties acknowledge and agree at all times during the term of this Agreement to comply with all applicable federal, state, and local laws in performing its obligations hereunder, including but not limited to Family Educational Rights and Privacy Act ("FERPA"), the Deficit Reduction Act of 2005, the Federal False Claims Act and other federal and state laws addressing anti-kickback, self-referral, fraud, abuse and waste, as well as whistleblower protections for those reporting violations of such laws.

9. **OTHER PRIVILEGES AND REFERRALS NOT AFFECTED.** Nothing in this Agreement affects or



precludes either Party's ability to engage in a similar service arrangement and/or make referrals to any other laboratory in any manner, whether located within or outside the Referring Entity's service area.

- 10. MAINTENANCE OF BOOKS, DOCUMENTS AND RECORDS.** If and to the extent that this Agreement is subject to Medicare statutes and regulations governing access to books and records of contractors and subcontractors, Referring Entity shall, for a period of four (4) years following the furnishing of Services, maintain and make available, upon written request, to the Secretary of the United States Department of Health and Human Services or the Comptroller General of the United States, or to any of their duly authorized representatives, this Agreement and any of the Referring Entity books, documents and records which are necessary to verify the nature and extent of the cost of the Services provided hereunder. Furthermore, if the Referring Entity carries out any of the Services through any subcontract with a value or cost of Ten Thousand Dollars (\$10,000) or more over a twelve (12) month period with related organizations (as that term is defined under federal law), the Referring Entity agrees that each such subcontract shall provide for such access to the subcontract, books, documents and records of the subcontractor. If UMPA is requested to disclose books, documents or records pursuant to this Agreement for purposes of an audit, it shall notify Referring Entity of the nature and scope of such request. These requirements are effective as of the date of execution of this Agreement and pertain to all records, which have or should have been maintained on or after that date. This Agreement pertains solely to the maintenance and disclosure of specified records and shall have no effect on the rights of the Parties to this Agreement to make assignment or delegations.
- 11. NOTICES.** All notices or other communications under this Agreement shall be in writing and shall be deemed duly given if delivered in person or upon the earlier of receipt if mailed by certified or registered mail, or three days after certified or registered mailing, return receipt requested, postage prepaid, addressed and sent to:

If UMPA:

University of Maryland Pathology Associates, P.A.  
419 W. Redwood Street, Suite 200  
Baltimore, Maryland 21201

If REFERRING ENTITY:

Towson University  
8000 York Rd, Towson, MD 21252  
Attention: Office of General  
Counsel

**12. MISCELLANEOUS.**

- a. RESPONSIBILITY FOR ACTIONS.** Each Party shall be responsible for its own acts and omissions and the acts and omissions of its employees, officers, directors, and affiliates. A Party shall not be liable for any claims, demands, actions, costs, expenses, and liabilities, including reasonable attorneys' fees, which may arise in connection with the failure of the other party or its employees, officers, directors, or agents to perform any of their obligations under this Agreement.
- b. NON-DISCRIMINATION.** Both Parties warrants that they do not and will not discriminate against any person because of race, creed, color, national origin, gender, veteran status, or handicap, or as otherwise may be prohibited by law. Both Parties warrant that they are in full initial and ongoing compliance with all current applicable federal, state, and local laws, regulations, and ordinances,

included but not limited to:

1. Civil Rights Act of 1964;
2. The Rehabilitation Act of 1973;
3. The Fair Labor Standards Act;
4. Equal Opportunity Clause (41 CFR 60.250.5(a); 41 CFR 60-300.5(a); and 41-CFR 60.741.5(a)
5. Affirmative Action Programs (41 CFR 60-1.40(a)(2)
6. Other laws that may apply from time to time as amended.

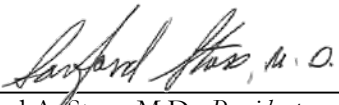
- c INTEGRATION.** This Agreement and all attachments hereto constitute the entire agreement between the Parties with regard to the subject matter hereof and thereof, and all attachments/documents referenced in the Agreement are incorporated by reference. This Agreement supersedes any and all previous agreements between or among the Parties relating to the subject matter hereof. There are no agreements, representations, or warranties between or among the Parties concerning the subject matter hereof other than those set forth in this Agreement.
- d ASSIGNMENT.** This Agreement may not be assigned by either Party without the other Party's written consent. Subject to the preceding sentence, all rights, privileges, duties and obligations under this Agreement shall inure to the benefit of, and be binding upon, the Parties' successors and permitted assigns.
- e FORCE MAJEURE.** Neither party will be liable for failure or delay in performing any of its obligations under this Agreement to the extent the failure or delay is required in order to comply with any governmental regulation, request or order, or necessitated by other circumstances beyond the reasonable control of the party so failing or delaying, including but not limited to Acts of God, war (declared or undeclared), insurrection, fire, flood, accident, labor strikes, work stoppage or slowdown (whether or not that labor event is within the reasonable control of the parties), or inability to obtain raw materials, supplies, power or equipment necessary to enable a party to perform its obligations. The party experiencing the event of force majeure shall: (i) promptly notify the other party in writing of an event of force majeure, and describe the event, the expected duration of the event, and its anticipated effect on the ability of the party to perform its obligations; and (ii) make reasonable efforts to mitigate (and to the extent possible, remedy) the event of force majeure.
- f GOVERNING LAW.** This Agreement shall be governed by, construed and interpreted in accordance with the laws of the State of Maryland without reference to its conflicts of laws principles.
- g INDEPENDENT CONTRACTOR RELATIONSHIP.** In the performance of all obligations and duties hereunder, UMPA and its employees, agents and subcontractors shall be deemed to be independent contractors with respect to Referring Entity, and the Parties shall not be considered joint ventures or partners.
- h WAIVER.** All waivers of rights, powers, and remedies by a Party to this Agreement must be in writing. No delay, omission, or failure by a Party to exercise any right, power, or remedy to which a Party may be entitled shall impair any such right, power, or remedy, nor shall such be construed as a release by a Party of such right, power, or remedy or as a waiver of or acquiescence in any such action, unless such action shall have been cured in accordance with the terms of this Agreement. A waiver by a Party of any right, power, or remedy in any one instance shall not constitute a waiver of the same or any other right, power, or remedy in any other instance.
- i COUNTERPARTS.** This Agreement may be executed in two or more counterparts, each of which

shall be deemed an original but all of which shall constitute one and the same instrument.

- j. **AMENDMENTS.** This Agreement may be amended at any time by mutual agreement of the Parties without additional consideration, provided that before any amendment shall become effective, it shall be received in writing and signed by each of the Parties.

**IN WITNESS WHEREOF**, the Parties hereto have executed this Agreement effective as of the Effective Date.

**UNIVERSITY OF MARYLAND PATHOLOGY ASSOCIATES, P.A.**

  
\_\_\_\_\_  
Sanford A. Stass, M.D., *President*

Date: 08/10/2020

**TOWSON UNIVERSITY**

By:   
\_\_\_\_\_

Title: Vernon J. Hurte, Ph.D., Vice President for Student Affairs

Date: August 28, 2020

**ATTACHMENT A:  
DESCRIPTION OF SERVICES AND FEES**

UMPA will provide the following Services and, in exchange, Referring Entity shall pay the following Fees:

Services	Fees
<p>SARS-CoV-2 RNA Amplification (“Test”), which shall include:</p> <ul style="list-style-type: none"> <li>• Provide Referring Entity with collection kits and requisitions for the Test;</li> <li>• Provide Courier Services for transportation of Collection Kits to the testing site and back to UMPA;</li> <li>• Performance of the Test;</li> <li>• Reporting of Test results as follows: <ul style="list-style-type: none"> <li>○ EPIC My Portfolio (if applicable);</li> <li>○ Individual patient report to the ordering provider;</li> <li>○ Provider access to EPIC Portfolio MD</li> <li>○ Reporting of positive and negative Test results to Maryland Department of Health in accordance with the most recent published guidance.</li> </ul> </li> <li>• The turn-around time (TAT) for test results is based on receipt of the specimen at UMPA until the test result is reported. If electronic/on-line ordering of tests is utilized, the TAT is 24-48 hours. If electronic/on-line ordering is not used, the TAT is &lt; 72 hours. For the avoidance of doubt, verbal notification of either Detected or Not- Detected SARS-CoV-2 (COVID-19) RNA is not required.</li> </ul>	<p>Thirty Five Dollars (\$35) per Test performed.</p> <ul style="list-style-type: none"> <li>• The Parties may change this per Test rate in accordance with Section 12(j) of the Agreement; and.</li> <li>• UMPA may change this per Test rate upon sixty (60) days prior written notice to Referring Entity.</li> </ul>

For the avoidance of any doubt, Referring Entity acknowledges and agrees that:

- UMPA shall not perform, control, supervise, or oversee the collection of patient samples for the Test. Referring Entity must separately arrange for the provision of sample collection services, including appropriate training and supervision of any personnel collecting patient samples.
- UMPA shall not be responsible for the storage of the Test kits after delivery to the Referring Entity.
- UMPA shall not be responsible for the collected samples until retrieved by UMPA.
- UMPA will have sole discretion to determine the testing viability of Test samples it receives.
- UMPA shall not be responsible for obtaining patient consent for testing, or notifying families, employers, or other persons of Test results except as may be described herein.

**ATTACHMENT B:  
DESCRIPTION OF REFERRING ENTITY DUTIES**

Referring Entity will provide the following Duties related to the provision of Services:

1. Secure a physician order or other qualified provider order for performance of Services (as may be necessary), containing accurate identifying codes and other diagnostic information as may be necessary and appropriate.
2. Ensure that each patient's essential data, as defined below, is provided to UMPA via a secure file transfer prior to performance of the Test by Contractor. The essential data for each patient is: first and last name, DOB, gender, SSN, race, gender and ethnicity, and insurance information (as needed).
3. Perform specimen collections from patients.
4. Provide patient samples to UMPA that are accurately and correctly labeled, with sufficient patient sample for testing.
5. Upon receipt of the positive or negative Test result from UMPA, the Referring Entity and/or the ordering provider shall be responsible reporting said Test result to the patient as soon as possible.
6. Cooperate with UMPA in establishing monitoring performance improvement programs
7. Maintain electronic distribution records of laboratory test results.
8. Communicate to UMPA requests for supplies, forms, etc., needed by Referring Entity in the performance of said Duties.

## **07-01.22 – SEPARATION FOR REGULAR EXEMPT EMPLOYEES**

### **I. Policy Statement:**

Towson University (the “University”) has established implementing procedures pursuant to the USM Policy VII-1.22, Policy on Separation of Regular Exempt Staff Employees, regarding the separation of Regular Exempt employees.

### **II. Responsible Executive and Office:**

Responsible Executive: Associate Vice President of Human Resources

Responsible Office: Office of Human Resources (“OHR”)

### **III. Entities Affected by this Policy:** All divisions, colleges, departments and operating units.

### **IV. Procedures:**

#### **A. Applicability**

This policy applies to all Regular Exempt Employees except those positions excluded by USM Policy VII-1.22, (Policy on Separation for Regular Exempt Staff Employees) Section I, B and any additional positions excluded by the President of the University and approved by the Chancellor. The Office of Human Resources shall notify, in writing, any employee excluded from this policy.

#### **B. General**

1. Regular Exempt Employees at the University are employed on an at-will basis. This means that, subject to applicable laws and policies, either the employee or the University may terminate the employment relationship at any time in accordance with the provisions of this policy.
2. The Separation Policy for Exempt Employees does not apply when an exempt employee is laid off. Layoffs will be in accordance with USM Policy VII-1.32, Policy on Layoff and Recall of Regular Exempt Staff Employees.
3. The provisions for probation and rejection on probation are covered under USM Policy VII-1.21, Policy on Probation for

Regular Nonexempt and Exempt Staff Employees.

C. Process for Voluntary Separation

1. An exempt employee who wishes to end his or her employment with the University should give at least thirty (30) calendar days written notice. This written notice should be given to the employee's Supervisor.
2. The Supervisor completes the Personnel Separation Form and attaches a copy of the letter of resignation or retirement from the employee. The form and attached letter are sent to the Vice President of the respective office or department and OHR. The Separation Form and Separation Checklists can be found on the OHR website.

D. Process for Involuntary Separation

1. Any Supervisor who is contemplating the involuntary separation of a regular exempt employee shall contact the Vice President for the respective office or department, and the Associate Vice President for Human Resources or the Employee/Labor Relations Manager prior to any action to terminate the employee.
2. The Supervisor completes the Personnel Separation Form and attaches a copy of the termination letter from the University or the resignation or retirement letter written by the employee in lieu of termination. The form and the attached letter are sent to the Vice President for the respective office or department, and the Associate Vice President for Human Resources or the Employee/Labor Relations Manager. The Separation Form and Separation Checklists can be found on the OHR website.
3. Termination letters shall be signed by the Vice President for the respective office or department (or their designee) with a copy to the Associate Vice President of Human Resources in accordance with either Sections IV.E or IV.F of this policy, as applicable.

E. Period of Notice for Involuntary Separation

1. An employee may be involuntarily separated and shall be provided with a defined period of notice. Service for determining length of notice is based on service at the University rather than University System of Maryland (USM) service and shall include prior service at the University provided there were no breaks in service longer than three (3) years. An exempt employee at one USM institution who is offered an exempt position at another USM institution may, at the discretion of the offering institution, be credited with prior

USM service for purposes of calculating the required period of notice upon separation. Any such decision to credit prior service at another USM institution shall be noted in the employee's personnel file at the time of appointment and become effective after satisfactory completion of the probation period. The period of notice shall be as follows:

<u>Years of Towson University Service</u>	<u>Period of Notice</u>
Less than one year	One month
One year but less than four years	Three months
Four years but less than seven years	Six months
Seven years but less than ten years	Nine months
Ten years or more	Twelve months

2. At the option of the President or Vice President for the respective area, an employee who has been notified of a separation, may be placed in an administrative leave with pay status for any part or all of the notification period. The employee shall not earn other paid leave (annual, sick, holiday, personal) during the period of administrative leave. The President or Vice President for the respective area may assign alternate duties and responsibilities to an employee who has been notified of separation for any part or all of the period of notice.
3. Failure to provide notice as set forth in this (Period of Notice for Involuntary Separation) section may be appealed in accordance with TU Policy 07-08.05, Policy on Grievances and Special Action Appeals for Regular Exempt Employees.

F. Termination for Cause

Section IV.E above does not apply if the employee is to be terminated for any of the following reasons: moral turpitude, incompetency, willful neglect of duty, illegal actions, gross misconduct, severe safety violations, failure to accept reassignment, or medical condition causing inability to perform essential job duties with or without reasonable accommodations required by law. Termination for cause may be appealed in accordance with TU Policy 07-08.05.

**Related Policies:**

USM Policy VII-1.21, Policy on Probation for Regular Nonexempt and Exempt Staff Employees

USM Policy VII-1.22 – Policy on Separation for Regular Exempt Employees



USM Policy VII-1.32, Policy on Layoff and Recall of Regular Exempt Staff  
Employees

TU Policy 07-08.05 – Policy on Grievances and Special Action Appeals for Regular  
Exempt Employees

**Effective Date:** 06/07/2004

**Amended Date:** 04/01/2020

**Approved by:** President's Council

**Approved by:** President Kim Schatzel

## USM Bylaws, Policies and Procedures of the Board of Regents

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### VII-1.22 - POLICY ON SEPARATION FOR REGULAR EXEMPT STAFF EMPLOYEES

Approved by the Board of Regents on December 3, 1999, EFFECTIVE January 2 and January 12, 2000; Amended, June 27, 2014; Amended October 9, 2015; Amended December 20, 2019)

#### I. PURPOSE AND APPLICABILITY

- A. The purpose of this policy is to establish a separation process for regular Exempt Staff employees in the University System of Maryland (USM).<sup>1</sup>
- B. Regular USM employees in the following Exempt positions are excluded specifically from sections III and IV of this policy:
  1. Officers: Vice Chancellors, Vice Presidents, Provosts and Academic Deans.
  2. Associate and Assistant Vice Chancellors, Associate and Assistant Vice Presidents, Associate and Assistant Provosts, Associate and Assistant Academic Deans.
  3. Subject to approval of the Chancellor, the President may designate other key executive positions for this exemption. Appointees to such positions shall be notified of such designation at the time of appointment. Current appointees notified of such designation prior to April 1, 2000, were not required to be notified at the time of appointment.

#### II. GENERAL

- A. Employment for regular USM employees in Exempt positions is on an at-will basis. This means that, subject to applicable laws and policies, the employment relationship may be terminated at any time by either the employee or the Institution, consistent with Section III of this policy.
- B. All actions taken under this policy and institutional procedures shall be reviewed by the institution's Chief Human Resources Officer in advance of the action being taken.
- C. An employee who wishes to end their employment with the Institution should give at least 14 calendar days written notice.

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<sup>1</sup>Sections II.A., II.D.2., II.E., and III of this policy do not apply to exempt employees who are represented by an exclusive representative under the collective bargaining law, Title 3 of the State Personnel & Pensions Article of the Maryland Code. Those employees may be terminated only for cause.

**D. Resignation in Lieu of Termination**

1. The President or designee has the discretion to permit, but not require, any employee to resign in lieu of involuntary separation. The institution shall maintain records documenting that the resignation was in lieu of involuntary separation, and the employee generally should be required to execute an appropriate release of legal claims.
2. The President or designee may determine an appropriate period of notice to be provided that serves the best interests of the institution. The length of the period of notice provided is not required to conform to the schedule contained in III.B. below.

**E. Compensation in Lieu of Notice**

In lieu of providing a full period of notice to an employee who is being involuntarily separated, including those permitted to resign in lieu of involuntary separation under section II.D. above, the President or designee may determine that the employee should be separated prior to the end of the notice period. In that case, the employee shall receive alternative compensation to compensate for the loss of salary and benefits that the employee otherwise would have received during the notice period. In consultation with the Office of the Attorney General, the institution will develop an appropriate compensation arrangement for such an employee that complies with applicable laws.

**III. TERMINATION BY PERIOD OF NOTICE**

**A. Determination of Period of Notice**

An employee covered by this section III who is involuntarily separated shall be provided with a defined period of notice.

1. Service for determining length of notice period is based on institutional service rather than USM service and shall include prior institutional service, provided there were no breaks in service longer than three years.
2. An Exempt employee at one USM institution who is offered an Exempt position at another USM institution may, at the discretion of the offering institution, be credited with prior USM service for purposes of calculating the required period of notice upon separation. Any such decision to credit prior service at another USM institution shall be noted in the employee's personnel file at the time of appointment and shall be effective after satisfactory completion of the probation period.

## USM Bylaws, Policies and Procedures of the Board of Regents

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B. Length of Period of Notice. The period of notice shall be as follows:

<b>Years of Institutional Service</b>	<b>Period of Notice</b>
Less than one year	One month
One year but less than four years	Three months
Four years but less than seven years	Six months
Seven years but less than ten years	Nine months
Ten years or more	Twelve months

C. Employee Work Assignments During Period of Notice

During the period of notice, the President or designee may:

1. Continue the employee in his or her regular position; or
2. Assign the employee alternate duties and responsibilities at a level of service of at least 25% of their existing average workload over the past thirty-six months.

D. An employee covered by this section III may grieve the institution's failure to comply with section III, except in situations where the employee has resigned in lieu of termination.

### IV. TERMINATION FOR CAUSE

With the approval of the President or designee, the period of notice or alternative compensation as set forth in section III above is not required if the employee is to be terminated for cause, including without limitation any of the following reasons:

- A. Moral Turpitude
- B. Incompetency or Inefficiency in the Performance of the Employee's Duties, including Failure to Meet Performance Expectations as Documented in a Performance Evaluation and/or Disciplinary Action
- C. Willful Neglect of Duty or Abandonment of Job
- D. Illegal Actions, including Violation of the State Ethics Law
- E. Gross Misconduct or Wantonly Offensive Behavior Toward Fellow Employees, Students, Patients, Clients, Users of University Facilities, or the General Public
- F. Insubordination or Serious Breach of Discipline

## **USM Bylaws, Policies and Procedures of the Board of Regents**

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- G. Serious Breach of Professional Behavior that Reasonably may be Expected to Result in Lower Morale in the Organization or Loss or Injury to the University or Public
- H. Professional or Scholarly Misconduct
- I. Severe Safety Violations or Actions that Cause Significant Damage to Public Property or Waste of Public Resources
- J. Failure to Accept Reassignment
- K. Medical Condition Causing Inability to Perform Essential Job Duties with Reasonable Accommodations Required by Law

### **IMPLEMENTATION PROCEDURES:**

Each President shall identify their designee(s) as appropriate for this policy, develop procedures as necessary to implement this policy, communicate this policy and applicable procedures to their institutional community, and post it on its institutional website.