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To Montgomery County Council Members,

I am writing to update you on AdvaGenix's progress to address the issues raised during the Clinical Laboratory Improvement Amendments (CLIA) inspection last week.

AdvaGenix was notified yesterday by the State of Maryland that the order issued to us and made public last week ordering us to stop our COVID-19 saliva testing contained a mistake and was amended. The order inaccurately stated AdvaGenix's laboratory license was suspended. That is not correct. Our license has not been suspended and there is no basis to do so.

While I am relieved to have the error corrected in the form of a revised order, the mistake did not come without consequences to the County and our residents. This error caused great disruption to the County's testing program. As a result of the error, the County paused testing at its clinics where residents could receive free testing. The error also caused confusion to the public, calling into question test results for more than 17,000 residents.

AdvaGenix is proud to be a small business in Rockville, Maryland operated by residents of Montgomery County, employing hard working staff who also live in the County. When this virus hit our community, we moved quickly to help our neighbors by expanding our lab's capacity and contributing our scientific expertise. In the last two months, we have processed more than 18,000 tests for Montgomery County.

AdvaGenix tests are safe and reliable. Our laboratory processes are of the highest quality, achieving 100% concordance with test results from Rutgers Clinical Genomics Laboratory, a leading academic laboratory, which helped develop the COVID-19 saliva test. Additionally, AdvaGenix was inspected in November 2019 and received its certification.

In May, AdvaGenix received "pre-emergency authorization (EUA)," approval from the Food and Drug Administration (FDA). The lab completed all FDA requirements and official approval to perform molecular diagnostic testing with saliva tests was posted on the agency's website. Pre-EUA approval is a standard practice by the FDA in this public health crisis.

On August 10th, an unscheduled CLIA inspection occurred at AdvaGenix. We passed our most recent CLIA inspection in November 2019. CLIA is a federal program administered by multiple agencies that regulate laboratories.

After two days of working cooperatively with investigators, providing full access to our facilities and data, the inspectors talked with us about additional specimen validation studies that they felt were necessary. We have complied with their requests and will have these additional studies completed shortly.

We have cooperated and done all that has been asked of us at every step, and are continuing to cooperate fully with federal, state, and local authorities to resolve this situation as quickly as possible. Since the inspection last week, AdvaGenix has been working to understand and address inspectors' concerns by:

- Engaging with the state health department to correct and clarify their original order as well as to coordinate notice to impacted patients;
- Working with federal departments of jurisdiction to determine any further information required for CLIA or EUA certification; and,
- Conducting our own in-house temperature stability study. This is currently underway, scheduled to be completed by the end of the week to complement the manufacturer's study and should resolve stated concerns by the state.

We should be fighting the virus, not red tape. We want to serve our neighbors during this time of need. As a small business operating in Montgomery County, we would like to do all we can to keep the residents of Montgomery County safe and healthy.

Respectfully,

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