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| **From:** | Esther Manheimer |
| **To:** | Amanda Edwards; Brownie W. Newman; Jasmine Beach-Ferrara |
| **Subject:** | Fwd: Announcement of Sciteck"s expansion of Covid-19 testing |
| **Date:** | Saturday, April 18, 2020 7:41:35 AM |
| **Attachments:** | WHO antibody point-of-care article 040920.pdf<br>FDA - SCITECK listing - FAQs on Diagnostic Testing for SARS-CoV-2__FDA.....pdf |

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FYI

---------- Forwarded message ---------
From: **Chris Stanton BS CS** <chrisstanton@sciteck.org>
Date: Fri, Apr 17, 2020 at 6:38 PM
Subject: Announcement of Sciteck's expansion of Covid-19 testing
To: Jennifer L. Mullendore <Jennifer.Mullendore@buncombecounty.org>
CC: <mwicker@citizentimes.com>, <news@wlos.com>, <esthermanheimer@avlcouncil.com>, <gwenwisler@avlcouncil.com>, <kerstinlanier@sciteck.org>, <Edwardsla@ncleg.net>

Good Afternoon Dr. Mullendore,

Thank you and your staff for assisting the people of Buncombe County during this hard time. I wanted to inform you that we are expanding our SARS-CoV-2 (COVID-19) testing capabilities (see attached FDA authorization), that I discussed with county health officials by phone and email the other day, to enable Sciteck to perform antibody testing for IgM and IgG antibodies specific to COVID-19.

We will not be using the rapid test kits that are currently being used at drive by collection sites for COVID-19 antibodies and other care facilities. Please note and as stated by the WHO (see attached) the lateral flow assay kits should be for R&D purposes only. As referenced by the WHO and discovered during our research the assay(s) performance are suspect (essentially they do not work) and should only be used for R&D as the WHO suggest.

If theses POC devices have been authorized by Buncombe County for use it would be unfortunate as these POC devices do not meet the CLIA standard for testing. As stated, we have tested these kits numerous times including from a known individual whom had recovered from COVID-19 and none of the POC devices work successfully. And all of the devices used were from FDA EUA cleared COVID-19 antibody POC kits. We will instead will be using ELISA technology to test for the Covid-19 antibodies, which has significantly more sensitivity and specificity and we should have the testing available by Friday of next week once the validations are complete.

I also saw from your previous email that you were curious about our supply chain. Sciteck

Clinical Laboratory has been a Nationally Accredited Clinical Reference laboratory since 2001. Our lab prior to the pandemic was capable of large scale Molecular Diagnostic testing in our state of the art PCR lab for respiratory infections, UTI's, and other pathogenic infections. Due to this, we already have supplies for our in-house assays for up to 12,000 samples per assay run which takes about 1.5 hours. As we had already ordered bulk amounts of items that are needed to do PCR testing, we do not have a shortage on any equipment. Unlike most Nationally Accredited Clinical Reference Labs, Sciteck Clinical has a sister company at its main facility that is an FDA registered facility that manufactures over 100 FDA cleared devices from design to clearance that are distributed worldwide. So many of the reagents that are used for PCR analysis are manufactured right here at our facility. With that said, we are not at this time experiencing any supply chain issues with raw chemicals, nor do we expect any, as we are the supply chain. We understand that the other labs that are not in this area but may be around regionally, like QUEST and LAB CORP, do not manufacture their own kits or reagents and are in fact over extended because they are completely reliant on their supply chain. In fact, it has been reported that just between QUEST and LAB CORP they have over 500,000 samples waiting for testing and the time frame are 3 to 4 from weeks to receive results – these samples might as well just be sent to the State lab. Though according to staff at the state level, due to antiquated instruments they are struggling with only 200 samples a day and have had to establish 24-hour workdays with staggered lab personnel.

Sciteck has been very successful in getting Clemson University, UT Austin, Icahn Mt. Sinai School of Med and the University of Illinois to assist us in developing an Immunoassay assay that will solve the problems of the POC devices that do not work as stated by the WHO - with the help and support of the Science community and the Universities mentioned, Sciteck is developing a methodology that will allow the testing of hundreds of thousands of samples per hour with the specificity and precision for true clinical analysis.

People are dying during this pandemic and time is of the essence. Delaying a test for weeks at a time when it could be done within days is unacceptable. There are reports of people dying and the test results are coming in 3 weeks later. Let us team together and not send out erroneous reports to the local media or public that adequate testing is not readily available, alarming them unnecessarily in this trying time.

Thank you for your time and stay safe,

Chris Stanton BS CS

Certifying Scientist

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