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Dear Client of A2Z Diagnostics,

In keeping our clients informed during this pandemic, we have been closely following all aspects of testing regarding COVID-19 including molecular PCR testing and serology testing.

A2Z Diagnostics continues to offer respiratory and COVID-19 testing as we continue to expand our ability to test several hundred samples daily by utilizing only FDA EUA (emergency use authorization) approved testing and technology.

As you may have recently read the FDA is beginning to carefully scrutinize many (in excess of 200) of the unapproved FDA EUA serology tests that are currently being falsely marketed and advertised. The market was flooded with non-FDA EUA serology testing kits, often manufactured in foreign countries. Many of these tests are unreliable with poor sensitivity, specificity, accuracy, and erratic performance characteristics.

Just yesterday, the FDA announced that all current testing companies promoting their serology platform must go through the accepted EUA FDA approved process to be considered valid.

A2Z will only offer FDA EUA approved serology testing for our clients.

Several studies are possibly demonstrating the superiority of a venipuncture obtained specimen over a fingerstick specimen in terms of increased sensitivity, specificity, and accuracy. Therefore at least initially, we will be offering serology testing of IgM and IgG COVID-19 antibodies via venous sampling.

Currently only high complexity labs such as A2Z Diagnostics are authorized to perform FDA EUA approved serology tests on point of care platforms.

Unless the office or ASC holds a CLIA certificate of compliance or accreditation for high complexity testing for COVID-19 they are not authorized to perform rapid or other serology testing. Specimens originating in an office or ASC can be obtained by the office or ASC and referred to a high complexity lab for testing.

As clients strive to return to the workforce testing protocols for employees and patients will need to be formulated and adopted. If you are interested in our current respiratory and COVID-19 pathogen testing and serology testing, please call the lab and we can review your protocol with you.

Stay safe and thank you for your continued confidence in A2Z during this pandemic.

Regards,

A2Z Diagnostics