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A LETTER FROM THE DESK OF DR. ARIN PIRAMZADIAN

I respect and understand why the Mecklenburg Health Department issued their statement. *They are not wrong*. If clinics do this test without doing proper education while having the correct processes in place, there is inherent risk of giving individuals false assurance and making the spread worse. However, *that is not us*. We do have the processes in place for testing and patient education. We welcome further constructive dialogue with the health department.

POINTS TO ADDRESS RELIABILITY CONCERNS FOR RAPID ANTIBODY TESTS

- These tests have been widely used across the globe.
- The way South Korea accomplished mass testing so quickly was by using a combination of Rapid Serum Antibody testing along with Nasal Swabs and laboratory analysis. We are using the same type of tests that South Korea used. Germany used a similar system as well. South Korea and Germany are global examples of how to flatten the curve.
- None of these tests were approved by the FDA but rather the FDA gave clinics permission to use them under the Emergency Use Act. We speculate that there just haven't been enough studies yet for the FDA to validate them. The FDA is likely working to get individual companies approved, but it takes time - time we don't have.
- We address the potential these tests have for false negatives by creating a clinical protocol whereby patients in early stages of symptomatology and/or high risk patients will still receive a nasal swab and have their specimen sent to the lab.
- The reason we don't swab everyone instead of rapid tests is because the entire United States doesn't have enough swab inventory to do the mass testing that is needed right now, thus we address this by only swabbing recent symptom/high risk individuals.
- Swab testing results have taken as long as 7-10 days to receive results, which are often inconclusive. No tests are perfect.
- We are located in a predominantly underserved area where testing is scant. There are simply no other options.
- We feel strongly that since we are using the proper education, combined with procedures, we are absolutely not creating false sense of hope.
- We hope others can use our combination model of education along with rapid and swab laboratory testing so together we can do mass testing across the United States. We are happy to share our lessons learned with any facility interested (more on this below).
- It is our aim to be a part of the solution, not just an entity that looks at the problem without acting. Not to be political but there a lot of politicians on both sides of the isle not taking action because they are more interested in covering their own butts.
- We invite anyone to take one of our tests and have it independently verified with an outside lab. We are confident the tests we use work as described.
- McKesson, a national medical supplier, is rolling out their Rapid Serum antibody test this week. It is rumored these will have the official FDA stamp of approval. StarMed is scheduled to get the first batch of these tests. As previously mentioned and shown through action, we've been proactive at almost every turn of this pandemic.
- We anticipate that in the coming months, the FDA will approve more rapid tests from companies working hard to be a part of the solution across the globe. We are confident that the tests we have already used will eventually be FDA approved.
- The Abbott test is a fine machine, but from what we've seen it won't be available in the quantity necessary for another few months to do mass testing.
- Although there is a charge for our rapid test at this time, we hope that once insurers recognize this test, we will be able to offer it at no charge (as should the rest of the country).
- The reality is we can either stand back and look at the problem or take action on possible solutions. I expect that we will be second guessed or criticized, but we know in our hearts we are doing the right thing for our patients and our community. I would highly prefer having a constructive dialogue with those that disagree with rapid testing, but too often they are the ones only pointing out all the problems, not offering solutions. We took action and I am confident in three weeks or less everyone will see we were right.
- We are prepared to create an operating procedure manual and/or video to teach other clinics and facilities how to use these serum rapid tests properly and address the very real concerns that the health dept has. It would not surprise us if the government eventually turned to us to help be a solution to this challenge. We warmly welcome that opportunity.
- Last point, we have been sending blood serum of our patients' rapid results off to our lab to validate our tests since the very beginning of our endeavor. I'm not sure what else we can do to be an example for how to do this the right way.

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