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House of Representatives
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April 23, 2020

Mr. John Constantine
President and Chief Executive Officer
ARCpoint Labs Franchise Group, LLC
131 Falls Street, Suite 302
Greenville, SC 29601

Dear Mr. Constantine:

The Subcommittee on Economic and Consumer Policy requests information about ARCpoint Labs' serological antibody tests for SARS-CoV-2. The Subcommittee has concerns about your company's testing program and the information you are communicating to the public and your patients about antibody tests.

Your company's website states that your "simple test provides qualitative (yes/no) results that determine if you may have been exposed to COVID-19 based on your antibodies."[1] This simplistic "yes/no" interpretation overstates the significance of antibody tests, none of which is authorized for clinical diagnosis. According to the Centers for Disease Control and Prevention, "Serologic test results have limitations that make them less than ideal tools for diagnosing people who are sick."[2]

The Subcommittee received a copy of an ARCpoint Labs document titled "Guidelines for COVID-19 Antibody Test Results/Interpretation," which is in an Appendix to this letter. In it, your company claims that a positive result for IgG antibodies "[s]uggests functional immunity" and encourages people to "[d]iscontinue social distancing." When a positive IgG result is paired with a positive IgM result, it suggests there is a "[r]ecent infection."

At this time, scientists do not yet know whether a person with antibodies has immunity, and studies from South Korea and China suggest that antibodies may not offer protection from another infection.[3] In addition, positives for both IgG and IgM antibodies do not rule out an

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[1] ARCPoint Labs, *Coronavirus Antibody Test* (online at www.arcpointlabs.com/covid-19-antibody-testing/) (accessed Apr. 16, 2020).

[2] Centers for Disease Control and Prevention, *Coronavirus Disease 2019: Serology Testing* (online at www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html) (accessed Apr. 17, 2020).

[3] *Coronavirus Antibody Tests Could Help Us Get Back to Normal— Or They Could Be the Next Testing Crisis*, Buzzfeed News (Apr. 16, 2020) (online at www.buzzfeednews.com/article/stephaniemlee/coronavirus-antibody-tests-fda).

active infection that is still contagious. A fact sheet for one serology test that recently received Emergency Use Authorization from the Food and Drug Administration (FDA) states:

> When IgG antibodies are present[,] it[] often indicates a past infection but does not exclude recently infected patients who are still contagious, especially if detected with IgM antibodies. It is unknown how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.[4]

Also, ARCpoint appears to have violated FDA policy prohibiting testing outside of certain certified laboratories. There are reports that ARCpoint Labs offered point-of-care finger-prick tests, despite FDA's requirement that antibody tests be performed at labs certified for high complexity.[5]

For these reasons, the Subcommittee requests responses to the following questions regarding your company's SARS-CoV-2 antibody testing by May 1, 2020:

1. How many point-of-care SARS-CoV-2 antibody tests were performed at ARCpoint Labs?

2. What were the manufacturer, model, and distributor for the SARS-CoV-2 antibody point-of-care tests? Please provide all manufacturer's documentation, including instructions for use, provided with any such tests.

3. Did ARCpoint Labs independently validate the SARS-CoV-2 antibody point-of-care tests?

4. What was the clinical validation data for the SARS-CoV-2 antibody point-of-care tests, including cross-reactivity or analytical specificity, class specificity, and clinical agreement?

5. When did ARCpoint Labs start performing SARS-CoV-2 antibody point-of-care tests, and when did it stop?

6. How many laboratory-performed antibody tests for SARS-CoV-2 have been done by ARCpoint Labs?

7. What are the manufacturer, model, and distributor for the laboratory-performed SARS-CoV-2 antibody tests? Please provide all manufacturer's documentation, including instructions for use, provided with any such tests.

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[4] Food and Drug Administration, *Fact Sheet for Healthcare Providers, qSARS-CoV-2 IgG/IgM Rapid Test--Celllex Inc.* (Apr. 1, 2020) (online at www.fda.gov/media/136623/download).

[5] *13 Investigates Consumer Warning: Health Officials Question Accuracy of Antibody Testing*, WTHR (Apr. 14, 2020) (online at www.wthr.com/article/13-investigates-consumer-warning-health-officials-question-accuracy-antibody-testing).

8. Did ARCpoint Labs, or the laboratories performing the tests, independently validate the laboratory-performed SARS-CoV-2 antibody tests offered by ARCpoint Labs?

9. What laboratories perform SARS-CoV-2 antibody tests for ARCpoint labs?

10. What was the clinical validation data for the laboratory-performed SARS-CoV-2 antibody tests used by ARCpoint Labs, including cross-reactivity or analytical specificity, class specificity, and clinical agreement?

11. When did ARCpoint Labs start offering laboratory-performed SARS-CoV-2 antibody tests?

12. What information has ARCpoint Labs given to its patients with their test results? Please provide a generic copy or template for all documents given to patients at the point of care, during sample collection, or with test results.

13. With respect to the ARCpoint Labs printout in the Appendix below:

    a. Who prepared the printout?
    b. What was the basis of the statements in the printout regarding "functional immunity" and social distancing?
    c. Do you have any scientific studies showing that COVID-19 patients with both IgG and IgM antibodies are not infectious or contagious?
    d. For whom was the printout prepared?
    e. How many patients received the printout?
    f. During what days was this printout in circulation?
    g. Have you issued any correction to the printout?

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member

Appendix: ARCpoint Labs Printout

arcpoint labs
accurate. reliable. confidential testing.

Drug Alcohol DNA Wellness LabTests Background

Guidelines for COVID-19 Antibody Test Results/Interpretation

Antibody tests are an effective way to evaluate immunity. Because our knowledge of COVID-19 immunity is still evolving, the following recommendations are ***conservative*** estimates for patient behavior after testing, and are modeled after SARS-CoV comparison research and H1N1 Antibody distributions. These diseases were used for modeling due to similar pathogenesis and persistent antibodies/immunity status for several years after exposure or vaccination. They are not a guarantee of immunity and these behavioral concepts are only examples, for informational purposes only.

*Please note that all antibody tests should be performed on **completely** asymptomatic individuals – conservatively, at least seven days since last symptom or never symptomatic. If test is performed earlier than that, the clinical reliability may be compromised.*

Negative IgG, Negative IgM (two possibilities):
- Patient has never encountered COVID-19 and is healthy, but susceptible. Continue social distancing protocols.
- Early latent infection – too early for antibody detection. Continue social distancing approx weeks.

Negative IgG, Positive IgM:
- Early stages of antibody response. Possible virus carrier/latent infection. Continue social distancing for approximately 5-7 additional days.

Positive IgG, Positive IgM:
- Recent infection. Suggests functional immunity. Discontinue social distancing.

Positive IgG, Negative IgM:
- Past infection. Suggests functional immunity. Discontinue social distancing.

Per FDA Guidance, test reports resulting from the use of the COVID-19 IgG/IgM Rapid Test Cassette for whole blood, plasma, and serum must bear the information:
- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a mol diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis or diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as HKU1, NL63, OC43, or 229E.
- Not for the screening of donated blood.

ARCpoint Franchise Group, LLC makes no warranties which extend beyond the description contained herein. To the best of our knowledge, the information provided is accurate and reliable, however, we do not assume any liability whatsoever for the accuracy and completeness of the above information. It is the Franchisee's responsibility to consult with their legal counsel and/or professional advisors to ensure compliance with federal and state regulatory requirements.