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IN THE DISTRICT COURT OF DOUGLAS COUNTY, NEBRASKA

STATE OF NEBRASKA, ex rel. DOUGLAS J. PETERSON, ATTORNEY GENERAL, Plaintiff, v. **PIVOT CONCIERGE HEALTH, LLC and BANYAN MEDICAL SYSTEMS, LLC,** Defendants.	Case No: CI 20 - _____ **COMPLAINT**

COMES NOW, the State of Nebraska, ex rel. Douglas J. Peterson, Nebraska Attorney General, by and through the undersigned Assistant Attorney General (hereinafter "Attorney General", "State", or "Plaintiff"), and brings this action against Defendant Pivot Concierge Health, LLC and Defendant Banyan Medical Systems, LLC (hereinafter collectively "Defendants") for violating the Consumer Protection Act, Neb. Rev. Stat. § 59-1601 *et seq.* (hereinafter "Consumer Protection Act") and the Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-301 *et seq.* (hereinafter Uniform Deceptive Trade Practices Act), in connection with the advertising, marketing, distribution, and sale of COVID-19 antibody tests.

INTRODUCTION

1. The Attorney General brings this action pursuant to the Consumer Protection Act and the Uniform Deceptive Trade Practices Act to protect the public and pursuant to his statutory and common law authority, powers, and duties.

2. The Attorney General is responsible for enforcement of the Consumer Protection Act, Uniform Deceptive Trade Practices Act, and other state and federal laws that affect Nebraska consumers. Pursuant to Neb. Rev. Stat. § 59-1608, the Attorney General may bring an action in the name of the State against any person to restrain and prevent the doing of any act prohibited by the Consumer Protection Act.

3. In addition, pursuant to Neb. Rev. Stat. § 87-303.05, the Attorney General may apply for and obtain, in an action in any district court of Nebraska an injunction prohibiting a person from engaging in deceptive trade practices or doing any act in furtherance thereof.

4. The Attorney General has cause to believe that Defendants have violated the Consumer Protection Act and the Uniform Deceptive Trade Practices Act and brings this action in the public interest because Defendants have deceived and misled Nebraska consumers.

PARTIES

5. Plaintiff is the State of Nebraska, ex rel. Nebraska Attorney General Douglas J. Peterson. Pursuant to the Consumer Protection Act and Uniform Deceptive Trade Practices Act, the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the Consumer Protection Act and Uniform Trade Practices Act and secure such equitable and other relief as may be appropriate in each case.

6. Defendant Pivot Concierge Health, LLC (hereinafter "Pivot"), is a Nebraska limited liability company with its principal place of business at 2801 S 88th Street, Omaha, NE 68124. At all times relevant hereto, Pivot engaged in trade or commerce in the state of Nebraska by advertising, marketing, distributing, and selling COVID-19 antibody tests, both within Nebraska and to Nebraska consumers.

7. Defendant Banyan Medical Systems, LLC (hereinafter "Banyan"), is a Nebraska limited liability company with its principal place of business at 8701 F Street, Omaha, NE 68127. At all times relevant hereto, Banyan engaged in trade or commerce in the state of Nebraska by advertising, marketing, distributing, and selling COVID-19 antibody tests, both within Nebraska and to Nebraska consumers.

8. At least one officer of Defendant Banyan maintains ownership interest in Defendant Pivot.

9. Defendants Pivot and Banyan have operated as a common enterprise while engaging in the deceptive acts and practices alleged below. Defendants have conducted the business practices described below, with a common pecuniary interest, through interrelated companies that have common ownership, officers, and business functions. Because Defendants have operated as a common enterprise, they are each jointly and severally liable for the acts and practices alleged below.

JURISDICTION AND VENUE

10. The District Court of Douglas County has jurisdiction over Defendants and the subject matter of this action pursuant to Neb. Rev. Stat. § 59-1608 and Neb. Rev. Stat. § 87-303.05(1) because Defendants have transacted business within the State of Nebraska at all times relevant to this Complaint.

11. Venue for this action properly lies in the District Court of Douglas County pursuant to Neb. Rev. Stat. § 59-1608.01 and Neb. Rev. Stat. § 87-303.05(1) because Defendants have transacted business in Douglas County, Nebraska.

FACTUAL ALLEGATIONS

12. The U.S. Food and Drug Administration (hereinafter "FDA") is responsible for validating and authorizing the safety and effectiveness of drugs and medical devices, such as drug test kits.[1]

13. There is currently a pandemic of respiratory disease caused by a novel coronavirus. The virus has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2) and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19).[2]

14. The harms of the COVID-19 pandemic are made worse by the spread of confusion, misinformation, and the proliferation of consumer scams and frauds regarding this novel coronavirus.

15. In this public health emergency, consumers require—and under Nebraska law are entitled to—accurate, reliable, and truthful information about products and services offered to reduce the spread of, detect, or treat COVID-19.

Background on COVID-19 Testing

16. In response to the COVID-19 pandemic, the FDA has identified two different types of tests that may be administered to consumers who are experiencing COVID-19 symptoms or who otherwise believe they may have had, or been exposed to, the COVID-19 virus: (1) diagnostic tests and (2) antibody tests. [3]

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[1] *What We Do*, About FDA https://www.fda.gov/about-fda/what-we-do#:~:text=FDA%20Mission,and%20products%20that%20emit%20radiation. (last accessed June 16, 2020).

[2] The SARS-CoV-2 virus is referred to throughout this Complaint as either "SARS-CoV-2" or "the COVID-19 virus".

[3] *Coronavirus Testing Basics*, Consumer Updates (May 2020), https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics (last accessed June 10, 2020).

17. Diagnostic tests can show if a person has an active infection of the COVID-19 virus.[4] One type of diagnostic test is called a polymerase chain reaction test (hereinafter "**PCR Test**").

a. A PCR Test looks for the virus's genetic material to determine whether a person has an *active infection* of the COVID-19 virus.

b. PCR Tests are performed using a nose or throat swab.

c. PCR Tests can take up to a week to produce results.

d. PCR Tests do not utilize blood draws or finger pricks.

18. Antibody tests, also referred to as serology tests by the FDA (hereinafter **Antibody Test**"), look for antibodies that are made by the immune system in response to a threat, such as a virus.[5]

a. Antibody Tests are not meant to diagnose or exclude active infection of the COVID-19 virus.

b. Rather, Antibody Tests look for certain antibodies in the blood which, if present, may indicate that a person has been infected with a strain of the coronavirus *in the past*.

c. Positive results of Antibody Tests may be due to past infection with non-SARS-CoV-2 coronavirus strains.

d. At this time, researchers do not know if the presence of antibodies means that a person is immune to the COVID-19 virus in the future.

e. Antibody Tests are performed using a blood sample.

f. Antibody Tests can produce results in the same day.

[4] *Id.*

[5] *Id.*

19. Specifically, the FDA issued guidance (hereinafter, "FDA Guidance")[6] initially published on February 29, 2020, and thereafter updated on March 16, 2020, May 4, 2020, and May 11, 2020.

20. Through its March 16, 2020 FDA Guidance, the FDA modified its pre-existing regulatory requirements to allow market participants, including manufacturers and healthcare providers, to begin distributing and administering non-FDA reviewed Antibody Tests.[7]

21. This regulatory flexibility was "based on the consideration that serology tests are not meant to diagnose active SARS-CoV-2 infection[s]. . . "[8]

22. In fact, the FDA has specifically warned that Antibody Testing should not be used alone without other tests or diagnostics tools:

> Serology tests measure the amount of antibodies or proteins in the blood when the body is responding to a specific infection, like COVID-19. In other words, the test detects the body's immune response to the infection caused by the virus itself. In the early days of an infection when the body's immune response is still building, antibodies may not be detected. This limits the test's effectiveness for diagnosing COVID-19 and why it should not be used as the sole basis to diagnose COVID-19. [9]

23. Nevertheless, the marketplace saw a concerning number of commercial Antibody Tests being promoted inappropriately, "indicating that greater FDA oversight of commercial serology tests is important to protect the public health."[10]

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[6] The FDA Guidance can be found on the FDA webpage entitled "*COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders*" available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, as well as on the FDA webpage entitled *"Search for FDA Guidance Documents"* available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[7] May 11, 2020 FDA Guidance, pg. 7.

[8] *Id.*

[9] Stephen M. Hahn M.D., *Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts*, U.S. Food and Drug Administration, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts (last accessed May 14, 2020).

[10] May 11, 2020 FDA Guidance, pg. 7.

24. The FDA indicated that it did "not intend to object to the development and use of serology tests to identify antibodies to SARS-CoV-2. . . where the test has been validated, notification is provided to FDA, and **information is included in the test reports** as described in subsection D.3 below."[11] Subsection D.3 of the FDA Guidance, entitled "Labeling and Reporting of Results", states:

> In order to provide important information about the intended use of the serology test and its limitations, FDA recommends that instructions for use and **patient test reports include information that helps users and patients understand the test results, such as the following:**
>
> - This test has not been reviewed by the FDA.
> - *Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.*
> - Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection.
> - *Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.* [12]

25. More recently, the Nebraska Department of Health and Human Services issued a Health Advisory on COVID-19 serology testing.[13] The Health Advisory underscores the fact that serology tests have limitations and should not be used at this point to routinely diagnose acute or

[11] May 11, 2020 FDA Guidance, pg. 16 (emphasis added). The same language also appears in the March 16, 2020 version of the FDA Guidance on pg. 15.

[12] May 11, 2020 FDA Guidance, pg. 16-17 (emphasis added). This information is also available on the FDA website, *Serology/Antibody Test FAQ*s, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#serology (last accessed on May 14, 2020).

[13] June 19, 2020, Nebraska Department of Health and Human Services, *Health Alert Network Advisory*, http://dhhs.ne.gov/han%20Documents/ADVISORY06192020.pdf (last accessed June 29, 2020).

prior SARS-CoV-2 infection, nor should they be used in an attempt to establish immune status to SARS-CoV-2.[14]

Defendants' Business Activities

26. Defendant Pivot is a membership-based health clinic that offers primary care and wellness treatments.

27. Defendant Banyan is a business-to-business software company specializing in telemedicine products and services.

28. Defendant Pivot advertised on its website that Pivot Concierge Health Clinic and Banyan Medical Systems "joined forces to open a drive-thru clinic in Omaha."

29. Since at least March 19, 2020, and until at least April 29, 2020, Defendants have advertised, offered for sale, sold, and distributed Antibody Tests, specifically including the CoronaCHEK Covid-19 IgG/IgM Rapid Test (supplied by CLIAwaived, Inc.), at a drive-thru clinic in Omaha, Nebraska.

30. In addition to the Antibody Tests, for an indeterminate amount of time, Defendants also advertised, offered for sale, sold, and distributed PCR Tests, specifically including the Diatherix SARS-CoV-2 Tem-PCR Test (supplied by Diatherix – Eurofins Clinical Labs), at the same drive-thru clinic in Omaha, Nebraska.

31. As of April 29, 2020 Defendants represented on www.COVIDomaha.com that they were shutting down their Omaha drive-thru COVID-19 testing location.

32. It is unclear whether Defendants continued, after April 29, to offer Antibody Testing or PCR Testing at their membership-based private clinic.

[14] *Id.*

33. In April, 2020, Thomas J. Safranek, M.D., Nebraska State Epidemiologist, and Anne O'Keefe, M.D., Douglas County Health Department Senior Epidemiologist, contacted Defendant Pivot's Medical Director, David Bouda, M.D., and expressed concerns regarding Defendants' antibody testing. Specifically, Dr. Safranek and Dr. O'Keefe emphasized that antibody test results lacking proper disclosures pose a significant risk to public health.

34. As detailed below, Defendants' advertisements often failed to: 1) distinguish between the two tests; and 2) disclose the differences between those tests, including the limitations of the Antibody Test.

Advertising Antibody Testing

35. Defendants advertised their Antibody Tests through social media and websites including but not limited to www.COVIDomaha.com, www.banyanmed.com, and www.Pivotch.com. Examples of Defendants' social media promotional posts and statements appearing on Defendants' websites are referenced below as Figures 1, 2, and 3, and attached hereto as Exhibit A.

Figure 1

Figure 2

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Figure 3

36. The advertisement depicted in Figure 1 shows a consumer receiving a finger prick and promotes "same-day" "COVID-19 testing with rapid results".

37. Since it is impossible to administer a PCR Test via a finger prick, and because it would have been impossible at the time for Defendants to deliver PCR Test results on a "rapid" or "same day" schedule, the advertisement in Figure 1 could only be an advertisement for Defendants' Antibody Test.

38. The advertisement depicted in Figure 2 shows a line of cars, presumably at Defendants' drive-thru testing location, along with statements such as "Early detection is key" and "Get your results back in the same day."

39. Since it would have been impossible at the time for Defendants to deliver results of a PCR Test on a "same day" schedule, the advertisement in Figure 2 could only be an advertisement for Defendants' Antibody Test.

40. The advertisement depicted in Figure 3 shows a nasal swab along with statements such as "Same-Day Testing & Results" and "rapid results."

41. Since it would have been impossible at the time for Defendants to deliver PCR Test results on a "rapid" or "same-day" schedule, the advertisement in Figure 3 could only be an advertisement for Defendants' Antibody Test.

42. Yet, none of the advertisements depicted in Figures 1, 2, or 3 include any disclosure informing consumers that Antibody Tests are not meant to diagnose or test for active infections of the COVID-19 virus.

43. The advertisements depicted in Figures 1, 2, and 3 also fail to contain any disclosure regarding the known limitations of Antibody Test results as disseminated by the FDA at the time of these advertisements.

44. Moreover, the advertisement depicted in Figure 2 contains an affirmatively misleading statement when made in the context of an advertisement for an Antibody Test – that "Early detection is the key." This statement is misleading in this context because, by its very nature, an Antibody Test cannot provide "early detection" of the COVID-19 virus.

45. It often takes about a week for symptoms to appear after being infected with the COVID-19 virus, and it can take 1-2 weeks after the first symptoms appear for antibodies to develop in the body. Therefore, it can take anywhere from 2-3 weeks to develop enough antibodies to be detected in an Antibody Test.[15]

[15] *Coronavirus Testing Basics,* Consumer Updates (May 2020), https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics.

46. Thus, the advertisements and promotional materials depicted in Figures 1, 2, and 3 contain misleading and deceptive statements and depictions of material fact by leading consumers to believe that Defendants' Antibody Tests can determine whether he or she has the COVID-19 virus.

Antibody Test Results

47. To get tested at Defendants' drive-thru location, consumers were required to make an appointment by filling out an online form that includes a request for insurance information.

48. Consumers without insurance coverage could receive Defendants' Antibody Test for a fee of $30.

49. At their appointment, consumers would drive up to a tent where they rolled down their window and took part in a telehealth consultation with a physician or nurse who asked about symptoms, travel history, and other information.

50. After the consultation, a worker in gloves and mask would approach the consumer and draw a finger prick of blood for the Antibody Test.

51. After their appointment, consumers would receive their Antibody Test results by email or letter (hereinafter "Test Result Correspondence").

52. Examples of the Test Result Correspondence provided to consumers by Defendants are referenced as Figures 3 and 4, and attached hereto as Exhibits B and C respectively.

COVID-19 Serology Surveillance Strategy, Coronavirus Disease 2019 (COVID-19) (May 17, 2020), https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html

Figure 4

YOU HAVE BEEN TESTED FOR COVID-19 WITH THE CORONACHEK™ COVID-19 RAPID TESTS. YOUR TEST RESULT WAS **NEGATIVE.**

IF YOU ARE ASYMPTOMATIC (NO Symptoms: no fever, no cough, no shortness of breath), SELF-QUARANTINE MAY BE DISCONTINUED. REMEMBER TO:

- WASH HANDS OFTEN WITH SOAP AND WARM WATER FOR AT LEAST 20 SECONDS OR USE HAND SANITIZER AFTER TOUCHING YOUR FACE OR COMMON CONTACT SURFACES
- DON'T TOUCH YOUR MOUTH, NOSE OR EYES, ESPECIALLY WITH UNWASHED HANDS
- AVOID CONTACT WITH OTHERS WHO MAY BE SICK OR ILL
- COVER YOUR MOUTH AND NOSE WITH A TISSUE OR SLEEVE WHEN COUGHING OR SNEEZING. DO NOT COUGH OR SNEEZE INTO YOUR HANDS. ALWAYS WASH YOUR HANDS AFTER COUGHING, SNEEZING OR BLOWING YOUR NOSE.
- CLEAN AND DISINFECT FREQUENTLY TOUCHED SURFACES FREQUENTLY IN YOUR HOME, CAR AND WORKPLACE
- AVOID TRAVEL AND ALWAYS FOLLOW CDC GUIDELINES
- CONTACT US AT PIVOT OR YOUR PRIMARY CARE PHYICIAN IF YOUR RESPIRATORY SYMPTOMS WORSEN

IF YOU HAVE SYMPTOMS AND ARE NEGATIVE, YOU MAY DISCONTINUE HOME QUARANTINE; **HOWEVER**, YOU MAY HAVE ANOTHER RESPIRATORY PATHOGEN THAT IS CIRCULATING IN THE COMMUNITY. AVOID SCHOOL, WORK, AND GROUP SETTINGS UNTIL TWO DAYS FOLLOWING THE LAST DAY OF YOUR RESPIRATORY SYMPTOMS AND/OR FEVER.

CONTINUE TO:

- WASH HANDS OFTEN WITH SOAP AND WARM WATER FOR AT LEAST 20 SECONDS OR USE HAND SANITIZER AFTER TOUCHING YOUR FACE OR COMMON CONTACT SURFACES
- DON'T TOUCH YOUR MOUTH, NOSE OR EYES, ESPECIALLY WITH UNWASHED HANDS
- AVOID CONTACT WITH OTHERS WHO MAY BE SICK OR ILL
- COVER YOUR MOUTH AND NOSE WITH A TISSUE OR SLEEVE WHEN COUGHING OR SNEEZING. DO NOT COUGH OR SNEEZE INTO YOUR HANDS. ALWAYS WASH YOUR HANDS AFTER COUGHING, SNEEZING OR BLOWING YOUR NOSE.
- CLEAN AND DISINFECT FREQUENTLY TOUCHED SURFACES FREQUENTLY IN YOUR HOME, CAR AND WORKPLACE
- AVOID TRAVEL AND ALWAYS FOLLOW CDC GUIDELINES
- CONTACT US AT PIVOT OR YOUR PRIMARY CARE PHYICIAN IF YOUR RESPIRATORY SYMPTOMS WORSEN

RESOURCE:

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html

Figure 5

From: Info Pivot <info@pivotch.com>
Sent: Wednesday, April 29, 2020 3:06 PM
To: [redacted]
Subject: COVID-19 Screening Results

PIVOT Concierge Health Team performed a COVID-19 Rapid Screening at the COVID Omaha Drive Up Clinic. Your COVID-19 Rapid Screening results were:

NEGATIVE.

This means there are no IgG/IgM antibodies present.

Please review the information below on what those results mean.

- Continue infection prevention per CDC guidelines.
- Use social distancing, cover your mouth and nose with a cloth, or a face-cover when around others, continue to avoid contact with sick individuals, use frequent hand washing, avoid touching your face, and frequently clean and disinfect high touch surfaces.
- Should you develop any possible Covid-19 symptoms. We advise that you repeat the screening or seek the advice of your provider.
- If you have additional questions about your screening results you can reach us at **(402) 885-8125**

Should you have any additional questions, please visit www.pivotch.com [pivotch.com]

Find more at CDC "How to protect yourself and others" https://www.cdc.gov/coron [cdc.gov] avirus/2019-ncov/preventgetting-sick/prevention.html

[pivotch.com]

www.pivotch.com [pivotch.com]

53. The Test Result Correspondence referenced in Figures 4 and 5 do not include any of the information that the FDA recommends be included in patient Antibody Test reports. Specifically, the Test Result Correspondence referenced in Figures 4 and 5 do not inform consumers that:

a. The Antibody Test administered by Defendants has not been reviewed by the FDA;

b. Negative results of Defendants' Antibody Test do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary;

c. Results from Defendants' Antibody Tests should not be used to diagnose or exclude acute SARSCoV-2 infection; or

d. Positive results of Defendants' Antibody Test may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

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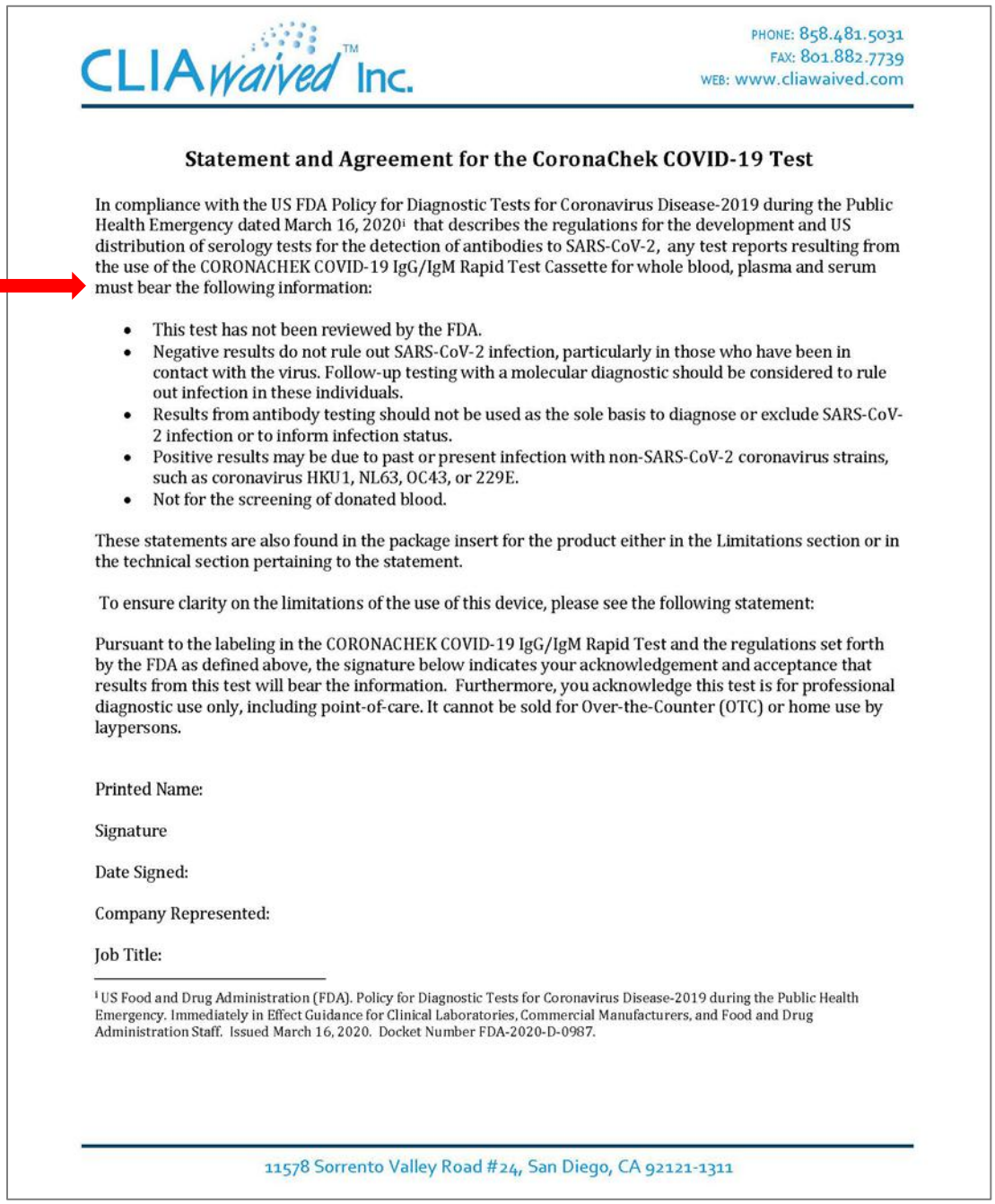
54. Defendants failed to include the above information, or any similar information, in their Test Result Correspondence, despite the supplier of the CoronaCHEK Covid-19 IgG/IgM Rapid Test explicitly directing Defendants to do so.



CLIAwaived™ Inc.

PHONE: 858.481.5031
FAX: 801.882.7739
WEB: www.cliawaived.com

Statement and Agreement for the CoronaChek COVID-19 Test

In compliance with the US FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency dated March 16, 2020[i] that describes the regulations for the development and US distribution of serology tests for the detection of antibodies to SARS-CoV-2, any test reports resulting from the use of the CORONACHEK COVID-19 IgG/IgM Rapid Test Cassette for whole blood, plasma and serum must bear the following 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 molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to 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 coronavirus HKU1, NL63, OC43, or 229E.
- Not for the screening of donated blood.

These statements are also found in the package insert for the product either in the Limitations section or in the technical section pertaining to the statement.

To ensure clarity on the limitations of the use of this device, please see the following statement:

Pursuant to the labeling in the CORONACHEK COVID-19 IgG/IgM Rapid Test and the regulations set forth by the FDA as defined above, the signature below indicates your acknowledgement and acceptance that results from this test will bear the information. Furthermore, you acknowledge this test is for professional diagnostic use only, including point-of-care. It cannot be sold for Over-the-Counter (OTC) or home use by laypersons.

Printed Name:

Signature

Date Signed:

Company Represented:

Job Title:

[i] US Food and Drug Administration (FDA). Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff. Issued March 16, 2020. Docket Number FDA-2020-D-0987.

11578 Sorrento Valley Road #24, San Diego, CA 92121-1311

55. Defendants received the above "Statement and Agreement for the CoronaChek COVID-19 Test" acknowledgment.

56. The Test Result Correspondence referenced in Figure 4, contains statements that mislead and confuse consumers by overstating the conclusions that can be drawn from a negative Antibody Test result. For example, the top of Figure 4 states: "IF YOU ARE ASYMPTOMATIC (NO Symptoms: no fever; no cough; no shortness of breath), SELF-QUARANTINE MAY BE DISCONTINUED."

57. This statement can only leave the consumer with the impression that a negative Antibody Test result means he or she does not, and could not, have an active infection of the COVID-19 virus.

58. As the FDA statements cited in Paragraphs 22 and 24 indicate, this is simply not true.

CAUSE OF ACTION I
VIOLATIONS OF THE CONSUMER PROTECTION ACT, NEB. REV. STAT. § 59-1601 *ET SEQ.*

59. The State re-alleges and incorporates by reference all of the factual allegations contained in the preceding paragraphs, as though fully set forth herein.

60. Defendants are "persons" within the meaning of the Consumer Protection Act, Neb. Rev. Stat. § 59-1601(1).

61. Defendants conduct "trade" or "commerce" within the meaning of the Consumer Protection Act, Neb. Rev. Stat. § 59-1601(2).

62. The Consumer Protection Act, Neb. Rev. Stat. § 59-1602, prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

63. An act or practice is deceptive or unfair if it possesses the tendency or capacity to mislead, or creates the likelihood of deception.

64. Defendants engaged in unfair and deceptive acts or practices in the conduct of trade or commerce, in violation of Neb. Rev. Stat. § 59-1602 by, without limitation:

a. Advertising their Antibody Tests in a manner that creates a likelihood of confusion or misunderstanding as to the characteristics, uses, benefits and limitations of Defendants' Antibody Tests;

b. Distributing Test Result Correspondence in a manner that creates a likelihood of confusion or misunderstanding as to the characteristics, uses, benefits and limitations of Defendants' Antibody Tests;

c. Failing to comply with the FDA Guidance issued on March 16, 2020, specifically the FDA recommendation that all Antibody Test results be accompanied with the disclosures identified in Paragraph 24;

d. Representing, expressly or by implication, that Defendants' Antibody Tests have characteristics, uses, and benefits that they do not have, including that such tests have the ability to diagnose or exclude acute infections of the COVID-19 virus.

65. Defendants' representations and omissions were material and are deceptive within the meaning of the Consumer Protection Act because they had the capacity to mislead a substantial number of consumers.

66. Defendants acquired insurance and fee payments from consumers as a result of their illegal conduct, causing those consumers to suffer an ascertainable loss.

67. Each and every false or misleading representation or omission by Defendants constitutes a separate violation of the Consumer Protection Act.

CAUSE OF ACTION II
VIOLATIONS OF THE UNIFORM DECEPTIVE TRADE PRACTICES ACT, NEB. REV. STAT. § 87-301 *ET SEQ.*

68. The State re-alleges and incorporates by reference all of the factual allegations contained in the preceding paragraphs, as though fully set forth herein.

69. The Uniform Deceptive Trade Practice Act specifies multiple practices, which, when conducted in the course of business may constitute a deceptive trade practice.

70. Specifically, Neb. Rev. Stat. § 87-302 prohibits the following business activities as deceptive trade practices:

a. Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services (§ 87-302(a)(2));

b. Representing that goods or services have characteristics, uses, or benefits that they do not have (§ 87-302(a)(5)); and

c. Representing that goods or services are of a particular standard, quality, or grade, if they are of another (§ 87-302(a)(8)).

71. Defendants are "persons" within the meaning of the Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-301.

72. Defendants engaged in deceptive acts or practices in the conduct of its business, in violation of Neb. Rev. Stat. § 87-302 by, without limitation:

a. Making misrepresentations expressly or by implication, regarding the characteristics, uses and benefits of Defendants' Antibody Tests in advertisements disseminated to consumers, in violation of Neb. Rev. Stat. § 87-302(a)(5);

b. Making misrepresentations expressly or by implication, regarding the standard, quality, or grade of Defendants' Antibody Tests in advertisements disseminated to consumers, including that such tests have the ability to diagnose or exclude acute infections of the COVID-19 virus, violation of Neb. Rev. Stat. § 87-302(a)(8);

c. Making misrepresentations expressly or by implication, regarding the characteristics, uses and benefits of Defendants' Antibody Tests in Test Result Correspondence disseminated to consumers, in violation of Neb. Rev. Stat. § 87-302(a)(5);

d. Making misrepresentations, expressly or by implication, regarding the standard, quality or grade of Defendants' Antibody Tests in Test Result Correspondence disseminated to consumers, including that such tests have the ability to diagnose or exclude acute infections of the COVID-19 virus, in violation of Neb. Rev. Stat. § 87-302(a)(8);

e. Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of Defendants' Antibody Tests in advertising disseminated to consumers, by specifically failing to note that such tests are not FDA approved, in violation of Neb. Rev. Stat. § 87-302(a)(2);

f. Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of Defendants' Antibody Tests in Test Result Correspondence delivered to consumers, by failing to include in such test results the disclosure that "This test has not been reviewed by the FDA," in violation of Neb. Rev. Stat. § 87-302(a)(2).

73. As described above and without limitation, Defendants' actions had the tendency or capacity to deceive or mislead consumers, and therefore constitute deceptive trade practices in violation of Neb. Rev. Stat. § 87-302.

74. Defendants acquired insurance and fee payments from consumers as a result of their illegal conduct, causing those consumers to suffer an ascertainable loss.

75. Each and every misrepresentation, failure to disclose information, or instance in which Defendant created confusion or misunderstanding, constitutes a separate and independent violation of the Uniform Deceptive Trade Practices Act.

PRAYER FOR RELIEF

WHEREFORE, the State respectfully requests this Court:

A. Permanently enjoin and restrain Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with Defendants, from engaging in unfair or deceptive acts or practices, in violation of the Consumer Protection Act and the Uniform Deceptive Trade Practices Act, in connection with the advertising, marketing, distribution, and sale of Antibody Tests, pursuant to Neb. Rev. Stat. §§ 59-1608 and 87-303.05;

B. Permanently enjoin and restrain Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with Defendants, from violating the Consumer Protection Act and Uniform Deceptive Trade Practices Act, and any amendments thereto, pursuant to Neb. Rev. Stat. §§ 59-1608 and 87-303.05;

C. Order Defendants to pay civil penalties for each violation of the Consumer Protection Act and Uniform Deceptive Trade Practices Act pursuant to Neb. Rev. Stat. §§ 59-1614 and 87-303.11, respectively;

D. Grant such relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the CPA, including but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies;

E. Order Defendants to restore to every person any money acquired by Defendants' as a result of their violations of the Consumer Protection Act and Uniform Deceptive Trade Practices Act, pursuant to Neb. Rev. Stat. §§ 59-1608(2) and 87-303.05(1);

F. Order Defendants to pay the State's costs and attorney fees in this matter, pursuant to Neb. Rev. Stat. §§ 59-1608 and 87-303(b); and

G. Grant such further relief as the Court may deem just and equitable.

Respectfully submitted this 7th day of July, 2020.

BY: Douglas J. Peterson, #18146
Attorney General of Nebraska

BY: */s/ Michaela J. Lutz*
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Counsel for Plaintiff

EXHIBIT A
(Figs. 1-3)

PLAINTIFF'S EXHIBIT A

EXHIBIT B
(Fig. 4)

YOU HAVE BEEN TESTED FOR COVID-19 WITH THE CORONACHEK™ COVID-19 RAPID TESTS. YOUR TEST RESULT WAS **NEGATIVE.**

IF YOU ARE ASYMPTOMATIC (NO Symptoms: no fever, no cough, no shortness of breath), SELF-QUARANTINE MAY BE DISCONTINUED. REMEMBER TO:

- WASH HANDS OFTEN WITH SOAP AND WARM WATER FOR AT LEAST 20 SECONDS OR USE HAND SANITIZER AFTER TOUCHING YOUR FACE OR COMMON CONTACT SURFACES
- DON'T TOUCH YOUR MOUTH, NOSE OR EYES, ESPECIALLY WITH UNWASHED HANDS
- AVOID CONTACT WITH OTHERS WHO MAY BE SICK OR ILL
- COVER YOUR MOUTH AND NOSE WITH A TISSUE OR SLEEVE WHEN COUGHING OR SNEEZING. DO NOT COUGH OR SNEEZE INTO YOUR HANDS. ALWAYS WASH YOUR HANDS AFTER COUGHING, SNEEZING OR BLOWING YOUR NOSE.
- CLEAN AND DISINFECT FREQUENTLY TOUCHED SURFACES FREQUENTLY IN YOUR HOME, CAR AND WORKPLACE
- AVOID TRAVEL AND ALWAYS FOLLOW CDC GUIDELINES
- CONTACT US AT PIVOT OR YOUR PRIMARY CARE PHYICIAN IF YOUR RESPIRATORY SYMPTOMS WORSEN

IF YOU HAVE SYMPTOMS AND ARE NEGATIVE, YOU MAY DISCONTINUE HOME QUARANTINE; **HOWEVER**, YOU MAY HAVE ANOTHER RESPIRATORY PATHOGEN THAT IS CIRCULATING IN THE COMMUNITY. AVOID SCHOOL, WORK, AND GROUP SETTINGS UNTIL TWO DAYS FOLLOWING THE LAST DAY OF YOUR RESPIRATORY SYMPTOMS AND/OR FEVER.

CONTINUE TO:

- WASH HANDS OFTEN WITH SOAP AND WARM WATER FOR AT LEAST 20 SECONDS OR USE HAND SANITIZER AFTER TOUCHING YOUR FACE OR COMMON CONTACT SURFACES
- DON'T TOUCH YOUR MOUTH, NOSE OR EYES, ESPECIALLY WITH UNWASHED HANDS
- AVOID CONTACT WITH OTHERS WHO MAY BE SICK OR ILL
- COVER YOUR MOUTH AND NOSE WITH A TISSUE OR SLEEVE WHEN COUGHING OR SNEEZING. DO NOT COUGH OR SNEEZE INTO YOUR HANDS. ALWAYS WASH YOUR HANDS AFTER COUGHING, SNEEZING OR BLOWING YOUR NOSE.
- CLEAN AND DISINFECT FREQUENTLY TOUCHED SURFACES FREQUENTLY IN YOUR HOME, CAR AND WORKPLACE
- AVOID TRAVEL AND ALWAYS FOLLOW CDC GUIDELINES
- CONTACT US AT PIVOT OR YOUR PRIMARY CARE PHYICIAN IF YOUR RESPIRATORY SYMPTOMS WORSEN

RESOURCE:

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html

EXHIBIT C
(Fig. 5)

From: Info Pivot <info@pivotch.com>
Sent: Wednesday, April 29, 2020 3:06 PM
To: [redacted]
Subject: COVID-19 Screening Results

PIVOT Concierge Health Team performed a COVID-19 Rapid Screening at the COVID Omaha Drive Up Clinic. Your COVID-19 Rapid Screening results were:

NEGATIVE.

This means there are no IgG/IgM antibodies present.

Please review the information below on what those results mean.

- Continue infection prevention per CDC guidelines.

- Use social distancing, cover your mouth and nose with a cloth, or a face-cover when around others, continue to avoid contact with sick individuals, use frequent hand washing, avoid touching your face, and frequently clean and disinfect high touch surfaces.

- Should you develop any possible Covid-19 symptoms. We advise that you repeat the screening or seek the advice of your provider.

- If you have additional questions about your screening results you can reach us at **(402) 885-8125**

  Should you have any additional questions, please visit www.pivotch.com [pivotch.com]

  Find more at CDC "How to protect yourself and others" https://www.cdc.gov/coron [cdc.gov] avirus/2019-ncov/preventgetting-sick/prevention.html

[pivotch.com]

www.pivotch.com [pivotch.com]

PLAINTIFF'S EXHIBIT C