CAROLYN B. MALONEY
CHAIRWOMAN

ONE HUNDRED SIXTEENTH CONGRESS

JIM JORDAN, OHIO
RANKING MINORITY MEMBER

Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND REFORM
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WASHINGTON, DC 20515–6143
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http://oversight.house.gov

April 28, 2020

Dr. Frank Wang
Chief Executive Officer
BioMedomics, Inc.
6 Davis Drive
Durham, NC 27709-0003

Dear Dr. Wang:

The Subcommittee on Economic and Consumer Policy is requesting documents and information regarding BioMedomics' serological antibody test, the COVID-19 IgM/IgG Rapid Test, which your website says is available in the United States for "testing in laboratories or by healthcare workers at the point-of-care."[1]

The Subcommittee is investigating the adequacy of regulation by the Food and Drug Administration (FDA) of serological tests for antibodies to the novel coronavirus SARS-CoV-2. The Subcommittee is concerned that FDA is not conducting substantive review of serological tests that it has allowed on the market and that those tests may not meet a reasonable standard of accuracy.[2]

Under Section IV.D of FDA's March 16, 2020, policy, also known as "Pathway D," manufacturers are allowed to distribute coronavirus serology tests "where the test has been validated, notification is provided to FDA, and information" regarding the lack of FDA review and limitations of serological testing results is provided to patients with their test results. In the alternative, manufacturers of serological tests can submit their test kit and testing protocols for FDA review in an application for Emergency Use Authorization (EUA).[3]

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[1] *COVID-19 IgM/IgG Rapid Test*, BioMedomics (online at www.biomedomics.com/products/infectious-disease/covid-19-rt/).

[2] Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Preliminary Findings of the Subcommittee's Coronavirus Antibody Testing Investigation* (Apr. 24, 2020) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/ECP%20Staff%20Report%20on%20Preliminary%20Findings%20of%20the%20Subcommittee%E2%80%99s%20Coronavirus%20Antibody%20Testing%20Investigation.pdf).

[3] Food and Drug Administration, *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* (Mar. 16, 2020) (online at www.fda.gov/media/135659/download).

BioMedomics' test is listed among the 150 tests currently identified on FDA's website as being marketed under Pathway D.[4]

The Subcommittee has concerns about the reliability of your company's tests. A study conducted by researchers at University of California San Francisco, University of California Berkeley, Chan Zuckerberg Biohub, and Innovative Genomics Institute evaluated the performance of a dozen commercially available antibody tests, including BioMedomics' test.[5] In this evaluation, BioMedomics' test did not meet the performance standards BioMedomics claimed in the test's instructions for use. BioMedomics appears to have tested for cross-reactivity for only a limited number of infections, and you did not test for cross-reactivity with the coronaviruses that cause the common cold.[6] Testing for cross-reactivity is essential to ensuring that the test does not register positive results for other infections.

A comparison of the researchers' performance results to the performance results claimed in BioMedomics' instructions for use reveals stark differences:[7]

	UCSF/UCB Study			**BioMedomics Instructions for Use**		
	# specimens	# positive results	% clinical agreement	# specimens	# positive results	% clinical agreement
Confirmed Positives (sensitivity)	128	83	**64.84%**	397	352	**88.66%**
Confirmed Negatives (specificity)	107	14	**86.92%**	128	12	**90.63%**
Cross-reactivity testing	52	11	**78.85%**	--	--	--

The discrepancies in these performance characteristics are deeply troubling. The researchers report a much higher risk of false negatives from this test. Though BioMedomics claims that its test has a sensitivity of 88.66%, the researchers observed a drastically lower sensitivity of 64.84%. This means that there is a high risk that BioMedomics' test will produce a

[4] Food and Drug Administration, *FAQs on Diagnostic Testing for SARS-CoV-2* (online at www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2) (accessed Apr. 28, 2020).

[5] COVID-19 Testing Project, *Homepage* (online at https://covidtestingproject.org) (accessed on Apr. 28, 2020).

[6] *Covid-19 IgM-IgG Rapid Test: Instructions for Use*, BioMedomics, Inc. (online at www.biomedomics.com/?fldl=3070) (accessed on Apr. 28, 2020).

[7] Dr. Jeffrey D. Whitman et al., *Test Performance Evaluation of SARS-CoV-2 Serological Assays*, Pre-Publication Manuscript (Apr. 24, 2020) (online at www.dropbox.com/s/cd1628cau09288a/SARS-CoV-2_Serology_Manuscript.pdf?dl=0).

negative result for an individual who has actually been infected with SARS-CoV-2. Similarly, BioMedomics claims for its test's specificity—essentially, the risk of false positives—were not reproduced by the researchers. While BioMedomics claims its test has a specificity of 90.63%, which is troubling by itself, the researchers observed an even lower specificity of 86.82%.[8]

For these reasons, please produce the following documents and information regarding your company's coronavirus serology test by May 11, 2020:

1. All communications with FDA referring or relating to marketing BioMedomics' test under Section IV.D of the FDA's March 16 policy, including the notice to FDA, confirmation from FDA, and any related exchanges;

2. All communications with FDA regarding an EUA for BioMedomics' test, including any formal EUA submission and preliminary discussions;

3. All validation data for BioMedomics' test, including results of all testing for sensitivity broken down by days since onset of symptoms, specificity, and cross-reactivity, broken down by non-SARS-CoV-2 infections, as well as related processes and procedures concerning specimen sourcing, variations in test procedure, and standards for interpretation of results;

4. All documents prepared for or provided to distributors or end users of BioMedomics' test, including brochures, test packaging, package inserts, instructions for use, and fact sheets; and

5. A list of all recipients of BioMedomics' test, including number of test kits ordered or delivered.

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. An attachment to this letter provides additional instructions for responding to the Committee's request. 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

Enclosure

cc: The Honorable Michael Cloud, Ranking Member

[8] *Id.*

Responding to Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committees.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committees' preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committees should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committees should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committees' letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee on Oversight and Reform, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building. When documents are produced to the Committee on Financial Services, production sets shall be delivered to the Majority Staff in Room 2129 of the Rayburn House Office Building and the Minority Staff in Room 4340 of the O'Neill House Office Building. When documents are produced to the Permanent Select Committee on Intelligence, production sets shall be delivered to Majority and Minority Staff in Room HVC-304 of the Capital Visitor Center.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a

part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term "including" shall be construed broadly to mean "including, but not limited to."

5. The term "Company" means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term "identify," when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; (b) the individual's business or personal address and phone number; and (c) any and all known aliases.

7. The term "related to" or "referring or relating to," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term "employee" means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term "individual" means all natural persons and all persons or entities acting on their behalf.