

**UNITED STATES OF AMERICA**  
**Before the**  
**SECURITIES AND EXCHANGE COMMISSION**

**ADMINISTRATIVE PROCEEDING**  
**File No. 3-19788**

<p><b>In the Matter of</b> <b>DECISION DIAGNOSTICS CORP.</b></p>
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**INFORMATION BEFORE THE COMMISSION**  
**AT THE TIME OF THE TRADING SUSPENSION**

Pursuant to the Commission’s Order Requesting Additional Written Submissions (“the Order”), the Division of Enforcement (“Division”) has attached the Declaration of Carlisle E. Perkins dated May 20, 2020, setting forth the substantive facts before the Commission at the time it issued an order suspending trading in the securities of Decision Diagnostics Corp. on April 23, 2020. Pursuant to footnote 6 of the Order, the Declaration does not disclose privileged analysis or sensitive information about the staff’s investigative methods. The Division additionally is not filing information that if disclosed would otherwise violate applicable federal law or regulations.

Respectfully submitted,  
DIVISION OF ENFORCEMENT  
By its attorneys,

\_\_\_\_\_  
/s/ David Misler  
David Misler, Trial Counsel  
Carlisle Perkins, Senior Counsel  
Lesley Atkins, Senior Counsel  
Securities and Exchange Commission  
Division of Enforcement  
100 F Street, N.E.  
Washington, D.C. 20549-5041

Dated: May 20, 2020

**CERTIFICATE OF SERVICE**

Pursuant to Commission Rule of Practice 151, I hereby certify that true copies of the Division of Enforcement’s Notice of Information Before the Commission at the time of the Trading Suspension were served on the following on this 20<sup>th</sup> day of May, 2020, in the manner indicated below:<sup>1</sup>

**By Email:**

Office of the Secretary  
Securities and Exchange Commission  
100 F Street, N.E.  
Washington, D.C. 20549-2557  
apfilings@sec.gov

Decision Diagnostics Corp.  
c/o Keith Berman, Chief Executive Officer  
kberman@decisiondiagnostics.net

Ronald S. Herzog  
Goldberg Segalla LLP  
50 Main Street, Suite 425  
White Plains, New York 10606  
rherzog@goldbergsegalla.com  
*Counsel for Decision Diagnostics Corp.*

        /s/ David Misler          
David Misler

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<sup>1</sup> Pursuant to the Commission’s Order, dated March 18, 2020, concerning electronic service of papers, service is being made upon the Office of the Secretary via email. In addition, the Petitioner and its counsel agreed to waive paper service of opinions and orders, and accept service by email delivery.

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**DECLARATION OF CARLISLE E. PERKINS**

I, Carlisle E. Perkins, declare pursuant to 28 U.S.C. § 1746 as follows:

1. I am a Senior Counsel with the United States Securities and Exchange Commission (“Commission”) and have been employed by the Commission as an attorney since 1995 in the Washington, DC Home Office.

2. I submit this Declaration in compliance with the Commission’s May 13, 2020 Order Requesting Additional Written Submissions (“the Order”) ordering that the Division of Enforcement (“Division”) file all information that was before the Commission as of April 23, 2020, the date the Commission ordered a suspension of trading in the securities of Decision Diagnostics Corp. (“DECN”).

3. Pursuant to footnote 6 of the Order, the Declaration does not disclose privileged analysis or sensitive information about the staff’s investigative methods. The Division additionally is not filing information that if disclosed would otherwise violate applicable federal law or regulations.

## Information Before the Commission

### **I. Background**

4. DECN has CIK No. 0001144225 and is a Nevada corporation incorporated in 2001 with its principal executive offices in Westlake Village, California.

5. Keith M. Berman (“Berman”) serves as DECN’s chief executive officer, chief financial officer and sole Director. Berman is solely responsible for issuing press releases for the company, which are not reviewed by anyone.

6. Berman was the CEO of a company called Access HealthNet until 1995 when he was fired amid reports of unexpected losses and an infusion of cash from directors and others. Berman, who was described in the complaint as “cavalier about everything,” was a named defendant in a class action securities fraud case brought on behalf of investors, which appears to have settled in 1999. Allegations in the complaint included misleading information in the company’s financial statements as well as false press releases which Berman had overseen. (*See Kalmus, et al. v. Wertz et al.* No. SACV-96-1250-GLT).

7. The company describes itself as a prescription and non-prescription diagnostics and home testing products distributor, and a manufacturer of glucose test strips. It also manufactures a “diabetes test strip” named the “GenUltimate!” and has four subsidiaries, including Pharma Tech Solutions, Inc. DECN also has a Korean partner named The Bio Co., Ltd.

8. DECN’s common stock is not registered with the Commission and is quoted on OTC Link (previously “Pink Sheets”) operated by OTC Markets Group Inc.

9. DECN filed a Form 15 in 2016 suspending its duty to make filings with the Commission. DECN continues to submit financial statements with OTC Markets, but the financial statements are unaudited.

10. As of April 21, 2020, DECN had 13 market makers. As of April 21, 2020, DECN's common stock was eligible for the "piggy back" exception of the Securities Exchange Act of 1934 ("Exchange Act"), Rule 15c2-11(f)(3).

11. According to DECN's most recent annual financial statements, submitted to OTC Markets on March 30, 2020, DECN reported cash of approximately \$50,000, total assets of approximately \$5.1 million (the majority of which is the reported value of certain intellectual property), and revenues of approximately \$528,000. Additionally the company reported, total liabilities of approximately \$2.9 million and an accumulated deficit of approximately \$47.6 million since its inception. The company's annual report for 2019, as well as prior quarterly reports, includes a going concern statement questioning whether it could continue as a financially solvent company.

## **II. DECN Disseminated False and Misleading Information in Press Releases**

12. In January and February 2020, DECN issued three press releases concerning its diabetes glucose test kits, and just weeks later issued a press release announcing its entry into the screening and testing for COVID-19 by using its "innovative impedance technology" first used for diabetes.

13. Between March 3, 2020 and April 7, 2020, DECN issued eleven press releases claiming to have "technology perfected" to allow it to manufacture and sell a "revolutionary" COVID-19 test kit that would provide results "in 15 seconds based on a small finger prick blood sample."

14. On March 3, 2020, DECN began to issue a series of apparently false and misleading press releases concerning the company’s development and sale of COVID-19 rapid test kits. On March 3, 2020, DECN announced its “new screening methodology” for COVID-19 stating that the product was “timely, simple to use, cost effective” and that it would be “commercial [sic] ready in the summer of 2020.” Berman stated that DECN had the “technology perfected” for the COVID-19 tests and that the product would be “field tested” in Korea. Berman also noted that, while the COVID-19 tests would be initially available to medical professionals, once production increased the test would be sold for home use.

15. The following week, on March 11, 2020, DECN issued a press release stating that it expected to sell 420 million COVID-19 test kits in the first year of production, beginning September 2020. The press release included this apparently baseless forecast chart:

GenViro! 12-Month Forecast

Number of Months	1	2	3	4	5	6	7	8	9	10	11	12	SUM
Year 1	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	
New Facility Customers	0	0	0	0	0	5000	5000	5000	5000	5000	5000	5000	
Retained Facilities	0	0	0	0	0	0	5000	10000	15000	20000	25000	30000	
Total Facility Customers	0	0	0	0	0	5000	10000	15000	20000	25000	30000	35000	35,000
Kits Consumed	0	0	0	0	0	15,000,000	30,000,000	45,000,000	60,000,000	75,000,000	90,000,000	105,000,000	420,000,000

16. Berman asserted, without providing supporting evidence, that DECN’s COVID-19 test kits should “allow 80% of the suspected carriers of Coronavirus to exit the quarantine system in places where Coronavirus is rampant.” The press release included a picture of DECN’s purported COVID-19 test kit. The kit for the purported COVID-19 test looks identical to the company’s diabetes glucose test kit – marketed “4Pets” listed on its website.



\*Not yet available for sale in U.S.A. or Puerto Rico

17. In a press release dated March 16, 2020, DECN stated that its COVID-19 test kit could produce results “through a finger-stick” in “less than one minute.” The company also stated that it was waiting for COVID-19 blood samples so that DECN could complete its testing and file an “Emergency Waiver” with the FDA. DECN further claimed that its “plan is designed to bring at least 100,000 of our kits to market in the USA and Canada, and another 100,000 in Europe during the month of May 2020.” DECN also increased its forecast to 480 million test kits sold in its first full year of production.

18. In a press release the following day, March 17, 2020, DECN announced that it anticipated selling 525 million COVID-19 test kits in its first full year of production. The press release included another image of the company’s purported COVID-19 test kit. The release included an updated forecast chart reflecting 21 million in sales in September 2020 alone:

Revised GenViro! 12-Month Forecast

Number of Months	1	2	3	4	5	6	7	8	9	10	11	12	SUM
Year 1	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	
New Facility Customers	0	0	0	0	0	6000	6000	6000	6000	6000	6000	6000	
Retained Facilities	0	0	0	0	0	0	6000	12000	18000	24000	30000	36000	
Total Facility Customers	0	0	0	0	0	6000	12000	18000	24000	30000	36000	43000	169,000
Kits Consumed	0	0	0	0	0	21,000,000	36,000,000	54,000,000	72,000,000	92,000,000	120,000,000	150,000,000	525,000,000

19. According to statements Berman made to the Division staff, the forecasts included in DECN’s press releases came from spreadsheets that Berman’s assistant maintained that estimated segments of the population, such as religious institutions, that could in theory buy test kits.

20. At the time of the March 3, 2020, press release – when DECN claimed that its “product” would be “commercial [sic] ready in the summer of 2020” – DECN had not applied for authorization from the FDA to sell or distribute its COVID-19 test kit. In addition, as of April 13, 2020, Berman, who alone drafted the press releases on behalf of DECN, stated or suggested in interviews with staff that he:<sup>2</sup>

- knew that the company had no COVID-19 test kits;
- had not seen any of DECN’s prototype COVID-19 test kits;
- had no idea how many test kits DECN could produce;
- knew that the COVID-19 test kits would require component parts that were different from DECN’s current diabetes products, which the company did not yet have and would need before any sales could be made;

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<sup>2</sup> The Commission was informed that Berman conducted interviews with Division staff.



- was looking for sources that could provide the component parts but had no idea how much the component parts would cost and the time it would take for the company to obtain the parts in the midst of the pandemic; and
- knew that no COVID-19 test kits could be sold without FDA approval, which the company did not have.

### **III. Misleading Statements Concerning FDA Approval**

21. In press releases issued in late March and early April, DECN claimed to have filed an Emergency Use Authorization (“EUA”) application with the FDA concerning its COVID-19 test kit.

22. In a press release dated April 7, 2020, DECN announced that it received a “Pre-EUA Acknowledgment and device serial number,” touting this as a huge development akin to FDA approval of the test kits. The release included the following statement from Berman:

We submitted the application late in the afternoon EDT, and incredibly we received our Pre-EUA Acknowledgement the morning of April 4, 2020, less than 24 hours later, and on the weekend. We were so stunned by the rapid acknowledgment that we waited almost two days to inquire whether the acknowledgment was what we have come to know as the ‘Pre-EUA.’ We were assured that this letter from the FDA and the device serial number assigned are exactly what we had been hoping for.

The press release further claimed that “it was clear that the FDA review staff was aware that our methodology was different than those slower and older methods that had received FDA EUAs, or were in review.”

23. However, while anyone may register a product with the FDA, it does not confer any rights to the applicant. Further, registering a device does not mean that the device is FDA approved or exempt from approval by the FDA. In addition, as we understand, anyone may submit an EUA application with the FDA and the serial number assigned to the application is for

internal tracking purposes and does not represent FDA approval. FDA's review of a pre-EUA submission is not an indication of FDA's views on the product's potential to be used under an EUA, or that the company has obtained or submitted all the information necessary for FDA to review a formal request for consideration of an EUA.

24. The press releases were also published on the company's website, which included a banner advertising COVID-19 kits on the home page. In the "About Us" section of DECN's website, it states:

Through our subsidiary, PharmaTech Solutions, Inc., we provide blood glucose home testing test strips and exciting new concepts for blood testing monitors! All of our products are FDA cleared and have entered the market as an economical alternative for patients and healthcare providers.

The COVID-19 test kit is elsewhere listed as one of the subsidiary's products. While the banner for its COVID-19 test kits state that the product is still in development, the statements on the website give the misleading impression that the COVID-19 kit is ready or near-ready for purchase.

25. As of April 23, 2020, Division staff were unable to identify any FDA-approved medical devices relating to COVID-19 in the FDA's publically available databases under the name of DECN, Berman, or its subsidiaries.

26. DECN did not produce documents substantiating its press releases and the FDA EUA application, although the staff requested them. Between March 25, 2020, the date Division staff first contacted the company, and April 21, 2020, Berman issued four press releases. Berman also expressed concern to Division staff about producing the EUA application because he believed it contained proprietary information.

**IV. Recent Surge in DECN’s Share Price and Trading Volume**

27. In the three months prior to March 3, 2020, DECN’s share price fluctuated between \$0.0101 and \$0.023 per share with an average daily trading volume of 237,701 shares. On March 2, 2020, DECN’s share price remained at \$0.019 per share with a trading volume of 8,000 shares. After DECN’s first COVID-19 related press release on March 3, 2020, the share price fluctuated between \$0.017 and \$0.0449 per share with a trading volume of 7,299,706 shares. Between the time of the March 3 press release and the March 25 press release, DECN’s stock price and volume fluctuated, but daily trading volumes remained high compared to the stock’s average daily trading volume prior to that time.

28. DECN’s share price and volume spiked again following its April 7 press release announcing the receipt of its “Pre EUA Acknowledgement and device serial number” raising concerns that the market misunderstood the news to believe it to mean that a device had been approved by the FDA.

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1. DECN announces that it is jumping into screening and testing for COVID-19 using the same technology first implemented in its diabetes test kit;
2. DECN makes first year product forecast of 420 million kit;
3. DECN announces that its “Swift Kit” will be offered to commercial labs and religious groups as 12 month forecast is raised to 525 million kits;
4. DECN announces FDA guidance allows for near immediate distribution of kits prior to Emergency Waiver Grants;
5. DECN announces that it received a “Pre-EUA Acknowledgement Letter.”

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: May 20, 2020

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Carlisle Perkins, Senior Counsel  
 Securities & Exchange Commission  
 Division of Enforcement