UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

ADMINISTRATIVE PROCEEDING
File No. 3-19788

In the Matter of
DECISION DIAGNOSTICS CORP.

DIVISION OF ENFORCEMENT'S ANSWERING BRIEF IN OPPOSITION TO DECISION DIAGNOSTICS CORP.'S PETITION TO TERMINATE TRADING SUSPENSION

Respectfully submitted,
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Dated: July 1, 2020

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The Division of Enforcement (the "Division") hereby submits its Answering Brief in Opposition to Decision Diagnostics Corp.'s Petition to Terminate Trading Suspension in *In the Matter of Decision Diagnostics Corp.*, A.P. File No. 3-19788, and Declaration of Carlisle E. Perkins dated July 1, 2020 (the "Perkins July 1 Decl.").

INTRODUCTION

This adversary proceeding arises out of Decision Diagnostics Corp.'s ("DECN" or "Petitioner") challenge to the Securities and Exchange Commission's ("Commission") suspension of trading in its securities because the Commission determined that the public interest and the protection of investors required it. DECN was a penny-stock company that manufactured diabetes test strips for over a decade until, on March 3, 2020, it announced that it was changing its business and would produce a COVID-19 test kit. From March 3, 2020, to April 23, 2020, DECN issued thirteen press releases that announced unsupported forecasts and misleading and false representations related to its new COVID-19 business, driving up its share price and daily volume. After the Division's interview with DECN's CEO yielded more questions than answers, the Division sought a temporary suspension in the trading of DECN's securities. The Commission's decision was proper in all respects.

Out of DECN's thirteen press releases, at least two claimed that the company had "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." DECN also announced sales forecasts for the COVID-19 test kits stating, for example, that up to 525 million test kits would be sold in the first year of production. However DECN had not produced a single COVID-19 test kit at the time of those pronouncements and to the best of the staff's knowledge still has not. Moreover, DECN's ability to secure the parts to produce test kits was

and remains uncertain. DECN has not had audited financial statements for several years, meaning that there is no currently reliable financial information available to investors; however, the company does admit that its financial condition is such that it may not be able to continue as a viable company. The company also misrepresented and lied about the import of an automated Food and Drug Administration ("FDA") acknowledgment it received and presented conflicting information about the FDA approval it received on its website. DECN's press releases led to a surge in trading and volume and a 2,400% increase in its shares price.

The Commission reviewed this information and relied on its expertise, experience, and knowledge in issuing a temporary 10-day trading suspension. The Commission's decision remains the right one and DECN's Rule 550 petition[1] should be denied.

PROCEDURAL HISTORY

On April 23, 2020, pursuant to Section 12(k) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. § 781(k)], the Commission issued an Order of Suspension of Trading in the Securities of Decision Diagnostics Corp. (the "Order"). The trading suspension ran from April 24, 2020, to May 7, 2020. The Commission's Order notes that the suspension was due to "questions regarding the accuracy and adequacy of information in the marketplace" about DECN.

On May 7, 2020, DECN filed a petition pursuant to Commission Rule of Practice 550(a) to terminate the trading suspension (the "Petition"). On May 13, 2020, the Commission entered an order requesting additional written submissions by the parties. On May 15, 2020, DECN filed

[1] Commission Rule of Practice 550(a) provides, in relevant part:

> Any person adversely affected by a suspension pursuant to Section 12(k)(1)(A) of the Exchange Act … who desires to show that such suspension is not necessary in the public interest or for the protection of investors may file a sworn petition with the Secretary, requesting that the suspension be terminated.

an amended petition to terminate the trading suspension. On May 20, 2020, the Division filed the information that was before the Commission at the time of the Order's issuance and accompanying Declaration of Carlisle E. Perkins (the "Perkins May 20 Decl."). On June 17, 2020, DECN filed its opening brief, accompanied by the affidavit of Keith M. Berman ("Berman Aff.") and Affirmation of Ronald S. Herzog ("Herzog Aff.").[2]

STATEMENT OF FACTS

I. Issuer Background

DECN has CIK No. 0001144225 and is a Nevada corporation incorporated in 2001 with its principal executive offices located in Westlake Village, California. Perkins May 20 Decl. 4. The company describes itself as a prescription and non-prescription diagnostics and home testing products distributor, and a manufacturer of glucose test strips. Perkins May 20 Decl. 7. It also manufactures a "diabetes test strip" named "GenUltimate!" and has four subsidiaries, including Pharma Tech Solutions, Inc. Perkins May 20 Decl. ¶ 7. DECN has a South Korean partner named The Bio Co., Ltd. Perkins May 20 Decl. ¶ 7. DECN's common stock is not registered with the Commission and its common stock is quoted under the ticker symbol DECN on OTC Link (previously "Pink Sheets") operated by OTC Markets. Perkins May 20 Decl. ¶ 8.

Keith M. Berman ("Berman") serves as DECN's chief executive officer, chief financial officer and sole Director. Perkins May 20 Decl. ¶ 5. Berman is solely responsible for issuing

[2] The Commission's May 13, 2020 Order Requesting Additional Written Submissions set June 3, 2020 as the deadline for DECN to file its opening brief. On May 29, 2020, counsel for DECN emailed Division counsel requesting a two-week extension to file its opening brief to which the Division consented with the agreement that the deadline for the Division to file its brief also be extended two weeks.

press releases for the company, which are not reviewed by anyone to ensure compliance with the federal securities laws. Perkins May 20 Decl. ¶ 5.

DECN filed a Form 15 in 2016 suspending its duty to make filings with the Commission. Perkins May 20 Decl. ¶ 9. DECN continues to submit financial statements with OTC Markets, but the financial statements are unaudited. Perkins May 20 Decl. ¶ 9. As of April 21, 2020, DECN had 13 market makers. Perkins May 20 Decl. ¶ 10. As of April 21, 2020, DECN's common stock was eligible for the "piggy back" exception of the Exchange Act, Rule 15c2-11(f)(3). Perkins May 20 Decl. ¶ 10.

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. Perkins May 20 Decl. ¶ 11. Additionally the company reported total liabilities of approximately $2.9 million and an accumulated deficit of approximately $47.6 million since its inception. Perkins May 20 Decl. ¶ 11. 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. Perkins May 20 Decl. ¶ 11.

II. From March 3, 2020 to April 23, 2020 DECN Issued 13 Press Releases

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 screening and testing for COVID-19 by using its "innovative impedance technology," first used for diabetes. Perkins May 20 Decl. ¶ 12. In an interview on March 25, 2020, Berman told the Division staff that his concept to get into COVID-19 testing originated after he saw a news report

in mid-February that "ground zero" of the virus was in Daegu, South Korea, where DECN's Korean partner is located. Perkins July 1 Decl. ¶ 17.

Approximately two weeks after Berman first got the idea of COVID-19 testing, 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. Perkins July 1 Decl. Exs. 1-13. 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." Perkins July 1 Decl. Ex. 1 (March 3, 2020 Press Release). Berman stated that DECN had "the technology perfected" for the COVID-19 tests and that the product would be "field tested" in Korea. *Id*. Berman noted that, while the COVID-19 test would be initially available to medical professionals, once production increased the test would be sold for home use. *Id*.

The following week, on March 11, 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. Perkins July 1 Decl. Ex. 3 (March 11, 2020, Press Release). 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

In the press release Berman asserted, without providing 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." *Id*. The press release included a picture of its purported

COVID-19 test kit. *Id*. The kit for the purported COVID-19 test looked identical to one of the company's current diabetes glucose test kit - marketed "4Pets" listed on its website.[3] *Id*.

Photograph from March 11, 2020 Press Release *Photograph from DECN Website*[4]

In press releases issued by DECN on March 16 and March 17, the company provided additional information regarding the functionality of its supposed COVID-19 test kits, distribution of the test kits, and updated sales forecast for the test kits. Perkins July 1 Decl. Exs. 4, 5 (March 16 & March 17, 2020, Press Releases). On March 16, DECN stated that its COVID-19 test kit could produce results "through a finger-stick" in "less than one minute." Perkins July 1 Decl. Ex. 4 (March 16, 2020 Press Release). 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. *Id*. 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

[3] As discussed below, this image was taken from DECN's website *prior to* the Commission's issuance of the Order.
[4] *See* Perkins July 1 Decl. ¶ 22.

month of May 2020." *Id*. Finally, DECN increased its "forecast" stating that 480 million test kits would be sold in its first full year of production. *Id*.

The following day, in yet another press release DECN announced that it had "raised our 12-month forecast to 525 million kits." Perkins July 1 Decl. Ex. 5 (March 17, 2020 Press Release). The press release included another image of the company's purported COVID-19 test kit and an updated "forecast" chart reflecting 21 million units 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

In total, from March 3, 2020 to April 23, 2020, DECN issued thirteen press releases related to its purported COVID-19 test kit. Perkins July 1 Decl. Exs 1-13.

Division staff conducted two interviews of Berman prior to the Order, on March 25 and April 7, 2020. Perkins May 20 Decl. ¶ 20. His answers to the Division staff's questions raised additional concerns about the accuracy and veracity of the information contained in DECN's press releases. Indeed, after Berman's second interview with the Division staff, it appeared that DECN's sales forecasts in the press releases between March 3 and March 17, concerning both the quantity of sales and the time by which the sales would be made, were false and misleading because they omitted material information. Perkins May 20 Decl. ¶ 20. For example, the Division learned from Berman at the time that:

- DECN had no COVID-19 test kits;
- Berman had not seen any of DECN's prototype COVID-19 test kits;
- Berman had no idea how many test kits DECN could produce;

- the COVID-19 test kits would require component parts that are different from DECN's current diabetes products, and the company did not yet have and would need these parts before any sales could be made;

- Berman was looking for sources that could provide the component parts and had no idea how much the component parts would cost and how much time it would take for the company to obtain the parts in the midst of the pandemic;

- DECN's "forecasts" came from spreadsheets Berman's assistant maintained that simply estimated segments of the population—like religious institutions—that could in theory buy the test kits; and

- Berman knew that no COVID-19 tests kits could be sold without actual FDA approval which the company did not yet have (and still does not have).

Perkins May 20 Decl. ¶ 20. Berman also admitted that he, alone, drafted all the press releases and that they were not reviewed by anyone before he posted them publicly. *Id*.

In press releases issued in late March and early April, DECN claimed to have filed an Emergency Use Authorization application with the FDA concerning its COVID-19 test kit. Perkins May 20 Decl. ¶ 21. In a press release issued on April 7, DECN announced that the company received a "Pre-EUA Acknowledgement and device serial number," touting this as a huge development akin to FDA approval of the test kits. Perkins May 20 Decl. ¶ 22. The press release included this 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.

Perkins May 20 Decl. ¶ 22; Perkins July 1 Decl. Ex. 11. The same press release also 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." *Id*. However, according to the FDA, submissions assigned under the [EUA] are still going through the pre-approval process to determine if the submission will be accepted to undergo the EUA process to potentially be approved for use. Accordingly, anyone may register a product with the FDA but it does not confer any rights to the applicant. Perkins May 20 Decl. ¶ 23. Further, registering a device does not mean that the device is FDA approved or exempt from approval by the FDA.[5] *Id*.

The press releases were also published on the company's website which included a banner across the top of its homepage advertising COVID-19 kits. Perkins May 20 Decl. ¶ 24. In the "About Us" section of DECN's website, it stated: "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." *Id*. The COVID-19 test kit was elsewhere listed as one of the subsidiary's products. *Id*. While a disclaimer for DECN's COVID-19 test kits states that the product is still in development, the statements appearing elsewhere on the website gave the misleading impression that the COVID-19 kit was ready or near-ready for purchase. *Id*.

III. The Surge in DECN's Share Price and Trading Volume

In the period leading up to the Order, DECN's stock price and trading volume both surged—almost in lockstep with the press releases issued by the company. Perkins May 20 Decl. ¶ 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. *Id*. On

[5] Information relating to the FDA's EUA process is publicly available, including from *"*Emergency Use Authorization of Medical Products and Related Authorities*"* (FDA January 2017/OMB Control No. 0910-0595).

March 2, DECN's share price remained at $0.019 per share with a trading volume of 8,000 shares. *Id*. On March 3, after DECN's first COVID-19 related press release, the share price rose between $0.017 and $0.0449 per share with a spike in trading volume of 7,299,706 shares. *See Id*. After DECN's March 3, 2020 and March 25, 2020 press releases, DECN's stock price and volume fluctuated, but daily trading volumes remained high compared to the stock's average daily trading volume prior to March 3, 2020. [6] *Id*. DECN's share price and volume spiked again following its April 7 press release announcing the receipt of its "Pre EUA Acknowledgement and device service number" raising concerns that the market misunderstood the news believing it to mean that a device had been approved by the FDA. Perkins May 20 Decl. ¶ 28.

LEGAL STANDARD GOVERNING TRADING SUSPENSIONS

Section 12(k)(1)(A) of the Exchange Act authorizes the Commission to issue an order summarily suspending trading in any security (other than an exempted security) for a period not exceeding ten business days if "in its opinion the public interest and the protection of investors so require."[7] The law authorizes the Commission to act "without any notice, opportunity to be heard, or findings based upon a record." *SEC v. Sloan*, 436 U.S. 103, 112 (1978). Importantly, there is no express statutory requirement "to allege or find that an issuer has violated a specific

[6] Berman told the Division that he owns 400,000 shares of DECN (approximately less than 1 percent of the shares outstanding), but that he has not traded any of the stock.

[7] A trading suspension order prohibits brokers, dealers, and members of a national securities exchange from using any instrumentality of interstate commerce "to effect any transaction in, or induce the purchase or sale of," a security subject to a suspension order while the suspension is in effect. Section 12(k)(4). After a trading suspension expires, Exchange Act Rule 15c2-11 governs the ability of brokers to initiate and resume securities quotations for securities not listed on a national securities exchange. *See* 17 C.F.R. 240.15c2-11. "Once there has been a lapse in two-way quotations for more than four business days for any reason, including a trading suspension, a broker-dealer cannot re-initiate quotations without complying with the informational and other requirements of Rule 15c2-11 and. filing a Form 211 with FINRA, or otherwise demonstrating that it qualifies for an exception or exemption under Rule 15c2-11(f) or (h)." *Bravo Enter. Ltd*, 2015 WL 5047983 at *12, n.72.

provision of the federal securities laws before suspending trading...." *Bravo Enter. Ltd.*, Exch. Act Rel. No. 75775, 2015 WL 5047983, at *3 (Aug. 27, 2015) (Commission Opinion).

A decision to suspend trading is "rooted in [the Commission's] opinion based on [its] expertise, experience, and knowledge, that a trading suspension [is] in the public interest and would protect investors." *Id.* at *3. The question of whether the Commission is of the "opinion" that a trading suspension is warranted is a subjective one - and there is a "significant 'distinction between a subjective standard (whether the agency thinks that a condition has been met) and an objective one (whether the condition has in fact been met),' with the former giving the agency more discretion to act." *Id*. at * 2, citing *Drake v. FAA*, 291 F.3d 59, 72 (D.C. Cir. 2002). Likewise, while the phrase "in the public interest" is not statutorily defined, it is an "inherently 'broad standard[] for administrative action.'" *Id*. at *2, citing *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 104 (1946). And, the phrase "investor protection" implies an "expansive mandate." *Id*. at *2.

In determining whether to suspend trading, "the primary issues normally to be considered ... are whether or not there is sufficient public information about which to base an informed investment decision or whether the market for the security appears to reflect manipulative or deceptive activities." *Id*. at *4 (quoting Rules of Practice, Exch. Act Rel. No. 35833, 60 Fed. Reg. 32738, 32787 (June 23, 1995) (adopting release) (Comment to Rule 550 discussing the Commission's process for petitions to terminate a suspension of trading)). Following these considerations, the Commission has, as it did here, "suspended trading when there were questions about the accuracy of publicly available information about the company, whether in press releases, public filings, or other statements." *Id*. at *5. It has also ordered

trading suspensions "in situations involving fraud or manipulation by individuals unconnected with the issuer." *Id*. at *3.

Even though the trading suspension terminated on May 7, 2020, it is still proper for the Commission to hear DECN's petition to remove the trading suspension pursuant to Commission Rule 550(b), because DECN filed its request for Commission review within the 10-day suspension. *Bravo Enter. Ltd.*, 2015 WL 5047983, at *6. On review, the Commission seeks to determine whether it remains of the opinion that the public interest and the protection of investors required suspension of trading in DECN's shares. *See Id*. at *1.

ARGUMENT

I. The Commission Properly Imposed a 10-Day Trading Suspension in the Securities of DECN

Petitioner's challenge to the trading suspension relies on inaccurate assumptions and conclusions regarding the Division's investigation and airs grievances against unidentified third-parties. These arguments are irrelevant and miss the point. As discussed in more detail below, the Commission was fully justified in its assessment that information in the marketplace about DECN raised adequacy and accuracy questions because: (1) DECN's proclamations regarding the efficacy of its COVID-19 test were mere conjecture; (2) DECN's forecasts regarding production capacity and sales were wholly unsupported; (3) DECN's statements concerning the FDA's review and approval of its COVID-19 test were, at best, misleading; and (4) DECN's share price and trading volume spikes raised concerns that investors misunderstood, and possibly, were misled by the press releases DECN issued.

A. Petitioner's Press Releases Misled Investors

After operating as a company that produced diabetes glucose test kits "since early 2013," Berman Aff. ¶ 5, DECN announced on March 3, 2020 its entry into the field of screening and

testing for COVID-19. Perkins May 20 Decl. ¶ 12. While at first glance DECN's announcements may have seemed laudable given the pandemic facing the world, the frequency with which Petitioner issued press releases and the content in those press releases raised concerns that the company was misleading investors with misleadingly inadequate and inaccurate information. Perkins July 1 Decl. Exs 1-13.

1. Petitioner's claims about a product it never produced or tested

Over the course of several weeks, Petitioner unleashed a flurry of press releases about its COVID-19 test kit in which it made unsupportable claims regarding the efficacy of its product. Perkins July 1 Decl. Exs 1-13. For example, Petitioner claimed it had "technology perfected" and its test kits could produce results "through a finger-stick" in "less than one minute." Perkins May 20 Decl. ¶ 13. Petitioner now asserts that these statements were "completely accurate." Berman Aff. ¶ 18. While these statements may have been true for Petitioner's glucose test kit, they were wholly speculative and misleading in connection with COVID-19 testing. DECN and Berman fail to explain how a diabetes test translates into a blood finger prick test for a coronavirus. Petitioner made these claims even though it had never manufactured, let alone tested a single COVID-19 kit using the method it promoted. Perkins May 20 Decl. ¶ 20; Berman Aff. ¶ 35. DECN did not even have a COVID-19 blood sample from which it could run tests. Perkins May 20 Decl. ¶ 17.

2. Petitioner's forecasts were wholly unsupported

On March 11, 2020, less than two weeks after announcing its entry into producing COVID-19 test kits, DECN conveyed to the public that it expected to sell 420 million test kits in the first year of production. Perkins July 1 Decl. Ex. 3 (March 11, 2020 Press Release). Less than one week later, on March 17, 2020, DECN announced that it had *increased* its projections

by over 100 million kits to 525 million. Perkins July 1 Decl. Ex. 5 (March 17, 2020 Press Release). DECN forecasts presented serious questions about their veracity and, at a minimum, were misleading and lacked adequate information and justification.

Petitioner's own admissions demonstrate the speculative and unsupported nature of DECN's forecasts. At the time of the March 3 press release when DECN claimed that its "product" will be "commercial [*sic*] ready in the summer of 2020" DECN had not even applied for authorization from the FDA to sell or distribute its COVID-19 test kit. Perkins May 20 Decl. ¶ 20; Perkins July 1 Decl. Ex. 1 (March 3, 2020 Press Release). Once again, at the time these forecasts were made DECN had no prototype nor actual COVID-19 test kits. Berman Aff. ¶ 35 ("[A] small company with limited resources like DECN could not simply rush into production in the hope that regulatory approval would be forthcoming."). DECN also had not secured the necessary component parts to manufacture the COVID-19 tests and did not know if it could secure the necessary amount to meet its forecasts. *Id*. at ¶ 36. As a result, DECN had no basis to claim in its March 11, March 16, and March 17 press releases that the company expected to sell 200,000 kits in the U.S., Canada and Europe by May 2020 and as many as 525 million COVID-19 test kits in the first year of production. Perkins July 1 Decl. Exs. 3-5 (March 11, 2020, March 16, 2020, & March 17, 2020 Press Releases).

Still unable to support these forecasts, Petitioner now argues that because the Commission did not reference them in its Order, it did not factor them into its decision. Berman Aff. ¶ 14. However, this information was before the Commission. *See*, *e.g.*, Perkins May 20 Decl. ¶¶ 15, 18.

Petitioner also argues that these were not sales projections but "DECN's good-faith projection of the significant demand." Berman Aff. ¶ 15. However, DECN's own press release

(which Berman alone drafted and published) belies that claim: "We anticipate the sale of 420,000,000 kits in the first full year of commercial sale." Perkins July 1 Decl. Ex. 3 (March 11, 2020 Press Release). DECN's clear and unambiguous statement related to *sales* and not, as Berman now claims, a projection of "demand." In addition, DECN's "forecast" that it would produce 200,000 test kits worldwide by May 2020, a period that has come and gone, was wrong. Indeed, the wholly speculative nature of those estimates is proven through Berman's concession that it was based on "expected expedited approval by the FDA of DECN's EUA, *which despite DECN's efforts, has not yet been received*." Berman Aff. ¶ 18 (emphasis added). The continued lack of approval demonstrates another concern – DECN's inaccurate forecasting regarding FDA approval. Perkins May 20 Decl. ¶¶ 21-26.

Moreover, without providing any empirical support for these very large sales projections, Petitioner lays fault on the Division for not accepting these statements as being made in good-faith. In doing so, Petitioner completely ignores that the unsupportable projections appeared in public press releases that were being relied upon by investors who the Commission is tasked with protecting. Perkins July 1 Decl. Exs. 1-13.

DECN projected these numbers to investors and the public, but failed to provide the Division with any supporting documentation. Perkins May 20 Decl. ¶ 26. Petitioner argues that it was not required to provide documents to the Division's staff. *See* Herzog Aff. However, that point was never in controversy as the Division asked DECN to provide documents on a voluntary basis. The argument, however, fails to address the more important point; namely, DECN was given ample opportunity to demonstrate that it had support for the claims it made in its press releases but failed to produce a single document in support of any of the statements at issue from the time documents were first requested on March 25, 2020, through the date of the

Order on April 23, 2020.[8] DECN's failure to provide any support for its statements was a relevant factor the Commission considered in deciding whether a trading suspension served the public interest and protected investors. *See Immunotech Labs., Inc.*, Exchange Act Release No. 75790, 2015 WL 5081237, at *9 n.41 (Aug. 26, 2015) (Commission Opinion) (drawing an adverse inference from "unexplained failure to clarify or deny suspicious circumstances").

3. Misleading statements concerning the FDA approval process

DECN had not started seeking FDA approval through the Pre-EUA process when it issued its first press release on March 3, 2020, and it issued an additional press release about a technology it "perfected" on March 11, 2020. *See* Perkins July 1 Decl. Ex. 3 (discussing how the impedance technology used in its glucose test strip it had effectively "shaved months off the development time for the GenViro! device"). Again, these statements were made before DECN had even submitted its initial pro forma paperwork to the FDA. *See* Berman Aff. ¶ 8 ("DECN filed Emergency Use Applications ('EUA') with the Food and Drug Administration, first on April 3, 2020…").

After DECN started the FDA approval process, it continued to mislead the public and investors in its April 7, 2020 press release in which it overstated the import of receiving a "Pre-EUA Acknowledgment and device serial number," something anyone may obtain by registering with the FDA. Perkins May 20 Decl. ¶¶ 22-23. Anyone is free to apply for an EUA with the FDA and, as the Division understands it, after filing, all applicants are automatically provided with a number that tracks the agency's applicant pool; the number does not represent FDA approval but is an internal number assigned to applications. Perkins May 20 Decl. ¶ 23. DECN,

[8] Ironically, Petitioner decries the length of time it took for the Division to seek the trading suspension while at the same time failing to address his failure to produce support for his forecast numbers despite having this "inordinate" delay. *See* Berman Aff. ¶ 4.

however, proclaimed it was "stunned" by the FDA's rapid acknowledgment and described it as "exactly what we had been hoping for" statements that had further potential to mislead reasonable investors. *Id*. ¶ 22 (quoting Apr. 7 Press Release).

4. Petitioner's website contained conflicting and misleading information about FDA approval and its purported COVID-19 test kit

DECN's website also contained conflicting and misleading statements concerning FDA approval. Perkins May 20 Decl. ¶ 24. An investor who visited the website and viewed the "About Us" section would reasonably be left with the impression that all of DECN's products (to include its COVID-19 test kit) were "FDA cleared" and "have entered the market." Perkins May 20 Decl. ¶ 24. Even though the website banner referring to its COVID-19 test kits stated that the product was still in development, the statements appearing elsewhere on the website, taken as a whole, left investors with, at best, confusing and inadequate information. *Immunotech Labs., Inc.*, 2015 WL 5081237 at *2-4 (upholding trading suspension where "information available to potential investors was, at best, contradictory and confused"). Perkins May 20 Decl. ¶ 24.

Moreover, DECN's inclusion in the March 11, 2020 Press Release of the photograph of DECN's purported COVID-19 test was misleading to investors. Perkins July 1 Decl. Ex. 3 (March 11, 2020 Press Release). At the time, DECN did not even have a prototype of its COVID-19 test kit, however, the photograph left readers with the false and misleading impression that DECN's test had already been produced.[9] *Id*.

DECN does not challenge the conflicting and misleading nature of this information head-on. Instead, Petitioner argues that the Division did not visit Pharma Tech's website prior to May 11, 2020. Berman Aff ¶ 10. This is a red-herring. Prior to the trading suspension, Division staff

[9] Berman argues, without support, that the FDA and not the SEC is tasked with monitoring and enforcing "these types of issues." Berman Aff. ¶ 17. Of course, the SEC's jurisdiction includes the enforcement of securities laws and Petitioner falls within its gambit.

visited DECN's website on a number of occasions. Perkins July 1 Decl. ¶ 3. On the webpages viewed by the Division staff they observed the misleading and conflicting representations regarding FDA approval. Perkins May 20 Decl. ¶ 22. Lastly, during its first interview with Berman, he commented to the Division that he noticed that the Division had visited the DECN website. Perkin July 1 Decl. ¶ 22.

B. The Dissemination of Misleading Statements by DECN had a Discernable Impact on its Stock

Trading charts revealed that DECN's press releases had a significant impact on the price of the stock and its trading volume. Perkins May 20 Decl. ¶ 28.

1. DECN announced development of COVID-19 test kit using the same technology as its diabetes test kit
2. DECN made first year product forecast of 420 million kits
3. DECN announced that its "Swift Kit" would be offered to commercial labs and religious groups as 12 month forecast is raised to 525 million kits
4. DECN announced FDA guidance allowed for near immediate distribution of kits prior to Emergency Waiver Grants
5. DECN announced that it received a "Pre-EUA Acknowledgement Letter"

The above volume and stock price surges demonstrate how Commission action was necessary to stem the flow of inaccurate and inadequate information to protect investors. Perkins May 20 Decl. ¶¶ 27-28. DECN consistently closed at $.02 per share from January 7, 2020 through

March 2, 2020 when it began climbing to a high of $.50 per share on April 23, 2020, which represented an overall increase of 2,400%. Perkins May 20 Decl. ¶¶ 27, 28. *See In the Matter of Efuel Enf. Corp.*, Exch. Act Rel. No. 86307, 2019 WL 2903941, at *7 (July 5, 2019) (Commission Opinion) ("In issuing a trading suspension, we must consider not only current shareholders but also the interests of *prospective* or *potential* investors who might be harmed because they purchase shares in reliance on potentially inaccurate or inadequate information about the issuer.") (internal quotations omitted).

C. The Lack of Reliable Financial information for DECN was an Important Factor for the Commission to Consider

Petitioner's financial statements are not audited and have not been audited for years. Perkins May 20 Decl. ¶¶ 9, 11. Consequently, there is no reliable financial information for the company. The Commission has recognized that penny stocks, such as DECN, already often have a dearth of accurate, publicly available information about the issuer upon which investors may safely rely, which make them susceptible to fraud, manipulation, and abuse. *Bravo*, 2015 WL 5047983, at *5.

At the time Petitioner announced its incredible forecasts, it had significant debt, limited physical assets, and only about $50,000 in cash. Perkins May 20 Decl. ¶ 11. Moreover, concerns as to whether DECN would continue to operate as a viable company is a significant consideration because it calls into question whether the company had the financial ability to do the things necessary to produce the COVID-19 test kits consistent with its representations in its press releases. Perkins May 20 Decl. ¶ 11. For example, Petitioner's financial instability, cast doubts about its ability to: (1) hire qualified scientists and other parties to develop its new product, (2) obtain all of the component parts for the new test kit (especially in sufficient quantities to enable it to sell over 500 million test kits), (3) manufacture all of the test kits,

(4) test the product to make sure it was safe and effective, (5) obtain approval to sell the product, (6) market the product, and (7) distribute the product. Perkins May 20 Decl. ¶¶ 11, 20.

D. FINRA's Referral

On March 18, 2020, the Financial Industry Regulatory Authority ("FINRA") referred Petitioner to the Division because it found the press releases issued between March 3, 2020 and March 18, 2020 to be suspicious and possible indications of an attempt to manipulate DECN's stock price. Perkins July 1 Decl. ¶ 19. FINRA routinely evaluates statements made in press releases, especially when combined with dramatic changes in trading volume and prices, to determine whether there is evidence that an individual or company has violated or may be violating the federal securities laws. Perkins July 1 Decl. ¶ 18. FINRA's referral of DECN was an additional factor justifying the Commission's trading suspension to protect to the public.

II. The Conspiracy Theories Espoused by Petitioner Were Not Part of the Information Before the Commission and are Irrelevant

The conspiracy theories espoused by Berman regarding efforts "by a group of outsiders" to mislead the Division are irrelevant because the Commission's trading suspension order was not based on any of the information he cites. The Commission's Order relied upon publicly available information on DECN's own website, statements DECN made in its press releases, the Division's interviews with Berman, DECN's unaudited financial statements, and trading data. *See* Perkins May 20 Decl. ¶¶ 16, 24, 27; Perkins July 1 Decl. Exs. 1-13. Nevertheless, Berman asserts that the Division had been in regular contact with "outsiders with no connection to the company" who have a purported but unexplained bias against Berman and DECN, and who provided the Division with false information. Berman Aff. ¶ 2. Berman's claim is patently false. At no time prior to the trading suspension did the Division staff assigned to this matter speak to anyone regarding DECN except Berman and his counsel. Perkins July 1 Decl. ¶ 20. Moreover,

none of the information Berman discusses regarding purportedly "stolen" slides and message board posts were before the Commission at the time of the trading suspension nor has the Division relied upon them in connection with this opposition. *See* Berman Aff. ¶¶ 21-24.

CONCLUSION

As discussed above, the Commission's opinion that the public interest and the protection of investors required suspension of trading in DECN's securities was the right decision and remains the right decision. Accordingly, the Petition should be denied.

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
(202) 551-2210 (Misler)

Dated: July 1, 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 1st day of July, 2020, in the manner indicated below:[10]

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

[10] 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.

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

ADMINISTRATIVE PROCEEDING
File No. 3-19788

In the Matter of
DECISION DIAGNOSTICS CORP.

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 connection with the Division of Enforcement's ("Division") Answering Brief in Opposition to Decision Diagnostics Corp.'s ("DECN" or "Petitioner") Petition to Terminate Trading Suspension in *In the Matter of Decision Diagnostics Corp*.

3. Prior to the trading suspension, Division staff visited *DECN*'s website on a number of occasions. The website address used by Division staff was www.decisiondiagnostics.com. On the webpages viewed by the Division staff, we observed the misleading and conflicting representations regarding Food and Drug Administration approval. I copied and pasted language directly from the DECN website from its "Home" tab, "About Us" tab, and "Investor Information" tab and shared that information with other members of the staff as part of our review of DECN.

4. Attached as Exhibit 1 to my Declaration is a true and correct copy of a press release issued by DECN on March 3, 2020.

5. Attached as Exhibit 2 to my Declaration is a true and correct copy of a press release issued by DECN on March 4, 2020.

6. Attached as Exhibit 3 to my Declaration is a true and correct copy of a press release issued by DECN on March 11, 2020.

7. Attached as Exhibit 4 to my Declaration is a true and correct copy of a press release issued by DECN on March 16, 2020.

8. Attached as Exhibit 5 to my Declaration is a true and correct copy of a press release issued by DECN on March 17, 2020.

9. Attached as Exhibit 6 to my Declaration is a true and correct copy of a press release issued by DECN on March 18, 2020.

10. Attached as Exhibit 7 to my Declaration is a true and correct copy of a press release issued by DECN on March 20, 2020.

11. Attached as Exhibit 8 to my Declaration is a true and correct copy of a press release issued by DECN on March 23, 2020.

12. Attached as Exhibit 9 to my Declaration is a true and correct copy of a press release issued by DECN on March 25, 2020.

13. Attached as Exhibit 10 to my Declaration is a true and correct copy of a press release issued by DECN on April 6, 2020.

14. Attached as Exhibit 11 to my Declaration is a true and correct copy of a press release issued by DECN on April 7, 2020.

15. Attached as Exhibit 12 to my Declaration is a true and correct copy of a press release issued by DECN on April 21, 2020.

16. Attached as Exhibit 13 to my Declaration is a true and correct copy of a press release issued by DECN on April 23, 2020.

17. In an interview, Berman told Division staff that his concept to get into COVID-19 testing happened after he saw a news report in mid-February that "ground zero" of the virus was in Daegu, South Korea, where DECN's Korean partner is located.

18. The Financial Industry Regulatory Authority ("FINRA") is a highly regarded institution and routinely evaluates statements made in press releases, especially when combined with dramatic changes in trading volume and prices, to determine whether there is evidence that an individual or company has violated or may be violating the federal securities laws.

19. On March 18, 2020, FINRA referred Petitioner to Division staff because it found the press releases issued between March 3, 2020 and March 18, 2020 to be suspicious and possible indications of an attempt to manipulate DECN's stock price.

20. At no time prior to the trading suspension did the Division staff assigned to this matter speak to DECN investors, message board bloggers or other members of the general public regarding DECN, except Berman and his counsel.

21. During our first interview with Berman, he said that he noticed that Division staff had visited the DECN website.

22. The following photograph was taken from DECN's website available at: https://www.decisiondiagnostics.co/assets/reports/OTC%20PINK%202Q2019%20MANAGEMENTS%20DISCUSSION_&_ANALYSIS.pdf

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

Dated: July 1, 2020

_____

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

EXHIBIT 1

← Back to Newsroom (/newsroom)

Decision Diagnostics Corp.

Company Profile on Investor Network (https://www.accesswire.com/social_visits.ashx?articleid=588463&networkid=inv&link=https://www.investornetwork.com/company/C-EC60CD8C91E41)

Companies Mentioned:

Primary Exchange: OTC PINK
Under the Symbol: DECN

$0.32

▲ $0.0000
0.0000

DECN Jumps into Screening and Testing Channel For Coronavirus (COVID19) Using Its Innovative Impedance Technology First Implemented In Its GenUltimate TBG

Tuesday, March 3, 2020 8:55 AM EST

new genviro[tm] technology anticipated to be commercial ready in summer 2020, government fast track and waivers begun, cost per screen expected to be $4.95, unique reporting method to be used

LOS ANGELES, CA / ACCESSWIRE / March 3, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) is an 18-year old, diabetes-focused bio-technology development firm, manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for the GenUltimate! ("Sunshine") diabetes test strip,

its GenAccord! systems for the uninsured and under-insured, its GenChoice! ("Ladybug") test strip now in the later stages of FDA 510(k) prosecution, and its GenUltimate Precis products manufactured for International markets.

Today, in a break-through discussed for the first time, DECN announces in this first of three releases, expected in the next 10 days, the introduction of our new screening methodology for the Coronavirus (Covid19). Our product is timely, simple to use, cost effective and will be commercial ready in the summer of 2020.

Keith Berman, CEO of DECN commented, "We have the technology perfected which will take months off of the development schedule. Our impedance powered diagnostic will be field tested at ground-zero in Daegu, Korea, where 700+ people have already been overcome by Coronavirus (COVID19) and where all of the clinical studies for our "Gen" products were tested. Our timing here is spot-on."

DECN also markets its PetSure! test strip for the diabetic testing of dogs and cats, a diagnostic specifically designed to run on the market leading Zoetis Alpha Trak meter system as well as the GenUltimate! 4Pets Test strip and Avantage! meter. The company has also just introduced its GenExpidient! Universal Translator for bio-sensor devices of different manufacture. And finally the company is rolling out its GenUltimate TBG ("Dragonfly") product in International markets. The TBG Precise meter is now complete and available for US license to our strategic partner.

Mr. Berman concluded, "I want to say straight on that we have developed a Coronavirus screening method, not a cure or a vaccine for this virus. That being said, our screening method should allow for 80% of the suspected carriers of Coronavirus to exit the quarantine systems in the places where Coronavirus is rampant. But we are not done with our GenViro development. Later product entries will be test methods for Polio, Ebola (Marburg), Bird Flu, and SARS. The cost of our test kits will be sold in a price range of $4.95 to $7.95 per use. We plan to provide our diagnostics initially for use at hospitals, doctors' offices, and clinics. Once production ramps up, we will offer testing kits and meters to patients for testing at-home.

ABOUT DECISION DIAGNOSTICS CORP

Decision Diagnostics Corp. is the leading manufacturer and worldwide distributor of diabetic test strips engineered to operate on legacy glucose meters. DECN's products are designed to operate efficiently and less expensively on certain glucose meters already in use by almost 7.5 million diabetics worldwide. With new inspired technology diabetic test strips already in the final stages of

development, DECN products compete on a worldwide scale with legacy manufacturers currently selling to 71+ percent of a $15+ billion at-home testing market. The company's GenUltimate TBG product is not yet available for sale in the United States or Puerto Rico but is for sale in select International markets since late February 2020.

Forward-Looking Statements:

This release contains the company's forward-looking statements which are based on management's current expectations and assumptions as of March 2, 2020, regarding the company's business and performance, its prospects, current factors, the economy, and other future conditions and forecasts of future events, circumstances, and results.

CONTACT INFORMATION:

Decision Diagnostics Corp.
Keith Berman (805) 446-2973

info@decisiondiagnostics.co (mailto:info@decisiondiagnostics.com)
www.genultimate.com (http://pr.report/sD3XEn6e)
www.genultimatetbg.com (https://pr.report/pjQvX2YT)
www.petsureteststrips.com (https://pr.report/l0YpgJcw)
www.pharmatechdirect.com (http://pr.report/clyJvz8Q)

SOURCE: Decision Diagnostics Corp.

EXHIBIT 2

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Decision Diagnostics Corp.

Company Profile on Investor Network (https://www.accesswire.com/social_visits.ashx?articleid=588463&networkid=inv&link=https://www.investornetwork.com/company/C-EC60CD8C91E41)

Companies Mentioned:

Primary Exchange: OTC PINK
Under the Symbol: DECN

$0.31

▲ $0.05
19.23%

DECN Fills in the Gaps, Adds to Knowledge Base for its GenViro(TM) Coronavirus (Covid19) Multi-Dimensional Diagnostic Methodology Announced March 2

Wednesday, March 4, 2020 8:55 AM EST

GenViro™ Anticipated to be Commercial Ready in Summer 2020, Advanced Development Taking Place at "Ground Zero" in Daegu, Korea, Cost Per Screen Set at $4.95, Unique Reporting Method to be Used

LOS ANGELES, CA / ACCESSWIRE / March 4, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) is an 18-year old, diabetes-focused bio-technology development firm, manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for the GenUltimate! ("Sunshine") diabetes test strip,

its GenAccord! systems for the uninsured and under-insured, its GenChoice! ("Ladybug") test strip now in the later stages of FDA 510(k) prosecution, and its GenUltimate Precis products manufactured for International markets.

On March 3, 2020, in a break-through discussed then for the first time, DECN announced the introduction of its new screening methodology for the Coronavirus (covid19). This innovative, precise and cost effective product is timely, simple to use, and most importantly will be commercial ready in the late summer of 2020. This is the second of a planned three discussions covering the revolutionary DECN GenViro screening diagnostic for the Coronavirus **(covid19) and other infectious disease states.**

Keith Berman, CEO of DECN commented, "GenViro for the Coronavirus (covid19) began as an outgrowth of our GenUltimate TBG product line. What makes the testing for the Coronavirus possible, and the GenUltimate TBG special, is the company's Impedance measurement technology.

https://www.frontiersin.org/articles/10.3389/fmicb.2015.00940/full (https://pr.report/HSwOa7WG)

While infectious disease testing and management has not previously been a part of our business model, we seized on this "do good" opportunity because our "Gen" line of products are and have been manufactured since 2016 in what is ground zero for Coronavirus (covid19) in Daegu, Korea. The company will have available samples of the blood of those previously infected available for testing as the company quickly converts its GenUltimate TBG methods and Precise meter, into a precise infectious disease testing device for the screening for Coronavirus."

In addition, the company has also just introduced its GenExpidient! Universal Translator for bio-sensor devices of different manufacture. Pictured above, this device allows for a disposable screening method while testing for Coronavirus, lessening the need to cleanse, disinfect and sanitize the meter (reading device). With the completion of the company's Precise meter in late February, there is no need to develop instrumentation to read the answers from the diagnostic itself. Development of "hardware" always adds time to a major development project. But not here.

Mr. Berman concluded, "I again want to reiterate that the development of our Coronavirus screening method is not a cure or a vaccine for this virus. That is not to infer that unexpected clever and useful features are not built into our Coronavirus screening solution. For example, not only will the screening device provide the expected NEGATIVE or POSITIVE result (answer), but with each result

provided, the answer will be accompanied by a probability statistic that will allow the user to determine the probability that the POSITIVE or NEGATIVE reported by the system may be a false rendering -- a false POSITIVE or a false NEGATIVE."

ABOUT DECISION DIAGNOSTICS CORP

Decision Diagnostics Corp. is the leading manufacturer and worldwide distributor of diabetic test strips engineered to operate on legacy glucose meters. DECN's products are designed to operate efficiently and less expensively on certain glucose meters already in use by almost 7.5 million diabetics worldwide. With new inspired technology diabetic test strips already in the final stages of development, DECN products compete on a worldwide scale with legacy manufacturers currently selling to 71+ percent of a $15+ billion at-home testing market. The company's GenUltimate TBG product is not yet available for sale in the United States or Puerto Rico but is for sale in select International markets since late February 2020.

Forward-Looking Statements:

This release contains the company's forward-looking statements which are based on management's current expectations and assumptions as of March 3, 2020, regarding the company's business and performance, its prospects, current factors, the economy, and other future conditions and forecasts of future events, circumstances, and results.

CONTACT INFORMATION:

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info@decisiondiagnostics.co (mailto:info@decisiondiagnostics.com)
www.genultimate.com (http://pr.report/sD3XEn6e)
www.genultimatetbg.com (https://pr.report/D8CRH-Fw)
www.pharmatechdirect.com (http://pr.report/clyJvz8Q)

SOURCE: Decision Diagnostics Corp.

EXHIBIT 3

Back to Newsroom (/newsroom)

Decision Diagnostics Corp.

Company Profile on Investor Network (https://www.accesswire.com/social_visits.ashx?articleid=588463&networkid=inv&link=https://www.investornetwork.com/company/C-EC60CD8C91E41)

Companies Mentioned:

Primary Exchange: OTC PINK
Under the Symbol: DECN

$0.30
($0.0300)
-9.0909

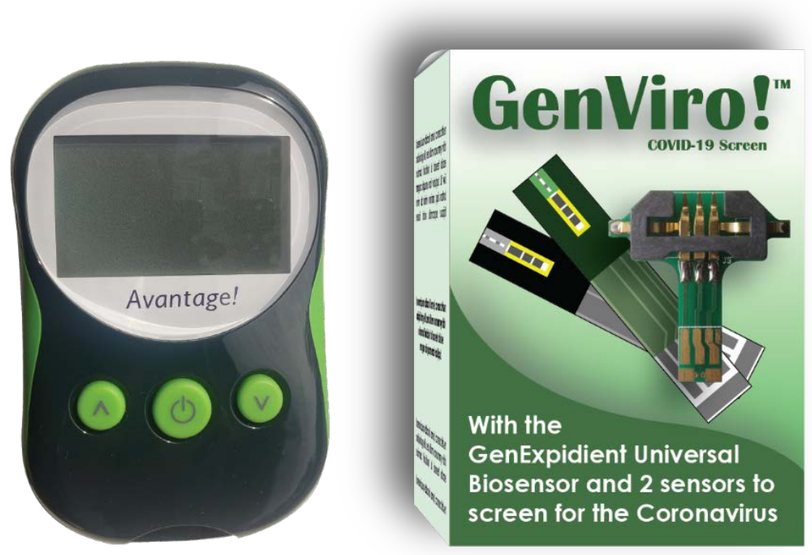
DECN Provides First Looks At Its GenViro(TM) Corona Virus Screening Kit & First Year Product Forecast of 420 Million Kits, with Sales Beginning Late 3Q 2020

Wednesday, March 11, 2020 10:15 AM EST

Initial Sales of GenViro^{tm} Covid19 to be to Big Box Pharmacies, Group Practices, Long Term Care Facilities and Stand-alone Clinics; Average Wholesale Price of the Kit Expected to be @ $6.95

LOS ANGELES, CA / ACCESSWIRE / March 11, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) is an 18-year old, diabetes-focused bio-technology development firm, manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for the GenUltimate! ("Sunshine") diabetes test strip, its GenAccord! systems for the uninsured and under-insured, its GenChoice! ("Ladybug") test strip now in the later stages of FDA 510(k) prosecution, and its GenUltimate Precis products manufactured for International markets.

Today, in the third discussion of our break-through test for the coronavirus (COVID19), we present the Coronavirus test kit and the Phase 1 unit forecast. The introduction of our new screening methodology for the Coronavirus (Covid19) will provide a timely, simple to use and cost effective solution for the screening of the frightening COVID19 virus. First uses of our kits will be in pharmacies, doctor's offices, clinics and urgent care centers, and long term care facilities. We anticipate the sale of 420,000,000 kits in the first full year of commercial sale. The company has retained FDA counsel who is in the process of securing expected emergency waiver for diagnostics and diagnostic devices.



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

Keith Berman, CEO of DECN commented, "Because we perfected the Impedance technology in 2019 for our GenUltimate TBG glucose test strip and meter, we have shaved months off of the development time for the GenViro! device. Our GenViro! impedance powered diagnostic will be field tested at ground-zero in Daegu, Korea, the location of our factory and the hospital based testing site, and where 1200+ people have already been overcome by Coronavirus (COVID19). Everyone who has succumbed to this type of flu, has been a blood donor at their testing facility or hospital. Daugu, Korea is one of the few places where acquiring donors will not be an issue. GenViro! will be a perfect storm product and our timing here is spot-on. Our biggest challenge will be meeting the expected crushing demand. For that we prepared, and are interviewing most likely partners currently."

Mr. Berman continued, "I cannot say often enough, we are developing a Coronavirus screening method, not a cure or a vaccine for the Covid19 virus. That being said, our screening method should allow for 80% of those who suspect that they carry the Coronavirus, to exit the potential quarantine in those places where Coronavirus is rampant, and a higher percentage where it is not.

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

We are not resting our laurels with our GenViro development. Later product entries will be test methods for Polio, Ebola (Marburg), Bird Flu, and SARS. The cost of our test kits will be sold in a price range of $4.95 to $7.95 per use. The Coronavirus kit will be sold for $6.95. Each kit sold will carry enough diagnostic for two tests, a primary test, and a test in reserve in case of human error in administrating the primary test. We plan to provide our diagnostics initially for use at hospitals, doctors' offices, and clinics. Once production ramps up, we will offer testing kits and meters to patients for testing at-home.

Mr. Berman concluded, "As you might imagine with a product announcement of such importance, we have been contacted by a number of potential partners for our kit, as well as companies who were not chosen last time to proceed past the proposition stage. The company's first choice for partnering will be a company that made "the cut" last time for our GenUltimate! TBG product. We will discuss partnering potential in a coming release. For the moment, the company is content calling on big box and long term care chains through its existing distributors and agents."

DECN also markets its PetSure! test strip for the diabetic testing of dogs and cats, a diagnostic specifically designed to run on the market leding Zoetis Alpha Trak meter system as well as the GenUltimate! 4Pets Test strip and Avantage! meter. The company has also just introduced its GenExpidient! Universal Translator for bio-sensor devices of different manufacture. A GenExpidient! device will be included in every Covid19 kit. Having such a device will lower the incidence of cleaning and disinfecting the GenViro! meter.

ABOUT DECISION DIAGNOSTICS CORP

Decision Diagnostics Corp. is the leading manufacturer and worldwide distributor of diabetic test strips engineered to operate on legacy glucose meters. DECN's products are designed to operate efficiently and less expensively on certain glucose meters already in use by almost 7.5 million diabetics worldwide. With new inspired technology diabetic test strips already in the final stages of development, DECN products compete on a worldwide scale with legacy manufacturers currently selling to 71+ percent of a $15+ billion at-home testing market. The company's GenUltimate TBG product is not yet available for sale in the United States or Puerto Rico but is for sale in select International markets since late February 2020.

Forward-Looking Statements:

This release contains the company's forward-looking statements which are based on management's current expectations and assumptions as of March 11 2020, regarding the company's business and performance, its prospects, current factors, the economy, and other future conditions and forecasts of future events, circumstances, and results.

CONTACT INFORMATION:

Decision Diagnostics Corp.
Keith Berman (805) 446-2973

info@decisiondiagnostics.co (mailto:info@decisiondiagnostics.com)
www.genultimate.com (http://pr.report/sD3XEn6e)
www.genultimatetbg.com (https://pr.report/hx1X2w-U)
www.petsureteststrips.com (file:///C:/Users/KMB/AppData/Local/Temp/www.petsureteststrips.com)
www.pharmatechdirect.com (http://pr.report/clyJvz8Q)

SOURCE: Decision Diagnostics Corp.

EXHIBIT 4

Back to Newsroom (/newsroom)

Decision Diagnostics Corp.

Company Profile on Investor Network (https://www.accesswire.com/social_visits.ashx?articleid=588463&networkid=inv&link=https://www.investornetwork.com/company/C-EC60CD8C91E41)

Companies Mentioned:

Primary Exchange: OTC PINK
Under the Symbol: DECN

$0.30
($0.0300)
-9.0909

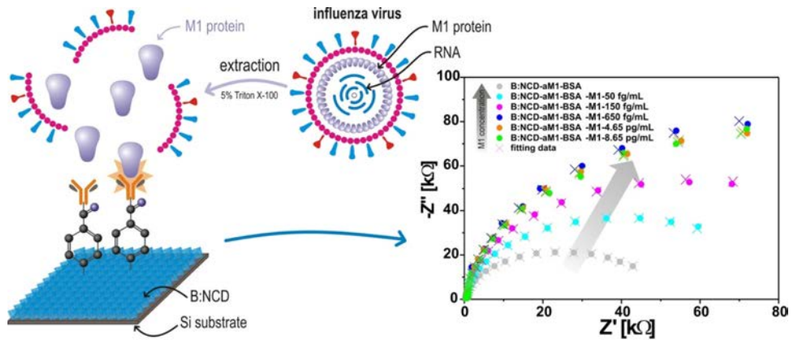
DECN Updates on Its Corona Virus Testing Product Genviro! (TM), With 200,000 Kits to Be Provided in USA & EU Prior to the Summer, 12 Month Forecast Updated to 480mm

Monday, March 16, 2020 10:15 AM EST

Emergency Waiver in Progress With U.S. FDA for Use in Entities That Employ Staff Professionals, Wholesale Price to Be $6.95, Walk-In Patient Cost Expected to Be $29.95

LOS ANGELES, CA / ACCESSWIRE / March 16, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) is an 18-year old, diabetes-focused bio-technology development firm, manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for the GenUltimate! ("Sunshine") diabetes test strip, its GenAccord! systems for the uninsured and under-insured, its GenChoice! ("Ladybug") test strip now in the later stages of FDA 510(k) prosecution, and its GenUltimate! Precis products manufactured for International markets.

Today, DECN announces in this first of four releases expected in the next 14 days, further details of our revolutionary Coronavirus (Covid19) screening test GenViro!™. Our product, introduced to the world only 14 days ago has entered its crucial development stage. We are awaiting release of blood samples from previously infected people in Daegu, Korea, so that we can complete testing and make a final report to the U.S. FDA so that we may secure our Emergency Waiver. In the meantime, all other requests made by the FDA will be met this week and next. Further, we will engage in the EU with administrators of the ISO standard CE regulatory process this week. Only two diagnostic methodologies have been approved in the EU, none with the cost effectiveness or promise of GenViro! Our 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.



Although the overall goal of our marketing plan for GenViro!™ is to sell the product directly to consumers for self-testing. Our initial efforts will be to provide overall verification of the GenViro!™ efficacy by working directly through organizations that regularly employ licensed medical technologists, or nurses (chain pharmacies, nursing home chains, and walk-in clinics). Our GenViro!™ will allow for the administration of the Covid-19 test through a "finger-stick," producing results in less than one-minute.

Keith Berman, CEO of DECN commented, "We plan a total of three additional releases in the coming days, the first new release discussing the product itself and why it is so special, the second release will discuss a roll-out plan, and the third release will summarize everything we have discussed to date, and talk about a second product we are working on, making use of the same technology, that is uber precise and destined to find its way into hospitals.

Our second GenViro™ product will be a confirmatory method for the GenViro™ screening methodology we have talked about in great detail, but also this second methodology will be capable of confirming other methodologies that may be in use."

Mr. Berman concluded, "I will say again, that we have developed a Coronavirus screening method, not a cure or a vaccine for this virus. The cost of our test kits will be sold at the wholesale level at $6.95. We expect our partners, chain pharmacies, nursing homes, clinics etc. to charge $24.95 to $29.95. We strongly believe there will be no shortage of people lining up to be tested. Once we complete the Emergency Waiver portion of our launch and move into ramping up of commercial production, we plan to offer testing kits and meters to patients for testing at-home. We expect the vast majority of the 420 million test kits we plan to manufacture in the first year of production will be sold to individuals for self-testing."

ABOUT DECISION DIAGNOSTICS CORP

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Forward-Looking Statements:

This release contains the company's forward-looking statements which are based on management's current expectations and assumptions as of March 15, 2020, regarding the company's business and performance, its prospects, current factors, the economy, and other future conditions and forecasts of future events, circumstances, and results.

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www.genultimatetbg.com (https://pr.report/D8CRH-Fw)
www.pharmatechdirect.com (http://pr.report/clyJvz8Q)

SOURCE: Decision Diagnostics Corp.

EXHIBIT 5

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Decision Diagnostics Corp.

Company Profile on Investor Network (https://www.accesswire.com/social_visits.ashx?articleid=588463&networkid=inv&link=https://www.investornetwork.com/company/C-EC60CD8C91E41)

Companies Mentioned:

Primary Exchange: OTC PINK
Under the Symbol: DECN

$0.30
($0.0300)
-9.0909

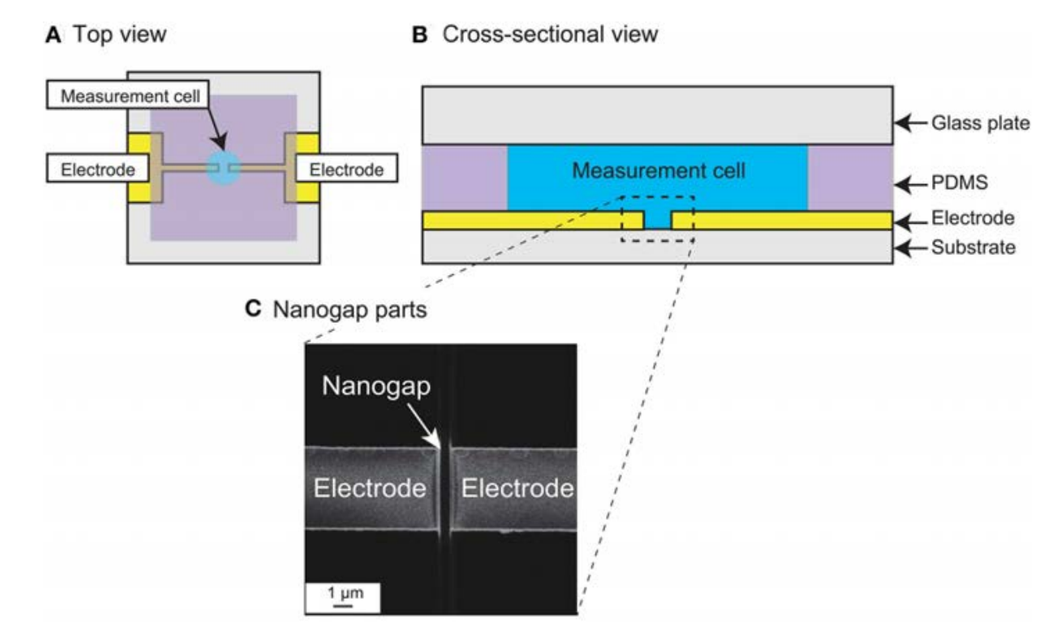
DECN'S GenViro!(TM) Corona Virus "Swift" Kit, Now to Be Additionally Offered to Commercial Labs and Religious Groups as 12 Month Forecast is Raised to 525MM

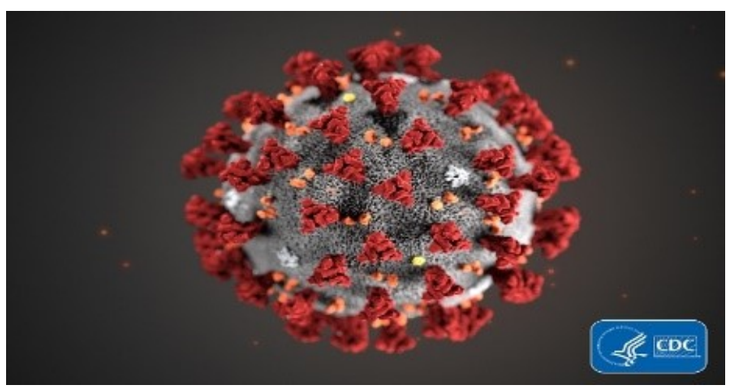
Tuesday, March 17, 2020 10:15 AM EST

RESPONSE FROM MEDICAL/HEALTHCARE ENTITIES & WHOLESALERS HAS BEEN CRUSHING AS GROUPS QUEUE UP FOR COVID-19 "SWIFT" KIT WHILE WE AWAIT FDA EMERGENCY APPROVAL

LOS ANGELES, CA / ACCESSWIRE / March 17, 2020 / Decision Diagnostics Corp. (OTCPINK:DECN) is an 18-year old, diabetes-focused bio-technology development firm, manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for the GenUltimate! ("Sunshine") diabetes test strip, its GenAccord! systems for the uninsured and under-insured, its GenChoice! ("Ladybug") test strip now in the later stages of FDA 510(k) prosecution, and its GenUltimate Precis! products manufactured for International markets.

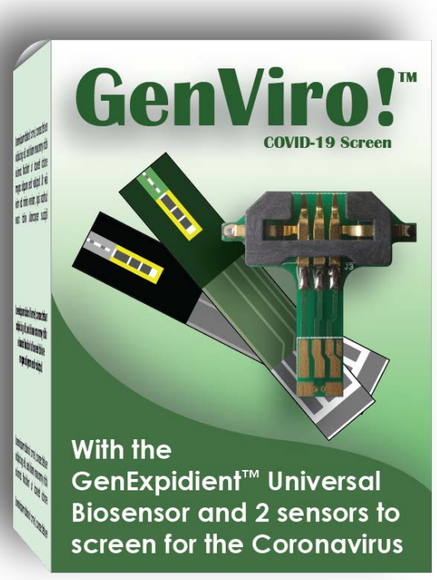
Today, in this second of four updates about our GenViro™ Swift" kit for the testing of COVID-19, we will focus on our expected roll-out. We are happy to inform all interested parties that we have raised our 12-month forecast to 525 million kits. We have also added commercial laboratories, those labs with remote blood drawing stations (an estimated 27,000 nationwide), and religious groups to those entities that will receive the first kits manufactured post FDA Emergency Approval. These additional groups join chain pharmacies and grocers with pharmacies, clinics, home health service providers, and medical group practices as the first to receive our GenViro™ kits.

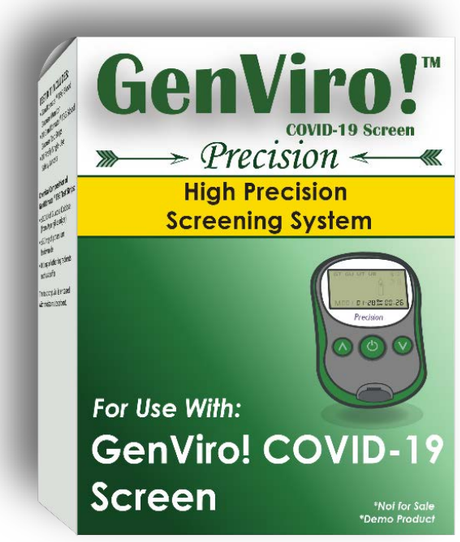




Keith Berman, CEO of DECN commented, "Our first roll-out of 150,000 GenViro™ kits in the US and Canada will be paired with a roll-out of 100,000 GenViro™ kits in the EU. The first kits manufactured will be provided, free of charge or at a nominal fee, to professional entities. These groups include chain pharmacies and grocery store pharmacies, commercial laboratories with remote blood drawing stations, churches and other places of worship, as well as clinics and long term care facilities. Ultimately, GenViro™ will be sold directly to consumers, as our roll-out progresses."

Mr. Berman continued, "Over the weekend, and after receiving a plan from our technical and R&D director, we decided to take the next step with GenViro™and further refine its use for hospitals. While we have not yet forecast sales to hospitals, and while most of the lesser but competitive products are directed toward hospital uses, we nonetheless believe that hospitals will be a large future source of revenues. When we complete this round of information releases, our fourth release will include a hospital forecast.





*Not yet for Sale in the U.S. or Puerto Rico

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

Mr. Berman concluded, "As you might imagine with a product announcement of such importance, we have been contacted by a number of potential partners for our kit. To date we have discussed our GenViro™ product with a big box pharmacy chain, a master medical products distribution company, a large commercial lab, and a home health organization. All of these entities want the kits and we intend to write their business.

We are not resting our laurels with our GenViro development. Later product entries will be test methods for Polio, Ebola (Marburg), Bird Flu, and SARS. The cost of our test kits will be sold in a price range of $4.95 to $7.95 per use. The Coronavirus kit will wholesale $6.95. Each kit sold will carry enough diagnostic for two tests, a primary test, and a test in reserve in case of human error in administrating the primary test. We plan to provide our diagnostics initially for use at hospitals, doctors' offices, and clinics. Once production ramps up, we will offer testing kits and meters to patients for testing at-home.

DECN also markets its PetSure! test strip for the diabetic testing of dogs and cats, a diagnostic specifically designed to run on the market leding Zoetis Alpha Trak meter system as well as the GenUltimate! 4Pets Test strip and Avantage! meter. The company has also just introduced its GenExpidient! Universal Translator for bio-sensor devices of different manufacture. A GenExpidient! device will be included in every Covid19 kit. Having such a device will lower the incidence of cleaning and disinfecting the GenViro! meter.

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Forward-Looking Statements:

This release contains the company's forward-looking statements which are based on management's current expectations and assumptions as of March 16, 2020, regarding the company's business and performance, its prospects, current factors, the economy, and other future conditions and forecasts of future events, circumstances, and results.

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www.genultimatetbg.com (https://pr.report/HEDONYKI)
www.petsureteststrips.com (https://pr.report/cv4qCjG6)
www.pharmatechdirect.com (http://pr.report/clyJvz8Q)

SOURCE: Decision Diagnostics Corp.

EXHIBIT 6

Back to Newsroom (/newsroom)

Decision Diagnostics Corp.

Company Profile on Investor Network (https://www.accesswire.com/social_visits.ashx?articleid=588463&networkid=inv&link=https://www.investornetwork.com/company/C-EC60CD8C91E41)

Companies Mentioned:

Primary Exchange: OTC PINK
Under the Symbol: DECN

$0.30
($0.0300)
-9.0909

DECN's GenViro!(TM) COVID-19 "Rapid" Kit to Reap Huge Boost from 3/16 FDA Guidance Allowing for Near Immediate Distribution of Kits Prior to Emergency Waiver Grant

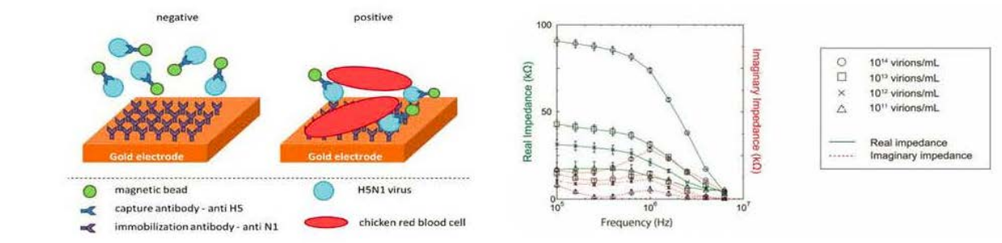
Wednesday, March 18, 2020 10:00 AM EST

Significant regulatory policy is changed so that once diagnostic validation is completed, test kits can be distributed subject only to certain labeling and testing presentations

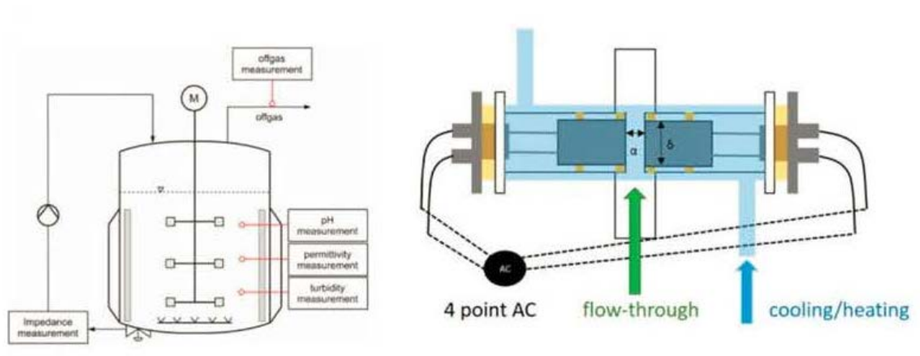
LOS ANGELES, CA / ACCESSWIRE / March 18, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) is an 18-year old, diabetes-focused bio-technology development firm, manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for the GenUltimate! ("Sunshine") diabetes test strip, its GenAccord! Enhance ("Caterpillar") strip and meter systems for the uninsured and under-insured, its GenChoice! ("Ladybug") test strip now in the later stages of FDA 510(k) prosecution, and its GenUltimate! Precis products manufactured for International markets.

Today, DECN announces that the company is revising strategies (and forecasts) for its GenViro!™ Covid-19 test kit, a test kit that provides a coronavirus result in less than a minute, at the point of case. The company expects that it will receive a major boost from the most recent and thus far most optimistic FDA guidance for Coronavirus test kits.

On March 16, the FDA updated its COVID-19 test policy. A significant change to this policy is that once validation testing for a product has been completed, the test can be distributed to customers, entities and users, with certain labeling and a summary of test results provided on the company website (and/or the package). GenViro!™ has been validated at the company's R&D center in Daegu, Korea for the H5N1 virus and most recently the methodologically similar corona virus. The new FDA policy is available to read at: https://www.fda.gov/media/135659/download (https://pr.report/xlmRVnuv)



Keith Berman, CEO of DECN commented, "In the last 24 hours we have witnessed a sea change in how the FDA is processing applications for Covid-19 diagnostic kits, and in doing so is allowing some of these kit products to be sold or provided once test validation is provided. While the company will still need to provide ample data and a full discussion of its unique technology in the coming days, the new FDA policy will provide a channel that will allow the company to manufacture test kits and put these kits into distribution almost immediately. This same unperturbed policy will also allow us to quickly add our second GenViro™ product designed for hospitals and for clinics and commercial labs desirous of a confirmatory method for those who test positive for coronavirus."



Mr. Berman concluded, "I have been in and around the in-vitro diagnostics business for over 40 years, and never before in all of that time, have I witnessed a policy like this. This latest guidance from the FDA shaves months from our product development process, and we all shall reap these benefits. Tomorrow we will discuss our new plans going forward now that we will shortly be a two product coronavirus diagnostics company."

ABOUT DECISION DIAGNOSTICS CORP

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Forward-Looking Statements:

This release contains the company's forward-looking statements which are based on management's current expectations and assumptions as of March 17, 2020, regarding the company's business and performance, its prospects, current factors, the economy, and other future conditions and forecasts of future events, circumstances, and results.

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www.genultimatetbg.com (https://pr.report/D8CRH-Fw)
www.pharmatechdirect.com (http://pr.report/clyJvz8Q)

SOURCE: Decision Diagnostics Corp.

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EXHIBIT 7

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Decision Diagnostics Corp.

Company Profile on Investor Network (https://www.accesswire.com/social_visits.ashx?articleid=588463&networkid=inv&link=https://www.investornetwork.com/company/C-EC60CD8C91E41)

Companies Mentioned:

Primary Exchange: OTC PINK
Under the Symbol: DECN

$0.30
($0.0300)
-9.0909

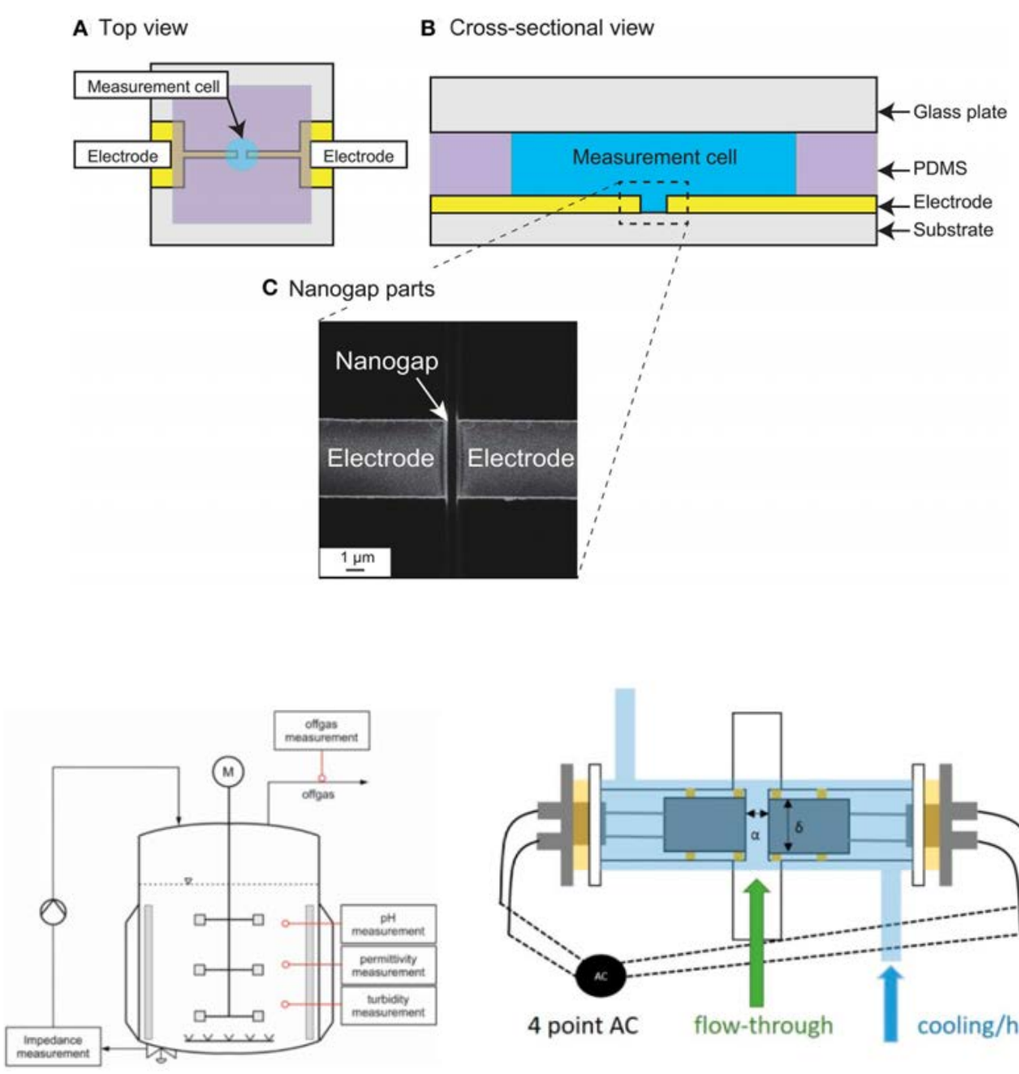
DECN to Finance 2Q 2020 Roll Out of its GenViro! Covid-19 "Rapid" Kits Using Non-Dilutive Debt Financing Totaling $13 Million Acquired in Near 0% Rate Environment

Friday, March 20, 2020 8:55 AM EST

COMPANY SEIZES OPPORTUNITY TO GET ITS 60 SECOND GENVIRO! "RAPID" KITS INTO THE MARKET, RECEIVES INITIAL DEBT COMMITMENT FROM PRIVATE FUNDS, PRODUCT UPDATES RESUME NEXT WEEK

LOS ANGELES, CA / ACCESSWIRE / March 20, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) is an 18-year old, diabetes-focused bio-technology development firm, manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for the GenUltimate! ("Sunshine") diabetes test strip, its GenAccord! Enhance ("Caterpillar") strip and meter systems for the uninsured and under-insured, its GenChoice! ("Ladybug") test strip now in the later stages of FDA 510(k) prosecution, and its GenUltimate! Precis products manufactured for International markets, and its GenViro! Rapid Kits for the real time testing for the Coronavirus (COVID-19).

Today, DECN announces that the company's Board of Directors has approved the offering of $13 million in non-dilutive debt financing, the first $2 million in Notes, followed by a $1 million credit facility to purchase manufacturing equipment for their Korean manufacturing facility, and the remaining $10 million in a revolving line of credit to finance inventory. Each of the three offerings are already subscribed to.



With interest rates at near zero% and equity at a premium, our Board moved quickly to secure the debt. There is no equity component or stock conversion feature in any of the debt instruments. Prior to structuring the debt offerings, the company received an unsolicited commitment for at least $1 million in Notes and is collecting these subscriptions. Almost $500,000 has been received thus far with the remainder promised prior to March 31, 2020

Mr. Berman commented, "If banks and finance companies insist on nearly giving money away, we will take all we can. The $13 million we seek, split by need, will carry us for the remainder of 2020. Using this debt as a cushion, we are also exploring partnerships and licensing arrangements. I have lost count of the people who have called me with the same one line opening, "stop your search, we're the only partner you will ever need." In more than one case the potential partner was spot-on. Our GenViro!^{TM} Rapid Kit will offer Covid-19 test results for $6.95, test a patient in under a minute, require less than 2 microliters of whole blood derived from a finger prick."

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Forward-Looking Statements:

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SOURCE: Decision Diagnostics Corp.

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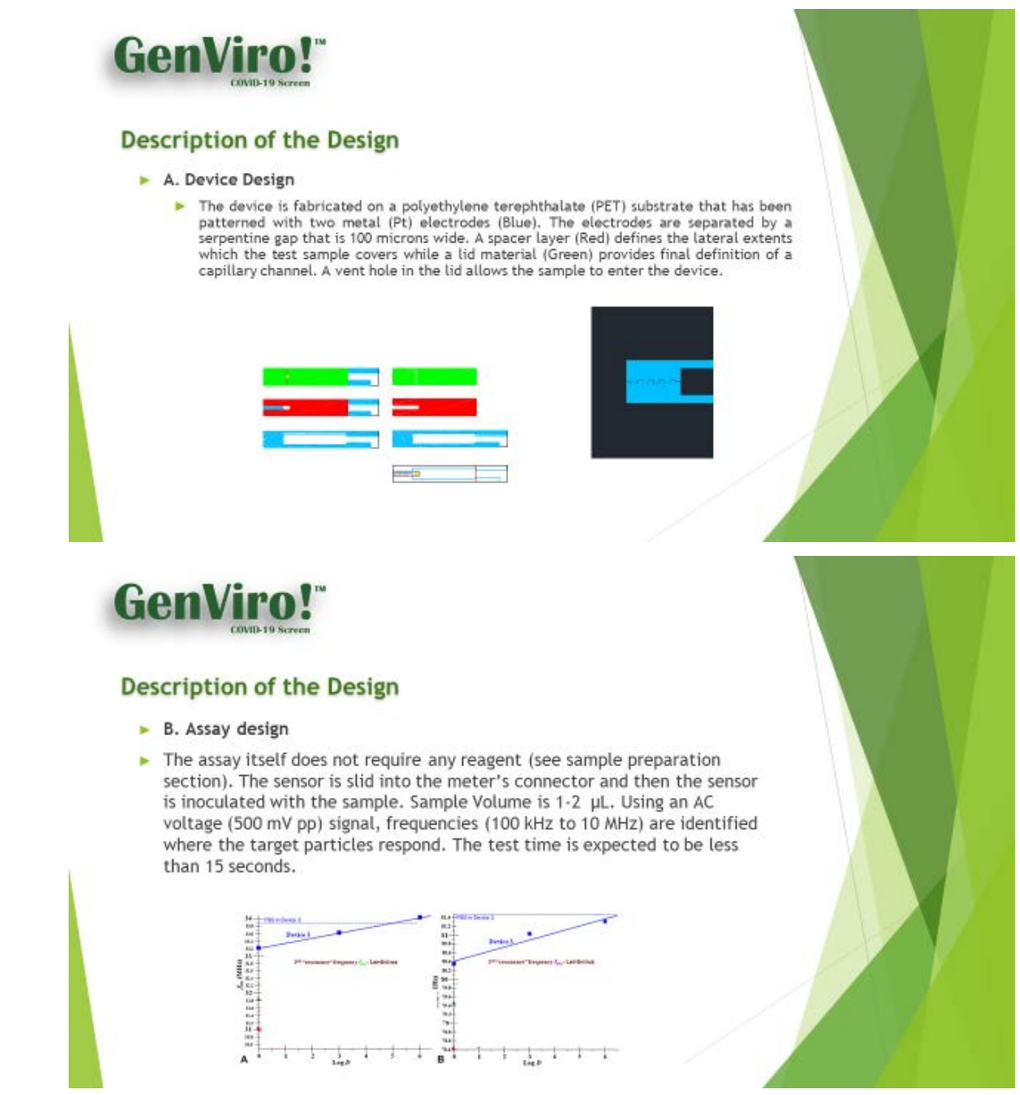
DECN Finalizes FDA Pre-EUA Version of Its Genviro! Screening Covid-19 Swift Kit, Providing Results in 15 Seconds Using Only 1.0-2.0 Microliters Whole Blood

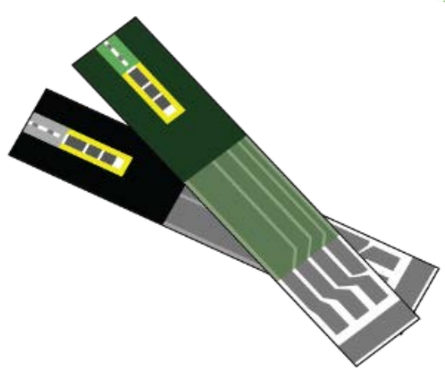
Monday, March 23, 2020 10:15 AM EST

COMPANY'S EMERGENCY USE (EUA) APPLICATION TO BE UPDATED IN THE NEXT WEEK AS MANUFACTURING SPECIFICATIONS FINALIZED, DISCUSSION OF GENVIRO! UNIQUE QUALITIES ENSUES

LOS ANGELES, CA / ACCESSWIRE / March 23, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) is an 18-year old, diabetes-focused bio-technology development firm, manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for the GenUltimate! ("Sunshine") diabetes test strip, its GenAccord! Enhance ("Caterpillar") strip and meter systems for the uninsured and under-insured, its GenChoice! ("Ladybug") test strip now in the later stages of FDA 510(k) prosecution, and its GenUltimate! Precis products manufactured for International markets, and its GenViro! Rapid Kits for the real time testing for the Coronavirus (COVID-19) now seeking FDA Emergency Waiver (EUA).

Today, DECN announces that the company, through its advanced development team in Korea, have finalized the configuration of the GenViro! Swift Kit test strip that will go into production just as soon as the FDA grants emergency status to the DECN product. The company's methodology employs a simple, easy to use, swift (15 seconds and faster than Rapid) method for determining the presence of a virus in blood lyced into blood plasma. Blood sample requirements are 1-2 microliters. The kits will be manufactured for DECN in Korea by its contract manufacturer, the same company that manufactures our diabetic test strips. While the manufacturing will occur in Korea, the test strip is 100% of American design.





Keith Berman, CEO of DECN commented, "The news channels are filled with talk about the coming rapid test kits for the detection of the virus Covid-19. These kits are recent creations based on traditional chemistry methods such as anti-body/antigen analysis or PCR (the nose swab RNA method). While these methods offer a path to results, we have not found any that will give a patient a result in less than minutes (and we have our doubts), or are methods that can provide on the spot analysis.

Further these methods and variations of same, typically require analyzers that are in the instrument arsenals of large hospitals or large commercial laboratories, not the shopping center parking lot or the flu shot clinic at the local pharmacy, or the meeting hall at a church. GenViro! provides results in 15 seconds, based on a small finger prick blood sample. The method is safe, effective, and its biggest benefit to the healthcare system is that the device can be used to screen out the 97% or 98% of those tested that are negative for COVID-19. Our method is quicker, provides the desired result, is much cheaper, and effective."

Serology Testing for COVID-19

According to the Johns Hopkins School of Medicine, "Serology tests are blood-based tests that can be used to identify whether people have been exposed to a particular pathogen. Serology-based tests analyze the serum component of whole blood. The serum includes antibodies to specific components of pathogens, called antigens. These antigens are recognized by the immune system as foreign and are targeted by the immune response. These types of tests are often used in viral infections to see if the patient has an immune response to a pathogen of interest, such as influenza, or in this case COVID-19. These methodologies are a focus of current test kit methodologies, particularly what are called rapid kits, which are not very rapid, and not self-contained so therefore only a partial kit. These tests have been around at least since the 1980s. GenViro! is not a Serology methodology.

PCR Based Testing for Coronavirus ("Take a Nose Swab")

PCR based (RNA) testing of virus and infections has been around since the early 1980s and make up a large number of methods used to detect Covid-19. For example the much discussed Roche methodology detects the genetic signature (RNA) of the SARS-CoV-2 virus in swab samples that a healthcare provider collects from the back of the patient's throat or nose. Most alternative methods work in the same manner. Test turn-around time, usually is 4 hours. However, the testing does not occur at the location where the nose swab is taken. Also, instrumentation needed to complete the tests and report them are expensive. Many feel that In the United States, the slow rollout of coronavirus PCR (nose swab) tests (https://pr.report/wBEZFLoN) has been widely attributed to a combination of previously

stringent FDA rules, and the slower, older methodologies. The DECN GenViro! kit does not employ a nose swab, rather it receives its small blood sample through a finger prick, is self-contained and disposable, does not require a hospital or clinical lab based instrument for analysis, and it only takes 15 seconds, a minute fraction of the nose swab tests.

Mr. Berman concluded, "DECN is also creating what we call our affirmation test, a kit that will affirm a positive reading from the GenViro! Screener. Similar in nature to the GenViro! screener, and readable by the Avantage meter, the affirmation test will be serology based, but will use our unique and charmed electrochemical impedance spectroscopy. We anticipate being tens of millions of GenViro! kits down the road when our serology version of Genviro! is completed. These are the most exciting days at DECN."

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www.genultimatetbg.com (https://pr.report/D8CRH-Fw)
www.pharmatechdirect.com (http://pr.report/clyJvz8Q)

SOURCE: Decision Diagnostics Corp.

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Decision Diagnostics Corp.

Company Profile on Investor Network (https://www.accesswire.com/social_visits.ashx?articleid=588463&networkid=inv&link=https://www.investornetwork.com/company/C-EC60CD8C91E41)

Companies Mentioned:

Primary Exchange: OTC PINK
Under the Symbol: DECN

$0.30
($0.0300)
-9.0909

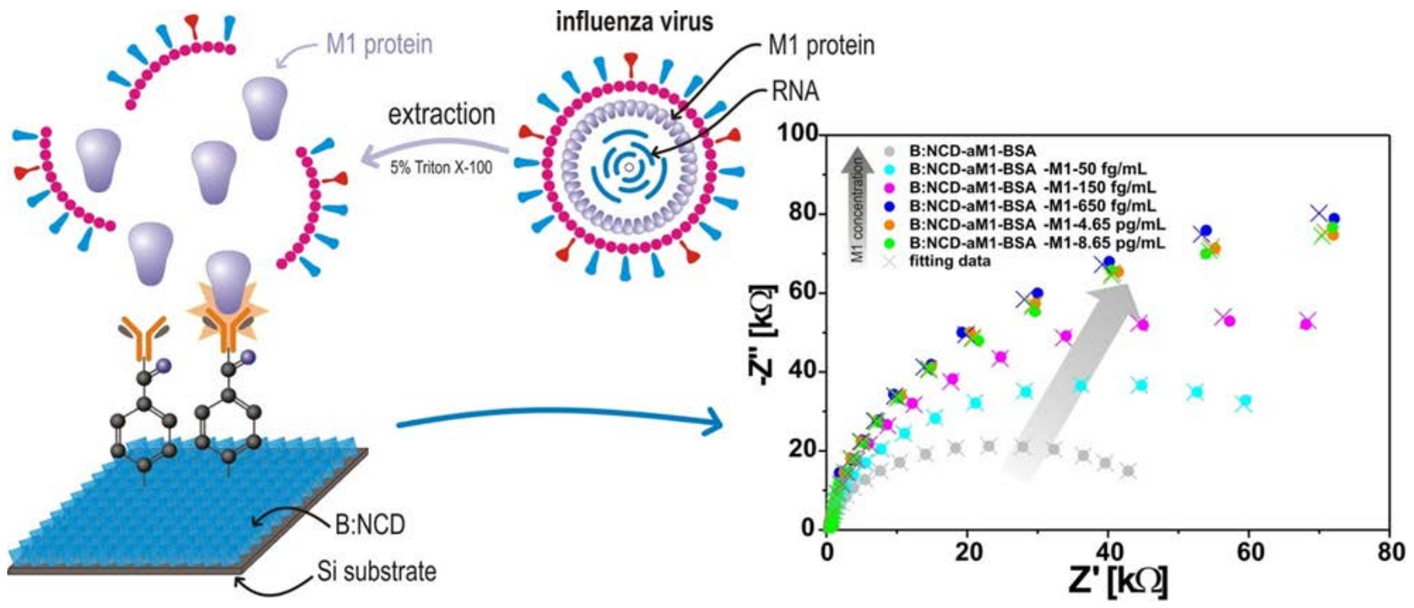
DECN to Add 2nd Covid-19 Test Kit Using Antibody/Antigen Methodology as a Determination Test for Patients Who Previously Tested Positive for Covid-19

Wednesday, March 25, 2020 10:15 AM EST

COMPANY TO AGAIN SEEK FDA EUA FOR ITS CONFIRMATION KIT MAKING DECN THE FIRST TO OFFER TWO TYPES OF COVID-19 TEST KITS, A SCREENING KIT AND A POST SCREEN CONFIRMATION KIT

LOS ANGELES, CA / ACCESSWIRE / March 25, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) is an 18-year old, diabetes-focused bio-technology development firm, manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for the GenUltimate! ("Sunshine") diabetes test strip, its GenAccord! Enhance ("Caterpillar") strip and meter systems for the uninsured and under-insured, its GenChoice! ("Ladybug") test strip now in the later stages of FDA 510(k) prosecution, and its GenUltimate! Precis products manufactured for International markets, and its GenViro! Rapid Kits for the real time testing for the Coronavirus (COVID-19) now seeking FDA Emergency Waiver (EUA).

Today, DECN announces that the company, through its advanced development team in Korea, has arrived at a second Covid-19 test methodology, a modified Serology method, that at the completion of documentation, be put through the FDA Emergency Waiver (EUA) process. This second kit will begin assembly for internal testing on April 1, with availability in late summer 2020. The method will again use a Biosensor (test strip-like device) and the company's Precise meter.



Keith Berman, CEO of DECN commented, "When we began exploring available testing methods for the Covid-19 virus, our goals were straight forward. Provide an easy to use, reliable, inexpensive test kit, designed for immediate use at the point of care, and eventually for at-home use. We accomplished these goals with our GinViro! Swift kit. And now we turn our attention to a second method for confirmation of those people who test positive during the Covid-19 screen. This second method will be true to our technology. GenViro! Confirm will be of our own creation and engineering and make use of our deep experience in Biosensors. This confirmation kit will have a wholesale price of $9.95. We will provide a kit unit forecast in coming days."

GenViro! Confirm will produce confirmatory results in less than a minute, also based on a small finger prick blood sample. The method is safe, effective, and its biggest benefit to the healthcare system is that the device will confirm or not confirm a positive result, saving the patient the trouble of going to a hospital or reference laboratory for confirmation testing. This is no small thing.

Mr. Berman concluded, "As this week goes on we will present a summary discussion of those specifics and issues we have considered in the past 21 days, a truly remarkable time for the company. We are truly thankful that the private sector, the Federal government and foreign governments are showing extreme interest in out GenViro! products. We have many more accounts to present."

ABOUT DECISION DIAGNOSTICS CORP

Decision Diagnostics Corp. is the leading manufacturer and worldwide distributor of diabetic test strips engineered to operate on legacy glucose meters. DECN's products are designed to operate efficiently and less expensively on certain glucose meters already in use by almost 7.5 million diabetics worldwide. With new inspired technology diabetic test strips already in the final stages of development, DECN products compete on a worldwide scale with legacy manufacturers currently selling to 71+ percent of a $15+ billion at-home testing market. The company's new GenViro!^{TM} product designed to test for the Coronavirus Covid-19, is not yet available in the United States or Puerto Rico but Emergency Waivers are in process, and the product concept has been presented to officials in Washington, DC by invitation and included follow up from Corona virus authorities both in the USA and from foreign governments.

Forward-Looking Statements:

This release contains the company's forward-looking statements which are based on management's current expectations and assumptions as of March 24, 2020, regarding the company's business and performance, its prospects, current factors, the economy, and other future conditions and forecasts of future events, circumstances, and results.

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SOURCE: Decision Diagnostics Corp.

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Under the Symbol: DECN

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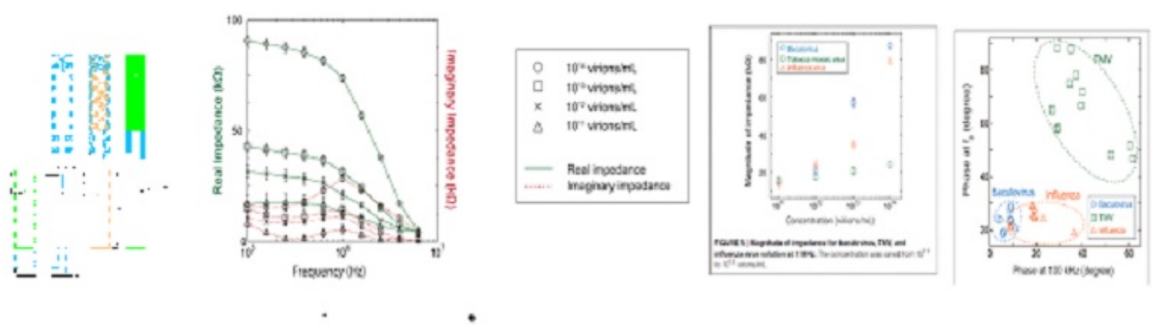
DECN Files Finalized FDA EUA Application for Its Genviro! Covid-19 Swift Kit, Receives Notification of Acceptance From FDA After-Hours on Friday 4/3/2020

Monday, April 6, 2020 10:15 AM EST

FDA Further Assigns Genviro COVID-19 Swift Kit Application to EUA Review Group on Saturday 4/4/2020, Pre-Uea Designation Anticipated Next

LOS ANGELES, CA / ACCESSWIRE / April 6, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) manufacturers and design specifiers for the GenViro! Covid-19 Swift Kit, is an 18-year old, diabetes and now disease testing bio-technology development firm, high level manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for its own proprietary regulated medical devices, announces today that the company has filed its formal and finalized Emergency Authorization for its Professional Use Covid-19 screening kit with the Emergency Authorization review group at the U.S. FDA. The application was filed on Friday 4/3/2020 late in the afternoon, acknowledged less than three hours later, and assigned for EUA review on Saturday 4/4/2020. There have already been several contacts between the FDA EUA review group and the company's FDA counsel.

DECN had originally intended to submit its application for both of its Covid-19 Swift Kit products, the Professional version kit to be administered to by nurses, doctors, pharmacists and other professionals, and the at-home personal use kit we envision to be distributed by big box pharmacies, governmental agencies, home health agencies and directly by our own distributors. But because the FDA had yet to approve a kit designed for individual use, we decided to proceed first with the Pro version Swift kit and follow on as soon as possible with a separate EUA application for the at-home kit as a stand-alone application. We plan to use the same application with minor changes to reflect the individual use.



Keith Berman, CEO of Decision Diagnostics commented, "In February 2020, several weeks before the Covid-19 virus began to spread through Europe and then the USA, we prayed for our Korean colleagues who had the misfortune of living and working at Ground Zero for the Covid-19 virus in the city of Daegu. Watching that terrible news gave all of us the desire to open hearts, re-examine our past products and successes, all in an effort to create a diagnostic method based our own core technology competencies even though virus detection was not in our mainstream. I have always believed that our impedance based core technology, first used as a critical part of our GenUltimate TBG product in the fall of 2019, was an adjustable crescent wrench type tool with many and varied possible applications. The first result of our hard work is the Covid-19 Swift kit that will be administered by professional health responders.

We will continue with our stated practice to sell the kits in the wholesale markets for $6.95 each, each kit containing test materials and a back-up, in case of human test administration error. Our Swift kit will take a small amount of time to administer to a patient by a professional, such as poking a patient's finger-tip to achieve a drop of blood. Results will be available in about 15 seconds.

Mr. Berman continued, "Our Korean partners, my primary consultant, who came out of retirement to create the design drawings and commentary, our FDA lawyers, and our own employees and those of our Korean partner jumped all over our efforts in what became a fundamental initiative. The application we filed with the FDA last Friday is our first fulfillment of these efforts, after weeks of internal and external discussion, planning, designing and redesigning and finally completion of the method design. If April 3 is the date where we drove our product stake into the ground, then the new product was conceived, designed and readied for FDA EUA review in approximately 45 days. Our method is unique, minimally invasive, doesn't require a painful nose swab, and true to its trade name -- Swift."

The company plans additional releases for a further description of this FDA filing and review event, the first upcoming release to notify all interested parties when our EUA application is deemed Pre-UEA by the FDA, that seminal second step. We also plan a lay description of some of the unique properties of our method, to be described in detail to the USPTO in our upcoming patent applications, but in layman's terms for our interested parties which now include a number of foreign governments and/or their agents.

Mr. Berman concluded, "Work began in late March to incorporate the Covid-19 Pro kit into our overall QA Plan and the parallel QA plan of our partner in Korea. Work has begun lining up and ordering critical components needed for the methodology, such as the platinum glass electrodes. Given the Covid-19 crisis we find ourselves in, the flux in the rare earth and precious metals markets, delivery times for components have become much more important than price. Oh, and one last thing I am reminded of. The recent literature on the development of these tests, by us and other parties, has recently discussed President Trump's desire to have numerous "parking lot, drive up" testing centers in large retail, even church parking lots. The written accounts claim that these parking lot, drive up" testing centers have not materialized. In my humble opinion, while our Swift kits will have numerous uses in professionally administered settings, there is no better use for our Covid-19 Swift kit than these drive up centers, which we believe will quickly materialize."

ABOUT DECISION DIAGNOSTICS CORP

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Forward-Looking Statements:

This release contains the company's forward-looking statements which are based on management's current expectations and assumptions as of April 4, 2020, regarding the company's business and performance, its prospects, current factors, the economy, and other future conditions and forecasts of future events, circumstances, and results.

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www.pharmatechdirect.com (http://pr.report/clyJvz8Q)

SOURCE: Decision Diagnostics Corp.

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Companies Mentioned:

Primary Exchange: OTC PINK
Under the Symbol: DECN

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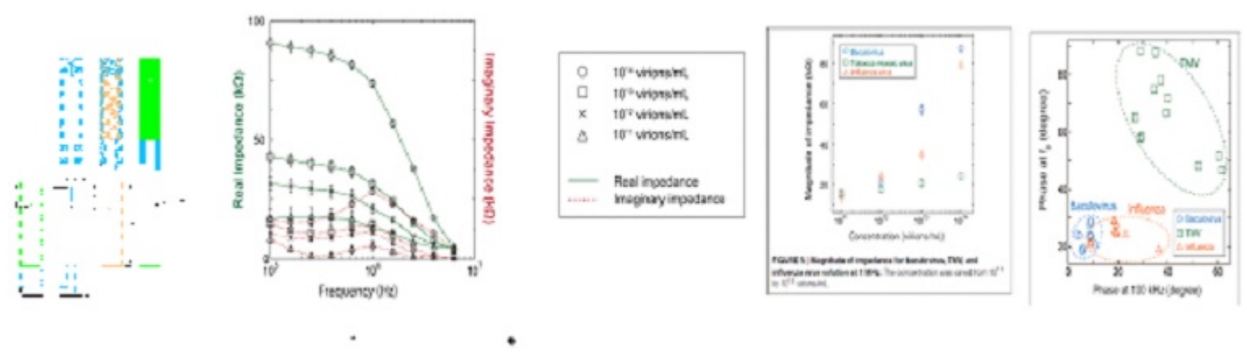
DECN Receives Pre-EUA Acknowledgement Letter And Product Serial Number From U.S. FDA For GenViro!(TM) Covid-19 Screening Kit For Professional Use

Tuesday, April 7, 2020 10:15 AM EST

COMPANY BEGINS SCALE PURCHASES OF GENVIRO!™ COMPONENTS, CREATING PACKAGING USING FDA EUA LABELING GUIDANCE, APPLICATION IN PROCESS FOR GENVIRO!™ AT-HOME SCREENING KIT

LOS ANGELES, CA / ACCESSWIRE / April 7, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) through its subsidiary Pharma Tech Solutions, Inc. the manufacturers and design specifiers for the GenViro! Covid-19 Swift Kit, is an 18-year old, diabetes and now disease testing bio-technology development firm, high-level manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for its own proprietary regulated medical devices, announces today that the company has received the Pre-EUA Acknowledgement letter from the U.S. FDA for device (serial number) PEUA200232, GenViro Covid-19 Screening Kit. This grant by the FDA is a major milestone in our GenViro!™ Covid-19 test kit development, now beginning its 7th week since we became aware that our manufacturer and R&D professionals were living and working at Ground Zero of the Korean Covid-19 epidemic.

DECN received the Pre-EUA Acknowledgement and device serial number on Saturday, April 4, 2020. Later on this same day FDA counsel had several exchanges with FDA EUA staff. In one of those exchanges, the FDA provided Guidance for our final product testing.



Keith Berman, CEO of Decision Diagnostics commented, "We filed our final application with the FDA for EUA approval on April 3, 2020, taking out all reference to our at-home use Covid-19 kit. 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."

As early as Saturday April 4, 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. Although the testing requested will be rigorous, it appears that testing will require 30 known Covid-19 positive samples and 30 known Covid-19 negative samples, all samples based on venous blood. The company is now looking to contract with a hospital or commercial laboratory to complete this testing.

Mr. Berman continued, "Upon receipt of these acknowledgments from the FDA, we contacted our partners in Korea, and provided specifications for all of the major components required for the GenViro!™ kit that are not used or a part of our GenUltimate! TBG product. Today our partners began ordering these components to begin build, assembly and bench testing for the post-prototype version of GenViro!™, Point of Care kit. These activities will become part of the completion of our Design Specifications file and Design History file for Genviro!™, and are necessary components of all FDA cleared medical devices. "

The company plans to discuss in the coming days how we intend to identify the various coronaviruses through GenViro!™. Reading that discussion will be a unique opportunity. The method the company intends to use will be based upon earlier products shepherded by Messrs. Berman and Musho. We expect industry people will be surprised.

ABOUT DECISION DIAGNOSTICS CORP

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Forward-Looking Statements:

This release contains the company's forward-looking statements which are based on management's current expectations and assumptions as of April 6, 2020, regarding the company's business and performance, its prospects, current factors, the economy, and other future conditions and forecasts of future events, circumstances, and results.

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SOURCE: Decision Diagnostics Corp.

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Companies Mentioned:

Primary Exchange: OTC PINK
Under the Symbol: DECN

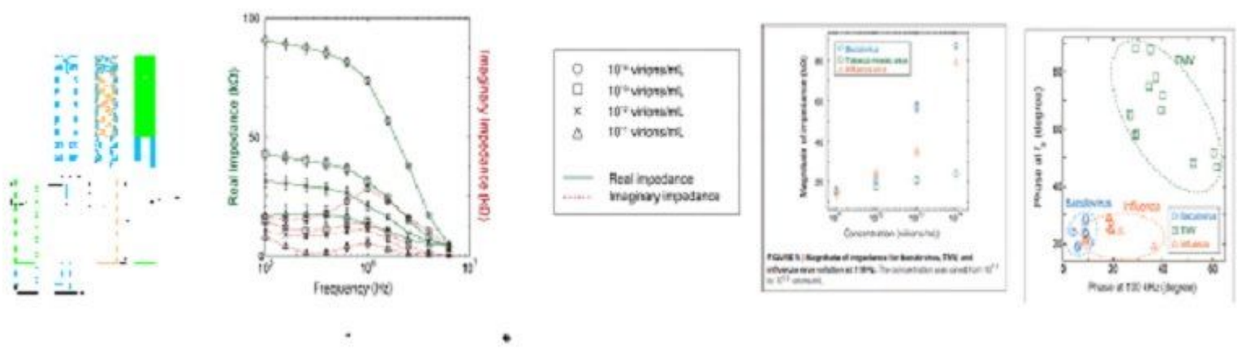
$0.30
▼ ($0.0300)
-9.0909

DECN to Provide Updates on the Progress of Our GenViro! Covid-19 Test Kits on Thursday April 23

Tuesday, April 21, 2020 9:15 AM EST

COMPANY WILL DETAIL CURRENT PROGRESS OF FDA EUA WAIVER, FILING OF 2ND EUA FOR AT-HOME USE KIT, & HUGE RESPONSE FROM AMERICAN COMPANIES LOOKING TO BUY 1ST IN LINE

LOS ANGELES, CA / ACCESSWIRE / April 21, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) through its subsidiary Pharma Tech Solutions, Inc. the manufacturers and design specifiers for the GenViro! Covid-19 Swift Kit, is an 18-year old, diabetes and now disease testing bio-technology development firm, high-level manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for its own proprietary regulated medical devices, announces today that the company will update shareholders and other interested parties on Thursday April 23 on issues concerning the progress of our GenViro! Covid-19 test kits as well as other company crucial business issues. Our GenViro! Covid-19 test kit is currently in the FDA EUA review process. We have received the Pre-EUA Acknowledgement letter from the U.S. FDA for device (serial number) PEUA200232, GenViro Covid-19 Screening Kit.



Keith Berman, CEO of DECN commented, "We plan several updates for our GenViro! Covid-19 test kits as our EUA application progresses through the FDA. The first of these updates will be Thursday, April 23, 2020. In this update we will also speak at length about our sister product, the GenViro! for at-home use, where we are now in the process of completing our FDA EUA application. Also in our plans is a first time update of the overwhelming interest from large businesses and medical distributors looking to be first in line to acquire our GenViro! kits as the nation attempts to return to normalcy. Businesses, large and small, are attempting to implement their plans to test employees returning to work, in a regimen that will be employed over a 5-6 week period, time and again."

Mr. Berman continued, "Our discussion this coming Thursday will be longer than usual, and it will contain quite a bit of information, especially as we discuss the overwhelming response received from business and distributors for the purchase of the kits. We are overcome with optimism we are witnessing daily for this truly remarkable product."

Serology Testing for COVID-19

According to the Johns Hopkins School of Medicine, "Serology tests are blood-based tests that can be used to identify whether people have been exposed to a particular pathogen. Serology-based tests analyze the serum component of whole blood. The serum includes antibodies to specific components of pathogens, called antigens. These antigens are recognized by the immune system as foreign and are targeted by the immune response. These types of tests are often used in viral infections to see if the patient has an immune response to a pathogen of interest, such as influenza, or in this case COVID-19. These methodologies are a focus of current test kit methodologies, particularly what are called rapid kits, which are not very rapid, and not self-contained so therefore only a partial kit. These tests have been around at least since the 1980s. GenViro! is not a Serology methodology. GenViro! does not selectively look for antibodies.

PCR Based Testing for Coronavirus ("Take a Nose Swab")

PCR based (RNA) testing of virus and infections has been around since the early 1980s and make up a large number of methods used to detect Covid-19. For example the much discussed Roche methodology detects the genetic signature (RNA) of the SARS-CoV-2 virus in swab samples that a healthcare provider collects from the back of the patient's throat or nose. Most alternative methods work in the same manner. Test turn-around time, usually is 4 hours. However, the testing does not occur at the location where the nose swab is taken. Also, instrumentation needed to complete the tests and report them are expensive. Many feel that In the United States, the slow rollout of coronavirus PCR (nose swab) tests (https://pr.report/5puoUPfN) has been widely attributed to a combination of previously stringent FDA rules, and the slower, older methodologies. The DECN GenViro! kit does not employ a nose swab, rather it receives its small blood sample through a finger prick, is self-contained and disposable, does not require a hospital or clinical lab based instrument for analysis, and it only takes 15 seconds, a minute fraction of the nose swab tests.

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DECN To Submit Second EUA Application For Covid-19 :15 Home Testing GenViro! Swift Kit, Reports Huge Response From Fortune 500 Companies

Thursday, April 23, 2020 10:20 AM EST

COMPANY ALSO PROVIDES UPDATE ON THE CURRENT TRAJECTORY OF ITS GENVIRO! COVID-19 PROFESSIONAL TESTING SWIFT KIT, FDA STATUS, MEDIA AND CONGRESSIONAL SUPPORT

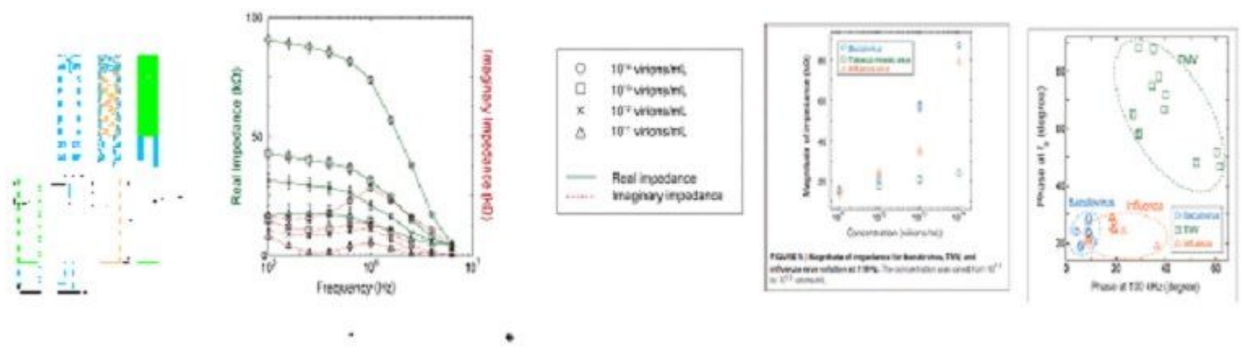
LOS ANGELES, CA / ACCESSWIRE / April 23, 2020 / Decision Diagnostics Corp. (OTC PINK:DECN) through its subsidiary Pharma Tech Solutions, Inc. the manufacturers and design specifiers for the **:15** GenViro! Professional Swift Kit for testing Covid-19 testing, today announced that it plans a second EUA submission for an individual home testing version of the GenViro! Swift Kit for home testing. Decision Diagnostics is an 18-year old, diabetes and now infectious disease testing bio-technology development firm, high-level manufacturer, quality plan administrator, FDA registered medical device customer support organization, and exclusive worldwide sales and regulatory process agent for its own proprietary regulated medical devices.

In addition to the announcement of its home testing submissions, the company is also providing an update today on several other critical business objectives and milestones. Our GenViro! Covid-19 test kit is currently in the FDA EUA review process (more about this below). We have received the Pre-EUA Acknowledgement letter from the U.S. FDA for device (serial number) PEUA200232, GenViro Covid-19 Screening Kit. In the next week we plan to ask the FDA through counsel, as other companies have, for a conditional but immediate EUA approval subject only to completion of testing. This conditional approval will replace the Pre-EUA designation and allow the company to begin large scale preparation of kits.

FDA Emergency Waiver (EUA) Progress

As previously stated, we were granted a Pre-UEA (PEUA) by the U.S. FDA on April 4, 2020, PEUA200323, for our GenViro! **:15** Swift kit for the testing of Covid-19. The PUEA is the formal notification from the FDA that a file (product) is under review for EUA clearance, that a reviewer has been assigned, and that testing protocols have been exchanged.

Subsequent to this grant, we have had two long conversations with FDA staff and management, the first of these discourses between our FDA counsel and FDA staff, the second conversation, on April 14, 2020, between our FDA counsel, DECN management and DECN technical and product development professionals. The purpose of these calls was to clarify and differentiate our GenViro! Swift kit, Pro Version, from the myriad of antibody/antigen methodologies that our product has been inaccurately compared to, primarily in public, but not scientific forums.



Discussions with FDA staff and management have focused on the differences inherent to our Genviro! Swift product, those differences that add to GenViro!'s value in use. For example the FDA is concerned with reagent and sample contaminants that may be present during testing, primarily because the samples taken from a patient using current methods must travel from the site of the patient to a laboratory for assay. This travel at times takes hours, sometimes days. GenViro! Swift does not make use of any reagent to provide a result. Therefore there will be no sample contaminant. Also, the patient sample it makes use of, a small drop of blood, does not have to travel. In fact the assay and answer are provided on the spot, in 15 seconds, right in front of the patient. We believe we have completed discussions and have come to an understanding with the FDA on all of the testing required to receive the EUA. We plan to engage a specialty reference laboratory to complete this testing in the next 10 days. Testing should take about a week.

On April 13, 2020 the company engaged a publicist and a lobbyist. The publicist has engaged three media outlets, who have shown great interest in the story of GenViro! Swift and want to interview DECN CEO Berman. One has already run a short introductory description of the product and is preparing a longer, more involved segment and has already accepted a number of visuals from us for the report. It is interesting to note that the media outlets are well versed in Covid-19 testing methods and are excited about GenViro! Swift not just for its promise but also because it is so different and so much faster to report than other methods currently available.

In addition, the company's lobbyist has engaged several influential members of Congress who have spoken at length with the company and its representatives. The Congressmen have agreed to carry the ball on behalf of the company, beginning with direct communication with the Pence Covid-19 Task Force. This process began on April 20. The company's goal for GenViro! is not just to receive EUA approval from the FDA, but when this approval is received, to become the go-to testing solution, in demand by Professional organizations as well as Fortune 500 companies, even sports teams.

New markets for our GenViro! have also been recently identified, the latest -- large businesses, Fortune 500 companies, seeking to reopen for business in the next month or two. This is perfect timing for the availability of kits. Some of these businesses have already contacted the company and even tried to place large purchase orders for GenViro! Swift kits, using the first in line principal, so that they may test and retest returning employees. No other test kit can accomplish this. The company has also accepted inquiries from restaurant chains and drinking establishments -- places where people congregate. We believe an outgrowth of this new market will be that off-duty nurses, medical technologists licensed to draw blood, and off duty pharmacists will be in large demand. The company has even been contacted by a sports franchise/league for the testing of players and ticket holders.

GenViro! for At-home (Individual) Use

Our original plan for GenViro! was to offer a single kit containing two PFUs (user's guide), one for Professional Use, one for at-home individual use. Otherwise, the contents of the kits were identical --- 3-test strips, 5-lancets, 1-check strip. However, as March moved into April it became clear that the FDA was not approving individual at-home use kits. So in order to move its application along within the EUA review system, DECN removed all of the description and data owing to the individual at-home kit. And now we bring it back -- by demand.

On April 21, 2020 the FDA approved an at-home sample collection device for Covid-19 testing, allowing individuals to purchase the collection kits, collect their own samples and then use the mails or other package service to deliver the sample to a laboratory for assay. Oftentimes government moves slowly, but they also tend to build large doors and then open them. DECN views this as an opportunity to

become the first company to provide an all-in-one, immediate result, individual at-home Covid-19 test kits with its GenViro! Swift kit for at-home use. We intend to file our stand-alone EUA application for the individual use GenViro! Swift kit by May 1. We anticipate the application to include data gleaned from our GenViro Professional kit application. We also anticipate a request to direct us to conduct a donor study of a modest group of donors. We have already identified a group in Pennsylvania to make use of the Genviro! Swift Home kit. Additional testing required for this kit is anticipated to take less than a week.

Unanticipated Large Response from Large Corporations

A question that has been on everyone's mind has been how will America go back to work. On April 20, the company engaged Universal Response LLC to manage the sales we expect from the transitioning of the country from shelter in place guidance to a back to work environment. Customers that the company has been introduced to are ready to place orders.

The key will be to test, as best as possible and on the spot, employees returning to work while at the same time providing individuals with a way they can test themselves for the virus at home. Employees and individuals testing at home and at work is a remedy for controlling the impact of the virus. Current testing methods simply do not meet the requirements that will be necessary for employees to keep themselves safe and also allow employers to keep their businesses up and running. Without immediate results, testing just won't work the way it must.

PharmaTech Solutions GenViro! "Swift Kit" testing kit will provide the quick answers individuals and employers need. It provides results on the spot with no delay. While the FDA assesses how to move forward with this technology, the company is moving to work with a large health care products distributor who has already received requests for the GenViro! Swift kits. Outlets ranging from Fortune 50 corporations to professional sports leagues have shown strong interest. The company estimates it will be asked to produce 1 million "Swift Kits" per month through the end of the year just for the "back to work" markets, based on the rapidly building demand.

FDA authorization for a test of the technology is more warranted than ever as demand for the "Swift Kits" rapidly expands. When available, the "Swift Kit" will provide an immediate, affordable and sure way to identify those that are infected with the Covid-19 virus and allow American's to get back to work.

ABOUT DECISION DIAGNOSTICS CORP

Decision Diagnostics Corp. is the leading manufacturer and worldwide distributor of diabetic test strips engineered to operate on legacy glucose meters. DECN's products are designed to operate efficiently and less expensively on certain glucose meters already in use by almost 7.5 million diabetics worldwide. With new inspired technology diabetic test strips already in the final stages of development, DECN products compete on a worldwide scale with legacy manufacturers currently selling to 71+ percent of a $15+ billion at-home testing market. The company's new GenViro!™ product designed to test for the Coronavirus Covid-19, is not yet available in the United States or Puerto Rico but Emergency Waivers are in process, and the product concept has been presented to officials in Washington, DC and members of Congress by invitation.

Forward-Looking Statements:

This release contains the company's forward-looking statements which are based on management's current expectations and assumptions as of April 22, 2020, regarding the company's business and performance, its prospects, current factors, the economy, and other future conditions and forecasts of future events, circumstances, and results.

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