SYNERGY
LABORATORIES
A lab with a conscience

To: Who it May Concern

Regarding: COVID-19 test conclusions and statement of facts in reference to Varigard Hand Sanitizer using ZT Polygel

Date: 9-08-20

The Protocols attached were executed at Synergy Labs (a government recognized Covid-19 testing facility) on Tuesday, September 01, 2020. The procedures listed were properly executed by Synergy Laboratory staff members with the cooperation of Varigard, LLC scientist. The Varigard medium viscosity hand sanitizer and the Varigard low viscosity surface/counter spray complex both successfully achieved negative swab test results, indicating the Covid-19 pathogen did not transfer to the swabbed surface. This test was performed in accordance to the attached written protocols, and the data representing the swab test were verified in accordance to laboratory testing guidelines. The test performed is an exact representation of the protocol provided and are not necessarily the full requirements of a regulatory submission document package. This is a statement of facts of the events and the test results, showing the absence of the Covid-19 pathogen material on the swabbed surfaces.

Sincerely,

Brad Pitts/CEO

SYNERGY Laboratories

5570 Rangeline Rd.

Mobile, AL 36619

VARIGARD HAND SANITIZER GEL COMPLEX

(COVID-19 TEST)

PROTOCOLS 1 AND 2

PURPOSE:

The purpose of this test is to demonstrate how the Varigard hand sanitizer using the Zero Thermal complex will perform when exposed to the COVID-19 viral pathogen under the conditions of exposure to surface contact to a pair of gloves (simulating human hands).

SCOPE:

The Scope of these tests includes preparing solutions, placing the solutions on surfaces, and allowing a 2 hour and 15 minute duration to transpire prior to the retrieval of the samples after swabbing procedures have been performed.

OBJECTIVE:

The objective of these tests is to determine the efficacy of the complex to sequester and hold the viral loads onto the gloves and not permit these organisms to be transferred to another surface whereby the evidence will show that there are no transferred living residuals once the coated surfaces have made direct contact with the pathogen in both wet or dry conditions.

1. PROTOCOL NO. 01

   GLOVES MAKE CONTACT TO A STAINLESS STEEL HARD SURFACE THAT HAD AN APPLICATION OF LIVE COVID-19 VIRAL PATHOGEN IN A LIQUID STATE

1.1 Apply Varigard hand sanitizer using Zero Thermal medium viscosity gel complex to both left hand and right hand gloves.

1.2 Remove gloves and allow both to dry for 2 hours and 15 minutes in a controlled environment under a laminar flow hood.

1.3 After the 2 hours and 15 minutes have transpired, place both gloves on both hands.

1.4 Allow lab tech to apply the living Covid19 viral pathogen load to the stainless steel counter of the laminar flow hood.

1.5 While the surface is visually wet, make direct surface contact with the left hand glove.

1.6 Move the left hand glove to another clean, non exposed area, of the stainless steel counter of the laminar flow hood and press down firmly onto the counter.

1.7 Using the right hand glove, make contact to the stainless steel counter of the laminar flow hood that was touched by the left hand glove and press down firmly onto that surface.

1.8 Swab the stainless steel counter surface area that was in direct contact with each of the gloves.

1.9 Use proper lab protocols for swabbing techniques for each of the gloves and the swab sample used to make contact with the stainless steel surface.

2. PROTOCOL NO. 02

SURFACE COUNTER DISINFECTION

For this test protocol the Low Viscosity Varigard using Zero Thermal liquid atomized complex will be used from an atomized spray dispenser.

2.1 Apply the Low Viscosity Varigard ZT liquid atomized complex to the original stainless steel counter surface that the viral pathogen was applied to.

2.2 Allow 30 seconds to transpire in order for the alcohol in the complex to evaporate.

2.3 Use a generic off the shelf paper towel not containing any other chemicals contributing to the disinfection process and wipe the stainless steel counter surface vigorously in a circular motion.

2.4 Swab the counter surface area in a zig zag pattern according to lab sampling protocols.

2.5 Identify and submit the sample for testing.

HAND SANITIZER SPRAYED ATOMIZED COMPLEX

(COVID-19 TEST)

PROTOCOL 3

PURPOSE:

The purpose of this test is to demonstrate how the Zero Thermal complex will perform when exposed to the COVID-19 viral pathogen under the conditions of exposure to surface contact to a membrane material made out of woven/unwoven fibers.

SCOPE:

The Scope of this test includes preparing a solution, placing the solution on woven fibers, and allowing a 2 hour and 15 minute duration to transpire prior to the retrieval of the samples after swabbing procedures have been performed.

OBJECTIVE:

The objective of this test is to determine the efficacy of the complex to sequester and hold the viral loads onto the textiles and not permit these organisms to be transferred to another surface whereby the evidence will show that there are no transferred living residuals once the coated textiles have made direct contact with the pathogen in both wet or dry conditions.

3. PROTOCOL NO. 03

TWO PLY TEXTILES FOR SEQUESTRATION TEST

For this test protocol the Low Viscosity Zero Thermal liquid atomized complex will be used from an atomized spray dispenser.

Acquire two sheets of membrane material approximately 100 square inches in surface area for each sheet for each membrane sample.

3.1 Lay both sheets side by side on the stainless steel surface counter.

3.2 Ensure the sheet Labeled L-15 is on the left side.

3.3 Coat and spray the right side sheet with the ZT spray complex.

3.4 Allow to dry for 2 hours and 15 minutes.

3.5 Apply the pathogen load onto the sheet that has been sprayed and place over the left side sheet Labeled L-15.

3.6 Swab both sheets in a zig-zag pattern according to lab sampling protocols.

3.7 Identify and submit the sample for testing.

Notes:

The two sheets represent the two ply layers of a face mask or a disposable garment.

The sheet making direct contact with the viral load is the control sample. The second layer labeled L-15 is the layer to be swabbed and tested to demonstrate non transference due to the polymer's ability to sequester the viral load and not allowing transference to L-15.

The first layer should contain the virus, and L-15 should be absent of the virus although making contact with the first layer as instructed in 3.5 of making contact with the virus.

Laboratory Report

Laboratory Director Dr. Kevin Harrell
CLIA Number: 01D2093765
5570 RANGELINE RD
MOBILE, AL 36619
(251) 662-9760

Clinic Information

Client: Synergy Laboratories
5570 Rangeline Road
Mobile, AL 36619
Requesting Physician / Practitioner:
William Blaylock

Patient Information

Patient Name: **Test, Glove**
Patient ID: **P9922997**
Date of Birth: 5/27/1997
Male/Female: Male
Patient Phone:
Current MME: N/A

Sample Information

Lab Sample ID: 20090140643
Specimen Type: Nasopharyngeal Swab
Collected: 09/01/2020 02:29 PM
Received: 09/01/2020 02:29 PM
Reported:

Medications Prescribed

General Comment

Order Code(s)

GEN_COVID19

Test	Normal	Abnormal	Reference Range	Units	Previous Result	Date
COVID-19 Interpretive Result	Not Detected		--			

Testing performed by RT-PCR.

Positive results generated by any laboratory testing under the CDC EUA may be interpreted as positive instead of presumptive. No confirmation of positive results is required.

A negative result does not completely exclude infection by SARS-CoV-2, and should not be used as the sole basis for treatment or patient management decisions.

If COVID-19 is still suspected based upon exposure history together with other clinical findings, re-testing should be considered.

Repeat testing has been performed on all inconclusive results. Additional confirmation testing (such as an additional swab) should be conducted if clinically indicated.

Limitation: An absence of detection does not imply the absence of microorganisms other than those listed or does not exclude the possibility that the target sequence is present below the limit of detection. The Respiratory Microbiota Report does not take into consideration patient history, drug-drug-interactions, drug sensitivity, and/or allergies. It is the responsibility of the physician to determine appropriate drug and closing choices based on all available data.

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(251) 662-9760

Clinic Information

Client: Synergy Laboratories
5570 Rangeline Road
Mobile, AL 36619
Requesting Physician / Practitioner:
William Blaylock

Patient Information

Patient Name: **Test, Cleaned Surface**
Patient ID: **P9923000**
Date of Birth: 12/16/1960
Male/Female: Female
Patient Phone:
Current MME: N/A

Sample Information

Lab Sample ID: 20090140663
Specimen Type: Nasopharyngeal Swab
Collected: 09/01/2020 02:39 PM
Received: 09/01/2020 02:39 PM
Reported:

Medications Prescribed

General Comment

Order Code(s)

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COVID-19 Interpretive Result	Not Detected		--			

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5570 RANGELINE RD
MOBILE, AL 36619
(251) 662-9760

Clinic Information

Client: Synergy Laboratories
5570 Rangeline Road
Mobile, AL 36619
Requesting Physician / Practitioner:
William Blaylock

Patient Information

Patient Name: **Test, Dirty Surface**
Patient ID: **P9922996**
Date of Birth: 9/13/2001
Male/Female: Female
Patient Phone:
Current MME: N/A

Sample Information

Lab Sample ID: 20090140622
Specimen Type: Nasopharyngeal Swab
Collected: 09/01/2020 02:20 PM
Received: 09/01/2020 02:20 PM
Reported:

Medications Prescribed

General Comment

Order Code(s)

GEN_COVID19

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COVID-19 Interpretive Result	Not Detected		--			

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5570 RANGELINE RD
MOBILE, AL 36619
(251) 662-9760

Clinic Information

Client: Synergy Laboratories
5570 Rangeline Road
Mobile, AL 36619
Requesting Physician / Practitioner:
William Blaylock

Patient Information

Patient Name: **Test, Textile 2nd layer**
Patient ID: **P9922999**
Date of Birth: 3/26/1981
Male/Female: Male
Patient Phone:
Current MME: N/A

Sample Information

Lab Sample ID: 20090140659
Specimen Type: Nasopharyngeal Swab
Collected: 09/01/2020 02:37 PM
Received: 09/01/2020 02:37 PM
Reported: 09/03/2020 09:09 AM

Medications Prescribed

General Comment

Order Code(s)

GEN_COVID19

Test	Normal	Abnormal	Reference Range	Units	Previous Result	Date
COVID-19 Interpretive Result	Not Detected		--			

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