

VARIGARD HYDROGEN PEROXIDE SURFACE SPRAY COMPLEX

SARS-CoV-2 (COVID-19)

PROTOCOL 1 (Positive Control Test)

PURPOSE:

The purpose of this test is to demonstrate that an actual SARS-CoV-2 (COVID-19) pathogen is being used for the remaining protocols in this test.

SCOPE:

The Scope of these tests includes preparing the SARS-CoV-2 (COVID-19) pathogen that will be applied to a clean surface for the following protocol.

OBJECTIVE:

The objective of this test is to show the presence of SARS-CoV-2 (COVID-19) pathogen in a controlled environment. The test will prove that after three (3) minutes the SARS-CoV-2 (COVID-19) pathogen will still be detectable and show a positive result. This test will be used as a control for the remaining protocols proving sequestration.

PROTOCOL NO. 01 – POSITIVE CONTROL TEST

1. Clean and disinfect a stainless-steel surface in a controlled environment under a laminar flow hood.
2. Apply LIVE SARS-CoV-2 (COVID-19) VIRAL PATHOGEN IN A LIQUID STATE. This application will be performed in a standard "X" pattern
3. Wait 3 minutes
4. Lab tech to use proper lab protocols for swabbing techniques to test for the presence of the SARS-CoV-2 (COVID-19) VIRAL PATHOGEN.

VARIGARD HYDROGEN PEROXIDE SURFACE SPRAY COMPLEX

(COVID-19 TEST)

PROTOCOL 2

(Sequester Pathogens for extended period of time)

PURPOSE:

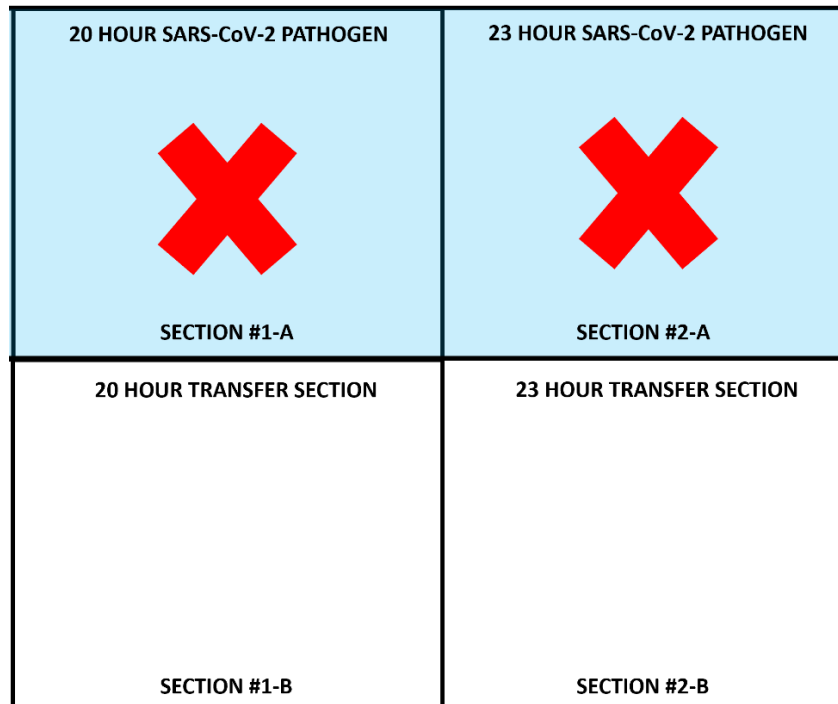
The purpose of this test is to demonstrate how the Varigard Surface Spray using the Zero Thermal complex will perform when exposed to the SARS-CoV-2 (COVID-19) viral pathogen. We intend to demonstrate that the Varigard Surface spray will sequester SARS-CoV-2 (COVID-19) for extended periods of time after being applied.

SCOPE:

The Scope of these tests includes preparing the Varigard Surface Spray Complex and spraying the atomized solution on a disinfected stainless-steel surface. The surface will be divided into four (4) different sections. Two (2) of the sections will be used to apply live SARS-CoV-2 (COVID-19) pathogen.

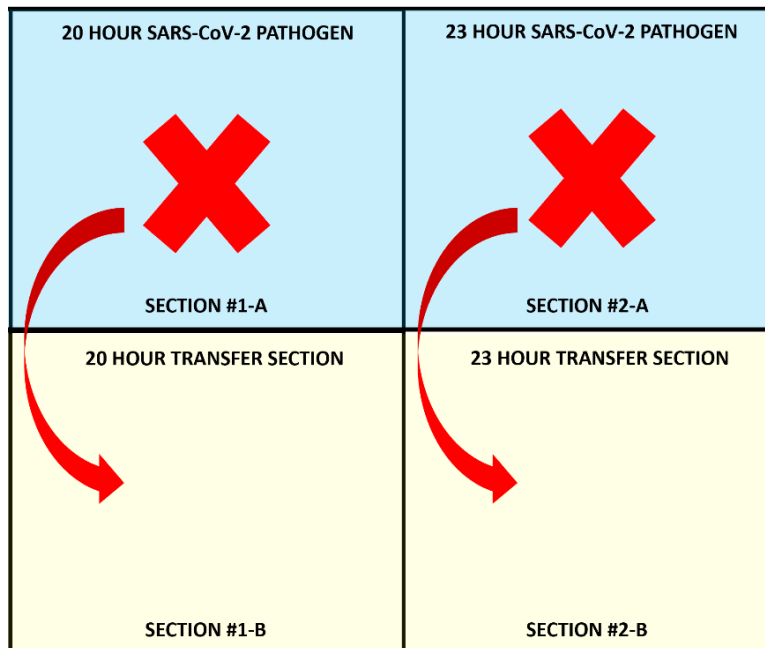
1. Section #1-A: 20 hours
2. Section #2-A: 23 hours

Diagram 1.1- LIVE SARS-CoV-2 PATHOGEN PLACEMENT



The other two (2) sections represented by (B) will be used as the transfer surface for SARS-CoV-2 (COVID-19) pathogen. Each section will be labeled according to the timeframe and diagram listed below.

Diagram 1.1- LIVE SARS-CoV-2 PATHOGEN TRANSFER



After the time has expired for each Coupon, SARS-CoV-2 (COVID-19) pathogen will be applied to test for sequestration based on the following protocols.

OBJECTIVE:

The objective of these tests is to determine the efficacy of the Varigard Surface Spray complex to sequester SARS-CoV-2 (COVID-19) pathogens for extended periods of time. The test will prove that the Varigard complex will trap and sequester the SARS-CoV-2 (COVID-19) pathogen on contact and not allow the pathogen to be transferred to a secondary surface.

PROTOCOL NO. 02 - SARS-CoV-2 (COVID-19) SEQUESTRATION TEST

1. Four (4) sections are labeled according to the scope in this document (Diagram 1.1 and 1.2) in a controlled environment under a laminar flow hood.
2. Apply Varigard surface spray complex to each of the sections.

3. Wait the allocated time for each section (A) and then apply LIVE SARS-CoV-2 (COVID-19) VIRAL PATHOGEN IN A LIQUID STATE. This application will be performed in a standard "X" pattern
4. Using a new nitrile or latex glove, the surface where the SARS-CoV-2 (COVID-19) pathogen was placed will be touched with a flat palm.
5. The glove will then touch the corresponding surface (B) for each timed test with the palm down.
6. Lab tech to use proper lab protocols for swabbing techniques for the glove and the new surface (B) and test for the presence of the SARS-CoV-2 (COVID-19).

Repeat this for each of the time section 1-2 A&B. based on the dry times indicated.

VARIGARD ETHANOL HAND SANITIZING LOTION COMPLEX

(COVID-19 TEST)

PROTOCOL 3

(Sequester Pathogens for extended period of time)

PURPOSE:

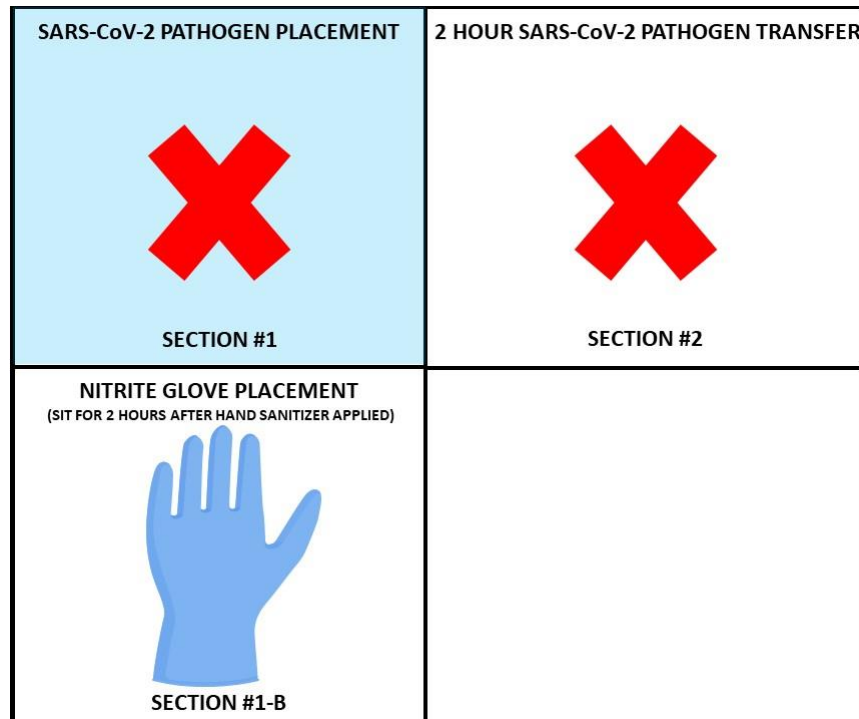
The purpose of this test is to demonstrate how the Varigard Hand Sanitizing Lotion, using the ZeroThermal complex will perform when exposed to the SARS-CoV-2 (COVID-19) viral pathogen. We intend to demonstrate that the Varigard Hand Sanitizing Lotion will sequester SARS-CoV-2 (COVID-19) for extended periods of time after being applied.

SCOPE:

The Scope of these tests includes preparing the Varigard Hand Sanitizing Lotion Complex and applying it to a nitrile or latex glove and then leaving it under a vented hood for 2 hours. The surface will then be divided into three (3) different sections. Two (2) of the sections will be used for the live SARS-CoV-2 (COVID-19) pathogen.

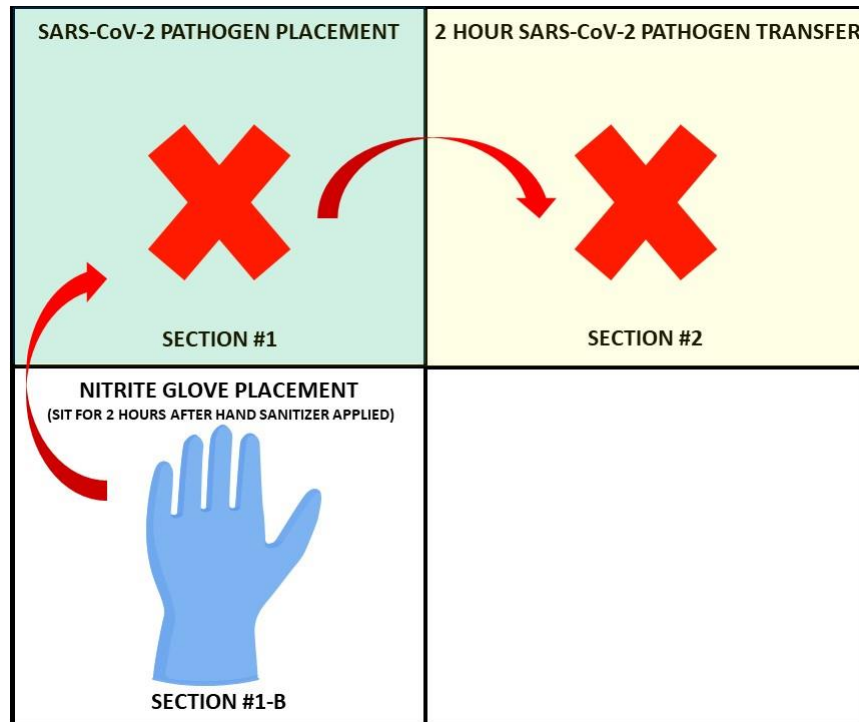
1. Section #1: Initial Pathogen Placement
2. Section #2: Initial Nitrile glove Placement

Diagram 1.1- LIVE SARS-CoV-2 PATHOGEN PLACEMENT



Section 2 represented by the “Blue Nitrile Glove” will be covered with the have the Varigard Hand Sanitizing Lotion and then sit for 2 hours untouched. Each section will be labeled according to the timeframe and diagram listed below.

Diagram 1.1- LIVE SARS-CoV-2 PATHOGEN TRANSFER



After the 2 hour time has expired, the SARS-CoV-2 (COVID-19) pathogen will be applied to test for sequestration based on the following protocols.

OBJECTIVE:

The objective of these tests is to determine the efficacy of the Varigard Hand Sanitizing Lotion Complex to sequester SARS-CoV-2 (COVID-19) pathogens for extended periods of time. The test will prove that the Varigard complex will trap and sequester the SARS-CoV-2 (COVID-19) pathogen on contact and not allow the pathogen to be transferred to a secondary surface.

PROTOCOL NO. 02 - SARS-CoV-2 (COVID-19) SEQUESTRATION TEST

1. Three (3) sections are labeled according to the scope in this document (Diagram 1.1 and 1.2) in a controlled environment under a laminar flow hood.
2. Apply Varigard Hand Sanitizing Lotion Complex to the nitrile gloves in section 1-B and wait 2 hours for them to dry.

3. Apply LIVE SARS-CoV-2 (COVID-19) VIRAL PATHOGEN IN A LIQUID STATE to Section 1. This application will be performed in a standard "X" pattern
4. Using the nitrile glove from Section 1-B, host will touch the surface of section 1 where the SARS-CoV-2(COVID-19) pathogen was placed. This will be done with a flat palm.
5. The glove will then touch the corresponding surface (Section 2) with the palm down. You will be able to see the fluid transfer to section 2. If a fluid is not present, the test will need to be repeated.
6. Lab tech to use proper lab protocols for swabbing techniques for the glove and Surface 2 and test for the presence of the SARS-CoV-2 (COVID-19).

Clinic Information

Client: Synergy Laboratories

5570 Rangeline Rd
Mobile, AL 36619

Requesting Physician / Practitioner:

Conner, Mitch M.D.

Patient Information

Patient Name: VARIGARD

SURFACE SPRAY

Patient ID: P9924930

Date of Birth: 2/2/1985

Male/Female: Male

Patient Phone:

Current MME: N/A

Sample Information

Lab Sample ID: 21071440192

Specimen Type: Nasopharyngeal Swab

Collected On: 07/14/2021 01:46 PM

Received: 07/14/2021 01:46 PM

Reported: 07/14/2021 07:02 PM

Medications Prescribed

General Comment Delta Variant - B.1.617.2

Order Code(s)

GEN_COVID19

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

Clinic Information

Client: Synergy Laboratories

5570 Rangeline Rd

Mobile, AL 36619

Requesting Physician / Practitioner:

Adjei, Vincentia NP

Patient Information

Patient Name: VARIGARD, Hand Sanitizer

2-Hour Test

Patient ID: P9924933

Date of Birth: 5/30/1945

Male/Female: Male

Patient Phone:

Current MME: N/A

Sample Information

Lab Sample ID: 21071440196

Specimen Type: Nasopharyngeal Swab

Collected On: 07/14/2021 01:52 PM

Received: 07/14/2021 01:52 PM

Reported: 07/14/2021 07:02 PM

Medications Prescribed

General Comment Delta Variant - B.1.617.2

Order Code(s)

GEN_COVID19

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

Testing performed by RT-PCR.

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