MICROCHEM LABORATORY

STUDY REPORT

## Study Title

Antimicrobial Activity and Efficacy of VYV's Device

## Test Method

Custom Device Study Based on: ASTM E1153

## Study Identification Number

NG17374

## Study Sponsor

Edward Kiegle
VYV
kiegle@vyv.com

## Test Facility

Microchem Laboratory
1304 W. Industrial Blvd
Round Rock, TX 78681
(512) 310-8378
Report Author: Samuel Hanley, B.S.

## Purpose of the Study

The purpose of this study was to determine the antimicrobial efficacy of VYV's submitted test device.

## Brief History of the Performing Laboratory

Microchem Laboratory is located in the greater Austin, Texas area. It is owned and operated by microbiologist Dr. Benjamin Tanner. The core of the company was founded by Dr. Tanner as Antimicrobial Test Laboratories in 2006. Antimicrobial Test Laboratories was later combined with a niche cosmetic testing lab and Microchem Laboratory, founded in 1988 by Dr. Norman Miner. The combined labs have operated under one roof as Microchem Laboratory since 2016. Microchem Laboratory is ISO 17025 accredited and offers testing in compliance with current Good Laboratory Practice (GLP) regulations as stipulated by EPA and FDA. Clients are always welcome to tour the lab, observe studies, and audit the lab's quality systems.

## Study Timeline

| Devices Received | Cultures Initiated | Carriers Inoculated | Carriers Treated | Enumeration Plates Evaluated | Report Delivered |
|---|---|---|---|---|---|
| 05FEB2021 | 25MAR2021 | 25MAR2021 | 25MAR2021 | 26MAR2021 | 31MAR2021 |

Amended report sent on 05APR2021





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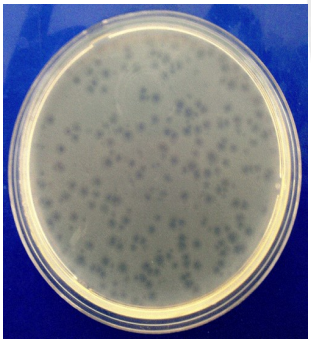
## Test Device Information

**Name of Test Device:** VYV Benchtop Unit
**Manufacturer:** VYV
**Mode of Active:** Germicidial Visible Light (405 nm)

A description of how to operate the device was provided by the Study Sponsor prior to test initiation.

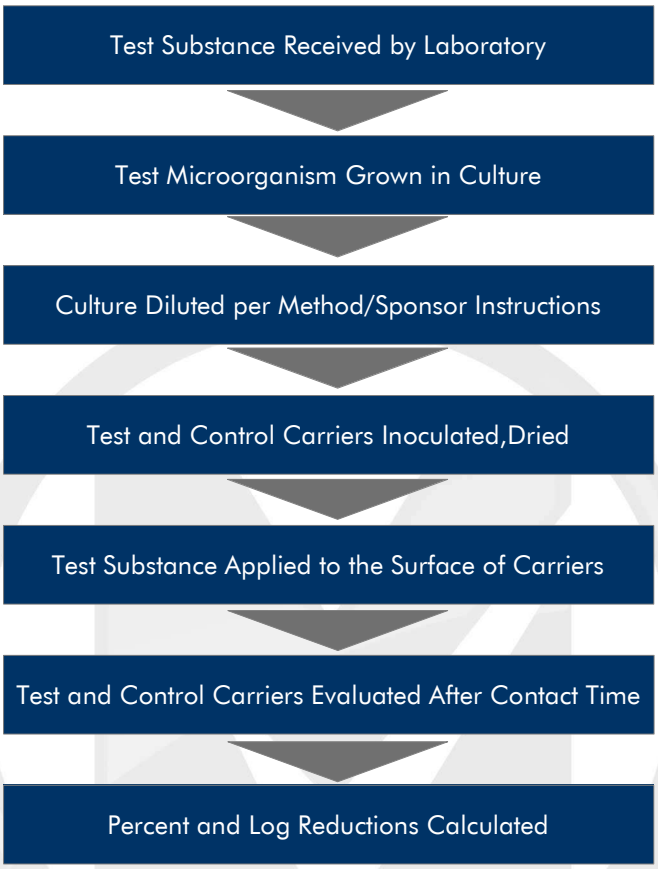
## Test Microorganism Information

The test microorganism(s) selected for this test:



**MS2 Bacteriophage (MS2), ATCC 15597-B1**
This virus is a non-enveloped positive-stranded RNA virus of the bacteriophage family Leviviridae. Bacterial cells are the hosts for bacteriophages, and *E. coli* 15597 serves this purpose for MS2 bacteriophage. Its small size, icosohedral structure, and environmental resistance has made MS2 ideal for use as a surrogate virus (particularly in place of picornaviruses such as poliovirus and human norovirus) in water quality and disinfectant studies.
**Permissive Host Cell System for MS2:** *Escherichia coli*, 15597

## Diagram of the Test Procedure




## Summary of the Procedure

- Test microorganism is prepared in appropriate liquid broth.
- Test microorganism is harvested and the resulting suspension is diluted to achieve $\geq 1x10^6$ PFU/mL.
- Test and control carriers are inoculated and allowed to dry in optimal conditions for test microorganism.
- Test carriers are placed in test device for the Sponsor-determined contact time.
- Test carriers are harvested into liquid media and plated in optimal incubation conditions and time for the test microorganism.
- After incubation, microbial concentrations are determined and reductions relative to pre-treatment controls are calculated.





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# Criteria for Scientific Defensibility of a Custom Device Study

For Microchem Laboratory to consider a Device Study study to be scientifically defensible, the following criteria must be met:

1. The initial and final concentration of microorganisms must be significantly high enough to observe the passing criteria/log reduction.
2. The media used for testing must be sterile.
3. The target microorganism must be pure colony morphology.

## Passing Criteria

Due to the modified nature of the study, passing criteria may be determined by the Study Sponsor prior to test initiation. If no passing criteria is established, a conclusion about the data is not provided by Microchem Laboratory, but the Study Sponsor may determine significance based on statistical interpretation or other means.

## Testing Parameters

| | | | |
|---|---|---|---|
| **Culture Growth Media:** | N/A, Freezer Stock | **Culture Growth Time:** | N/A |
| **Culture Dilution Media** | Phosphate Buffered Saline, Artificial Saliva | **Culture Supplement** | N/A |
| **Carrier Type** | 1" x 3" Glass Slides | **Inoculum Volume** | 0.020 ml |
| **Carrier Dry Time** | 30 minutes | **Carrier Dry Temp. and Humidity** | 23.1°C / 43% |
| **Contact Time** | 6 Hours | **Contact Temperature** | Ambient |
| **Irradiance** | 2 $mW/cm^2$ | **Harvest Media (Volume)** | Phosphate Buffered Saline w/ 0.1% Triton X-100 (20 ml) |
| **Enumeration Media** | 50% Tryptic Soy Broth | **Incubation Temperature** | 36°C |
| **Incubation Time** | 18-24 Hours | | |





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## Study Notes

Per study sponsor request artificial saliva was used to dilute the inoculum. The artificial saliva was prepared using study sponsor provided instructions.

Amended report on 05APR2021 to include updated photo of the wattage when the device is running, changed mode of action from UV light (Germicidal) to Germicidal Visible light (405nm), and included the irradiance of the device in the test parameters (this information was provided by the study sponsor and not taken at Microchem).

## Study Photographs

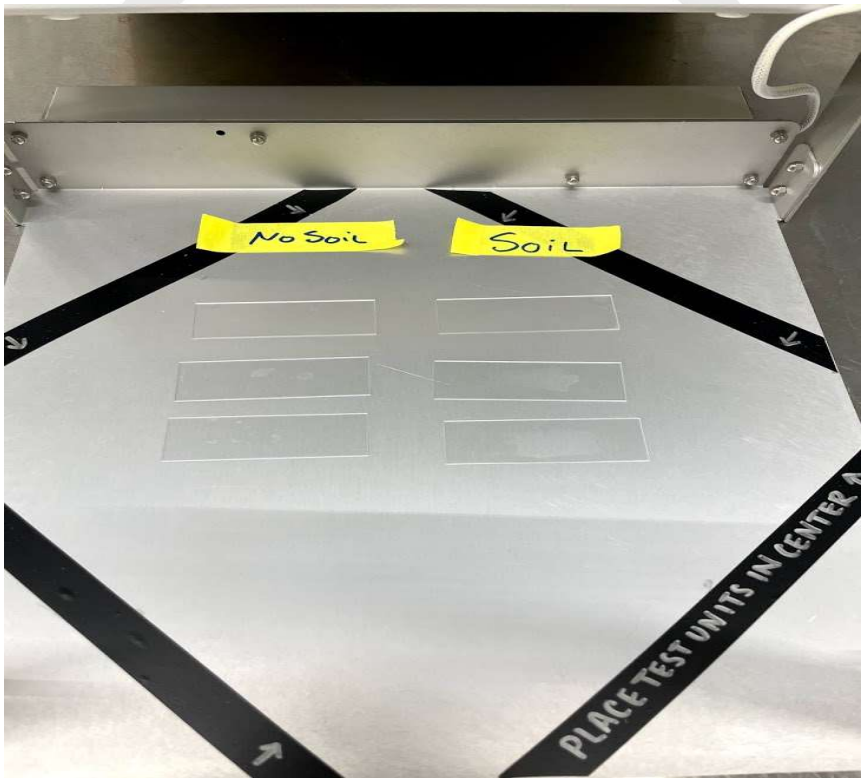



Image 1: Testing set up. Inoculum diluted in PBS is on the left and the inoculum diluted in the artificial saliva is on the right.

## Study Photographs


Image 2: Kill-A-WATT reading when device is on.

## Control Results

Neutralization Method: N/A
Growth Confirmation: Pure and Viable
Media Sterility: No Growth

## Calculations

PFU/ml = (Average plate count) x 1:10 serial dilution factor

PFU/carrier = (Average plate count) x 1:10 serial dilution factor x media dilution factor

PFU/carrier = PFU/ml x total harvest media volume

$$\text{Percent Reduction} = \frac{(B - A)}{B} \times 100\%$$

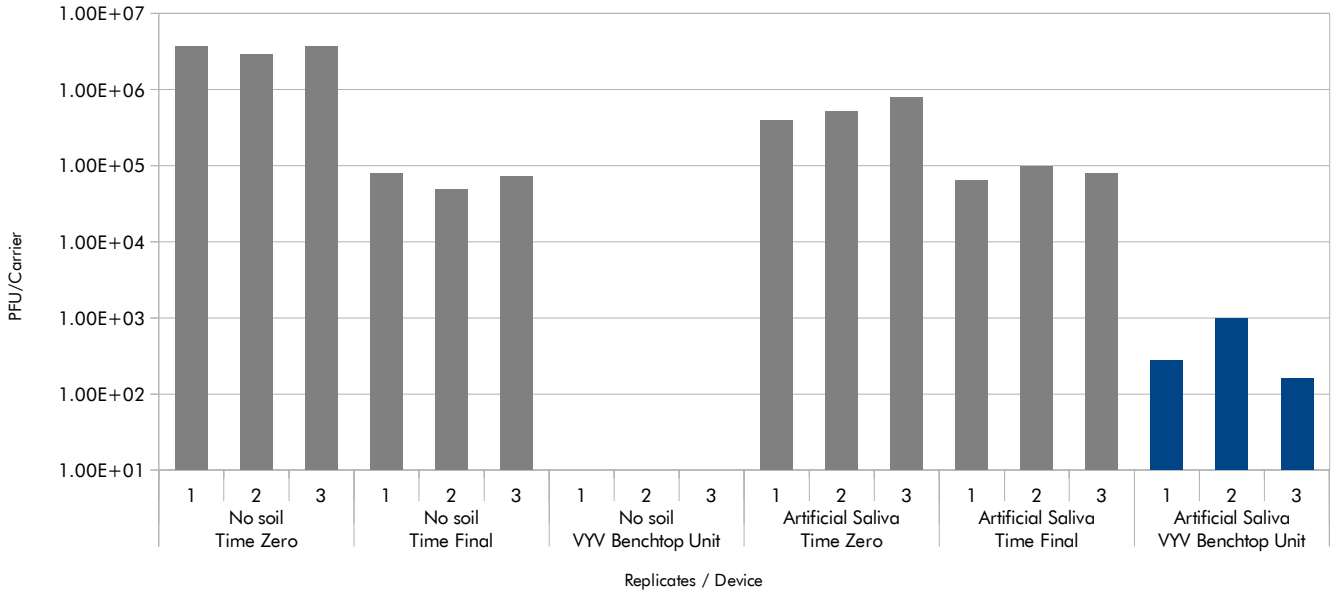
$$\text{Log}_{10}\ \text{Reduction} = \text{Log}(B/A)$$

Where:
B = Number of viable test microorganisms on the control carriers immediately after inoculation
A = Number of viable test microorganisms on the test carriers after the contact time

# Results of the Study

| Test Microorganism | Device | Culture Diluent | Contact Time | Contact Distance | Replicate | PFU/Carrier | Average PFU/Carrier | Percent Reduction Compared to Parallel Control | $Log_{10}$ Reduction Compared to Parallel Control |
|---|---|---|---|---|---|---|---|---|---|
| MS2 Bacteriophage ATCC 15597-B1 | Control | PBS | Time Zero | N/A | 1 | 3.60E+06 | 1.73E+06 | N/A | |
| | | | | | 2 | 2.90E+06 | | | |
| | | | | | 3 | 3.70E+06 | | | |
| | | | Time Final | | 1 | 7.90E+04 | 6.67E+04 | | |
| | | | | | 2 | 4.90E+04 | | | |
| | | | | | 3 | 7.20E+04 | | | |
| | VYV Benchtop Unit | PBS | 6 Hours | 6.5" | 1 | < 1.00E+01 | < 1.00E+01 | > 99.985% | > 3.82 |
| | | | | | 2 | < 1.00E+01 | | | |
| | | | | | 3 | < 1.00E+01 | | | |
| | Control | Artificial Saliva | Time Zero | N/A | 1 | 3.90E+05 | 5.60E+05 | N/A | |
| | | | | | 2 | 5.10E+05 | | | |
| | | | | | 3 | 7.80E+05 | | | |
| | | | Time Final | | 1 | 6.40E+04 | 8.00E+04 | | |
| | | | | | 2 | 9.80E+04 | | | |
| | | | | | 3 | 7.80E+04 | | | |
| | VYV Benchtop Unit | Artificial Saliva | 6 Hours | 6.5" | 1 | 2.70E+02 | 4.70E+02 | 99.41% | 2.23 |
| | | | | | 2 | 9.80E+02 | | | |
| | | | | | 3 | 1.60E+02 | | | |

*Note: The lower limit of detection for this study was 1.00E+01 PFU/carrier. Values observed less than the limit are reported as "<1.00E+01" in the results table and zero in the graph.*



*The results of this study apply to the tested substances(s) only. Extrapolation of findings to related materials is the responsibility of the Sponsor.*