

## Study to Evaluate the Efficacy of "Sterile-Gel & Spray" by Sterilize Technologies

<p><b>Objective</b> The objective of this study is to perform a challenge study to evaluate the efficacy of hand sanitizer ("Sterile-Gel &amp; Spray") on <i>Staphylococcus aureus</i></p> <p><b>Introduction</b> In this study, "Sterile-Gel &amp; Spray" was inoculated with a known level of <i>Staphylococcus aureus</i>. Bacteria were then enumerated after a 24 hour hold time.</p> <p><b>Organism Preparation</b> One strain of <i>Staphylococcus aureus</i> (DL58, ATCC #25923) was inoculated into a sterile 100 ml Trypticase Soy Broth (TSB Broth) and incubated at 35°C for 24 hours. After the initial 24 hours of incubation, an aliquot of broth culture was transferred to a second sterile 100 ml TSB and will incubate at 35°C for 24 hours. The broth culture was serially diluted and plated on Tryptic Soy agar (TSA) at 10<sup>1</sup> to 10<sup>8</sup> to determine bacterial density.</p> <p><b>Methods</b> The broth culture was then diluted to create an inoculum suspension with a bacterial density sufficient to deliver an initial inoculum of 10<sup>4</sup> to 10<sup>7</sup> cfu/gram. The inoculum suspension was serially diluted and plated on Tryptic Soy agar (TSA) 10<sup>1</sup> to 10<sup>8</sup> to determine initial bacterial density. TSA plates will incubate at 35 °C for 24 hours. Colonies were counted and recorded.</p>	<p><b>Results</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Staphylococcus aureus initial bacterial load</td> <td style="text-align: right; padding: 5px;">71,000,000 cfu/mL</td> </tr> <tr> <td style="padding: 5px;">Control (TSB) after 24-hours</td> <td style="text-align: right; padding: 5px;">150,000,000 cfu/mL</td> </tr> <tr> <td style="padding: 5px;">Sterile-Gel &amp; Spray Sample 1</td> <td style="text-align: right; padding: 5px;">&lt;10 cfu/mL</td> </tr> <tr> <td style="padding: 5px;">Sterile-Gel &amp; Spray Sample 2</td> <td style="text-align: right; padding: 5px;">&lt;10 cfu/mL</td> </tr> <tr> <td style="padding: 5px;">Sterile-Gel &amp; Spray Sample 3</td> <td style="text-align: right; padding: 5px;">&lt;10 cfu/mL</td> </tr> </table> <p><b>Summary</b> S. aureus was inoculated into the product with a bacterial density of 71,000,000 cfu/mL and after 24 hours of incubation all bacteria experienced die off when in contact with the test product ("Sterile-Gel &amp; Spray"). All three samples tested had a bacterial load below the detectable limit. A positive control was used with the same initial bacterial load and which showed a final concentration of 150,000,000 cfu/mL. S. aureus is unable to grow in the product and experienced total kill off.</p> <p style="text-align: right; padding-right: 20px;">DonLevy Laboratories Prepared for Sterilize Technologies April 14, 2020</p>	Staphylococcus aureus initial bacterial load	71,000,000 cfu/mL	Control (TSB) after 24-hours	150,000,000 cfu/mL	Sterile-Gel & Spray Sample 1	<10 cfu/mL	Sterile-Gel & Spray Sample 2	<10 cfu/mL	Sterile-Gel & Spray Sample 3	<10 cfu/mL
Staphylococcus aureus initial bacterial load	71,000,000 cfu/mL										
Control (TSB) after 24-hours	150,000,000 cfu/mL										
Sterile-Gel & Spray Sample 1	<10 cfu/mL										
Sterile-Gel & Spray Sample 2	<10 cfu/mL										
Sterile-Gel & Spray Sample 3	<10 cfu/mL										