STUDY TITLE  
MICRO SPECIAL - Adsorption Test Method for the Nasal Swabs

TEST ARTICLE NAME  
Digitally Manufactured Nasopharyngeal Swab V2 - Adsorption Study

TEST ARTICLE IDENTIFICATION  
Intrepid Smart NP Swab

TEST ARTICLE RECEIVED  
December 11, 2020

PURPOSE  
The purpose of this study was to demonstrate the adsorption capacity or volume of inoculum adhered to the nasal swabs (Digitally Manufactured Nasopharyngeal Swab V2) submitted for testing by Intrepid Automation.

RESULTS

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Starting Weight</th>
<th>Ending Weight</th>
<th>Absorption per tube/swab (Starting weight – Ending weight)</th>
</tr>
</thead>
<tbody>
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<td>4696.39 mg</td>
<td>4679.74 mg</td>
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<td>4696.50 mg</td>
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<td>16.76 mg</td>
</tr>
</tbody>
</table>

*Organisms used for testing are derived from ATCC® organism or an organism determined to be equivalent. ATCC® is a registered trademark for the American Type Culture Collection.
ORGANISM PREPARATION

*Staphylococcus aureus* ATCC 29213 was sub cultured onto a Tryptic Soy Agar (TSA) plate and incubated for 18-24 hours at 37±2°C. After incubation, the bacterial culture was harvested by washing the surface growth with sterile saline. The population was adjusted to 1 – 5 x 10^8 CFU/mL using spectrophotometer. Serial dilution were performed using 0.85% saline to bring the population down to 1 – 5 x 10^7 CFU/mL. Standard Plate Count Method was performed to verify the population of (1 – 5 x 10^7 CFU/mL). Serial dilutions were performed using 0.85% saline and appropriate dilutions were plated in duplicate to obtain colonies in countable range of 30-300 CFU. Incubated plates at 37±2°C for 48-72 hours.

TEST PROCEDURE

Study was performed following instructions listed in protocol 20C_75163_01 and Amendment I. Twenty (20) 5 mL tubes were appropriately labeled with lab number and appropriate number (1-20). In each labeled 5mL tube, 1.0 mL of the inoculum (1-5 x 10^7 CFU/mL) was added. Each 5mL tube were weighed separately and the starting weight was recorded using a calibrated scale. A nasal swab was immersed into each tube with the inoculum suspension for 15 seconds. After 15 seconds, the nasal swab was removed from the tube and each test tube was weighed again for the ending weight. This process was repeated with all twenty (20) tubes.

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Starting Weight (mg)</th>
<th>Ending Weight (mg)</th>
<th>Absorption per tube/swab (Starting weight – Ending weight)</th>
</tr>
</thead>
<tbody>
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<td>1</td>
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</tbody>
</table>

*Staphylococcus aureus* ATCC 29213

Inoculum Population

1.99 x 10^7 CFU/mL
COMMENT
Table 1 represent the data collected using 1.0 mL of the inoculum and Table 2 represent the data collected using 0.1 mL of the inoculum.

APPROVAL
Steven J. Elliott, BS
Director, Quality Control and Sterility Assurance
Date

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility. This test was performed under all applicable GMP regulations and in compliance with the ISO 13485 standard.