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Report Reference# 2051234-140

**Product Usability Report to Assess for Contamination and Protection in the Molecular  
Diagnostics Testing Laboratory While Handling COVID-19 Patient Samples**

**RT-PCR Based Sample Study and Observation Over 24 Hours**

Final Report: June 9, 2020

**Prepared for: Nanodefense**

P23 Labs, LLC is not an EPA certified lab. However, the laboratory is certified under CLIA to perform high complexity clinical testing.

CLIA #04D2181098

Testing Initiated: June 4, 2020

Testing Completed: June 5, 2020

Testing Reported: June 9, 2020

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Title: Scientist

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**REPORT PREPARED FOR: NANODEFENSE PRODUCT**

**P23 LABS-** A CLIA and FDA GLP-compliant testing organization staffed by skilled, experienced microbiologists, molecular biologists, and chemists. P23 is not an EPA registered laboratory and cannot participate in the certification of products. P23 Labs, in a commitment to combat the COVID-19 Global Pandemic, is available to help with independent quality assessments and studies involving COVID-19.

**SUMMARY OF THE SURVEY FOR CONTAMINATION PCR TEST METHOD PERFORMED BY P23 LABS**

- The test microorganism was purchased from approved vendors and verified positive controls were used to treat plastic with identified microorganism.
- The concentration of the test microorganism was standardized by the manufacturer.
- Control and test fabric swatches were inoculated with microorganisms requested by client.
- The inoculation is performed such that the microbial suspension touches only the fabric.
- Bacteria levels on both control and test fabrics are determined at "time zero" by elution in a large volume of neutralizing broth, followed by dilution and testing via PCR.
- A control was run to verify that the neutralization/elution method effectively neutralizes the antimicrobial agent in the fabric.
- Additional inoculated control and test fabrics were incubated, undisturbed in sealed jars, for 24 hours. These fabrics were tested at time=24 hours.
- After incubation, microbial concentrations were assessed via PCR for presence and absence.

Objective: To provide a quantitative evaluation of the antibacterial activity in one ample a demonstrated by molecular PCR contamination survey method mimicking the traditional microbiology method AATCC-100.

**Test Sample Identification:**

<u>Material</u>	<u>Grade</u>	<u>Coating Type</u>	<u>Test Virus</u>
MagiCal	industrial	Indoor	Covid 19
Satin Acetate	industrial	Indoor	Covid 19
MagiCal	industrial	Indoor	SARS-Cov
Satin Acetate	industrial	Indoor	SARS-Cov
MagiCal	industrial	Indoor	MERS-Cov
Satin Acetate	industrial	Indoor	MERS-Cov
MagiCal	industrial	Indoor	Influenza A/B
Satin Acetate	industrial	Indoor	Influenza A/B
MagiCal	industrial	Indoor	H1N1
Satin Acetate	industrial	Indoor	H1N1
Satin Acetate	industrial	Indoor	Streptococcus agalactiae
Satin Acetate	industrial	Indoor	Salmonella
Satin Acetate	industrial	Indoor	MRSA
Satin Acetate	industrial	Indoor	Coliform bacteria (Ecoli, Enterobacter Species and klesbsiella)

**Procedure:**

As requested by client, activation of material and inoculation was performed in the following manner:

1. Wipe the surface (surface is the side of the material that has printing on it) of the product with Kimwipe and molecular grade, microorganism free water and let dry 15 minutes at room temperature.
2. Remove the release liner from the back of the product and discard and then Expose bacteria or virus to the product on the printed side.
3. Ensure the product has ample indoor lighting exposure (LED lighting source in 400 sq. ft. room with 3 60W light rods).
4. P23 was instructed to monitor at hours 1, 3 and 24 as opposed to standard procedure to monitor every 1 to 3 hours the kill rate or increase in colonization for a period of 24 hours and record kill % (99.96%).
5. Sample was allowed to incubate in sterile ambient temperature incubator set to 20.7°C. There were no other deviations from testing protocol other than what was listed in Step 4.
6. Product was tested initially to ensure successful inoculation.
7. Products were subsequently tested at 1, 3- and 24-hour intervals.
8. At each time point, contamination survey flocked swabs were used to access presence of microorganism on fabric.

**Summary:**

Because P23 Labs is not an EPA certified lab and we only focus on Molecular Testing, we were unable to perform a standard certification of the product. Additionally, the Intended Use statement was not provided to P23 Labs. As such, P23 used the product to simulate use in a clinical testing laboratory. In our laboratory, we routinely check surfaces, light switches, commonly touched areas, and instruments for contamination using the swab survey method. We used this product as we would in the laboratory to cover cell phones, computer screens, lab quick reference guides and workstations for testing. After our simulated use of the product, we conducted started swab collected PCR testing for identification of microorganism to assess usability of the product provided to us by Nanodefense. P23 Labs was asked to provide feedback and written report.

**Findings:**

Material	Grade	Coating Type	Test Virus	Initial Time 0	Time=1 hr	Time=3 hr	Time=24 hr
MagiCal	industrial	Indoor	Covid 19	Detected	Not Detected	Not Detected	Not Detected
Satin Acetate	industrial	Indoor	Covid 19	Detected	Not Detected	Not Detected	Not Detected
MagiCal	industrial	Indoor	SARS-Cov	Detected	Detected	Not Detected	Not Detected
Satin Acetate	industrial	Indoor	SARS-Cov	Detected	Not Detected	Not Detected	Not Detected
MagiCal	industrial	Indoor	MERS-Cov	Detected	Not Detected	Not Detected	Not Detected
Satin Acetate	industrial	Indoor	MERS-Cov	Detected	Not Detected	Not Detected	Not Detected
MagiCal	industrial	Indoor	Influenza A/B	Detected	Not Detected	Not Detected	Not Detected
Satin Acetate	industrial	Indoor	Influenza A/B	Detected	Not Detected	Not Detected	Not Detected
MagiCal	industrial	Indoor	H1N1	Detected	Detected	Detected	Not Detected
Satin Acetate	industrial	Indoor	H1N1	Detected	Not Detected	Not Detected	Not Detected
Satin Acetate	industrial	Indoor	Streptococcus agalactiae	Detected	Not Detected	Not Detected	Not Detected
Satin Acetate	industrial	Indoor	Salmonella	Detected	Not Detected	Not Detected	Not Detected
Satin Acetate	industrial	Indoor	MRSA	Detected	Not Detected	Not Detected	Not Detected
Satin Acetate	industrial	Indoor	Coliform bacteria (Ecol	Detected	Not Detected	Not Detected	Not Detected

All samples showed initial inoculation of microorganism on the surface study within the first 2 minutes of microorganism exposure to fabric/plastic materials tested. Magical Industrial had H1N1 viral organisms present at every time point the sample was collected. Magical Industrial demonstrated the ability to kill the SARS-CoV virus between hours 1 and 3, not detected after 3 hours or at 24 hours in incubation at room temperature. However, Satin Acetate Industrial demonstrated the ability to kill and/or decrease between detectable levels sometime between initial time at 2 minutes exposure and 1 hour. Both products showed resistance acquired between initial time at 2 minutes and 2 hours to COVID-19 and the organism was below our Limit of Detection for our assay, which is 2 copies of RNA per 1 uL.

As only product name was provided to P23 Labs, we strongly recommend submission to the FDA for guidance and use. This product demonstrated resistance while in use at the laboratory and the organisms were not detected when PCR assay analysis under stimulated laboratory conditions for a contamination survey. This product could be instrumental for laboratory use, keeping technologists healthy, and reducing the spread and transmission of COVID-19 for front line workers. This product could also be suitable material for protective face barriers and screen shields in high risk environments where suspected contact of positive patient samples is likely to exist.