

The Five Pillars Of Safety
In Healthcare

Appendix

PDI, Inc.[™]

Appendix

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In situ evaluation of a persistent disinfectant provides continuous decontamination within the clinical environment

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Summary

- Evaluation of two EPA-registered quaternary ammonium disinfectants and **Sani 24® Germicidal Spray*** designed to evaluate the ability of persistent disinfection of each product.
- This study took place in a medical intensive care unit and each product was applied to the bedrails of an occupied patients bed.
- **Sani-24** Spray was compared individually to both disinfectants in separate trials.

Experiment:

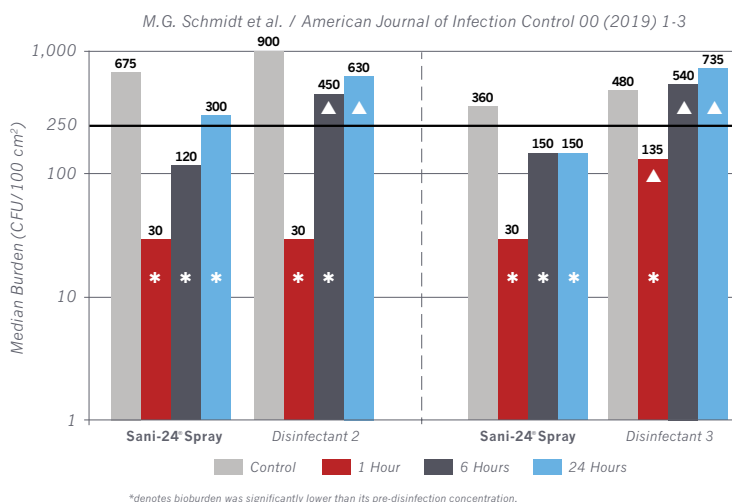
- Baseline cultures were taken prior to the application of the disinfectant on the bedrails of 132 patient beds.
- Each disinfectant was applied separately according to the manufacturer's instructions for use.
- **Sani-24** Spray was applied to 65 beds.
- Disinfectant #2 was applied to 34 beds.
- Disinfectant #3 was applied to 33 beds.
- After application, cultures were taken again at 1, 6 and 24 hours.

Results:

- **Sani-24** Spray was the only disinfectant to show continuous activity which was evident with bioburden significantly lower at 1, 6 and 24 hours post-disinfection.
- Disinfectant #2, which is similar in composition to **Sani-24** Spray, exhibited significant bacteria regrowth at 6 hours post-application.
- Disinfectant #3 was only able to maintain its disinfection activity for 1 hour after application.

Conclusions:

- **Sani-24** Spray was significantly better at preventing bacterial regrowth.
- **Sani-24** Spray was able to significantly control bioburden on bed rails, a high touch surface for up to 24 hours during active patient care.
- **Sani-24** Spray represents a first-of-its-kind disinfectant that offers continuously active disinfection in the environment.



*CAD addresses Enterobacter aerogenes, Enterococcus faecalis VRE (Vancomycin resistant enterococcus), Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus aureus (Methicillin Resistant) (MRSA with a 5 minute contact time).



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PATIENT CARE INTERVENTIONAL CARE ENVIRONMENT OF CARE



Assessed Impact of Sani Professional® Single-Use, Pre-Moistened Wipes Versus Bucket And Rag On Back-of-House Food Contact Surfaces

SCOPE:

Sani Professional, the Food Safety Division of PDI, Inc., a leading manufacturer of infection prevention products, implemented and assessed the impact of using single-use, disposable cleaning and sanitizing wipes versus using the traditional sanitizer bucket and rag method. Testing was conducted at the Ascension St. Vincent Riverside Hospital, located in Jacksonville, Florida. The 528-bed facility was chosen as the testing site due to their longstanding history of SOP compliance. The test included swabbing, cleaning and sanitizing 13 separate food contact surfaces throughout various back-of-house and catering prep stations of the hospital.

SUMMARY OF RESULTS:

- a) **Efficacy:** All 13 food contact surface locations experienced a remarkable 87% average decline in bioburden levels after the ongoing use of disposable, pre-moistened cleaning and sanitizing wipes. This means that through the use of a single-use wipe, the number of bacteria living on a surface decreased thereby preventing incidence of cross contamination on those food contact surfaces. (See Table A in Study Details)
- b) **Cost Implications:** It was also estimated that the cost impact of using single-use, pre-moistened wipes was marginal when compared to the cost of the traditional rag and bucket method. The cost calculation using the wipes showed an increase of only \$0.01 per meal; annually this translates to \$10,921 or 0.8% of total meal cost of \$1.24M over the 3-month test period. (See Table B in Study Details)
- c) **User Experience:** Of the 23 employees who participated in the test, the wipes generated 95%-98% preference over the rag and bucket. Top attributes liked were: Convenience, Less time to clean/sanitize, and Quality of wipes/cloth. (See Table C in Study Details).

BACKGROUND DISCUSSION:

ATP (Adenosine Triphosphate) Testing is widely used in foodservice as an environmental monitoring system to indicate surface cleanliness. It measures the number of bacteria living on a surface. The Hygiena ATP device used in the study provided digital measurement in RLU units (or, Relative Light Units) in 15 seconds.

The comparative testing methodology are described as follows:

- Food contact surface sites included in the test were: salad prep areas, food prep areas, bakery, chef station and catering.
- Existing SOP for cleaning and sanitizing food contact surfaces outlined the use of a reusable towel/rag with a sanitizing liquid chemical housed in the red sanitizer bucket, defined as the Pre-Test method and used during the months of August-September.
- The use of cleaning and sanitizing single-use pre-moistened wipes were implemented exclusively over a 3-month period (October through December), defined as the Post-Test Methods.
- Bioburden levels were measured on the above listed food contact surfaces using the Hygiena ATP device and swabs for both Pre- and Post-Test Methods.

STUDY DETAILS:

Table A

Ascension St. Vincent's Riverside Hospital, Jacksonville, Florida						
Location	Date (Pre-Test Method)	ATP Reading	Date (Post-Test Method)	ATP Reading	Change	Change %
Upstairs Prep area #3	16-Jul-19	320	11-Oct-19	0	-320	-100.0%
Upstairs Prep area #4	16-Jul-19	66	11-Oct-19	0	-66	-100.0%
Upstairs Bakery	16-Jul-19	164	11-Oct-19	0	-164	-100.0%
Upstairs Catering	16-Jul-19	37	11-Oct-19	0	-37	-100.0%
Bergs Prep	16-Jul-19	346	11-Oct-19	0	-346	-100.0%
Upstairs Chef station #1	16-Jul-19	587	11-Oct-19	9	-578	-98.5%
Upstairs salad prep area #2	16-Jul-19	404	11-Oct-19	8	-396	-98.0%
Dillion Salad	16-Jul-19	294	11-Oct-19	8	-286	-97.3%
Upstairs Prep area #2	16-Jul-19	500	11-Oct-19	14	-486	-97.2%
Dillon Prep table #1	16-Jul-19	820	11-Oct-19	26	-794	-96.8%
Dillion Prep table #2	16-Jul-19	165	11-Oct-19	42	-123	-74.5%
Upstairs salad prep area #1	16-Jul-19	267	11-Oct-19	94	-173	-64.8%
Upstairs Prep area #1	16-Jul-19	23	11-Oct-19	22	-1	-4.3%
Total						-1131.5%
Average Bioburden Overall Decrease						-87.0%

Results from the testing of the 13 food contact surface sites showed an 87% average decrease in bioburden levels from Pre-Test Method (rag and bucket) to Post-Test Method (single-use, pre-moistened wipes).

Worth noting with the single-use, pre-moistened wipes:

- 10 of the 13 tested surfaces resulted in over 95% decrease in bioburden left behind on these food contact surfaces
- 5 food contact surfaces had a complete 100% reduction in residual bioburden

Table B

Month	Cost	Budget	Total Meals Act	Total Meals Budget		Cost/ Meal Act	Cost/ Meal Budget	Variance	
August	\$4,901	\$7,399	\$138,255	\$139,600		\$0.04	\$0.05	(\$0.02)	
September	\$4,803	\$7,134	\$101,587	\$134,606		\$0.05	\$0.05	(\$0.01)	
Pre-Test Method Purchase	\$9,703	\$14,533	\$239,842	\$274,206		\$0.04	\$0.05	(\$0.01)	
October	\$9,404	\$7,489	\$126,405	\$141,308		\$0.07	\$0.05	\$0.02	
November	\$5,861	\$7,134	\$120,792	\$134,609		\$0.05	\$0.05	(\$0.00)	
December	\$6,982	\$7,399	\$112,873	\$139,603		\$0.06	\$0.05	\$0.01	
Post-Test Method Purchase	\$22,246	\$22,022	\$360,070	\$415,520		\$0.06	\$0.05	\$0.01	
Total Purchases	\$31,950	\$36,555	\$599,912	\$689,726		\$0.05	\$0.05	\$0.00	\$10,921

Table C

Sani Professional Sanitizing/Cleaning Wipe Evaluation Survey Results				
Evaluation Category	SANITIZING WIPES		CLEANING WIPES	
	Prefer Wipes	Prefer Bucket	Prefer Wipes	Prefer Bucket
Overall Wipe Use Experience	21	2	17	2
Helps Prevent Cross-Contamination	21	2	19	0
Cleaning/Sanitizing Effectiveness	21	2	19	0
Quality of Wipe/Cloth	23	0	19	0
Ease of Use	21	2	19	0
Ease of Dispensing	23	0	19	0
Less Time Needed to Clean/Sanitize	23	0	17	2
Convenience	23	0	19	0
Mild on Hands	21	2	19	0
Total	197		167	
Average # of Employee Preferred	21.89		18.56	
% of Employee Preferred	95%		98%	

STUDY DETAILS:

- ATP testing results improved dramatically upon transitioning to Sani Professional cleaning and sanitizing wipes.
 - o No additional steps or incremental cleaning took place. These outcomes are simply a result of using the Sani Professional Cleaning and Sanitizing wipes in place of the rag & bucket.
- Cost implications of moving from the rag/bucket method to pre-moistened wipes was just \$.01/meal or an overall annual increase of \$10,921 per healthcare facility.

SUMMARY:

This whitepaper is in support of the cleaning and sanitation product evaluation at Ascension St. Vincent Riverside Hospital located in Jacksonville, Florida. Prior protocol at this location included the use of red sanitation buckets and rags. The study, in support of implementing single-use cleaning and sanitizing wipes over liquid sanitation buckets and rags included:

- ATP surface testing prior to and following the use of:
 - o The traditional bucket and rag
 - o Sani Professional single-use cleaning and sanitizing wipes.

The surfaces monitored were food contact surfaces within the dining/food prep areas.

The Ascension St. Vincent Riverside Hospital location is highly regarded as a location that consistently follows organizational SOP's. The existing standard operating procedure included cleaning surfaces prior to sanitizing. Once the surface had been cleaned, employees would then sanitize with the bucket and rag.

Overall testing results showcased the reduction of germs/ bioburden on surfaces after the use of single-use pre-moistened wipes. All surfaces tested post single-use wipe conversion had a decrease in bioburden levels. Over 75% of the surfaces tested saw a 95% reduction of bioburden levels. Additionally, employee responses to the wipes product evaluations were overwhelmingly in favor of wipes versus the traditional rag and bucket method.



EMERGING PATHOGEN ALERT

Novel coronavirus (2019 -nCoV) infection

The U.S. Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have released guidance documents for the management of patients known or suspected to be infected with a novel coronavirus named 2019-nCoV, which is causing pneumonia with infection associated mortality similar to SARS-CoV and MERS-CoV. The WHO recommendations are based on a 2019 interim guidance document for MERS-CoV until further epidemiologic information is available.



Background Information on 2019-nCoV

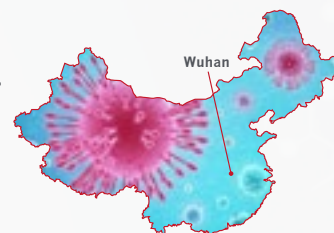
- 2019-nCoV is a newly identified coronavirus initially isolated in Wuhan, China on 12.31.2019 with confirmation the virus came from wild animals sold at a market in that province.
- 2019-nCoV is spreading across China with other countries reporting cases including Thailand, South Korea, Taiwan, and Japan.
- Five U.S. cases have now been confirmed in travelers from China and hospitalized in the U.S. (1.27.2020)
- A total of 2,014 confirmed cases have been reported for novel coronavirus (2019-nCoV) globally; 1,985 were reported from China; 56 deaths have been reported (all from Hubei or Hubei Province).
- Infection presents with respiratory symptoms, fever, cough, shortness of breath and breathing difficulties.
- Severe cases of infection may result in pneumonia, severe acute respiratory syndrome, sepsis, kidney failure and death.
- The incubation period for 2019-nCoV is unknown at this time but likely as with SARS-CoV and MERS-CoV is 2-7 days (range, up to 14 days).
- Patient risk factors for acquisition of 2019-nCoV have not yet been defined.
- Transmission dynamics of 2019-nCoV have not yet been fully elucidated; Human-to-human transmission is occurring.
- Previous coronavirus outbreaks suggest that environmental surfaces/equipment of infected cases will be contaminated contributing to viral transmission via hands and PPE of healthcare personnel (HCP), and possibly inadequately disinfected shared medical equipment.
- CDC has issued health alert for travelers from Wuhan, China and the U.S. has expanded illness screenings at major airports.



Case Count: **2,014**
(as of 01.26.20)



Deaths: **56**



CDC and WHO Interim Infection Prevention and Control Recommendations for Patients Under Investigation (PUI) for 2019-nCoV

Infection Control Recommendations:

Screening and signage

- Place entrance signs at all healthcare facilities alerting patients/visitors of possible disease exposure risk if Wuhan, China travel history and the signs/symptoms of infection with information about who to notify of their exposure/symptoms.
- Include messaging about possible exposure based on travel history and the signs and symptoms of 2019-nCoV in all telephone contacts regarding patient appointments.
- Patients with clinical features of illness should be evaluated for epidemiologic risk. (<https://www.cdc.gov/coronavirus/2019-nCoV/clinical-criteria.html>)
- Implement respiratory hygiene etiquette (i.e., immediate use of mask and proper disposal of tissues); use of hand sanitizer.

Triage

- Have appropriate personal protective equipment (PPE) (N95 respirators, face shields, gowns and gloves) immediately available for all healthcare personnel (HCP) in the ERs and ambulatory settings.
- Place Patients Under Investigation (PUI) on Standard, Contact and Airborne isolation precautions plus eye protection (i.e., use of a face shield or eye goggles) in an airborne isolation room (if available), or negative pressure private room (ideally with HEPA unit in the room).

Inpatient care

- Place PUI on Standard, Contact and Airborne isolation precautions plus use of face shield or eye goggles in an airborne isolation room; limit visitors; care by HCP trained in use of powered air purifying respirators (PAPRs) and proper donning/doffing of PPE.
 - NOTE: The appropriate donning and doffing of PPE by HCP plays a critical role in preventing the spread of coronaviruses as survival of these viruses on gloves and fabric has been demonstrated.
- Environmental services staff should adhere to the PPE recommendations while performing routine, daily or terminal cleaning of rooms occupied by PUI for 2019-nCoV.
- Initiate a log of all HCP providing care; use of only dedicated HCP; HCP to self-monitor for symptoms.

Clinicians should continue to use EPA-registered disinfectants and alcohol-based hand sanitizer in accordance with these guidance documents. Previously identified novel coronaviruses that have resulted in human acute respiratory syndromes (e.g. SARS, MERS) were found to contaminate environmental surfaces and to survive for days to weeks. Disinfection of environmental surfaces and medical equipment with an EPA-registered disinfectant is critical to disrupt viral transmission. Ensure that environmental cleaning/disinfection procedures are followed according to the manufacturer's instructions for use.



PDI offers several EPA-registered surface disinfectant products that have a label claim against a strain of human coronavirus (Strain 229E [ATCC VR-740]):

SUGGESTED PDI PRODUCTS



**Sani-Prime®
Spray & Wipes**



**Sani-24®
Spray**



**Super Sani-Cloth®
Wipes**



**Sani-Cloth® Bleach
Wipes**



**Sani-Cloth® AF3
Wipes**



Our products qualify for emerging viral pathogen claims per EPA's Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions. Currently, the 2019 Novel Coronavirus has not been available for testing. These products have demonstrated effectiveness against a virus similar to 2019-nCoV on hard, nonporous surfaces. Therefore, these products can be used against the 2019-nCoV when used in accordance with the directions for use against human coronavirus on hard, nonporous surfaces.

Utilizing **Tru-D® SmartUVC** is an added layer of disinfection for surfaces. While there is no peer-reviewed literature that specifically focuses on the efficacy of UVC devices against this unique strain of coronavirus, Tru-D was designed to combat bacteria, viruses, spores and fungi.



At PDI, we strive to include the most relevant epidemiologically important pathogens on our disinfectant product labels and continue to monitor for emerging pathogens to be included in future product label changes. Please don't hesitate to contact your PDI or Tru-D® SmartUVC sales representative or PDI Clinical Science Liaison with any additional questions. Thank you.

If you have any additional questions, please visit the CDC or WHO dedicated websites on 2019 nCoV:

- <https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>
- <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>

Source: Centers for Disease Control and Prevention and World Health Organization

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