Summary of Non-Clinical Bench Performance Testing

Study Information

Title: Validation of Two Manual Cleaning Processes for RiteWipe™

Study Director: Third Party Laboratory

Testing Facility: Third Party Laboratory

Study Summary

Cleaning prior to sterilization is crucial for ensuring patient safety and maintaining the integrity of dental tools. This process reduces bioburden, enhancing the effectiveness of sterilization by eliminating organic and inorganic matter that can protect microorganisms. Proper pre-cleaning prevents cross-contamination and complies with health standards from organizations like ANSI/AAMI, ADS/OSAP, and CDC.

A. Study Importance:

This study evaluates the efficacy of RiteWipe™ cleaning wipes in preparing dental handpieces for sterilization. This assessment ensures that the cleaning process effectively removes contaminants and meets regulatory guidelines.

B. Key Aspects:

Contaminant Removal: Tests removal of specific organisms (Corynebacterium striatum, Streptococcus mutans, Haemophilus influenzae) and hemoglobin from dental handpieces.

Standards Compliance: Follows ANSI/AAMI ST98, AAMI TIR12, FDA, CDC, and ISO 17664 standards.

Outcome Metrics: Evaluates residual hemoglobin levels and microbial load reduction, ensuring the cleaning process meets acceptance criteria.

C. Study Results:

This study validates that RiteWipe™ cleaning wipes effectively prepare dental handpieces for sterilization, supporting their use in dental practices for improved patient safety and compliance with hygiene standards.

Test Report Summary for RiteWipe™

1. Tests Performed:

Validation of the manual cleaning process using RiteWipe™ on a dental handpiece.

2. Objectives:

To determine the cleanability of the dental handpiece using RiteWipe™ following current industry guidelines.

3. Test Methods:

Sample Description: Dental handpiece contaminated with a mixed organism suspension (Corynebacterium striatum ATCC BAA-1293, Streptococcus mutans ATCC 25175, Haemophilus influenzae ATCC 19418) and hemoglobin.

Sample Size: Three replicates of the dental handpiece for each cleaning condition (with and without a sterile water rinse, before and after autoclaving).

Standards Utilized:
- ANSI/AAMI ST98:2022 - Cleaning validation of health care products
- AAMI TIR12:2020 - Designing, testing, and labeling reusable medical devices for reprocessing
- FDA Guidance Document (June 2017) - Reprocessing Medical Devices in Health Care Settings
- CDC Guideline (May 2019) - Disinfection and Sterilization in Healthcare Facilities
- ISO 17664:2021 - Processing of health care products

3.1 Preconditioning and Preparation of the Test Device:
Six preconditioning cycles were performed using defibrinated sheep blood. The test device was soiled with a 1 mL aliquot of test soil, spread uniformly over the test surfaces, and dried for 15 minutes at room temperature.

3.2 Cleaning and Sterilization Process:
Without Rinse:
One towelette was used to wipe the test areas until all visible soil was removed. A new towelette was used if visible soil remained, and the process was repeated until the device was visibly clean. The device was photographed when visibly dry.
With Sterile Water Rinse:
After initial wiping to remove visible soil, the test areas were wiped twice under running sterile tap water with a new wipe. The device was photographed when visibly dry.
Post-Cleaning Autoclave:
Cleaned devices were placed in sterilization pouches and autoclaved for 30 minutes at 121 °C using a fast exhaust cycle. The devices were cooled to room temperature and photographed again.

3.3 Recovery and Analysis:
Residual Hemoglobin Analysis:
Using the HemoCheck™ Test Kit, a standard curve was prepared with Hemiglobincyanide (HiCN) Hemoglobin Standard. Residual hemoglobin was determined by spectrophotometry at 540 nm.
Bacterial Enumeration:
A sterile swab was used to recover microorganisms from the test device. Serial dilutions and plating were performed to quantify the viable organisms.

4. Acceptance Criteria:

Residual hemoglobin must be < 2.2 µg/cm^2. Minimum 6-log reduction in microbial load for the cleaning process.

5. Results Summary:

Regardless of the cleaning approach utilized, RiteWipe™ successfully eliminated blood from all device replicates and conditions, bringing the levels below detectable limits (**Table 1**). Furthermore, RiteWipe™ demonstrated significant antimicrobial effectiveness in both no-rinse and rinse conditions, achieving log reductions exceeding the pass threshold of 6 against *Corynebacterium striatum*, *Streptococcus mutans*, and *Haemophilus influenzae* (**Tables 2 and 3**).

Table 1: Test Sample Results for Hemoglobin

Test Device	Cleaner	Replicate 1 (µg/cm²)	Replicate 2 (µg/cm²)	Replicate 3 (µg/cm²)	Performance Criteria (µg/cm²)	Pass/Fail
Dental HP	RiteWipe™ - Rinse	0.024	0.024	0.024	< 2.2	Pass
Dental HP	RiteWipe™ - No Rinse	0.024	0.024	0.024	< 2.2	Pass

Table 2: Log Reduction of Dental Handpiece with RiteWipe™ - No Rinse, Pre-Autoclave

Challenge Organism	Positive Control (CFU/device)	Replicate A, B, C (CFU/device)	Log Reduction
Corynebacterium striatum, Streptococcus mutans, Haemophilus influenzae	$3.3x10^9$	$< 1.0x10^1$, $< 1.0x10^1$, $6.0x10^1$	> 8.5185, > 8.5185, 7.7403

Table 3: Log Reduction of Dental Handpiece with RiteWipe™ - Rinse, Pre-Autoclave

Challenge Organism	Positive Control (CFU/device)	Replicate A, B, C (CFU/device)	Log Reduction
Corynebacterium striatum, Streptococcus mutans, Haemophilus influenzae	$5.7x10^8$	$2.9x10^2$, $2.0x10^2$, $1.2x10^2$	6.2935, 6.4549, 6.6767

Figure 1: No Rinse Hemoglobin and Bacteria Percentage Pre-Autoclave Removal - Summary

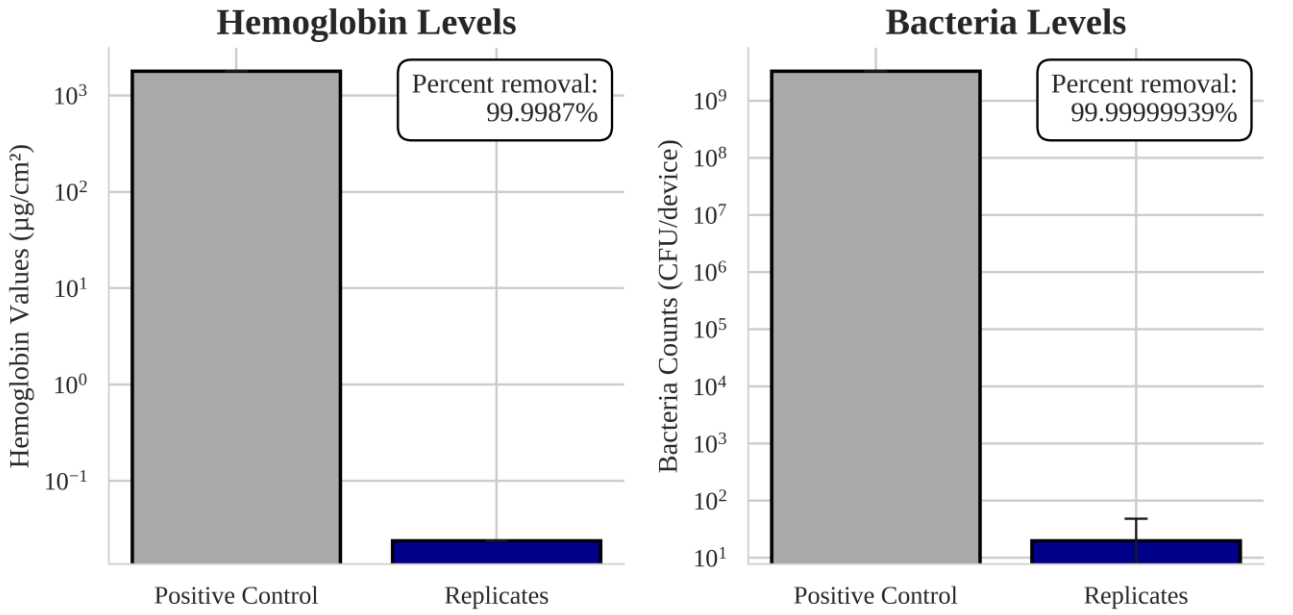

Figure 1: Summary of residual hemoglobin and bacteria levels before sterilization. Gray bars indicate hemoglobin and bacteria levels, respectively, on uncleaned soiled handpieces. Blue bars (n=3) indicate hemoglobin and bacteria levels, respectively, after cleaning with RiteWipe™.

D. Conclusion:

The results of this study demonstrate that the RiteWipe™ cleaning wipes are highly effective in the manual cleaning of dental handpieces. The data shows that both with and without a sterile water rinse, the wipes consistently achieved residual hemoglobin levels well below the acceptance criterion of < 2.2 µg/cm^2. Additionally, the microbial load was reduced by over 6 logs, surpassing the required performance threshold.

Residual Hemoglobin Analysis: All tested conditions (no rinse, no rinse after autoclave, rinse, rinse after autoclave) resulted in residual hemoglobin levels of 0.024 µg/cm^2, indicating effective removal of blood contaminants.

Microbial Load Reduction: Both no-rinse and rinse procedures achieved significant log reductions in bacterial counts, with log reductions exceeding 6 logs in all tested organisms (Corynebacterium striatum, Streptococcus mutans, Haemophilus influenzae). There were no detectable microorganisms post autoclave in both rinse and no-rinse procedures (data not shown).

These findings validate that RiteWipe™ cleaning wipes effectively prepare dental handpieces for sterilization by removing both visible soil and microbial contaminants. This supports their use in dental practices to enhance patient safety and ensure compliance with industry standards for reprocessing medical devices. The consistent performance across various conditions underscores the reliability and effectiveness of the RiteWipe™ cleaning system in maintaining dental instrument hygiene.