Validation of a Cleaning Verification Test for Lumened Medical Devices

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DISCLOSURES

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No compensation has been received for this presentation.

All opinions are those of the presenters.

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OBJECTIVES

Study Goal

Validate an easy-to-use, qualitative cleaning verification test to detect residual protein in channels of lumened devices after manual cleaning.

Subset Studies

1. Coupon testing study to establish the Limit of Detection
2. Channel testing study to determine Extraction Efficiency
3. Clinical testing to demonstrate the efficacy of this test in clinical use.

Testing performed by Eurofins Biotech-Germande

Dye-binding protein test

WHY PERFORM THESE STUDIES

- Standards and Guidelines around the world-- beginning to recommend/require cleaning verification after manual cleaning, before disinfection or sterilization.
  Example:
  - Per ANSI/AAMI ST91 for endoscope processing
    - High-risk scopes - Shall be monitored with cleaning verification after each cleaning.
    - Non-high-risk scopes: Should be verified using cleaning verification tests when new endoscopes are purchased *and* at established intervals (based on the number of procedures performed).

- Need to assess the quality of manual cleaning-- to determine if the lumened medical devices can continue to the subsequent steps of the process.

- The testing is to be done after manual cleaning, before HLD or sterilization. The test is meant to be part of a total quality assurance program, including visual inspection, functionality testing.

- The test is not meant to determine the patient readiness of the endoscope.

CLEANING INDICATOR / SWAB TEST

INTENDED USE

To detect protein residue inside various channels of lumened medical Devices.

MODE OF ACTION

The test utilizes the formation of Protein-Dye complex to detect proteins.

USE PROCEDURE

- Long channel swab is inserted through the channels of lumened medical devices and pushed all the way through, one time.
- The swab is placed into the indicator vial and then cut. Cap is placed back and shaken for proper mixing.
- The swab tip or the liquid is observed for color change.
- Visible color change indicates presence of protein.

STUDY 1 LIMIT OF DETECTION

EVALUATING THE LIMIT OF DETECTION (LOD)

- PTFE coupons were inoculated with FIVE known concentrations of Bovine Serum Albumin (BSA), with three replicates per concentration.

Samples	Theoretical concentration on coupons (µg)
S1	10
S2	2.5
S3	1
S4	0.5
S5	0

PTFE coupons

- 100µl of BSA solution was pipetted as a droplet on clean, sterile PTFE coupons.
- After drying, the dried solution was swabbed with a moistened swab and tested with the swab test.
- Negative controls were also performed.

STUDY 1 LIMIT OF DETECTION TEST RESULTS

Protein Levels on Coupons

Samples	Theoretical Concentration on coupon (µg)	Measured Concentration on coupon (µg)
S1	10	9.91
S2	2.5	3.27
S3	1	1.30
S4	0.5	0.18
S5	0	0.00

The Limit of Detection of the test is thus 1.3 **µg**

STUDY 2 EXTRACTION EFFICACY STUDY

ASSESSING THE EXTRACTION EFFICACY OF THE TEST

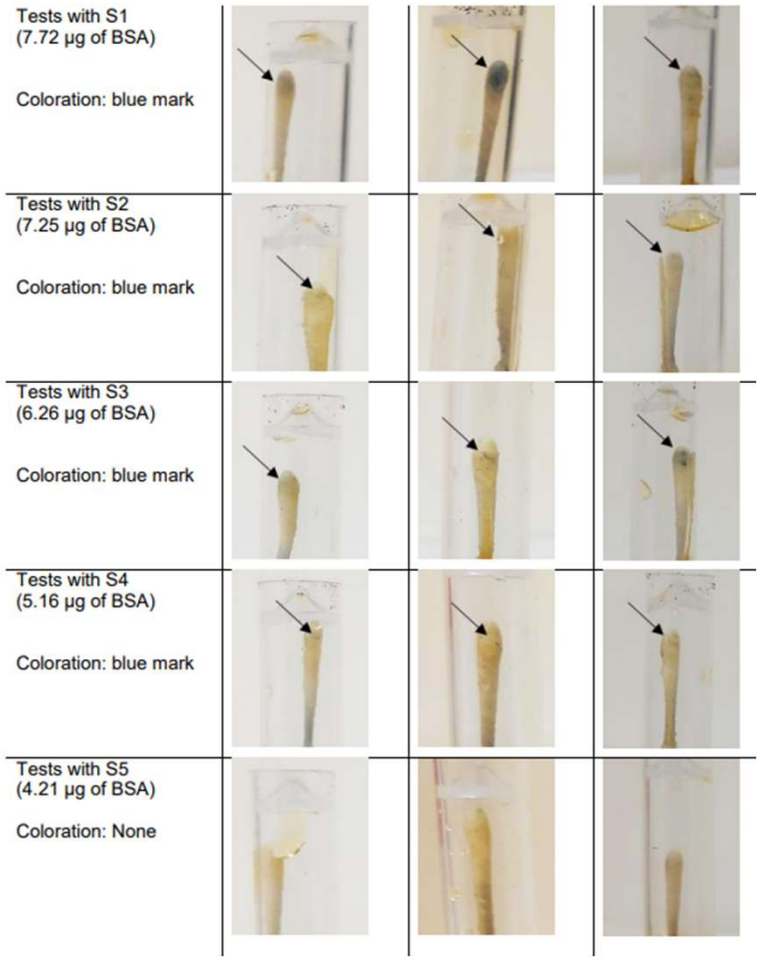
- PTFE tubing of 150mm (length) and 2.7mm (diameter): used to mimic an instrument channel.
- Tubing washed with a non-enzymatic detergent, brushed, rinsed with WFI
- Tubing inoculated with five known concentrations of BSA
- Dried in an oven at 50°C for 32 hours.

Samples	Theoretical concentration (µg/ml)	Theoretical concentration in 50µl (µg)	Measured concentration (µg/mL)	Measured concentration in 50µl (µg)
S1	160	8	154.45	7.72
S2	140	7	144.91	7.25
S3	120	6	125.17	6.26
S4	100	5	103.11	5.16
S5	80	4	84.19	4.21

PTFE Tubing

- Inoculated protein assessed by the Swab test.

STUDY 2 EXTRACTION EFFICACY TEST RESULTS



Test Results

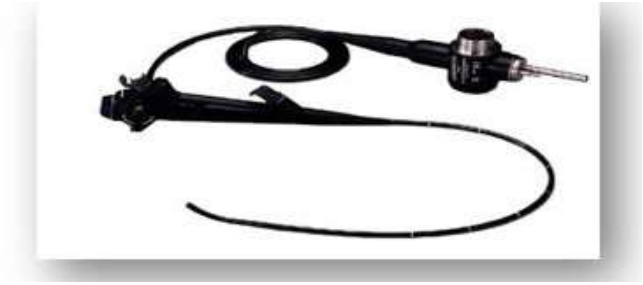
Protein was detected at 5.16µg of BSA

This value corresponds to 0.4µg/cm^2

The test detects well below the Alert level of 3 µg/cm^2 (ISO 15883-5:2021)

DEMONSTRATING EFFICACY AFTER CLINICAL USE

- 180 endoscopes were sampled from two healthcare facilities: 60 Gastroscopes, 60 Bronchoscopes, and 60 Colonoscopes
- Biopsy channels of these clinically used endoscopes were manually cleaned and assessed for analytes.
- The endoscopes were sampled for protein using BCA and swab test methods.



SAMPLING METHODS

Two Sampling Methods

Method 1: Extraction on Site + BCA (Quantitative)

- Biopsy channels sampled with 25ml of Water for Injection.
- Protein quantification of extract by BCA method (MicroBC Assay Protein Quantification kit, Interchim)

Method 2: Sampling with the Swab Test (Qualitative)

- Swab moistened, inserted into the biopsy channel and pushed all the way through one time.
- Swab end cut into the indicator vial.
- Vial shaken and the swab checked over a period of 5 minutes for a color change to blue-green, which indicated protein residues in the tested endoscope.

STUDY 3 OBSERVATIONS

The Percentage of Non-compliant endoscopes (≥6.4 µg/cm^2) – about five times higher with the Swab test than with the Standard sampling method.

		Percentage of Endoscopes	
		Standard Sampling + BCA	**Swab test**
Compliant	Below Action level	89%	49%
Non-compliant ≥6.4 µg/cm^2	Action level	**11%**	**51%**

Alert and Action Levels
(ISO 15883-5:2021)

	Alert level	**Action level**
Protein	≥3 µg/cm^2	≥6.4 µg/cm^2

STUDY 3 RESULTS

PERCENTAGE OF EACH TYPE OF NON-COMPLIANT ENDOSCOPES

	Percentage of Non-compliant Endoscopes	
	Standard Sampling + BCA	Swab test
Bronchoscopes	7%	80%
Gastroscopes	17%	33%
Colonoscopes	10%	40%

Bronchoscopes

- Difference between the swab test (80%) and the quantitative test (7%) is significant.
- The difference may be due to the nature of the soil remaining in the endoscope after manual cleaning.
  - Soil remaining in bronchoscopes could be more easily removed from the walls of the channels due to the mechanical action of the cotton swab compared to extraction with water flush.

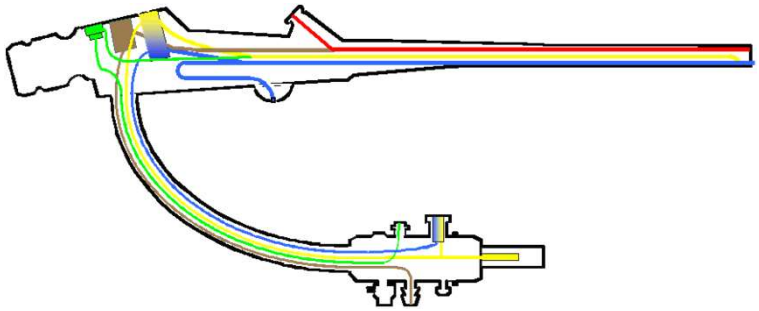
Gastroscopes and Colonoscopes

- Swab test results are comparable (33% - 40%)
- Quantitative protein test results are also comparable (10% - 17%)

CONCLUSIONS

To Sum Up

- The lowest tested protein concentration that showed a passing result was 1.3µg - determined to be the Limit of Detection (LOD) for the test.
- For the Extraction Efficacy study, the test detected 5.16µg of proteins, corresponding to 0.4 µg/cm^2.
- The percentage of endoscopes found to be non-compliant by swab testing method was ~ five times higher than the percentage of non-compliant endoscopes using the BCA method.
  This demonstrates a high sensitivity level of this cleaning verification test.



Questions?

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