TECHNOTES

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Sterile Dry Wipers

Package Integrity Testing for Shelf Life Determination

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Sterile Dry Wipers **Package Integrity Testing** for Shelf Life Determination

Introduction

Texwipe offers a wide selection of non-sterile and sterile dry wiper products. All of Texwipe's sterile (by gamma radiation) dry wipers are packaged in a header-opening-type bag, which protects the wipers from exposure to external contaminating factors, e.g., microbes.

All sterile dry wiper products are marked with a three-year expiration date and the statement "Sterility of contents assured if package is unopened or undamaged." It is important to know if the packaging is suitable for use for products having a three-year shelf life.

Purpose

A study was implemented to test the package integrity features.

For this purpose, the guidelines from ISO 11607 – **Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems** were used.

All header-type bags used for Texwipe dry wipers are made of a non-porous polyethylene material. According to ISO 11607-1, three categories of tests validate the shelf life of a bagged product: the Integrity, Strength and Microbial barrier tests. Each test must be performed on three different product lots. The number of bags for each test must be 60 for a 95% confidence level. Texwipe performed all tests at a third-party laboratory, Nelson Laboratories in Salt Lake City, Utah.

Based on bag material and sterilization method (gamma-irradiation) used for sterile dry wipers, Texwipe selected the following tests from each category:

- **Integrity Test** – the Bubble Emission Test (ASTM F2096 – Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)[1])
- **Strength Test** – the Burst Test (ASTM F1140 – Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages[2])
- **Microbial Barrier Test** (From ISO 11607-1[3]) – the Whole Package Aerosol Challenge Test

Bubble emission test (ASTM F2096)

Scope: Detects gross leaks in packaging (tray and pouch packages) with a method sensitivity to 250 µm (0.010 in.).

A sample is placed in a container filled with water at a depth greater than 150 mm and is maintained at that level for 20 to 60 seconds. The package is pressurized to a minimum of ten inches of water (in H2O) and inspected for evidence of bubble emissions originating from the package or seals. A bubble emission is an indicator of a broken seal film.

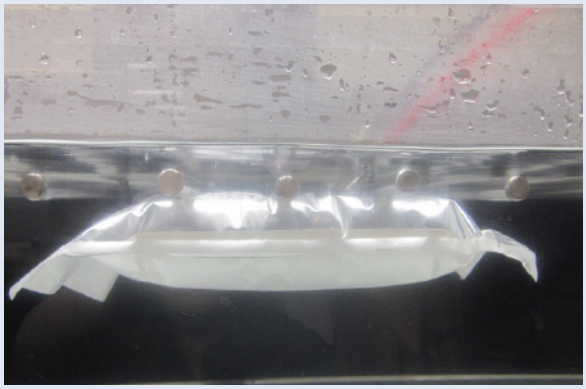


Figure 1. The experimental setup for performing the bubble emission test.

Burst test (ASTM F1140)

Scope: Determines the ability of a package to withstand internal pressurization.

A probe is inserted into a sample package through a package port. The machine inflates and pressurizes the package until it bursts. The machine records the burst pressure. The burst failure location is also recorded.

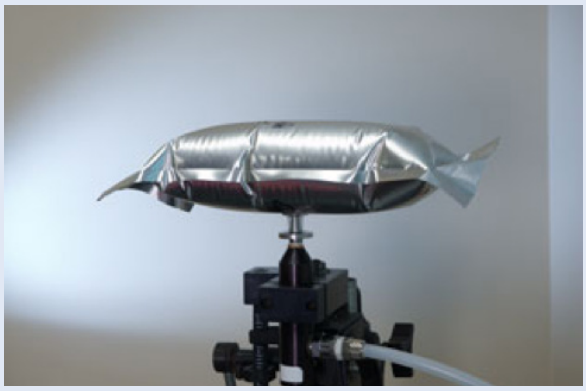


Figure 2. The experimental setup for performing the burst test.

Whole package aerosol challenge test

Scope: Determines package integrity of a finished product package. This includes a whole package microbial challenge and subsequent sterility testing on the packaged product to determine if the indicator organism penetrated the package.

The Whole Package Test procedure involves exposing the package to a large number of aerosolized *Bacillus atrophaeus* (ATCC 9372) spores having a particle size of 4.5 microns or smaller. Following the aerosol challenge, the package contents is tested with soybean casein digest broth looking for organism growth. The media is incubated and scored for the presence of the challenge organism.

All testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Figure 3. Chamber being filled with sample bags before exposure to the aerosol containing Bacillus *spores.*

Procedure

The experiment consisted of the following steps as shown in Figure 4.

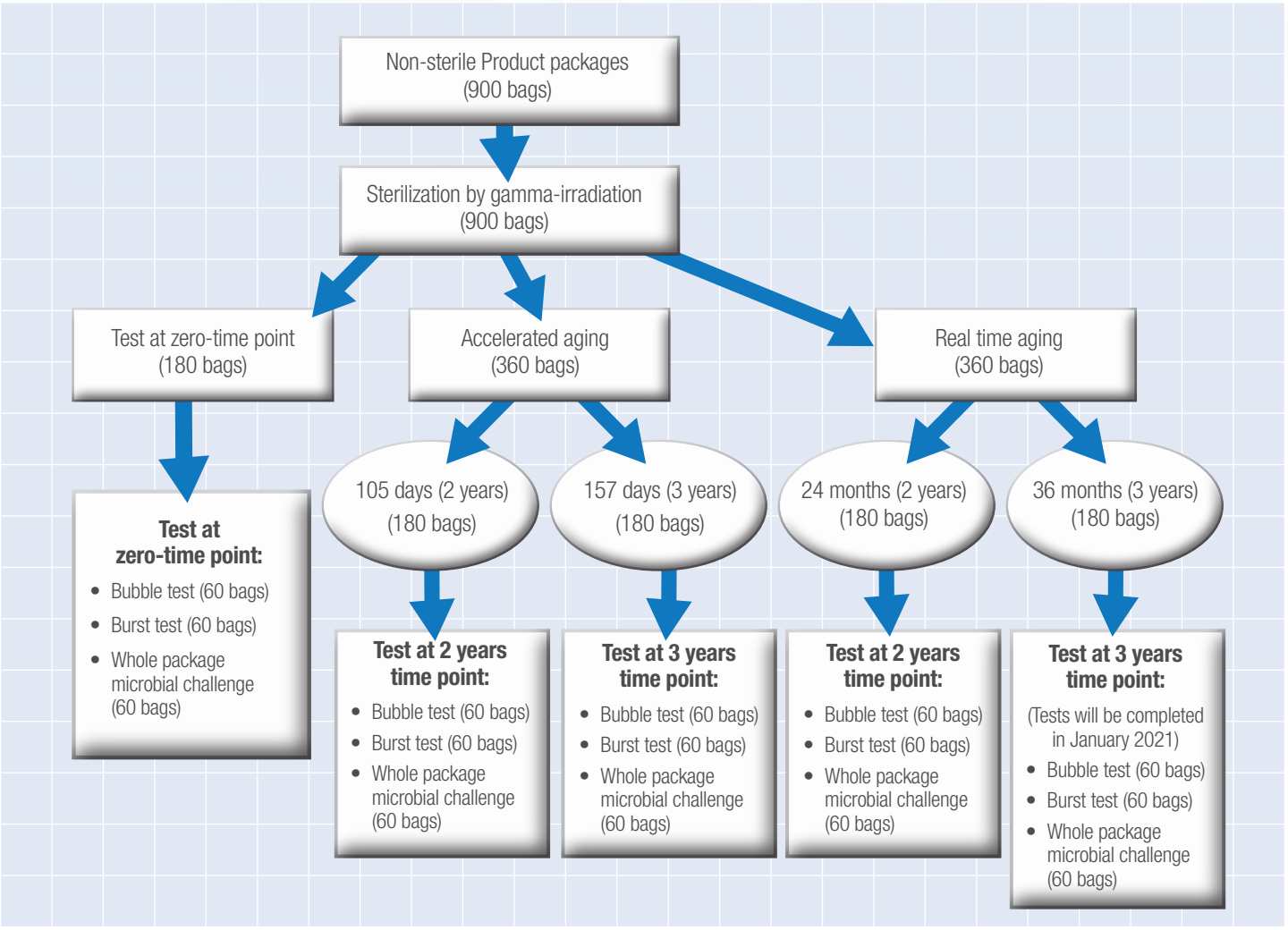


Figure 4. *A diagram of the experimental setup and activities, including the number of samples collected, separation of tthe accelerated and real time aging samples and the testing performed for each set of samples.*

A total of **900 header-type non-sterile bags** of three different lots were prepared for the experiment by inserting and sealing a wiper into each bag. This wiper will be used for microbial testing during the microbial barrier test. All bags were gamma-irradiated at the 21.6 – 40 kGy dose range.

One hundred-eighty bags were tested right after irradiation at the **zero-time point:** 60 bags (20 bags from each lot) were tested for the Bubble emission test; another 60 bags (20 bags from each lot) were tested for the Burst test and other 60 bags (20 bags from each lot) were tested for Whole package aerosol challenge test. The test reports are presented in **Appendix 1**. The results are found in **Table 1**.

Another set of 360 bags was placed in a convection oven for accelerated aging: 180 bags – for 105 days at 50°C, which is equivalent to two years of real time aging and 180 bags for 157 days at 50°C, which is equivalent to three years of real time aging.

After aging, the bags were tested at the **two-year accelerated aging time point** and **three-year accelerated aging time point** using the same tests that were used for zero-time point: 60 bags (20 bags from each lot) were tested for Bubble emission test; another 60 bags (20 bags from each lot) were tested for Burst test and another 60 bags (20 bags from each lot) were tested for Whole package aerosol challenge test. The test reports are presented in **Appendix 2** for the two-year time point and in **Appendix 3** for three-year time point. The results are summarized in **Table 1**.

Another set of 360 bags was placed in the storage for real time aging: 180 bags – for 24 months (2 years) and 180 bags – for 36 months (3 years).

After aging, the bags were tested at the **two-year real-aging time point** and **three-year real-aging time point** using the same tests: 60 bags (20 bags from each lot) were tested for Bubble emission test; another 60 bags (20 bags from each lot) were tested for Burst test and another 60 bags (20 bags from each lot) were tested for Whole package aerosol challenge test. The test reports are presented in **Appendix 4** for the two-year real-aging time point. The three-year real-aging samples will be ready for testing in Jan 2021. The results are summarized in **Table 1**.

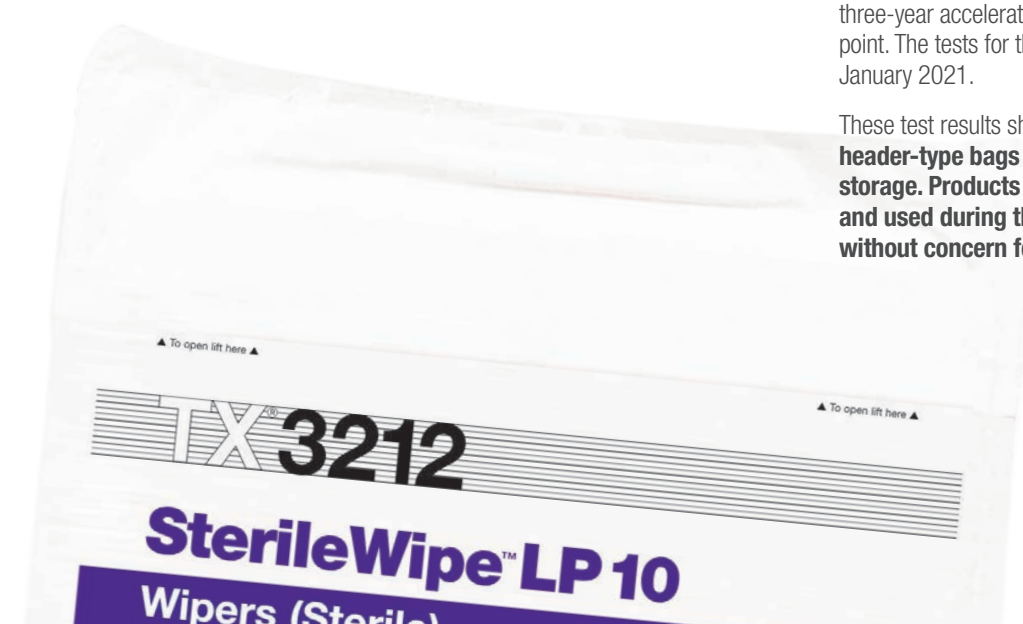
Results

The results for all tests are summarized in **Table 1**.

Table 1. The results of the Bubble Emission test, Burst test and Whole package microbial challenge test for time zero, accelerated aging and two-year real time aging samples.

Test name	Zero-Time Point Result	Two-Year Accelerated Aging Result	Three-Year Accelerated Aging Result	Two-Year Real Time Aging Result
Bubble emission leak test	No leaks for all 60 samples	No leaks for all 60 samples	No leaks for all 60 samples	No leaks for all 60 samples
Burst test pressure (in H2O)	Average = 1.83 Standard deviation = 0.04	Average = 1.83 Standard deviation = 0.04	Average = 1.86 Standard deviation = 0.08	Average = 1.76 Standard deviation = 0.20
Whole package microbial challenge	No growth 60 samples	No growth 60 samples	No growth 60 samples	No growth - 60 samples

*These test results show that the Texwipe wiper products bagged with the **header-type bags will remain sterile after three years** of product storage.*



Discussion

Bubble emission leak test

All bags were completely immersed in the fluid. Each package was pressurized to a minimum of ten in H2O and inspected for evidence of bubble emission originating from the package or seals while underwater.

The data results indicate that no leaks were observed for zero time point, for the two- and three-year accelerated aging time points and two-year real-time time points. The seal and film strength did not change over the accelerated and real time aging periods.

Burst test

For the test parameters, the pressure was set at ten pounds per square inch gauge (psig), and the test time for 60 seconds. The bag burst pressure and burst location were recorded as results.

The mean burst pressure was calculated for 20 samples from each lot, and then the average mean of all three lots was determined.

The average burst pressure did not meaningfully change throughout the experiment, indicating there is no change in the seal and film strength properties due to accelerated and real time aging.

Whole package microbial challenge test

All bags were placed in a chamber and exposed to a microbial aerosol using *Bacillus atrophaeus* (ATCC 9372) spores to challenge the whole sterile barrier system. The wiper placed in the interior of the bag was tested for the presence of the indicator organism.

The test articles demonstrated 100% no growth following the extreme bacterial aerosol challenge throughout the experiment. Package aging (by accelerated and real time aging) did not affect the seal and film strength properties.

Conclusion

Three types of tests were used to measure the package integrity of the header-type bags used for Texwipe's sterile dry wipers in order to confirm the three-year shelf life of this bag type. The tests challenged the integrity, strength and barrier features of the bag seals and film.

All tests showed a high performance of the seal and film barriers, high level of bag integrity and good strength at zero-time point, at two- and three-year accelerated aging time points and at two-year real aging time point. The tests for three-year real aging time point will be completed in January 2021.

These test results show that the **Texwipe wiper products bagged in the header-type bags will remain sterile after three years of product storage. Products packaged in header-type bags may be stored and used during the three years after the manufacturing date without concern for sterility failure.**

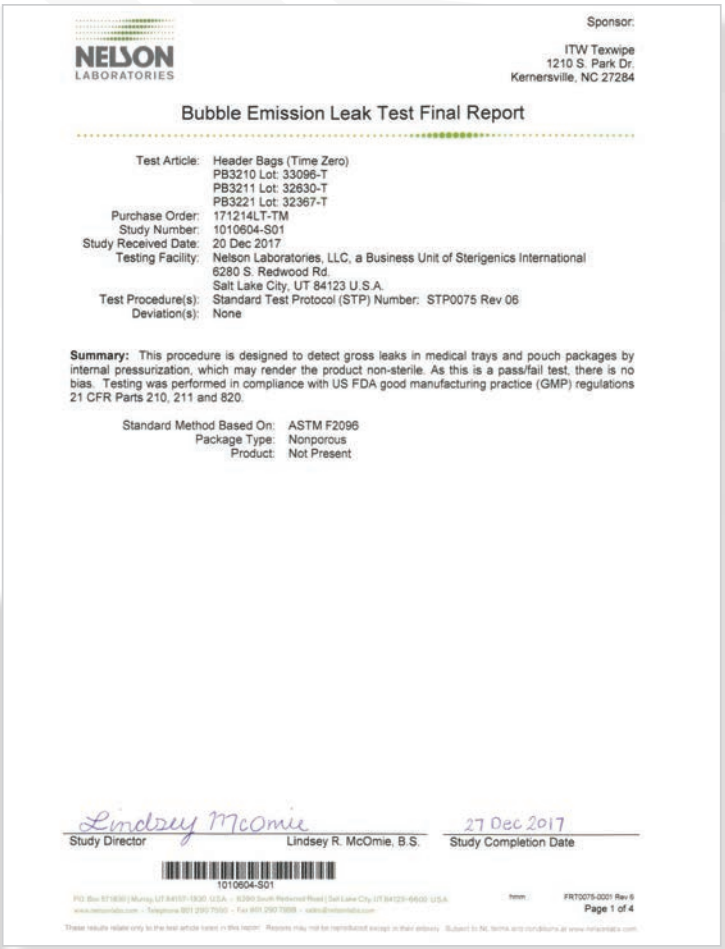
Appendix 1.

A compilation of the Nelson Laboratories test results for the **zero-time point.**

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge



NELSON LABORATORIES

Sponsor:

ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Bubble Emission Leak Test Final Report

Test Article: Header Bags (Time Zero)
PB3210 Lot: 33096-T
PB3211 Lot: 32630-T
PB3221 Lot: 32367-T
Purchase Order: 171214LT-TM
Study Number: 1010604-S01
Study Received Date: 20 Dec 2017
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0075 Rev 06
Deviation(s): None

Summary: This procedure is designed to detect gross leaks in medical trays and pouch packages by internal pressurization, which may render the product non-sterile. As this is a pass/fail test, there is no bias. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Based On: ASTM F2096
Package Type: Nonporous
Product: Not Present

Lindsey McOmie
Study Director Lindsey R. McOmie, B.S.

27 Dec 2017
Study Completion Date

1010604-S01

FRT0075-0001 Rev 6
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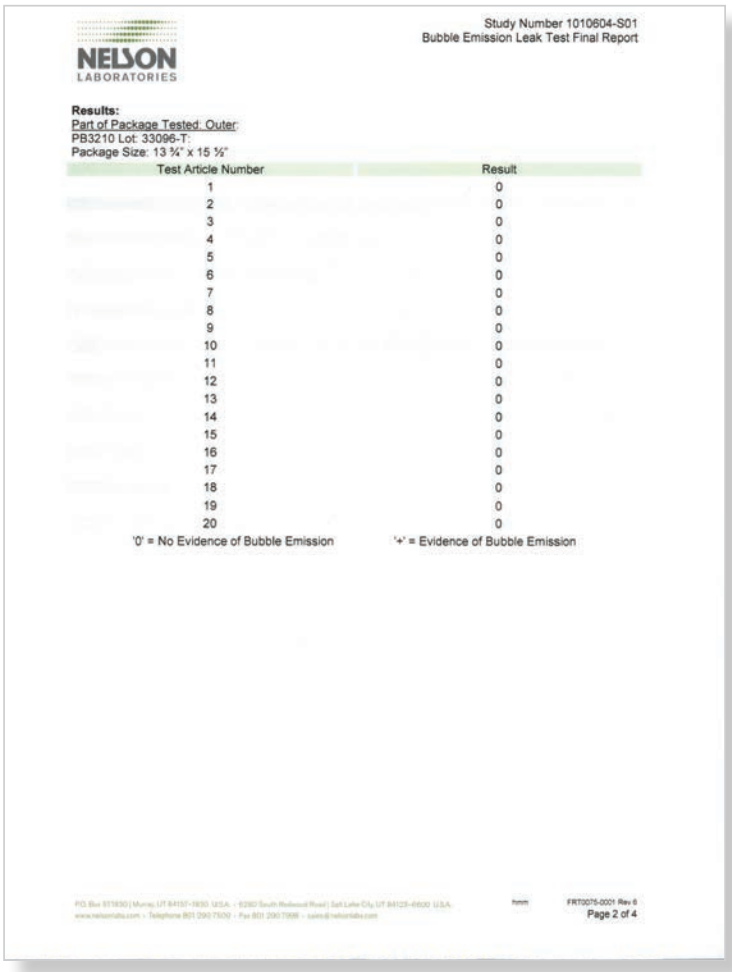

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Study Number 1010604-S01
Bubble Emission Leak Test Final Report

Results:
Part of Package Tested: Outer:
PB3210 Lot: 33096-T:
Package Size: 13 ¾" x 15 ⅜"

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

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NELSON LABORATORIES

Study Number 1010604-S01
Bubble Emission Leak Test Final Report

PB3211 Lot: 32630-T:
Package Size: 10 ¼" x 14"

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

NELSON LABORATORIES

Study Number 1010604-S01
Bubble Emission Leak Test Final Report

PB3221 Lot: 32367-T:
Package Size: 13 ⅛" x 16 ¼"

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

Test Method Acceptance Criteria: No Test Method Acceptance Criteria currently exist for this test.

Procedure: A probe was attached to a package then the test article was completely immersed in the fluid. Next, the package was pressurized to a minimum of 10 in H_2O and inspected for evidence of bubble emission originating from the package or seals.

Appendix 1.

A compilation of the Nelson Laboratories test results for the **zero-time point.**

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge

NELSON LABORATORIES

Sponsor:
Laura Taraban
ITW Texwipe
1210 South Park Drive
Kernersville, NC 27284

Package Burst Test Final Report

Test Article:	Header bags for dry wipers (Time Zero) Lot: 33096-T Lot: 32630-T Lot: 32367-T
Purchase Order:	171030LT
Study Number:	1001949-S01
Study Received Date:	08 Nov 2017
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0060 Rev 11
Deviation(s):	None

Summary: This procedure is designed to determine the ability of packages to withstand internal pressurization. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Based On:	ASTM F1140
Package Type:	Nonporous
Product:	Not Present
Test Start Date/Time:	10 Nov 2017 at 3:02 p.m.
Testing Analyst(s):	Jennifer Mussat
Blocking Agents:	No

Study Director — Jennifer Gygi, B.S., SM/RM(NRCM) — 14 NOV 2017 Study Completion Date

1001949-S01

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NELSON LABORATORIES

Results:
Lot #33096-T:

Set Pressure:	10.00 psig
Test Time (sec):	90.0
Flow Rate:	16

Specimen Number	Burst Pressure (psig)	Failure Location
1	1.74	Side C (Package Failure)
2	1.78	Non-Port Side (Package Failure)
3	1.76	Side C (Package Failure)
4	1.78	Side C (Package Failure)
5	1.76	Port Side (Package Failure)
6	1.70	Side C (Package Failure)
7	1.72	Non-Port Side (Package Failure)
8	1.68	Non-Port Side (Package Failure)
9	1.72	Side C (Package Failure)
10	1.74	Side C (Package Failure)
11	1.66	Non-Port Side (Package Failure)
12	1.72	Non-Port Side (Package Failure)
13	1.74	Side C (Package Failure)
14	1.76	Non-Port Side (Package Failure)
15	1.72	Non-Port Side (Package Failure)
16	1.80	Non-Port Side (Package Failure)
17	1.78	Side C (Package Failure)
18	1.78	Non-Port Side (Package Failure)
19	1.70	Non-Port Side (Package Failure)
20	1.76	Non-Port Side (Package Failure)
Mean	1.74	N/A
Standard Deviation	0.04	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the seals.

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NELSON LABORATORIES

Failure Locations:

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Lot #32630-T:

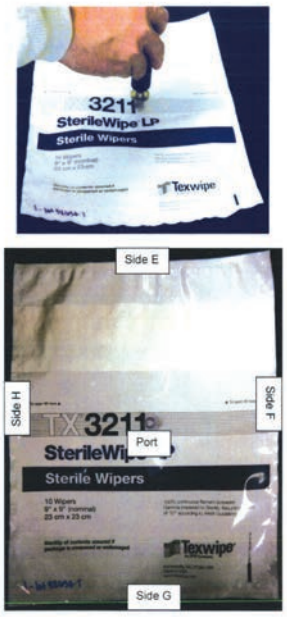
Set Pressure: 10.00 psig
Test Time (sec): 60.0
Flow Rate: 13

Specimen Number	Burst Pressure (psig)	Failure Location
1	2.06	Side F
2	2.14	Non-Port Side (Package Failure)
3	2.14	Non-Port Side (Package Failure)
4	2.14	Non-Port Side (Package Failure)
5	2.08	Side H
6	2.04	Side H
7	2.06	Non-Port Side (Package Failure)
8	2.08	Non-Port Side (Package Failure)
9	2.08	Non-Port Side (Package Failure)
10	2.06	Non-Port Side (Package Failure)
11	2.06	Side F
12	2.10	Non-Port Side (Package Failure)
13	2.14	Non-Port Side (Package Failure)
14	2.14	Side H
15	1.98	Side G (Package Failure)
16	2.00	Side H
17	2.08	Side F
18	2.14	Side H
19	2.12	Side H
20	1.94	Side G (Package Failure)
Mean	2.08	N/A
Standard Deviation	0.06	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the seals.

NELSON LABORATORIES

Failure Locations:



NELSON LABORATORIES

Lot #32367-T:

Set Pressure: 10.00 psig
Test Time (sec): 200.0
Flow Rate: 16

Specimen Number	Burst Pressure (psig)	Failure Location
1	1.66	Non-Port Side (Package Failure)
2	1.72	Non-Port Side (Package Failure)
3	1.66	Side K
4	1.64	Non-Port Side (Package Failure)
5	1.68	Non-Port Side (Package Failure)
6	1.68	Non-Port Side (Package Failure)
7	1.68	Non-Port Side (Package Failure)
8	1.66	Non-Port Side (Package Failure)
9	1.64	Non-Port Side (Package Failure)
10	1.72	Non-Port Side (Package Failure)
11	1.64	Non-Port Side (Package Failure)
12	1.68	Non-Port Side (Package Failure)
13	1.66	Non-Port Side (Package Failure)
14	1.66	Non-Port Side (Package Failure)
15	1.70	Non-Port Side (Package Failure)
16	1.70	Non-Port Side (Package Failure)
17	1.72	Non-Port Side (Package Failure)
18	1.68	Non-Port Side (Package Failure)
19	1.66	Side L (Package Failure)
20	1.64	Non-Port Side (Package Failure)
Mean	1.67	N/A
Standard Deviation	0.03	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the seals.

NELSON LABORATORIES

Failure Locations:

Test Method Acceptance Criteria: Calibration of T.M. Electronics BT series seal strength tester is current.

Procedure: Prior to testing, the test articles were conditioned for a minimum of 24 hours at 23 ± 2°C and 50 ± 5% relative humidity (RH).

The packages were attached to the T.M. Electronics package tester by adhesive package ports and pressurized at a constant rate until they burst.

Appendix 1.

A compilation of the Nelson Laboratories test results for the **zero-time point.**

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge

NELSON LABORATORIES

Sponsor:
Laura Taraban
ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Aerosol Challenge Procedure Final Report

Test Article: Header Bags (Time Zero)
PB3210 Lot: 33096-T
PB3211 Lot: 32630-T
PB3221 Lot: 32367-T
Purchase Order: 171120TM-LT
Study Number: 1006344-S01
Study Received Date: 30 Nov 2017
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0058 Rev 16
Deviation(s): None

Summary: This procedure is intended to challenge the whole sterile barrier system in order to determine integrity of a finished product sterile barrier system. The test articles are exposed to microbial aerosol challenge using *Bacillus atrophaeus*, ATCC #9372, spores.

The test articles demonstrated 100% no growth following an extreme bacterial aerosol challenge. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Based On: ISO 11607-1

Results:

Type	No Growth	Growth
PB3210 Lot: 33096-T (Test Articles 1-20)	20	0
PB3211 Lot: 32630-T (Test Articles 21-40)	20	0
PB3221 Lot: 32367-T (Test Articles 41-60)	20	0
Nelson Laboratories Positive Control Jar	0	1
Media Monitor	2	0
Environmental Monitor	1	0
Growth Promotion	0	1

Testing Parameters:

Run	Challenge Titer (CFU/mL)	Challenge Delivered (CFU)	Extraction Efficiency (%)	Average Fallout Value (CFU/cm²)	MPS (µm)	Average Calculated Fallout from the AGI (CFU/ft²)
1	1.6×10^{10}	~1.6×10^{11}	64.40	~7.6×10^{2}	2.6	~1.3×10^{4}

Note: Results reported as "~" are considered an approximation based on counts outside of the statistically accurate range.
CFU = colony forming unit
MPS = mean particle size
AGI = All Glass Impingers

Jaime Moore — Jaime G. Moore, A.S. — Study Director

05 Jan 2018 — Study Completion Date

1006344-S01

Test Method Acceptance Criteria: Aerosol challenge fallout must be greater than 100 CFU/cm². Average MPS must be ≤4.5 µm. The positive controls must demonstrate growth of the indicator organism.

Procedure: *B. atrophaeus* was inoculated onto soybean casein digest agar (SCDA) plates and incubated at 30-35°C for a minimum of 5 days. The growth was harvested, heat-shocked at 80-85°C for 10 minutes and filtered. The spore suspension was adjusted to achieve minimum fallout levels of 100 CFU/cm² and the titer was verified using standard plate count procedures.

The bacterial aerosolization test was conducted in a 1 m³ glass aerosol exposure chamber. The chamber had sampling ports on the side, an aerosol delivery port on the top, and an aerosol removal port on the bottom.

For each test, the first 30 minutes serve as a preconditioning period to equilibrate the chamber environment and prevent aerosol loss to the chamber walls. The challenge delivery rate was 20 mL per hour. This was determined to be sufficient to deliver the minimum required fallout. The challenge was delivered to a nebulizer that was attached to the aerosol exposure chamber. Fallout sampling and monitoring was conducted during the 60 minutes of bacterial challenge that followed the preconditioning period.

At 15 and 45 minutes, air samples were collected (10.4 seconds) with the Andersen sampler to permit valid sample collection and quantitation from high chamber aerosol levels. Colony counts from the Andersen sampler plates (bacterial filtration efficiency agar plates) were converted to probable hit values (stages 3-6) using a validated spreadsheet. This spreadsheet converts the actual number of CFUs to probable hit values using the Poisson distribution. The MPS of the aerosolized challenge was calculated. The MPS is a statistical representation of the average size of the particles collected by the Andersen sampler. At 30 minutes, replicate AGI samples were collected for 1 minute using 25 mL of peptone water. The impingers break up the aerosol particles; each particle may contain many organisms and thus higher counts are expected. The impinger fluid was quantitated by serial dilution and plated onto SCDA.

Fallout samples consisted of five 2 x 2 inch pieces of gauze aseptically placed inside the chamber prior to the challenge. The gauze pieces were aseptically placed into 50 mL of peptone Tween® (PEPT) and extracted, serially diluted and plated onto SCDA plates.

The gauze extraction process has been previously validated and an efficiency value calculated. The efficiency value is determined by exhaustive extraction of the same piece of gauze at least four times (or until the number recovered approaches zero or is negligible compared to the first extraction) using the same procedure for each extraction. The number extracted on the first extraction is then divided by the total organisms recovered from all extractions. This value is then applied to the actual counts of each piece of fallout gauze tested during an exposure run which results in counts being more representative of the actual organism load.

All plates from Andersen sampling, fallout samples and AGI replicates were incubated at 30-35°C for 24-48 hours.

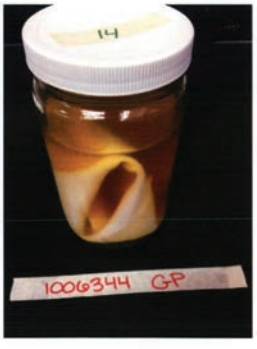
The exteriors of the test articles were decontaminated prior to testing for the indicator organism.

Testing for the indicator organism was performed in a HEPA filtered clean hood. Test articles were aseptically placed in an appropriate volume of soybean casein digest broth (SCDB). All media lots were tested for conformance with the current USP growth promotion requirements. The test articles were incubated for 7 days at 30-35°C. All test articles were inspected for growth of the challenge organism.

Following incubation, one non-growth test article was inoculated with less than 100 CFU of the challenge organism. Growth of the challenge organism was observed in the inoculated test articlefollowing incubation at 30-35°C.

Test Article Configuration:
Chamber Set-Up:

Example of Test Article Post Growth Promotion:



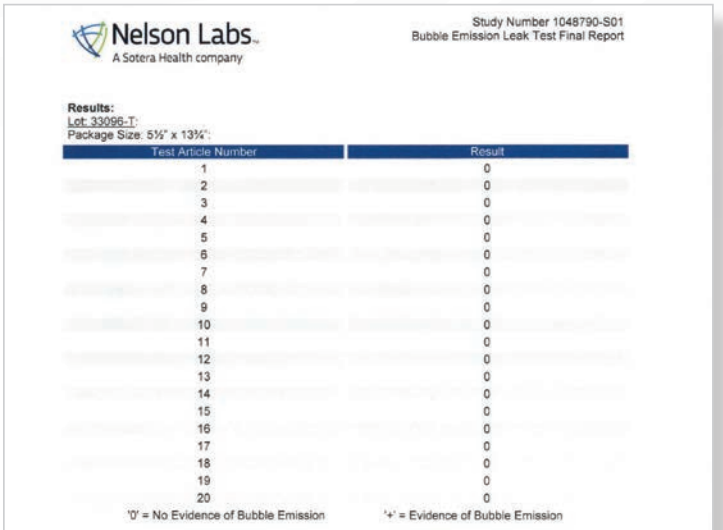
Appendix 2.

A compilation of the Nelson Laboratories test results for the **two-year accelerated aging time point**.

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge



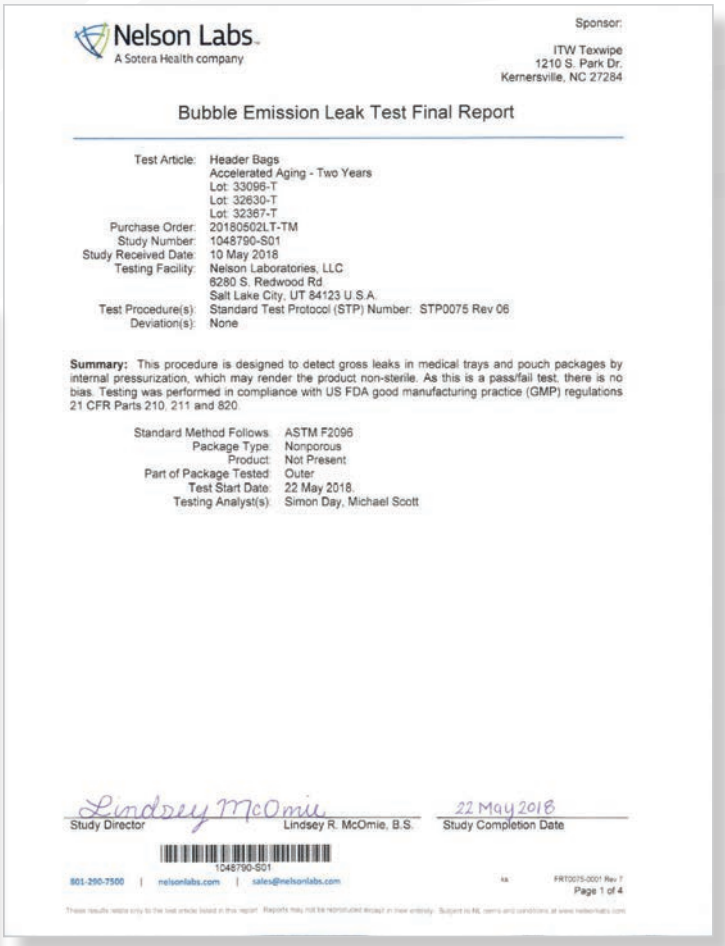
Nelson Labs
A Sotera Health company

Study Number 1048790-S01
Bubble Emission Leak Test Final Report

Results:
Lot: 33096-T:
Package Size: 5½" x 13¾":

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission



Nelson Labs
A Sotera Health company

Sponsor:
ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Bubble Emission Leak Test Final Report

Test Article: Header Bags
Accelerated Aging - Two Years
Lot: 33096-T
Lot: 32630-T
Lot: 32367-T
Purchase Order: 20180502LT-TM
Study Number: 1048790-S01
Study Received Date: 10 May 2018
Testing Facility: Nelson Laboratories, LLC
8280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0075 Rev 06
Deviation(s): None

Summary: This procedure is designed to detect gross leaks in medical trays and pouch packages by internal pressurization, which may render the product non-sterile. As this is a pass/fail test, there is no bias. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Follows: ASTM F2096
Package Type: Nonporous
Product: Not Present
Part of Package Tested: Outer
Test Start Date: 22 May 2018.
Testing Analyst(s): Simon Day, Michael Scott

Lindsey McOmie
Study Director Lindsey R. McOmie, B.S.

22 May 2018
Study Completion Date

1048790-S01

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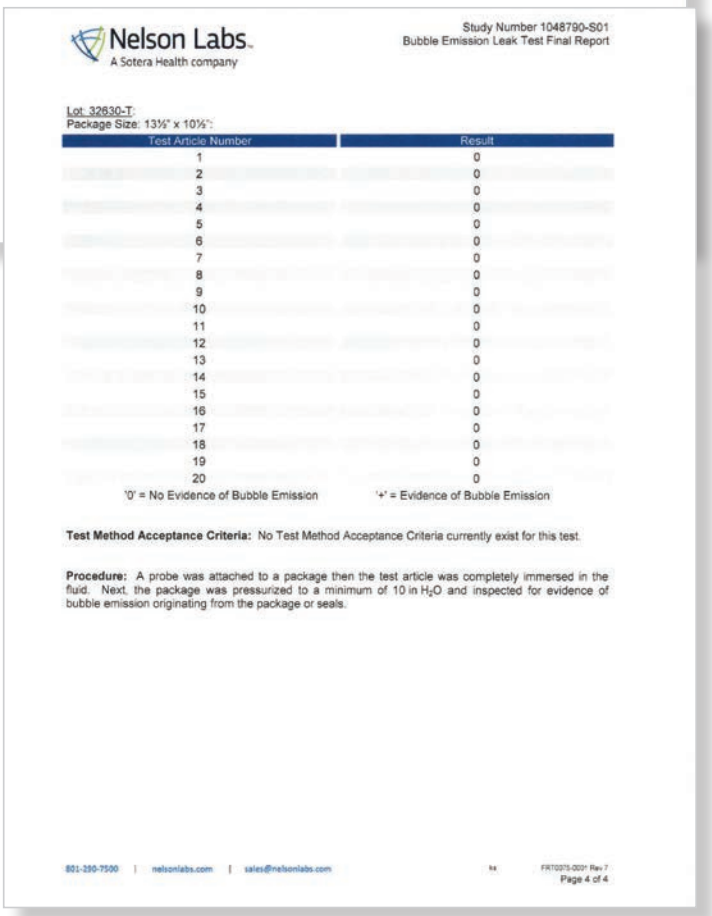

Nelson Labs
A Sotera Health company

Study Number 1048790-S01
Bubble Emission Leak Test Final Report

Lot: 32630-T:
Package Size: 13¾" x 10½":

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

Test Method Acceptance Criteria: No Test Method Acceptance Criteria currently exist for this test.

Procedure: A probe was attached to a package then the test article was completely immersed in the fluid. Next, the package was pressurized to a minimum of 10 in H_2O and inspected for evidence of bubble emission originating from the package or seals.

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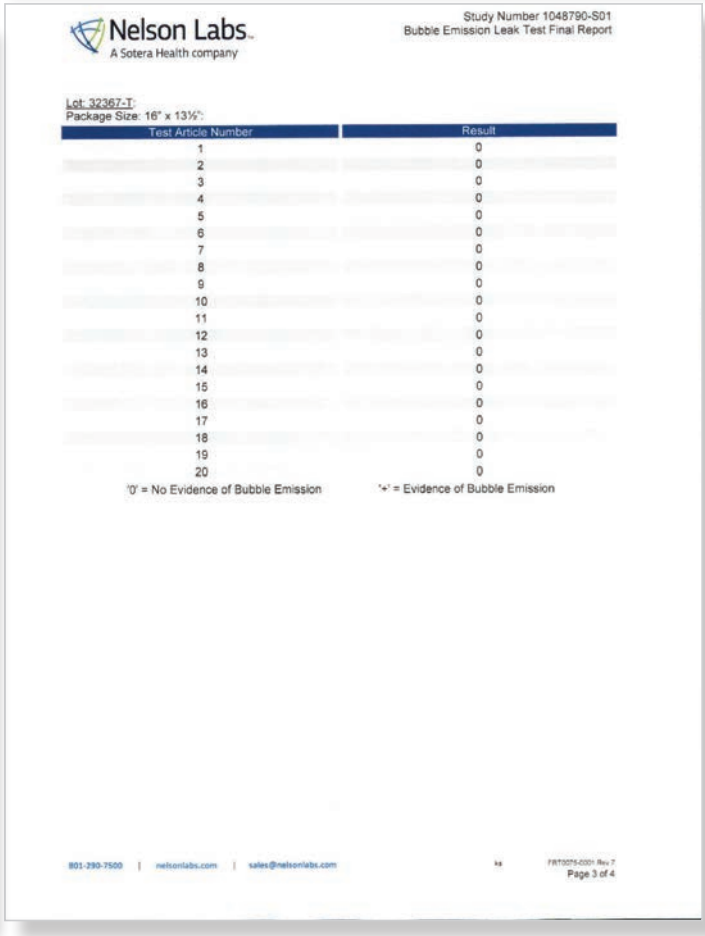

Nelson Labs
A Sotera Health company

Study Number 1048790-S01
Bubble Emission Leak Test Final Report

Lot: 32367-T:
Package Size: 16" x 13½":

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

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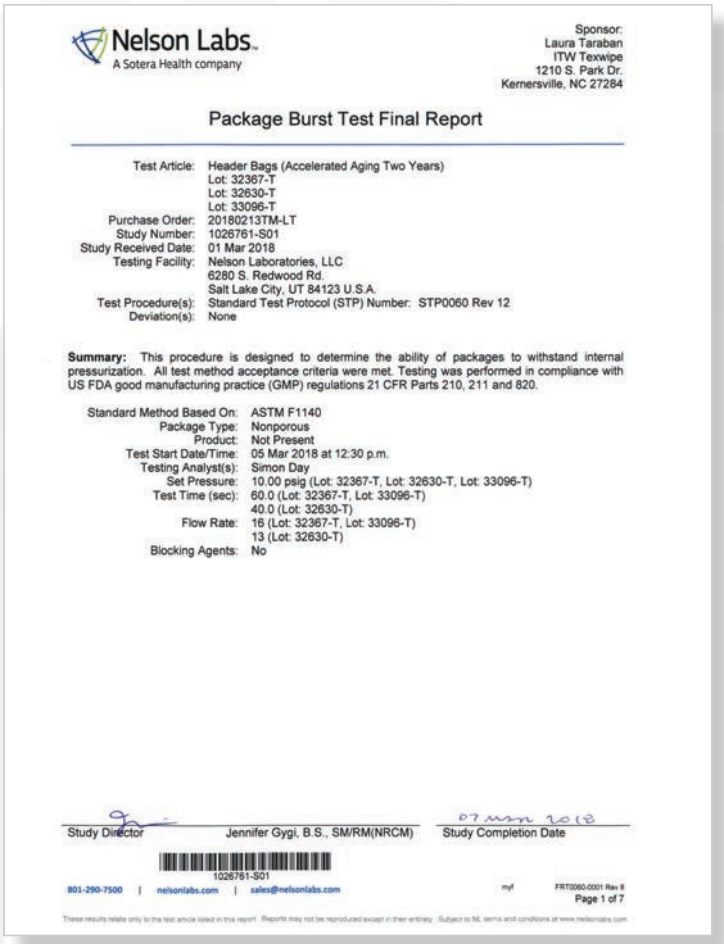
Appendix 2.

A compilation of the Nelson Laboratories test results for the **two-year accelerated aging time point**.

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge



Nelson Labs
A Sotera Health company

Sponsor:
Laura Taraban
ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Package Burst Test Final Report

Test Article: Header Bags (Accelerated Aging Two Years)
Lot: 32367-T
Lot: 32630-T
Lot: 33096-T
Purchase Order: 20180213TM-LT
Study Number: 1026761-S01
Study Received Date: 01 Mar 2018
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0060 Rev 12
Deviation(s): None

Summary: This procedure is designed to determine the ability of packages to withstand internal pressurization. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Based On: ASTM F1140
Package Type: Nonporous
Product: Not Present
Test Start Date/Time: 05 Mar 2018 at 12:30 p.m.
Testing Analyst(s): Simon Day
Set Pressure: 10.00 psig (Lot: 32367-T, Lot: 32630-T, Lot: 33096-T)
Test Time (sec): 60.0 (Lot: 32367-T, Lot: 33096-T)
40.0 (Lot: 32630-T)
Flow Rate: 16 (Lot: 32367-T, Lot: 33096-T)
13 (Lot: 32630-T)
Blocking Agents: No

Study Director — Jennifer Gygi, B.S., SM/RM(NRCM) — Study Completion Date: 07 Mar 2018

1026761-S01

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myf FRT0060-0001 Rev 8
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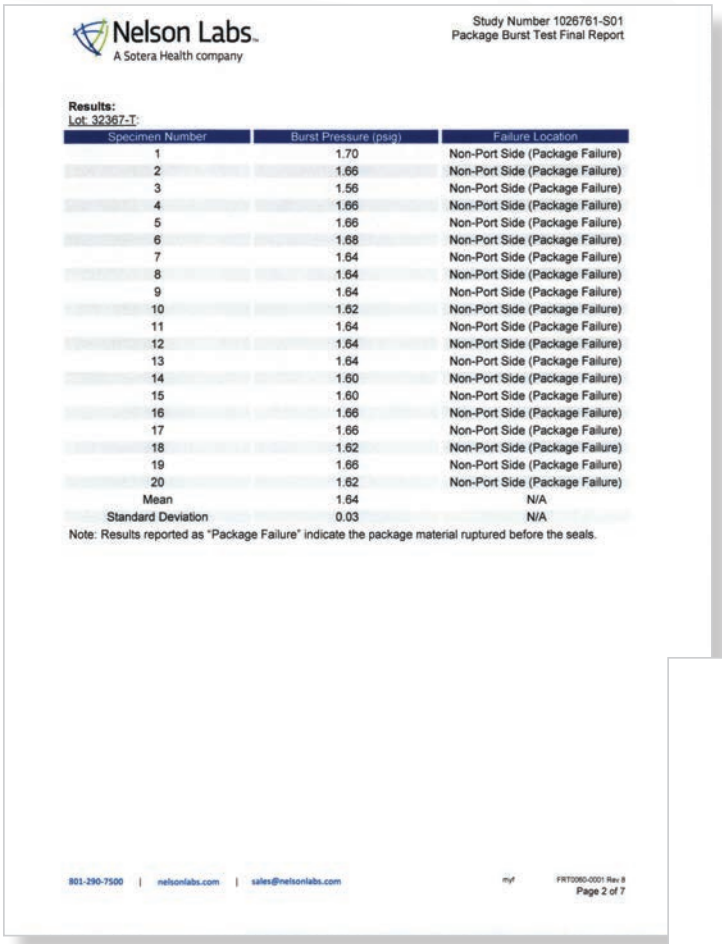

Nelson Labs
A Sotera Health company

Study Number 1026761-S01
Package Burst Test Final Report

Results:
Lot: 32367-T:

Specimen Number	Burst Pressure (psig)	Failure Location
1	1.70	Non-Port Side (Package Failure)
2	1.66	Non-Port Side (Package Failure)
3	1.56	Non-Port Side (Package Failure)
4	1.66	Non-Port Side (Package Failure)
5	1.66	Non-Port Side (Package Failure)
6	1.68	Non-Port Side (Package Failure)
7	1.64	Non-Port Side (Package Failure)
8	1.64	Non-Port Side (Package Failure)
9	1.64	Non-Port Side (Package Failure)
10	1.62	Non-Port Side (Package Failure)
11	1.64	Non-Port Side (Package Failure)
12	1.64	Non-Port Side (Package Failure)
13	1.64	Non-Port Side (Package Failure)
14	1.60	Non-Port Side (Package Failure)
15	1.60	Non-Port Side (Package Failure)
16	1.66	Non-Port Side (Package Failure)
17	1.66	Non-Port Side (Package Failure)
18	1.62	Non-Port Side (Package Failure)
19	1.66	Non-Port Side (Package Failure)
20	1.62	Non-Port Side (Package Failure)
Mean	1.64	N/A
Standard Deviation	0.03	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the seals.

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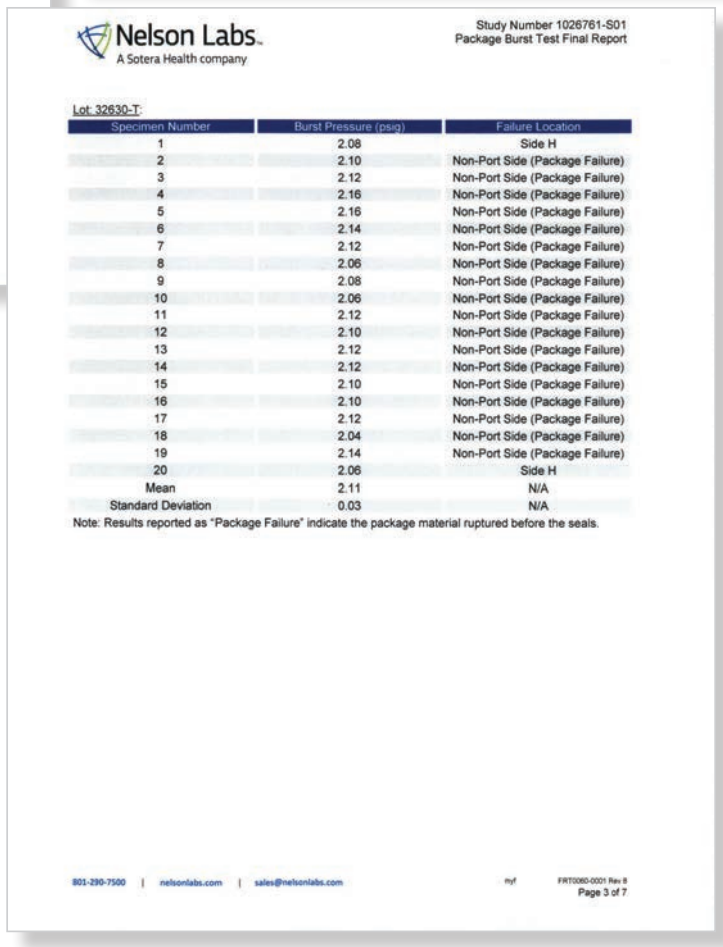

Nelson Labs
A Sotera Health company

Study Number 1026761-S01
Package Burst Test Final Report

Lot: 32630-T:

Specimen Number	Burst Pressure (psig)	Failure Location
1	2.08	Side H
2	2.10	Non-Port Side (Package Failure)
3	2.12	Non-Port Side (Package Failure)
4	2.16	Non-Port Side (Package Failure)
5	2.16	Non-Port Side (Package Failure)
6	2.14	Non-Port Side (Package Failure)
7	2.12	Non-Port Side (Package Failure)
8	2.06	Non-Port Side (Package Failure)
9	2.08	Non-Port Side (Package Failure)
10	2.06	Non-Port Side (Package Failure)
11	2.12	Non-Port Side (Package Failure)
12	2.10	Non-Port Side (Package Failure)
13	2.12	Non-Port Side (Package Failure)
14	2.12	Non-Port Side (Package Failure)
15	2.10	Non-Port Side (Package Failure)
16	2.10	Non-Port Side (Package Failure)
17	2.12	Non-Port Side (Package Failure)
18	2.04	Non-Port Side (Package Failure)
19	2.14	Non-Port Side (Package Failure)
20	2.06	Side H
Mean	2.11	N/A
Standard Deviation	0.03	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the seals.

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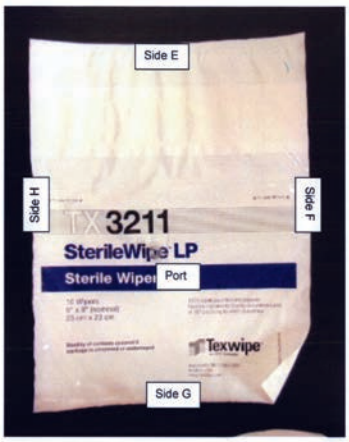
Lot: 33096-T:

Specimen Number	Burst Pressure (psig)	Failure Location
1	1.68	Non-Port Side (Package Failure)
2	1.74	Non-Port Side (Package Failure)
3	1.78	Non-Port Side (Package Failure)
4	1.84	Non-Port Side (Package Failure)
5	1.74	Non-Port Side (Package Failure)
6	1.78	Non-Port Side (Package Failure)
7	1.78	Non-Port Side (Package Failure)
8	1.70	Non-Port Side (Package Failure)
9	1.72	Non-Port Side (Package Failure)
10	1.68	Non-Port Side (Package Failure)
11	1.80	Non-Port Side (Package Failure)
12	1.70	Non-Port Side (Package Failure)
13	1.72	Non-Port Side (Package Failure)
14	1.68	Non-Port Side (Package Failure)
15	1.74	Non-Port Side (Package Failure)
16	1.74	Non-Port Side (Package Failure)
17	1.78	Non-Port Side (Package Failure)
18	1.78	Non-Port Side (Package Failure)
19	1.68	Non-Port Side (Package Failure)
20	1.76	Non-Port Side (Package Failure)
Mean	1.74	N/A
Standard Deviation	0.05	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the seals.

Failure Locations:
Lot: 32367-T:

Lot: 32630-T:



Lot: 33096-T:

Test Method Acceptance Criteria: Calibration of T.M. Electronics BT series seal strength tester is current.

Procedure: Prior to testing, the test articles were conditioned for a minimum of 24 hours at 23 ± 2°C and 50 ± 5% relative humidity (RH).

The packages were attached to the T.M. Electronics package tester by adhesive package ports and pressurized at a constant rate until they burst.

Appendix 2.

A compilation of the Nelson Laboratories test results for the **two-year accelerated aging time point**.

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge

Nelson Labs
A Sotera Health company

Sponsor:
ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Aerosol Challenge Procedure Final Report

Test Article: Header Bags
Accelerated Aging - Two Years
Lot: 33096-T
Lot: 32630-T
Lot: 32367-T
Purchase Order: 20180502LT-TM
Study Number: 1048786-S01
Study Received Date: 10 May 2018
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0058 Rev 16
Deviation(s): None

Summary: This procedure is intended to challenge the whole sterile barrier system in order to determine integrity of a finished product sterile barrier system. The test articles are exposed to microbial aerosol challenge using *Bacillus atrophaeus*, ATCC #9372, spores.

The test articles demonstrated 100% no growth following an extreme bacterial aerosol challenge. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Based On: ISO 11607-1

Results:

Type	No Growth	Growth
Lot: 33096-T	20	0
Lot: 32630-T	20	0
Lot: 32367-T	20	0
Nelson Laboratories Positive Control Jar	0	1
Media Monitor	5	0
Environmental Monitor	1	0
Growth Promotion	0	1

Study Director: Jaime G. Moore, A.S. — Study Completion Date: 31 May 2018

1048786-S01

Testing Parameters:

Run	Challenge Titer (CFU/mL)	Challenge Delivered (CFU)	Extraction Efficiency (%)	Average Fallout Value (CFU/cm²)	MPS (µm)	Average Calculated Fallout from the AGI (CFU/ft³)
1	2.2×10^{10}	~2.2×10^{11}	96.40	~1.6×10^{2}	2.3	~5.6×10^{3}

Note: Results reported as "~" are considered an approximation based on counts outside of the statistically accurate range.
CFU = colony forming unit
MPS = mean particle size
AGI = All Glass Impingers

Test Method Acceptance Criteria: Aerosol challenge fallout must be greater than 100 CFU/cm². Average MPS must be ≤4.5 µm. The positive controls must demonstrate growth of the indicator organism.

Procedure: *B. atrophaeus* was inoculated onto soybean casein digest agar (SCDA) plates and incubated at 30-35°C for a minimum of 5 days. The growth was harvested, heat-shocked at 80-85°C for 10 minutes and filtered. The spore suspension was adjusted to achieve minimum fallout levels of 100 CFU/cm² and the titer was verified using standard plate count procedures.

The bacterial aerosolization test was conducted in a 1 m³ glass aerosol exposure chamber. The chamber had sampling ports on the side, an aerosol delivery port on the top, and an aerosol removal port on the bottom.

For each test, the first 30 minutes serve as a preconditioning period to equilibrate the chamber environment and prevent aerosol loss to the chamber walls. The challenge delivery rate was 20 mL per hour. This was determined to be sufficient to deliver the minimum required fallout. The challenge was delivered to a nebulizer that was attached to the aerosol exposure chamber. Fallout sampling and monitoring was conducted during the 60 minutes of bacterial challenge that followed the preconditioning period.

At 15 and 45 minutes, air samples were collected (10.4 seconds) with the Andersen sampler to permit valid sample collection and quantitation from high chamber aerosol levels. Colony counts from the Andersen sampler plates (bacterial filtration efficiency agar plates) were converted to probable hit values (stages 3-6) using a validated spreadsheet. This spreadsheet converts the actual number of CFUs to probable hit values using the Poisson distribution. The MPS of the aerosolized challenge was calculated. The MPS is a statistical representation of the average size of the particles collected by the Andersen sampler. At 30 minutes, replicate AGI samples were collected for 1 minute using 25 mL of peptone water. The impingers break up the aerosol particles; each particle may contain many organisms and thus higher counts are expected. The impinger fluid was quantitated by serial dilution and plated onto SCDA.

Fallout samples consisted of five 2 x 2 inch pieces of gauze aseptically placed inside the chamber prior to the challenge. The gauze pieces were aseptically placed into 50 mL of peptone Tween® (PEPT) and extracted, serially diluted and plated onto SCDA plates.

The gauze extraction process has been previously validated and an efficiency value calculated. The efficiency value is determined by exhaustive extraction of the same piece of gauze at least four times (or until the number recovered approaches zero or is negligible compared to the first extraction) using the same procedure for each extraction. The number extracted on the first extraction is then divided by the total organisms recovered from all extractions. This value is then applied to the actual counts of each piece of fallout gauze tested during an exposure run which results in counts being more representative of the actual organism load.

Example of Test Article Post Growth Promotion:

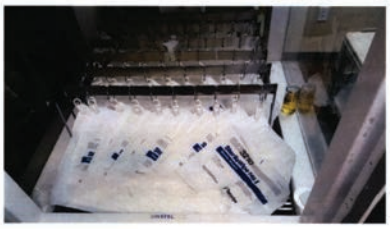
All plates from Andersen sampling, fallout samples and AGI replicates were incubated at 30-35°C for 24-48 hours.

The exteriors of the test articles were decontaminated prior to testing for the indicator organism.

Testing for the indicator organism was performed in a HEPA filtered clean hood. Test articles were aseptically placed in an appropriate volume of soybean casein digest broth (SCDB). All media lots were tested for conformance with the current USP growth promotion requirements. The test articles were incubated for 7 days at 30-35°C. All test articles were inspected for growth of the challenge organism.

Following incubation, one non-growth test article was inoculated with less than 100 CFU of the challenge organism. Growth of the challenge organism was observed in the inoculated test article following incubation at 30-35°C.

Test Article Configuration:
Aerosol Chamber Set-Up:



Example of Test Articles Post Incubation:

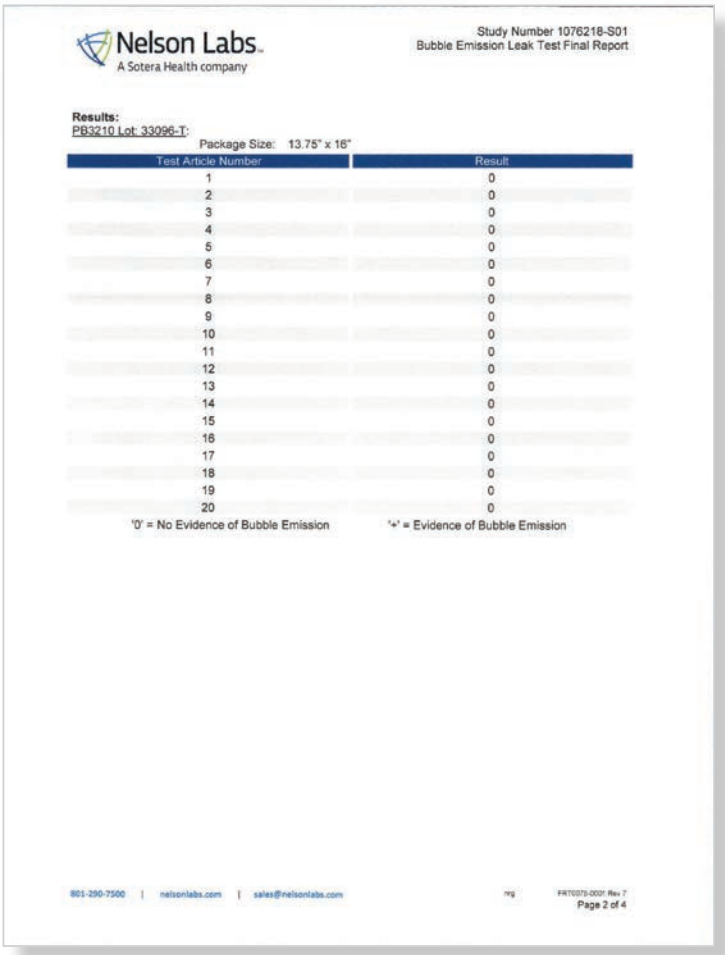
Appendix 3.

A compilation of the Nelson Laboratories test results for the **three-year accelerated aging time point**.

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge



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A Sotera Health company

Study Number 1076218-S01
Bubble Emission Leak Test Final Report

Results:
PB3210 Lot: 33096-T:
Package Size: 13.75" x 16"

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

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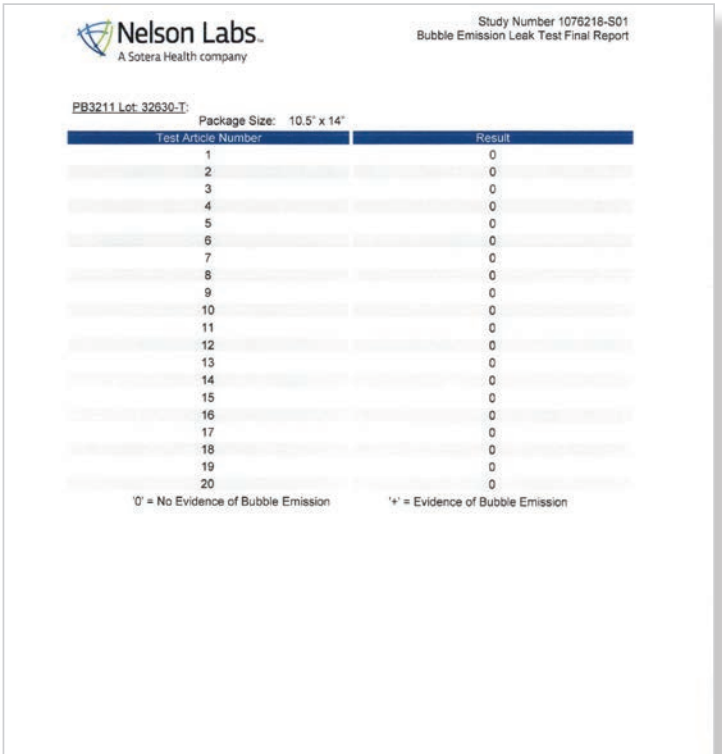


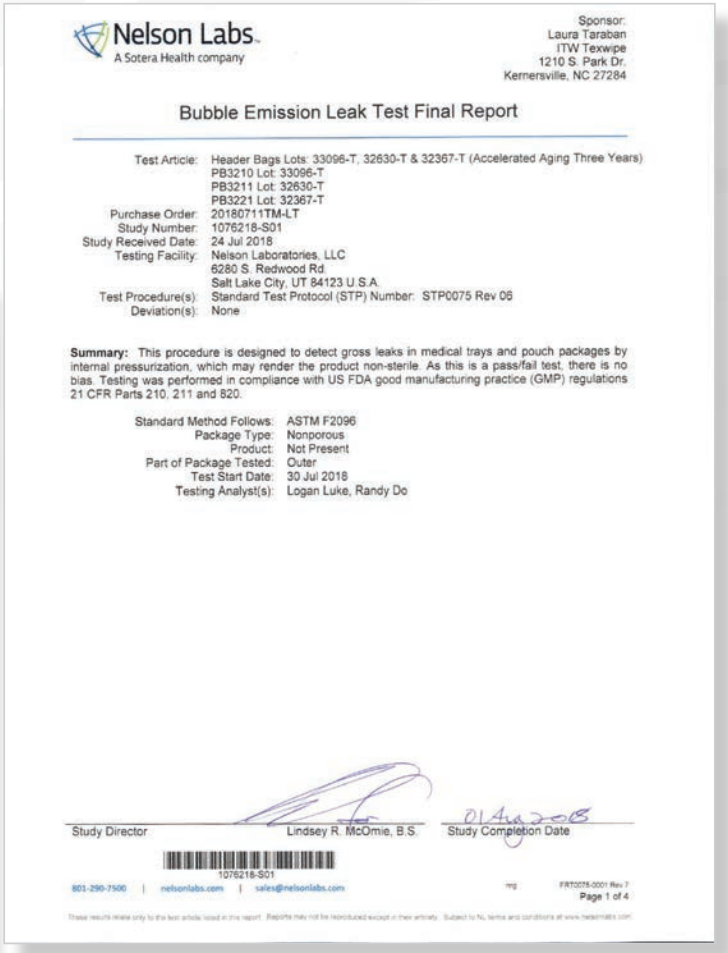
Nelson Labs
A Sotera Health company

Study Number 1076218-S01
Bubble Emission Leak Test Final Report

PB3211 Lot: 32630-T:
Package Size: 10.5" x 14"

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission



Nelson Labs
A Sotera Health company

Sponsor:
Laura Taraban
ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Bubble Emission Leak Test Final Report

Test Article: Header Bags Lots: 33096-T, 32630-T & 32367-T (Accelerated Aging Three Years)
PB3210 Lot: 33096-T
PB3211 Lot: 32630-T
PB3221 Lot: 32367-T
Purchase Order: 20180711TM-LT
Study Number: 1076218-S01
Study Received Date: 24 Jul 2018
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0075 Rev 06
Deviation(s): None

Summary: This procedure is designed to detect gross leaks in medical trays and pouch packages by internal pressurization, which may render the product non-sterile. As this is a pass/fail test, there is no bias. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Follows: ASTM F2096
Package Type: Nonporous
Product: Not Present
Part of Package Tested: Outer
Test Start Date: 30 Jul 2018
Testing Analyst(s): Logan Luke, Randy Do

Study Director Lindsey R. McOmie, B.S. Study Completion Date 01 Aug 2018

1076218-S01

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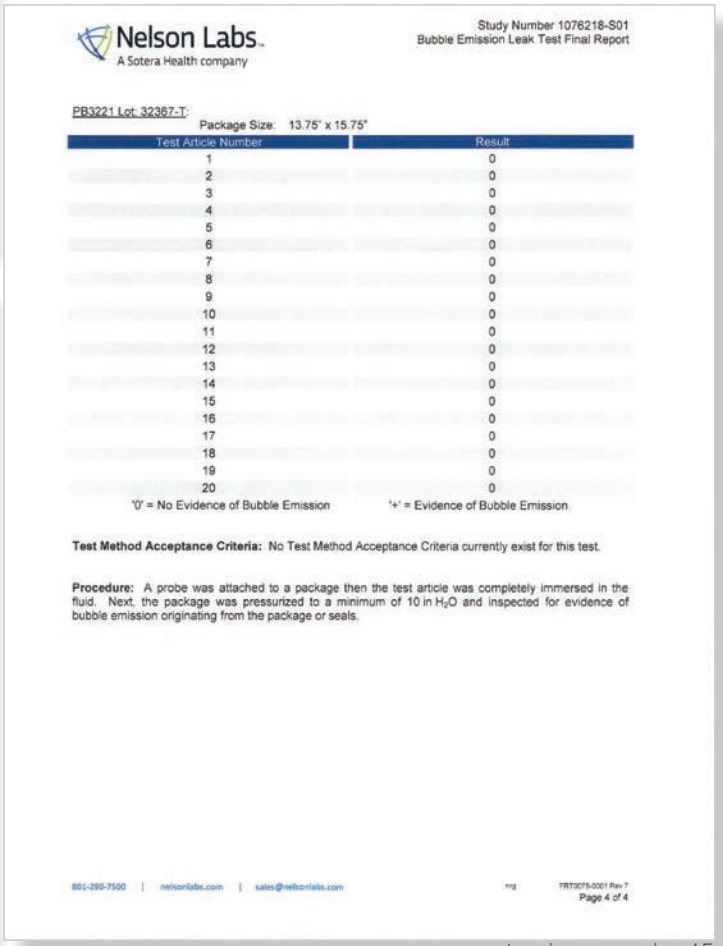

Nelson Labs
A Sotera Health company

Study Number 1076218-S01
Bubble Emission Leak Test Final Report

PB3221 Lot: 32367-T:
Package Size: 13.75" x 15.75"

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

Test Method Acceptance Criteria: No Test Method Acceptance Criteria currently exist for this test.

Procedure: A probe was attached to a package then the test article was completely immersed in the fluid. Next, the package was pressurized to a minimum of 10 in H_2O and inspected for evidence of bubble emission originating from the package or seals.

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Appendix 3.

A compilation of the Nelson Laboratories test results for the **three-year accelerated aging time point**.

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge

Nelson Labs
A Sotera Health company

Study Number 1041850-S01
Package Burst Test Final Report

Results:
Lot: 32367-T:

Set Pressure: 10.00 psig
Test Time (sec): 60.0
Flow Rate: 16

Specimen Number	Burst Pressure (psig)	Failure Location
1	2.52	Non-Port Side (Package Failure)
2	1.70	Non-Port Side (Package Failure)
3	1.70	Non-Port Side (Package Failure)
4	1.64	Non-Port Side (Package Failure)
5	1.70	Non-Port Side (Package Failure)
6	1.70	Non-Port Side (Package Failure)
7	1.72	Non-Port Side (Package Failure)
8	1.66	Non-Port Side (Package Failure)
9	1.60	Non-Port Side (Package Failure)
10	1.66	Non-Port Side (Package Failure)
11	1.68	Non-Port Side (Package Failure)
12	1.68	Non-Port Side (Package Failure)
13	1.62	Non-Port Side (Package Failure)
14	1.68	Non-Port Side (Package Failure)
15	1.66	Non-Port Side (Package Failure)
16	1.62	Non-Port Side (Package Failure)
17	1.66	Non-Port Side (Package Failure)
18	1.66	Non-Port Side (Package Failure)
19	1.66	Non-Port Side (Package Failure)
20	1.70	Non-Port Side (Package Failure)
Mean	1.71	N/A
Standard Deviation	0.19	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the seals.

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Nelson Labs
A Sotera Health company

Sponsor:
Tracey Teague
ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Package Burst Test Final Report

Test Article: Header Bags
Accelerated Aged Three Years
Lot: 32367-T
Lot: 32630-T
Lot: 33096-T
Purchase Order: 20180412TM-LT
Study Number: 1041850-S01
Study Received Date: 19 Apr 2018
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0060 Rev 12
Deviation(s): None

Summary: This procedure is designed to determine the ability of packages to withstand internal pressurization. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Based On: ASTM F1140
Package Type: Nonporous
Product: Not Present
Test Start Date/Time: 25 Apr 2018 at 9:43 a.m.
Testing Analyst(s): Randy Do
Blocking Agents: No

Study Director — Jennifer Gygi, B.S., SM/RM(NRCM)
Study Completion Date — 26 APR 2018

1041850-S01

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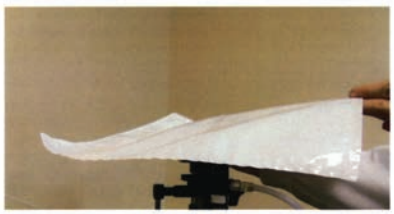
Nelson Labs
A Sotera Health company

Study Number 1041850-S01
Package Burst Test Final Report

Failure Locations:



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Lot: 32630-T:

Set Pressure: 10.00 psig
Test Time (sec): 40.0
Flow Rate: 13

Specimen Number	Burst Pressure (psig)	Failure Location
1	2.10	Non-Port Side (Package Failure)
2	2.06	Non-Port Side (Package Failure)
3	2.06	Non-Port Side (Package Failure)
4	2.14	Non-Port Side (Package Failure)
5	2.12	Side H
6	2.14	Non-Port Side (Package Failure)
7	2.14	Non-Port Side (Package Failure)
8	2.10	Side H
9	2.10	Non-Port Side (Package Failure)
10	2.08	Non-Port Side (Package Failure)
11	2.12	Side H
12	2.08	Side H
13	2.08	Non-Port Side (Package Failure)
14	2.08	Non-Port Side (Package Failure)
15	2.08	Side F
16	2.06	Side H
17	2.12	Non-Port Side (Package Failure)
18	2.06	Non-Port Side (Package Failure)
19	2.08	Non-Port Side (Package Failure)
20	2.12	Non-Port Side (Package Failure)
Mean	2.10	N/A
Standard Deviation	0.03	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the seals.

Failure Locations:

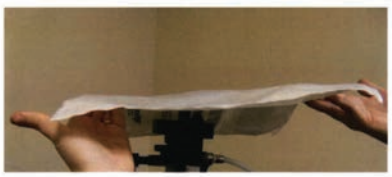
Lot: 33096-T:

Set Pressure: 10.00 psig
Test Time (sec): 60.0
Flow Rate: 16

Specimen Number	Burst Pressure (psig)	Failure Location
1	1.78	Non-Port Side (Package Failure)
2	1.78	Non-Port Side (Package Failure)
3	1.78	Non-Port Side (Package Failure)
4	1.78	Side C
5	1.80	Non-Port Side (Package Failure)
6	1.78	Non-Port Side (Package Failure)
7	1.78	Non-Port Side (Package Failure)
8	1.78	Non-Port Side (Package Failure)
9	1.74	Non-Port Side (Package Failure)
10	1.78	Non-Port Side (Package Failure)
11	1.74	Side C
12	1.76	Non-Port Side (Package Failure)
13	1.70	Non-Port Side (Package Failure)
14	1.76	Non-Port Side (Package Failure)
15	1.84	Non-Port Side (Package Failure)
16	1.74	Non-Port Side (Package Failure)
17	1.78	Side C
18	1.70	Side C
19	1.76	Non-Port Side (Package Failure)
20	1.76	Non-Port Side (Package Failure)
Mean	1.77	N/A
Standard Deviation	0.03	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the seals.

Failure Locations:



Test Method Acceptance Criteria: No test method acceptance criteria currently exist for this method.

Procedure: Prior to testing, the test articles were conditioned for a minimum of 24 hours at 23 ± 2°C and 50 ± 5% relative humidity (RH).

The packages were attached to the T.M. Electronics package tester and pressurized at a constant rate until they burst.

Appendix 3.

A compilation of the Nelson Laboratories test results for the **three-year accelerated aging time point**.

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge

Nelson Labs
A Sotera Health company

Sponsor:
Teresa Meadows / Laura Taraban
ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Aerosol Challenge Procedure Final Report

Test Article: Header Bags Lots: 33096-T, 32630-T & 32367-T (Accelerated Aging Three Years)
Purchase Order: 20180711TM-LT
Study Number: 1076214-S01
Study Received Date: 24 Jul 2018
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0058 Rev 16
Deviation(s): None

Summary: This procedure is intended to challenge the whole sterile barrier system in order to determine integrity of a finished product sterile barrier system. The test articles are exposed to microbial aerosol challenge using *Bacillus atrophaeus*, ATCC #9372, spores.

The test articles demonstrated 100% no growth following an extreme bacterial aerosol challenge. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Based On: ISO 11607-1

Results:

Type	No Growth	Growth
PB3210 Lot 33096-T #1-20	20	0
PB3211 Lot 32367-T #21-40	20	0
PB3221 Lot 32630-T #41-60	20	0
Nelson Laboratories Positive Control Jar	0	1
Media Monitor	3	0
Environmental Monitor	1	0
Growth Promotion	0	1

Testing Parameters:

Run	Challenge Titer (CFU/mL)	Challenge Delivered (CFU)	Extraction Efficiency (%)	Average Fallout Value (CFU/cm²)	MPS (µm)	Average Calculated Fallout from the AGI (CFU/ft²)
1	~2.5 x 10^{10}	~2.5 x 10^{11}	98.40	~2.6 x 10^{2}	2.5	~6.8 x 10^{3}

Note: Results reported as "~" are considered an approximation based on counts outside of the statistically accurate range.
CFU = colony forming unit
MPS = mean particle size
AGI = All Glass Impingers

Jaime Moore
Study Director — Jaime G. Moore, A.S.

14 Aug 2018
Study Completion Date

1076214-S01

Test Method Acceptance Criteria: Aerosol challenge fallout must be greater than 100 CFU/cm². Average MPS must be ≤4.5 µm. The positive controls must demonstrate growth of the indicator organism.

Procedure: *B. atrophaeus* was inoculated onto soybean casein digest agar (SCDA) plates and incubated at 30-35°C for a minimum of 5 days. The growth was harvested, heat-shocked at 60-65°C for 10 minutes and filtered. The spore suspension was adjusted to achieve minimum fallout levels of 100 CFU/cm² and the titer was verified using standard plate count procedures.

The bacterial aerosolization test was conducted in a 1 m³ glass aerosol exposure chamber. The chamber had sampling ports on the side, an aerosol delivery port on the top, and an aerosol removal port on the bottom.

For each test, the first 30 minutes serve as a preconditioning period to equilibrate the chamber environment and prevent aerosol loss to the chamber walls. The challenge delivery rate was 20 mL per hour. This was determined to be sufficient to deliver the minimum required fallout. The challenge was delivered to a nebulizer that was attached to the aerosol exposure chamber. Fallout sampling and monitoring was conducted during the 60 minutes of bacterial challenge that followed the preconditioning period.

At 15 and 45 minutes, air samples were collected (10.4 seconds) with the Andersen sampler to permit valid sample collection and quantitation from high chamber aerosol levels. Colony counts from the Andersen sampler plates (bacterial filtration efficiency agar plates) were converted to probable hit values (stages 3-6) using a validated spreadsheet. This spreadsheet converts the actual number of CFUs to probable hit values using the Poisson distribution. The MPS of the aerosolized challenge was calculated. The MPS is a statistical representation of the average size of the particles collected by the Andersen sampler. At 30 minutes, replicate AGI samples were collected for 1 minute using 25 mL of peptone water. The impingers break up the aerosol particles; each particle may contain many organisms and thus higher counts are expected. The impinger fluid was quantitated by serial dilution and plated onto SCDA.

Fallout samples consisted of five 2 x 2 inch pieces of gauze aseptically placed inside the chamber prior to the challenge. The gauze pieces were aseptically placed into 50 mL of peptone Tween® (PEPT) and extracted, serially diluted and plated onto SCDA plates.

The gauze extraction process has been previously validated and an efficiency value calculated. The efficiency value is determined by exhaustive extraction of the same piece of gauze at least four times (or until the number recovered approaches zero or is negligible compared to the first extraction) using the same procedure for each extraction. The number extracted on the first extraction is then divided by the total organisms recovered from all extractions. This value is then applied to the actual counts of each piece of fallout gauze tested during an exposure run which results in counts being more representative of the actual organism load.

All plates from Andersen sampling, fallout samples and AGI replicates were incubated at 30-35°C for 24-48 hours.

The exteriors of the test articles were decontaminated prior to testing for the indicator organism.

Testing for the indicator organism was performed in a HEPA filtered clean hood. Test articles were aseptically placed in an appropriate volume of soybean casein digest broth (SCDB). All media lots were tested for conformance with the current USP growth promotion requirements. The test articles were incubated for 7 days at 30-35°C. All test articles were inspected for growth of the challenge organism.

Following incubation, one non-growth test article was inoculated with less than 100 CFU of the challenge organism. Growth of the challenge organism was observed in the inoculated test article following incubation at 30-35°C.

Test Article Configuration:
Aerosol Chamber Setup:

Example of Test Article Post Incubation:

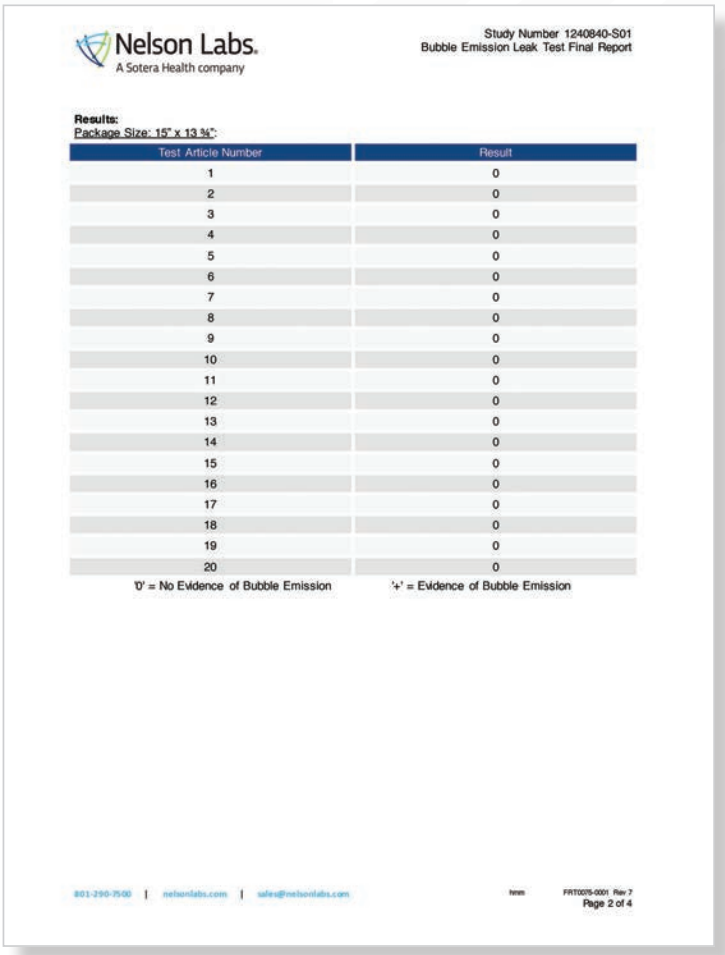
Appendix 4.

A compilation of the Nelson Laboratories test results for the **two-year real time aging time point**.

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge



Nelson Labs.
A Sotera Health company

Study Number 1240840-S01
Bubble Emission Leak Test Final Report

Results:
Package Size: 15" x 13 ¾":

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

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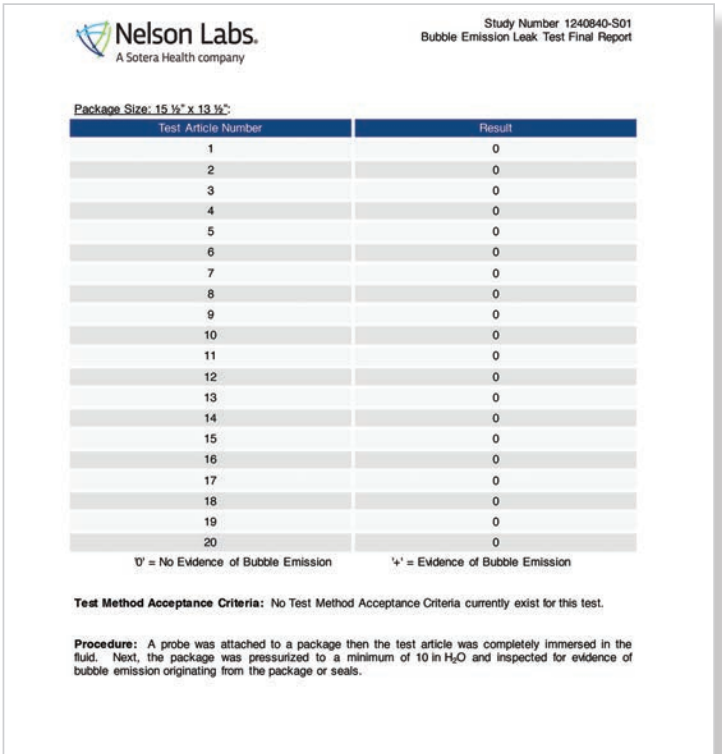


Nelson Labs.
A Sotera Health company

Study Number 1240840-S01
Bubble Emission Leak Test Final Report

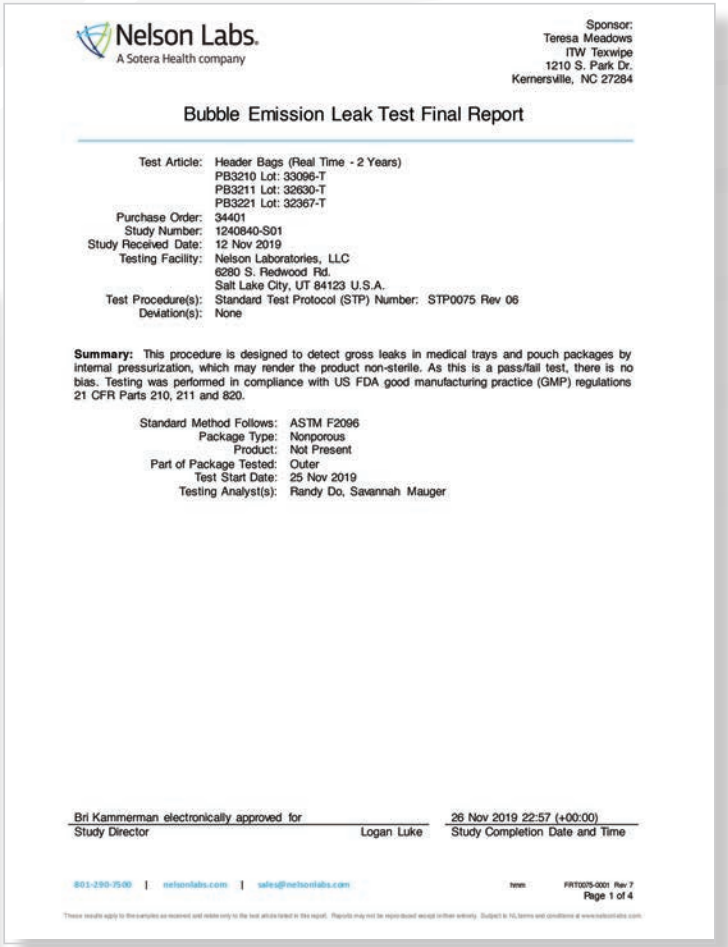
Package Size: 15 ½" x 13 ½":

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

Test Method Acceptance Criteria: No Test Method Acceptance Criteria currently exist for this test.

Procedure: A probe was attached to a package then the test article was completely immersed in the fluid. Next, the package was pressurized to a minimum of 10 in H_2O and inspected for evidence of bubble emission originating from the package or seals.



Nelson Labs.
A Sotera Health company

Sponsor:
Teresa Meadows
ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Bubble Emission Leak Test Final Report

Test Article: Header Bags (Real Time - 2 Years)
PB3210 Lot: 33096-T
PB3211 Lot: 32630-T
PB3221 Lot: 32367-T
Purchase Order: 34401
Study Number: 1240840-S01
Study Received Date: 12 Nov 2019
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0075 Rev 06
Deviation(s): None

Summary: This procedure is designed to detect gross leaks in medical trays and pouch packages by internal pressurization, which may render the product non-sterile. As this is a pass/fail test, there is no bias. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Follows: ASTM F2096
Package Type: Nonporous
Product: Not Present
Part of Package Tested: Outer
Test Start Date: 25 Nov 2019
Testing Analyst(s): Randy Do, Savannah Mauger

Bri Kammerman electronically approved for
Study Director Logan Luke

26 Nov 2019 22:57 (+00:00)
Study Completion Date and Time

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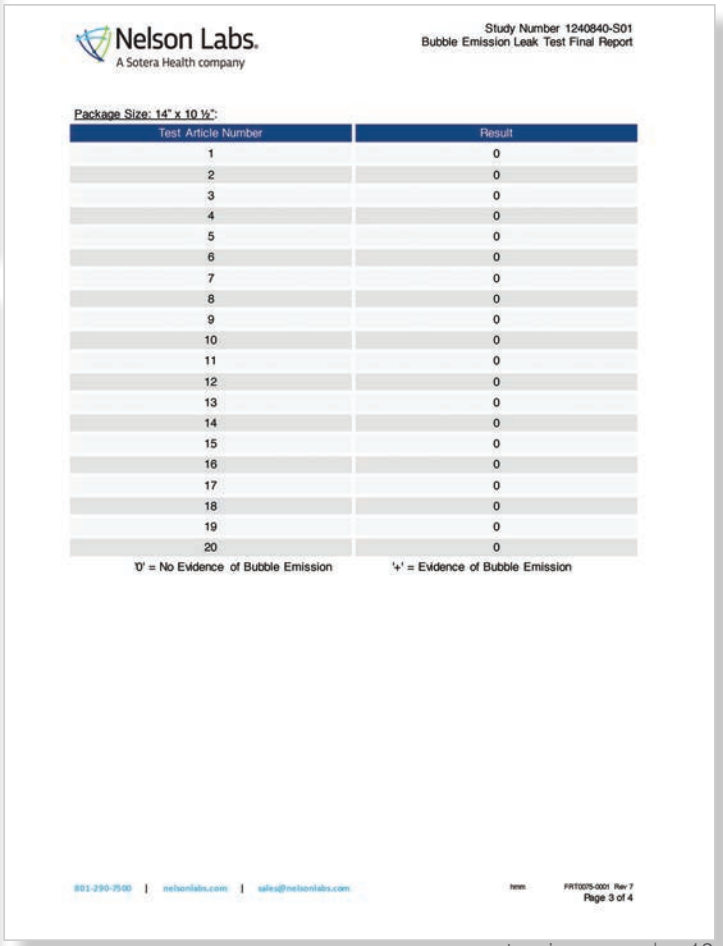

Nelson Labs.
A Sotera Health company

Study Number 1240840-S01
Bubble Emission Leak Test Final Report

Package Size: 14" x 10 ½":

Test Article Number	Result
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0
14	0
15	0
16	0
17	0
18	0
19	0
20	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

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Appendix 4.

A compilation of the Nelson Laboratories test results for the **two-year real time aging time point**.

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge

Nelson Labs.
A Sotera Health company

Sponsor:
Teresa Meadows
ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Package Burst Test Final Report

Test Article:	Header Bags (Real Time - Two Years) PB3210 Lot: 33096-T PB3211 Lot: 32630-T PB3221 Lot: 32367-T
Purchase Order:	34401
Study Number:	1238286-S01
Study Received Date:	05 Nov 2019
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0060 Rev 12
Deviation(s):	None

Summary: This procedure is designed to determine the ability of packages to withstand internal pressurization. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Based On:	ASTM F1140
Package Type:	Nonporous
Product:	Not Present
Test Start Date/Time:	12 Nov 2019 at 5:39 p.m.
Testing Analyst(s):	Alexander Patch
Set Pressure:	10.00 psig
Test Time (sec):	25.0 (PB3210 Lot 33096-T) 15.0 (PB3211 Lot 32630-T) 20.0 (PB3221 Lot 32367-T)
Flow Rate:	14
Blocking Agents:	No

Logan Luke electronically approved
Study Director — Logan Luke

13 Nov 2019 23:10 (+00:00)
Study Completion Date and Time

Results:
PB3210 Lot: 33096-T:

Specimen Number	Burst Pressure (psig)	Failure Location
1	1.68	Opposite of Port (Package Failure)
2	1.70	Side 3 (Package Failure)
3	1.70	Opposite of Port (Package Failure)
4	1.66	Opposite of Port (Package Failure)
5	1.68	Opposite of Port (Package Failure)
6	1.66	Opposite of Port (Package Failure)
7	1.66	Opposite of Port (Package Failure)
8	1.68	Opposite of Port (Package Failure)
9	1.68	Opposite of Port (Package Failure)
10	1.66	Opposite of Port (Package Failure)
11	1.64	Opposite of Port (Package Failure)
12	1.72	Opposite of Port (Package Failure)
13	1.66	Opposite of Port (Package Failure)
14	1.66	Opposite of Port (Package Failure)
15	1.58	Opposite of Port (Package Failure)
16	1.62	Opposite of Port (Package Failure)
17	1.68	Opposite of Port (Package Failure)
18	1.58	Opposite of Port (Package Failure)
19	1.68	Opposite of Port (Package Failure)
20	1.62	Opposite of Port (Package Failure)
Mean	1.66	N/A
Standard Deviation	0.04	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the seals.

Failure Location (Test Article 2):

Test Set Up:

Nelson Labs.
A Sotera Health company

Study Number 1238286-S01
Package Burst Test Final Report

PB3211 Lot: 32630-T:

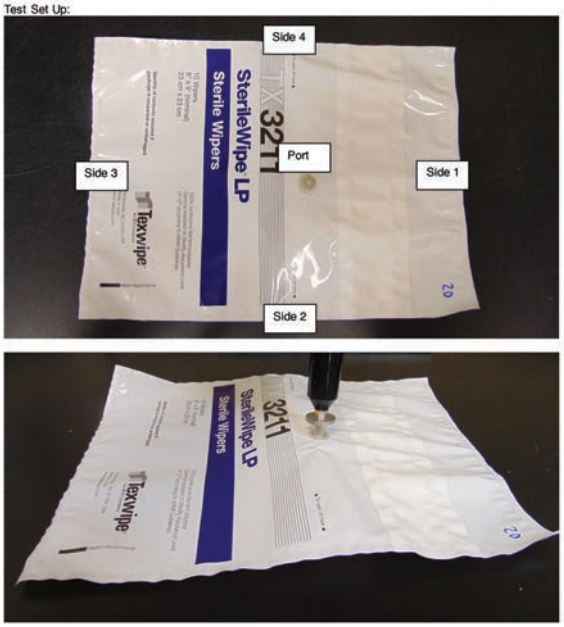
Specimen Number	Burst Pressure (psig)	Failure Location
1	1.96	Side 3 (Package Failure)
2	2.04	Side 3 (Package Failure)
3	2.02	Opposite of Port (Package Failure)
4	1.96	Opposite of Port (Package Failure)
5	2.08	Opposite of Port (Package Failure)
6	2.12	Opposite of Port (Package Failure)
7	2.04	Opposite of Port (Package Failure)
8	2.06	Opposite of Port (Package Failure)
9	2.08	Opposite of Port (Package Failure)
10	2.08	Opposite of Port (Package Failure)
11	2.04	Opposite of Port (Package Failure)
12	2.04	Opposite of Port (Package Failure)
13	2.02	Opposite of Port (Package Failure)
14	2.02	Side 1 (Package Failure)
15	2.08	Opposite of Port (Package Failure)
16	2.02	Opposite of Port (Package Failure)
17	2.00	Opposite of Port (Package Failure)
18	2.06	Opposite of Port (Package Failure)
19	2.08	Opposite of Port (Package Failure)
20	2.06	Opposite of Port (Package Failure)
Mean	2.04	N/A
Standard Deviation	0.04	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the

Nelson Labs.
A Sotera Health company

Study Number 1238286-S01
Package Burst Test Final Report

Test Set Up:



Nelson Labs.
A Sotera Health company

Study Number 1238286-S01
Package Burst Test Final Report

PB3221 Lot: 32367-T:

Specimen Number	Burst Pressure (psig)	Failure Location
1	1.58	Opposite of Port (Package Failure)
2	1.62	Opposite of Port (Package Failure)
3	1.60	Opposite of Port (Package Failure)
4	1.62	Opposite of Port (Package Failure)
5	1.58	Opposite of Port (Package Failure)
6	1.58	Opposite of Port (Package Failure)
7	1.58	Opposite of Port (Package Failure)
8	1.60	Opposite of Port (Package Failure)
9	1.58	Opposite of Port (Package Failure)
10	1.60	Opposite of Port (Package Failure)
11	1.60	Opposite of Port (Package Failure)
12	1.58	Opposite of Port (Package Failure)
13	1.58	Opposite of Port (Package Failure)
14	1.56	Opposite of Port (Package Failure)
15	1.56	Opposite of Port (Package Failure)
16	1.58	Opposite of Port (Package Failure)
17	1.58	Opposite of Port (Package Failure)
18	1.58	Opposite of Port (Package Failure)
19	1.58	Opposite of Port (Package Failure)
20	1.60	Opposite of Port (Package Failure)
Mean	1.59	N/A
Standard Deviation	0.02	N/A

Note: Results reported as "Package Failure" indicate the package material ruptured before the

Nelson Labs.
A Sotera Health company

Study Number 1238286-S01
Package Burst Test Final Report

Test Set Up:

Test Method Acceptance Criteria: No test method acceptance criteria currently exist for this method.

Procedure: Prior to testing, the test articles were conditioned for a minimum of 24 hours at 23 ± 2°C and 50 ± 5% relative humidity (RH).

The packages were attached to the T.M. Electronics package tester and pressurized at a constant rate until they burst.

Appendix 3.

A compilation of the Nelson Laboratories test results for the **two-year real time aging time point**.

A. Bubble emission leak test

B. Burst test

C. Whole package microbial challenge

Nelson Labs.
A Sotera Health company

Sponsor:
Teresa Meadows
ITW Texwipe
1210 S. Park Dr.
Kernersville, NC 27284

Aerosol Challenge Procedure Final Report

Test Article: Header Bags (Real Time - 2 Years)
PB3210 Lot: 33096-T
PB3211 Lot: 32630-T
PB3221 Lot: 32367-T
Purchase Order: 34401
Study Number: 1240891-S01
Study Received Date: 12 Nov 2019
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0058 Rev 16
Deviation(s): None

Summary: This procedure is intended to challenge the whole sterile barrier system in order to determine integrity of a finished product sterile barrier system. The test articles are exposed to microbial aerosol challenge using *Bacillus atrophaeus*, ATCC #9372, spores.

The test articles demonstrated 100% no growth following an extreme bacterial aerosol challenge. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Standard Method Based On: ISO 11607-1

Results:

Type	No Growth	Growth
Test Articles	60	0
Nelson Laboratories Positive Control Jar	0	1
Media Monitor	2	0
Environmental Monitor	1	0
Growth Promotion	0	1

Testing Parameters:

Run	Challenge Titer (CFU/mL)	Challenge Delivered (CFU)	Extraction Efficiency (%)	Average Fallout Value (CFU/cm^2)	MPS (µm)	Average Calculated Fallout from the AGI (CFU/ft^2)
1	2.2×10^{11}	~2.2×10^{12}	88.20	~5.7×10^{2}	2.6	5.1×10^{4}

Note: Results reported as "~" are considered an approximation based on counts outside of the statistically accurate range.
CFU = colony forming unit
MPS = mean particle size
AGI = All Glass Impingers

Logan Luke electronically approved
Study Director Logan Luke

16 Dec 2019 23:26 (+00:00)
Study Completion Date and Time

Test Method Acceptance Criteria: Aerosol challenge fallout must be greater than 100 CFU/cm^2. Average MPS must be ≤4.5 µm. The positive controls must demonstrate growth of the indicator organism.

Procedure: *B. atrophaeus* was inoculated onto soybean casein digest agar (SCDA) plates and incubated at 30-35°C for a minimum of 5 days. The growth was harvested, heat-shocked at 80-85°C for 10 minutes and filtered. The spore suspension was adjusted to achieve minimum fallout levels of 100 CFU/cm^2 and the titer was verified using standard plate count procedures.

The bacterial aerosolization test was conducted in a 1 m^3 glass aerosol exposure chamber. The chamber had sampling ports on the side, an aerosol delivery port on the top, and an aerosol removal port on the bottom.

For each test, the first 30 minutes serve as a preconditioning period to equilibrate the chamber environment and prevent aerosol loss to the chamber walls. The challenge delivery rate was 20 mL per hour. This was determined to be sufficient to deliver the minimum required fallout. The challenge was delivered to a nebulizer that was attached to the aerosol exposure chamber. Fallout sampling and monitoring was conducted during the 60 minutes of bacterial challenge that followed the preconditioning period.

At 15 and 45 minutes, air samples were collected (10.4 seconds) with the Andersen sampler to permit valid sample collection and quantitation from high chamber aerosol levels. Colony counts from the Andersen sampler plates (bacterial filtration efficiency agar plates) were converted to probable hit values (stages 3-6) using a validated spreadsheet. This spreadsheet converts the actual number of CFUs to probable hit values using the Poisson distribution. The MPS of the aerosolized challenge was calculated. The MPS is a statistical representation of the average size of the particles collected by the Andersen sampler. At 30 minutes, replicate AGI samples were collected for 1 minute using 25 mL of peptone water. The impingers break up the aerosol particles; each particle may contain many organisms and thus higher counts are expected. The impinger fluid was quantitated by serial dilution and plated onto SCDA.

Fallout samples consisted of five 2 x 2 inch pieces of gauze aseptically placed inside the chamber prior to the challenge. The gauze pieces were aseptically placed into 50 mL of peptone Tween® (PEPT) and extracted, serially diluted and plated onto SCDA plates.

The gauze extraction process has been previously validated and an efficiency value calculated. The efficiency value is determined by exhaustive extraction of the same piece of gauze at least four times (or until the number recovered approaches zero or is negligible compared to the first extraction) using the same procedure for each extraction. The number extracted on the first extraction is then divided by the total organisms recovered from all extractions. This value is then applied to the actual counts of each piece of fallout gauze tested during an exposure run which results in counts being more representative of the actual organism load.

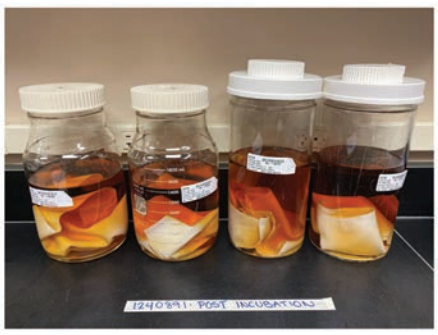
All plates from Andersen sampling, fallout samples and AGI replicates were incubated at 30-35°C for 24-48 hours.

The exteriors of the test articles were decontaminated prior to testing for the indicator organism.

Testing for the indicator organism was performed in a HEPA filtered clean hood. Test articles were aseptically placed in an appropriate volume of soybean casein digest broth (SCDB). All media lots were tested for conformance with the current USP growth promotion requirements. The test articles were incubated for 7 days at 30-35°C. All test articles were inspected for growth of the challenge organism.

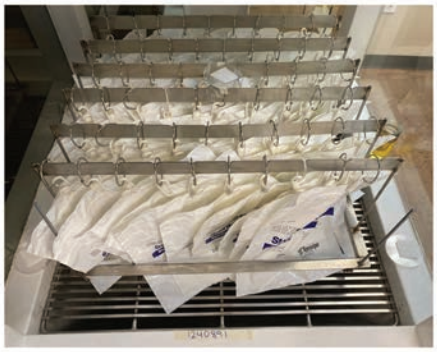
Following incubation, one non-growth test article was inoculated with less than 100 CFU of the challenge organism. Growth of the challenge organism was observed in the inoculated test article following incubation at 30-35°C.

Example of Test Article Post-Incubation:



Example of Growth Promotion Post-Incubation:

Test Article Configuration:
Chamber Set-Up:



TECHNOTES

Reference

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