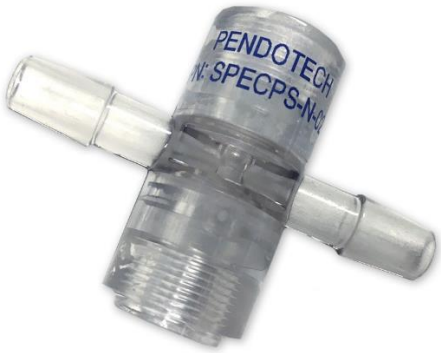
Validation Guide for PendoTECH® Single Use UV/Turbidity Flow Cells™

Revision 2



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Validation Guide for PendoTECH Single Use UV/Turbidity Flow Cells

PendoTECH assumes no responsibility for the use of this product except for what is covered in the Limited Warranty and Terms and Condition of Sale for products. The products are not designed, intended or authorized for use as components in life support or medical devices. They are not designed for any application in which the failure of the product could result in personal injury, death, or property damage.

The flow cells are designed for use with the PendoTECH Process Control Systems and UV/VIS/NIR transmitters offered by PendoTECH. Other flow cell monitors must be tested for compatibility and PendoTECH assumes no responsibility of compatibility of performance with other instruments. The end user must take proper precautions required to make sure there is no damage their monitor.

Revision 2
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Table of Contents

1 INTRODUCTION

1.1 Product overview

1.1.1 In bioprocess operations, the UV absorbance of a liquid solution can identify the absence or presence of the molecule of interest. The measurement, typically at 280nm, is made by a spectrophotometer or photometer either in-line or off-line in a cuvette. A collimated beam of light passes through a sample with a defined path length and the absorbance is determined as the ratio of the light applied from the source to what passed through the sample. The PendoTECH Single Use UV Flow Cell enables the measurement to be made non-invasively. The flow cell is connected to tubing, and the measurement is made by use of a compact photometer with fiber optic cables. This flow cell contains a special silica glass lens on the wall and compartments to attach the light source and detector. The stream to be measured flows between the lenses by way of tubing attached to the hose barb ends of the flow cell. The flow cell is low cost for single use applications and may be repeatedly cleaned and re-used.

1.2 Purpose of this document

1.2.1 The purpose of this document is to assist end users in qualifying the flow cells for use in their process. ***Each prospective user must test the flow cell for its proposed application to determine its suitability for the purpose intended prior to incorporating the flow cell to any process or application. The flow cell is not intended for use as a component in life support. The flow cell is not designed for any application in which the failure of the product could result in property damage, personal injury, or death. Proper safeguards must be put into place for the process in which the flow cell is used.***

1.3 Qualification testing comments

1.3.1 Testing was completed to qualify the product for use in bioprocess applications. In the product manufacturing process, O-rings and fused silica lens are installed into the polysulfone product bodies. Pre-existing specifications on certain materials used in the UV/Turbidity flow cell devices are as noted.

2 PRODUCT CATALOG NUMBERS

PendoTECH Product Catalog Numbers Covered in This Document	
Part Number	**Description**
SPECPS-N-012	Single Use UV Flow Cell, 2 mm path length, non-sterile, polysulfone, 1/8 inch hose barb
SPECPS-N-025	Single Use UV Flow Cell, 0.5 cm path length, non-sterile, polysulfone, 1/4 inch hose barb
SPECPS-N-050	Single Use UV Flow Cell, 1 cm path length, non-sterile, polysulfone, 1/2 inch hose barb
SPECPS-880-6CM	Single Use Turbidity Flow cell, 6.5cm path length, non-sterile, polysulfone, 3/4 inch sanitary flange inlet/outlet

3 MANUFACTURING INFORMATION

3.1 Product is manufactured in an FDA Registered, ISO 13485:2016 certified facility

3.2 Product manufacturing environment

3.2.1 Product is manufactured in a clean/controlled environment internally monitored to ensure less than 10,000 0.5-micron particles per cubic foot (ISO Class 7)

3.3 Each product is tested during manufacturing to verify physical integrity:

3.3.1 Each product is leak tested for proper O-ring sealing (Leak Test for integral assembly). This test is performed at 30 psi with air, and results documented and recorded

3.3.2 100% inspection to confirm optical clarity of silica windows

3.4 Component Inspection Criteria

3.4.1 Polysulfone molded product body: Proprietary Information- Contact PendoTECH for additional details

3.5 RoHS Statement

3.5.1 All sensors are in conformity with RoHS 3, EU Directive 2015/863.

3.6 REACH Statement

3.6.1 PendoTECH hereby certifies that its single use UV/Turbidity flow cells meet the requirements of Directive EC 1906/2006 commonly known as REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) and that to the best of its knowledge its products are free of any materials on the Candidate List of Substances of Very High Concern (SVHC) as stated by the European Chemical Agency (ECA) and that none of these materials are added or used in any of its manufacturing processes. This declaration is effective with production after September 11, 2015 for all products beginning with the prefix SPECPS.

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4 MATERIALS

4.1 Wet Volumes and Surface Areas

Part Number	Wet Volume	Wet Surface Area
SPECPS-N-012	0.004 in^3	0.27 in^2
SPECPS-N-025	0.046 in^3	1.06 in^2
SPECPS-N-050	0.34 in^3	3.33 in^2
SPECPS-880-6CM	0.44 in^3	4.72 in^2

4.2 Fluid path components

4.2.1 Polysulfone product body: Solvay UDEL P1700: Data provided by supplier states that product meets USP Class VI; claimed to be animal derived component free by supplier (letters on file at PendoTECH)

4.2.2 Lens: Fused Silica lens; A high purity synthetic amorphous silicon dioxide (99.99%-99.995%) manufactured by gaseous phase deposition. Typical chemical analysis of trace elements available upon request

4.2.3 O-Ring: Silicone, 70A, Translucent, Medical grade; Data provided by supplier states that product meets USP Class VI; claimed to be animal derived component free by supplier (letters on file at PendoTECH)

4.2.3.1 O-ring for SPECPS-880-6CM is the same material, but the hardness is only 50A

4.3 Non-fluid path components

4.3.1 Adhesive: Proprietary formulation; Data provided by supplier states meets USP Class VI; claimed to be animal derived component free by supplier (letter on file at PendoTECH)

4.3.2 Optical Coupler Nut: Polycarbonate

5 ASSEMBLED FLOW CELL CERTIFICATIONS

5.1 USP Class VI Statement

5.1.1 All polymeric materials in contact with product fluid path meet the acceptance criteria for USP Class VI Test (with 14 day subcutaneous implants) after exposure to 42-51 kGy of gamma irradiation. Study Summaries are in Appendix A and full reports are on file at PendoTECH. The test articles evaluated were polysulfone pressure sensors, however, the qualification holds true for UV/Turbidity Flow Cells as the polymeric fluid path components are 100% identical.

5.2 USP 661 post gamma irradiation

5.2.1 Fully assembled Single Use UV/Turbidity flow cells meet the criteria of the USP Physicochemical Test for Plastics based upon Nonvolatile Residue, Residue on Ignition, Heavy Metals, and Buffering Capacity after exposure to 60-77 kGy of gamma irradiation. The study was conducted based upon the following references: USP 38, National Formulary33, 2015. Monograph <661> Containers, Physicochemical Tests-Plastics. Test Result Certificates are in Appendix B.

5.3 ISO 10993-5 post irradiation (Gamma and X-ray)

5.3.1 Fully assembles Single Use UV/Turbidity flow cells were tested for cytotoxicity after exposure to 35-38 kGy of *gamma* irradiation. All flow cells were determined to meet the requirements of ISO 10993-5, Biological Evaluation of Medical Devices – Part5: Tests for In Vitro Cytotoxicity and are not considered to have a cytotoxic effect. Test Result Certificates are in Appendix C and full reports are on file at PendoTECH.

5.3.2 Fully assembles Single Use UV/Turbidity flow cells were tested for cytotoxicity after exposure to >50 kGy of *X-ray* irradiation. All flow cells were determined to meet the requirements of ISO 10993-5, Biological Evaluation of Medical Devices – Part5: Tests for In Vitro Cytotoxicity and are not considered to have a cytotoxic effect. Test Result Certificates are in Appendix K and full reports are on file at PendoTECH.

5.4 Bioburden

5.4.1 Samples of fully assembled UV sensors were randomly selected from production and tested for bioburden by Nelson Laboratories according to their Standard Test Protocol Number STP0036 Rev15. Testing is performed in accordance with ANSI/AAMI/ISO 11737-1:2018. Testing is performed in compliance with U.S. FDA good manufacturing practices (GMP) regulations 21 CFR Parts 210, 211, and 820. Following validation, the following results were obtained: Average Colony Forming Units (CFU) per sample was < 3.0. The bioburden estimate based on the recovery efficiency was 8.1 CFU/sample. Test report is available in Appendix D.

5.5 Bacteriostasis and Fungistasis (B&F)

5.5.1 B&F testing was carried out by the method suitability test via membrane filtration – USP. The study was conducted with accordance to the following references: USP 41, NF 36, 2018. <71> Sterility Tests. ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories. Testing determined the sensors are considered non-bacteriostatic. Test result Certificates are in Appendix E. The test articles evaluated were polysulfone pressure sensors, however, the qualification holds true for UV/Turbidity Flow Cells as the polymeric fluid path components are 100% identical.

6 PERFORMANCE SPECIFICATIONS

Attribute	Specification	Qualification Test Information
Pressure Range	75psi max	Qualification Testing by PendoTECH
Isolated Flow Cell Absorbance	0.20 AU maximum	Qualification Testing by PendoTECH
Gamma Irradiation	Up to 50 kiloGrays	Qualification Testing by PendoTECH
X-ray Irradiation	Up to 50 kiloGrays	Qualification Testing by PendoTECH
Operating Temperature	2°C to 50°C (other ranges with process qualification)	Raw Material Specifications
Storage Temperature	-25°C to 65°C	Raw Material Specifications
Shelf life	5 years	Qualification Testing by PendoTECH

7 PENDOTECH TEST METHOD SUMMARY

7.1 Pressure limit of 75 psi

7.1.1 8 flow cells from the same lot were challenged at 100 psi for leakage for 60 seconds. Each flow cell is placed in a test fixture fitted with calibrated Druck™ pressure gauge. Line pressure at 100 psi is applied to the flow cell in fixture; flow cells along with Druck™ gauge are then isolated for 60 seconds. Pressure is monitored in the isolated flow cell with the Druck™ and any pressure decay is noted. Acceptance Criteria: Pressure decay less than 0.03 psi/second at 100 psi over 60 seconds.

7.1.1.1 The UV flow cell specification is a 75 psi pressure rating when used with liquid. According to scientific leak test theory, there is a significant difference in leak rate between gasses and liquid, under the same conditions. With all else being equal (pressure, temperature, hole size, etc.), a gaseous leak rate will be approximately 205 times larger than an aqueous leak rate. When comparing liquid and gas leak rates, the leak rate increases due to the reduced viscosity and the expansion characteristics of the gas. For more details on leak rate theory, please refer to Cincinnati Test Systems Application Bulletin #120.

7.2 Flow Cell Absorbance, Max 0.20AU

7.2.1 PendoTECH has determined that a flow cell's maximum natural/isolated absorbance shall be no greater than 0.20AU, in order for the transmitter to meet its accuracy and precision claims. PendoTECH completed an experiment whereby a SPEC-280L UV-VIS-NIR Transmitter was tared on a calibrated SPEC-TRS Photometer Test Rig, with a blank cuvette inserted, establishing a stable 0.00 AU baseline. Then, the transmitter was connected to various flow cells of different sizes and lots, and AU values were recorded. This method determined the absorbance of just the flow cell.

7.3 Gamma Compatibility and Shelf Life of 5 years

7.3.1 PendoTECH has qualified its UV/Turbidity flow cells for a 5 year shelf life and compatible with gamma irradiation by evaluating flow cells that were real time aged for 2 years, accelerated aged for 3 years, gamma irradiated at 60-77kGy, and then real time aged for another 2 years. The performance of the flow cells was evaluated with a maximum absorbance test similar to what is described in section 7.2. The integrity of the flow cells was challenged with a leak test at 60 psi, in which a pressure decay was measured and the flow cells were visually inspected for leaks using soapy water.

7.4 X-ray Compatibility

7.4.1 In accordance with the BioProcess System's Alliance (BPSA) white paper on the requirements and risk evaluation of the X-ray sterilization of single use equipment, a risk assessment was performed to identify the tests required to qualify PendoTECH Single Use UV/Turbidity flow cells for X-ray irradiation for a dose > 50 kiloGrays (Certificate in Appendix I). As these flow cells contain no active electronics and are composed of robust, gamma compatible materials, they were deemed to be very low risk. Basic functionality and leak testing was still performed to demonstrate compatibility as a precaution. Testing procedures and results are documented below.

7.5 Operating Temperature range 2°C to 50°C

7.5.1 PendoTECH has determined a 2°C to 50°C operating temperature range for Single Use UV/Turbidity flow cells based on raw material specifications. PendoTECH has on file information from all flow cell component material suppliers stating very wide operating temperature ranges well outside the 2°C to 50°C claim. For consistency and an appropriate safety factor, PendoTECH has narrowed the range to be the same as other PendoTECH single use sensors. Other operating temperature ranges may be viable with proper end user process qualification.

7.6 Storage Temperature -25°C to 65°C

7.6.1 PendoTECH has determined a -25°C to 65°C storage temperature range for Single Use UV/Turbidity flow cells based on raw material specifications. PendoTECH has on file information from all flow cell component suppliers' manufacturers stating very wide operating temperature ranges well outside the -25°C to 65°C claim. For consistency and an appropriate safety factor, PendoTECH has narrowed the range to be the same as other PendoTECH single use sensors. Other storage temperature ranges may be viable with proper end user process qualification.

8 PENDOTECH TEST RESULTS

8.1 Pressure limit of 75 psi

Products: ¼ inch Single Use UV Flow Cell
Date of Inspection: 4/7/2016
Part No.: SPECPS-N-025
Lot Numbers: 1160582
Quantity: 8

- **Objective:** Confirm integral flow cell assembly of initial manufacturing lot of ¼" PendoTECH Single Use UV Flow Cells (SPECPS-N-025) with new molded nut and polysulfone UV flow cell body by means of pressure hold test at 100 psi for 60 seconds.
- **Procedure:** 8 flow cells from the same lot were challenged at 100 psi for leakage for 60 seconds. Each flow cell is placed in a test fixture fitted with calibrated Druck™ pressure gauge. Line pressure at 100 psi is applied to the flow cell in the fixture; flow cells along with Druck™ gauge are then isolated for 60 seconds. Pressure is monitored in the isolated flow cell with the Druck™ and any pressure decay is noted. (Calibration Certificate for Druck™ in Appendix F)
- **Acceptance Criteria:** Pressure decay less than 0.03 psi/second at 100 psi over 60 seconds.
- **Test Results:** Each flow cell exhibited a constant pressure decay of no more than 0.03 psi per second during testing. A molded flow cell body without the sensor compartment exhibited leakage of 0.03 psi per second confirming the validity of the acceptance criteria.

Test Equipment Used:	Make	Model	Serial #	Last Calibration
Pressure Gauge	DRUCK	DPI 104	36774169	7/13/2015

Applied High Pressure (psi)	Flow Cell Serial #	SPECPS-N-025 Lot#: 1160582	Acceptance Criteria (psi)
100	01	Pass	Pressure decay of less. than 0.03 psi per second
	02	Pass	
	03	Pass	
	04	Pass	
	05	Pass	
	06	Pass	
	09	Pass	
	10	Pass	

8.2 Flow Cell Absorbance, Max 0.20AU

Products: Single Use UV/Turbidity Flow Cell **Date of Inspection**: 10/6/2017

Part No.: SPECPS-N-025, SPECPS-N-050 **Lot Numbers**: 1163033, 1172263, 1133031, 1170950, 1161362

Quantity: 26

- **Objective:** Confirm that completed assembly of Single Use UV/Turbidity flow cells conforms to an absorbance of max 0.20 AU.
- **Procedure:** PendoTECH completed an experiment whereas a SPEC-280L UV-VIS-NIR Transmitter was tared on a calibrated SPEC-TRS Photometer Test Rig, with a blank cuvette inserted. This established a known good 0.00AU baseline. Then, the transmitter was connected to various flow cell of different sizes and lots, and AU values recorded. This method determined the absorbance of just the flow cell. Two different sizes and 5 different lots were tested.
- **Acceptance Criteria:** Absorbance (AU) max 0.20AU
- **Test Results:** Each flow cell exhibited an absorbance of max 0.20AU. This confirms that the design of the product, along with existing manufacturing processes, produces consistently the desired result of max 0.20AU.

Test Equipment Used:	Make	Model	Serial #	Last Calibration
Photometer Test Rig	PendoTECH	SPEC280-TRS	CH11017	10/2/17

SPECPS-N-050					SPECPS-N-025	
Serial #	Abs. (AU)				Serial #	Abs. (AU)
1163033-104	0.01				1170950-031	0.07
1172263-093	0.07				1170950-045	0.07
1172263-104	0.01				1170950-067	0.08
1172263-102	0.01				1170950-077	0.14
1172263-103	0.12				1170950-069	0.09
1172263-097	0.06				1161362-249	0.07
1163033-246	0.01				1161362-145	0.07
1163033-258	0.01				1161362-239	0.01
1163033-270	0.01				1161362-052	0.01
1163033-261	0.14				1161362-197	0.06
1163033-264	0.01					
1163031-073	0.01					
1163031-078	0.11					
1163031-084	0.01					
1163031-066	0.01					
1163031-080	0.01					

8.3 Gamma compatibility and Shelf life of 5 years

8.3.1 Post Gamma and 5 year Shelf Life Absorbance Testing

Products: Single Use UV/Turbidity Flow Cell **Date of Inspection**: 8/4/2021

Part No.: SPECPS-N-025, SPECPS-N-050 **Lot Numbers**: 1170950, 1161362, 1163031

Quantity: 16

- **Objective:** Confirm that completed assembly of Single Use UV/Turbidity flow cells conforms to an absorbance of max 0.20 AU, post 5 year shelf and gamma sterilization (60-77kGy, Certificate in Appendix G).

  Procedure: PendoTECH conducted an experiment whereas a SPEC-880L Photometer (SN: 472079385) was tared on an empty flow cell stand (SPEC-FCH-S SN: FCHS40620. This established a known good 0.00AU baseline. Then 16x flow cells of two different sizes across three lots were inserted into the stand and the change in absorbance was measured. These flow cells were all real time aged for two years, accelerated aged for 3 years, and then stored on a shelf for an additional 2 years of real time aging. The AU value for each sensor was recorded to confirm whether or not it is within the acceptance criteria.

- **Acceptance Criteria:** Absorbance (AU) max 0.20AU

- **Test Results:**

Part Number	Lot Number	Serial Number	Absorbance (AU)
SPECPS-N-025	1170950	72	0.12
SPECPS-N-025	1170950	71	0.09
SPECPS-N-025	1170950	35	0.08
SPECPS-N-025	1170950	48	0.03
SPECPS-N-025	1170950	2	0.05
SPECPS-N-025	1170950	73	0.04
SPECPS-N-025	1170950	74	0.06
SPECPS-N-025	1161362	249	0.05
SPECPS-N-050	1163031	86	0.04
SPECPS-N-050	1163031	81	0.05
SPECPS-N-050	1163031	66	0.05
SPECPS-N-050	1163031	19	0.04
SPECPS-N-050	1163031	20	0.06
SPECPS-N-050	1163031	9	0.05
SPECPS-N-050	1163031	73	0.05
SPECPS-N-050	1163031	69	0.05

- **Conclusion:** All flow cells were within the maximum absorbance of 0.20 AU confirming that UV/Turbidity flow cells are still suitable for use after a 5 year shelf life, and compatible with gamma irradiation

8.3.2 Post Gamma and 5 Year Shelf Life Leak Testing

Products: Single Use UV/Turbidity Flow Cell **Date of Inspection**: 8/10/2021

Part No.: SPECPS-N-025, SPECPS-N-050 **Lot Numbers**: 1163031, 1170950, 1161362

Quantity: 16

- **Objective:** Confirm the integrity of UV/Turbidity flow cells, post 5 year shelf and gamma sterilization (60-77kGy, Certificate in Appendix G) by means of a leak test.

- **Procedure:** 16x flow cells from 3 lots across two different sizes were real time aged for 2 years, accelerated aged for 3 years, gamma radiated between 60 and 77 kGys, and then real time aged for another 2 years. These flow cells were leak tested in a PendoTECH custom test rig to isolate the flow cell, where the pressure was monitored with a calibrated pressure gauge (Calibration Certificate in Appendix H). The flow cells were exposed to 60 psi for 90 seconds. A pressure decay test was performed to measure the pressure drop and soapy water was used to visually identity any leaks. The pressure decay was recorded and compared against the acceptance criteria.

Test Equipment Used:	Make	Model	Serial #	Last Calibration
Pressure Gauge	DRUCK	DPI 104	3674169	08/20/20

- **Acceptance Criteria:** Pressure decay less than 0.03 psi/second and no visual detection of leaks

- **Test Results:**

Part Number	Lot Number	Serial Number	P Initial	P final	ΔP	Pressure Decay (psi/sec)	Leak Visually Detected?
SPECPS-N-025	1170950	72	60.23	60.20	0.03	0.0004	**No**
SPECPS-N-025	1170950	71	60.25	60.21	0.04	0.0005	**No**
SPECPS-N-025	1170950	35	60.46	60.45	0.01	0.0001	**No**
SPECPS-N-025	1170950	48	60.22	60.20	0.02	0.0002	**No**
SPECPS-N-025	1170950	2	60.38	60.34	0.04	0.0005	**No**
SPECPS-N-025	1170950	73	60.34	60.33	0.01	0.0001	**No**
SPECPS-N-025	1170950	74	60.17	60.14	0.03	0.0004	**No**
SPECPS-N-025	1161362	249	60.39	60.38	0.01	0.0001	**No**
SPECPS-N-050	1163031	86	60.36	60.33	0.03	0.0004	**No**
SPECPS-N-050	1163031	81	60.40	60.37	0.03	0.0004	**No**
SPECPS-N-050	1163031	66	60.25	60.23	0.02	0.0003	**No**
SPECPS-N-050	1163031	19	60.29	60.27	0.02	0.0002	**No**
SPECPS-N-050	1163031	20	60.23	60.20	0.03	0.0004	**No**
SPECPS-N-050	1163031	9	60.24	60.22	0.02	0.0003	**No**
SPECPS-N-050	1163031	73	60.40	60.36	0.04	0.0005	**No**
SPECPS-N-050	1163031	69	60.31	60.29	0.02	0.0003	**No**

- **Conclusion:** All flow cells were within the acceptable pressure decay limit and no leaks were visually identified, confirming flow cell integrity post 5 year shelf life and gamma irradiation.

8.4 X-ray Compatibility

8.4.1 Post X-ray Functionality Testing

Products: Single Use UV/Turbidity Flow Cell **Date of Inspection**: 10/4/2021

Part No.: SPECPS-N-050 **Lot Numbers**: 1202529, 1202944, 1202606, 1210024

Quantity: 19

- **Objective:** Confirm the functionality of Single Use UV/Turbidity flow cells be ensuring they conform to an absorbance of max 0.20 AU, post X-ray Irradiation (> 50 kGy, Certificate in Appendix I).

- **Procedure:** 19x UV/Turbidity Flow Cells across 4 different lots (1202529, 1202944, 1202606, and 1210024) were tested for stability by evaluating the absorbance of an empty flow cell. All flow cells were X-ray irradiated with a dose >50 kGy. A PendoTECH SPEC-880L Photometer (SN: 472079358) was tared on an empty flow cell stand (SPEC-FCH-S SN: FCHS70320) to establish a known 0.00AU baseline. Then the flow cells were inserted into the stand and the change in absorbance was measured. The same test was performed prior to irradiating the flow cells to demonstrate that X-ray irradiation did not cause a significant change in the absorbance of the flow cell.

- **Acceptance Criteria:** Absorbance (AU) max 0.20AU

- **Test Results:**

Part Number	Lot Number	Serial Number	Absorbance (AU)		
			Pre X-ray	Post X-ray	Difference
SPECPS-N-050	1202529	107	0.08	0.06	-0.02
SPECPS-N-050	1202944	30	0.1	0.02	-0.08
SPECPS-N-050	1202529	108	0.06	0.08	0.02
SPECPS-N-050	1202944	305	0.02	0.03	0.01
SPECPS-N-050	1202944	248	0.07	0.08	0.01
SPECPS-N-050	1202944	312	0.06	0.04	-0.02
SPECPS-N-050	1202606	131	0.07	0.04	-0.03
SPECPS-N-050	1202944	208	0.07	0.09	0.02
SPECPS-N-050	1202606	123	0.08	0.06	-0.02
SPECPS-N-050	1202606	82	0.06	0.02	-0.04
SPECPS-N-050	1210024	234	0.05	0.03	-0.02
SPECPS-N-050	1210024	183	0.08	0.09	0.01
SPECPS-N-050	1210024	156	0.07	0.07	0.00
SPECPS-N-050	1210024	213	0.06	0.07	0.01
SPECPS-N-050	1210024	240	0.06	0.04	-0.02
SPECPS-N-050	1210024	203	0.09	0.02	-0.07
SPECPS-N-050	1210024	37	0.1	0.04	-0.06
SPECPS-N-050	1210024	273	0.05	0.07	0.02
SPECPS-N-050	1210024	138	0.09	0.06	-0.03
Average			0.07	0.05	-0.02

- **Conclusion:** All flow cells were within the acceptable limit of 0.20AU and did not change significantly following X-ray Irradiation, thus qualifying the performance of PendoTECH Single Use UV/Turbidity Flow cells post X-ray Irradiation.

8.4.2 Post X-ray Integrity Testing

Products: Single Use UV/Turbidity Flow Cell **Date of Inspection**: 10/4/2021

Part No.: SPECPS-N-050 **Lot Numbers**: 1202529, 1202944, 1202606, 1210024

Quantity: 19

- **Objective:** Confirm the integrity of UV/Turbidity flow cells via leak testing X-ray irradiation (> 50kGy, Certificate in Appendix I)

- **Procedure:** 19x UV/Turbidity flow cells across 4 different lots (1202529, 1202944, 1202606, and 1210024) were leak tested to validate flow cell integrity following a dose of X-ray irradiation > 50kGy. Each flow cell was placed in a custom test fixture where a 90 second pressure decay test at 60 psi and visual inspection using soapy water was performed to demonstrate that there were no leaks post X-ray irradiation. The pressure of the flow cell isolated inside the custom test fixture was monitored with a calibrated pressure gauge (Certificate in Appendix J).

Test Equipment Used:	Make	Model	Serial #	Last Calibration
Pressure Gauge	DigiSense	CP355333	1912310225	08/24/21

- **Acceptance Criteria:** Pressure Decay less than 0.03psi/second and no visual detection of leaks

- **Test Results:**

Post X-ray Leak Test Results						
Part Number	Lot Number	Serial Number	Initial Pressure (psi)	Final Pressure (psi)	ΔP	Pressure Decay (psi/sec)
SPECPS-N-050	1202529	108	60.04	59.95	-0.09	-0.0010
SPECPS-N-050	1202944	248	60.01	59.93	-0.08	-0.0009
SPECPS-N-050	1202944	305	60.03	59.93	-0.10	-0.0011
SPECPS-N-050	1202606	131	60.07	60.01	-0.06	-0.0007
SPECPS-N-050	1210024	203	60.03	59.94	-0.09	-0.0010
SPECPS-N-050	1202529	107	60.02	59.89	-0.13	-0.0014
SPECPS-N-050	1202606	123	60.02	59.94	-0.08	-0.0009
SPECPS-N-050	1202606	82	60.00	59.91	-0.09	-0.0010
SPECPS-N-050	1210024	138	60.11	60.02	-0.09	-0.0010
SPECPS-N-050	1210024	234	60.06	59.98	-0.08	-0.0009
SPECPS-N-050	1210024	273	60.02	59.93	-0.09	-0.0010
SPECPS-N-050	1210024	240	60.07	60.00	-0.07	-0.0008
SPECPS-N-050	1210024	156	60.06	59.98	-0.08	-0.0009
SPECPS-N-050	1210024	37	60.14	60.07	-0.07	-0.0008
SPECPS-N-050	1210024	213	60.00	59.89	-0.11	-0.0012
SPECPS-N-050	1210024	183	60.03	59.97	-0.06	-0.0007
SPECPS-N-050	1202944	312	60.03	59.95	-0.08	-0.0009
SPECPS-N-050	1202944	208	60.01	59.90	-0.11	-0.0012
SPECPS-N-050	1202944	30	60.03	59.91	-0.12	-0.0013

- **Conclusion:** No leaks were identified in any of the leak testing and all pressure decay tests were within the acceptable limit, thus validating the integrity of PendoTECH Single Use UV/Turbidity Flow cells post X-ray Irradiation.

9 APPENDICES

9.1 Appendix A- Assembled Flow Cell Certificate: Class VI post 40kGy gamma irradiation- Flow Cell Body and O-Ring

TOXIKON
RIGHT. FROM THE START.℠

TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	4/12/2019
Address	174 Nassau Street Suite 256 Princeton, NJ 08542	**Technical Completion** **Report Date**	5/29/2019 6/3/2019
Contact	Dennis Annarelli	**Amended Report Date**	6/17/2019
P.O. Number	2013094	**Final GLP Report**	19-00538-G1

Test Article	Polysulfone Pressure Sensor Body, Pressure Sensing Chip, Port Plate o-Ring Post 40 kGy Gamma Irradiation	**Ratio**	60 cm^2/20 mL
Lot/Batch #	1171477	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Study	Class VI Test – USP (With 14 Day Subcutaneous Implant)	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours

REFERENCES:

The study was conducted based upon the following references:

United States Pharmacopeia 41, National Formulary 36, 2018. <88> Biological Reactivity Tests, *In Vivo*.

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE:

The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted subcutaneously into rats for 14 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection.

RESULTS AND CONCLUSION:

None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, or edema in both test and control sites and no signs of clinical toxicity. In both the Systemic and Intracutaneous Tests, the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI – 70°C.

AUTHORIZED PERSONNEL:

Colin McFadden, B.S.
Quality Assurance

D. Radhika
Radhika Devalaraja, Ph.D.
Study Director

> 15 Wiggins Ave., Bedford MA 01730 > 800.458.4141 > Main: 781.275.3330 Toxikon.com

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FINAL GLP REPORT: 19-00538-G1
AMENDED

CLASS VI TEST – USP
(WITH 14 DAY SUBCUTANEOUS IMPLANT)

Test Article
Polysulfone Pressure Sensor Body, Pressure Sensing Chip, Port Plate o-Ring Post
40 kGy Gamma Irradiation

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Final Report Date
6/3/2019

Amended Final Report Date
6/17/2019

Study Director
Radhika Devalaraja, Ph.D.

Sponsor
PendoTECH
174 Nassau Street Suite 256
Princeton, NJ 08542

> 15 Wiggins Ave., Bedford MA 01730 > 800.458.4141 > Main: 781.275.3330 Toxikon.com

STUDY SUMMARY

The USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG) extracts of the test article, Polysulfone Pressure Sensor Body, Pressure Sensing Chip, Port Plate o-Ring Post 40 kGy Gamma Irradiation, following Intracutaneous Injection in rabbits, Systemic Injection in mice, and the test article, following Subcutaneous Implantation in rats, did not produce a biological response.

Based on the criteria of the protocol and the USP guidelines for Class VI Plastics - 70 °C, the test article meets the requirements of the test.

QUALITY ASSURANCE STATEMENT

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to Toxikon's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase	Inspection Date	Date Reported to Study Director	Date Reported to Management
EXPLANT	5/29/2019	5/29/2019	5/29/2019
DATA	6/3/2019	6/3/2019	6/3/2019
FINAL REPORT	6/3/2019	6/3/2019	6/3/2019
AMENDED REPORT	6/17/2019	6/17/2019	6/17/2019

Colin McFadden

Colin McFadden, B.S.
Quality Assurance

6/17/19
Date

GLP COMPLIANCE STATEMENT

This study meets the technical requirements of the protocol.

This study was conducted in compliance with the current U.S. Food and Drug Administration 21 CFR, Part 58 Good Laboratory Practices for Nonclinical Laboratory Studies.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article, 21 CFR, Part 58.105, and its mixture with carriers, 21 CFR, Part 58.113.

SIGNATURES

Signature Information	
Protocol Number	p19-0161-00b
Study Director	Radhika Devalaraja, Ph.D.
Study Supervisor	Catherine Maciaszek, B.S., LAT
Company	Toxikon Corporation

VERIFICATION DATES

The study initiation day is the date the protocol is signed by the Study Director.

Verification Dates	
Test Article Receipt	1/23/2019
Project Log	2/11/2019
Study Initiation	3/25/2019
Study Completion	6/3/2019

D. Radhika
Radhika Devalaraja, Ph.D.
Study Director

6/17/2019
Date

Certificate Of Processing

STERIS

Prepared for **EMD MILLIPORE – BEDFORD**

Gamma Process Run ID **117005A**

Product Code	Product Lot Number	Quantity	UOM
40-60 SAMPLES Cust Item ID: CAT. NO. CDRF1TN05	0020499769	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRF4HN05	0021039608	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRM8HN05	0022897176	1	CS
40-60 SAMPLES Cust Item ID: 20277484/00123958DR	MGBF620/MGDM180	1	CS
40-60 SAMPLES Cust Item ID: PENDOTECH POLYSULFONE SENSORS	NA	1	CS

PO Number: N1402721

Processing Run Start Date/Time:	20-Jan-2019 10:07:00 pm	Approx. Downtime (hours):	3.82
Processing Run End Date/Time:	21-Jan-2019 04:04:00 am		

Minimum Specified Dose (kGy):	**40.0**	**Minimum Delivered Dose (kGy):**	**42.1**
Maximum Specified Dose (kGy):	**60.0**	**Maximum Delivered Dose (kGy):**	**50.8**

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Francine Maranda (QS & RC Analyst)
Document Content Revision: 1

Signed On 1/21/2019 at 8:48 AM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS
435 Whitney Street
Northborough, MA 01532
Phone: 508-393-9323
Fax: 844-698-9776

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137 or EN ANSI/AAMI/ISO 11135. For items processed with gamma irradiation, STERIS certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.

WI-00034/01354/01369 Last Rev in Rel. 3.6.5.1 Release Date 05-Jun-2017 Page 1 of 1

STERIS

STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for EMD MILLIPORE – BEDFORD
Process Run ID 117005A
Date Prepared: 1/21/2019 8:47:34AM

Processing Location: **Northborough**
Irradiator / Method: **126, Nordion Cobalt-60 Irradiator #126, ON-STD**

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
Final Dose Measurements							
1	1	0C1	0BR600288204	TH0049	0484	28.7	42.1
			0BR600257802	TH0048	0481	13.4	
1	2	TA5	0BR600288439	TH0049	0484	34.4	50.5
			0BR600257878	TH0048	0481	16.1	
1	3	TE5	0BR600288499	TH0049	0484	34.7	50.8
			0BR600257886	TH0048	0481	16.1	

Minimum Dose for Record (kGy): 42.1
Maximum Dose for Record (kGy): 50.8

Signature Manifest

Prepared By:
Baez, Hector (Material Handler) — Signed On 1/21/2019 at 6:23 AM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
Francine Maranda (QS & RC Analyst) — Signed On 1/21/2019 at 8:47 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

9.2 Appendix B: Assembled Flow Cell Certificate: USP 661 post gamma irradiation

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TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	11/18/2015
Address	174 Nassau Street Ste. 256 Princeton, New Jersey 08542	**Technical Completion**	11/20/2015
Contact	Dennis Annarelli	**Report Date**	11/24/2015
P.O. Number	2009258	**Final Non-GLP Report**	15-04022-N1

Test Article	PendoTECH Single Use UV Sensor Post Gamma Irradiation	**Ratio**	120 cm^2/20 mL
Lot/Batch #	1151263	**Vehicle**	Purified Water
Study	Physicochemical Test for Plastics – USP	**Extraction Conditions**	70 ± 2°C for 24 ± 2 hours
Comments	None.		

REFERENCES: The study was conducted based upon the following references: United States Pharmacopeia 38, National Formulary 33, 2015. Monograph <661> Containers, Physicochemical Tests–Plastics.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The test article was extracted in purified water after rinsing in purified water. The following tests were conducted in order to determine physical and chemical properties of the test article's extracts: Nonvolatile Residue, Residue on Ignition, Heavy Metals, and Buffering Capacity.

RESULTS:

TEST	ACCEPTABLE LEVEL	TEST RESULT
Nonvolatile Residue	≤ 15 mg	1.5 mg, Meets Criteria
Residue on Ignition*	≤ 5 mg	Not Applicable
Heavy Metals	≤ 1 ppm	< 1 ppm, Meets Criteria
Buffering Capacity	≤ 10 mL	0.66 mL, Meets Criteria

*The Residue on Ignition test is only performed if the nonvolatile residue is 5 mg or above.

CONCLUSION: The test article meets criteria of the USP Physicochemical Test for Plastics based upon the methods employed.

AUTHORIZED PERSONNEL:

Lakshmi Chandrasekaran, M.S.
Quality Assurance

Amtul Qamar, M.S.
Study Director

Toxikon Corporation 15 Wiggins Ave., Bedford, MA 01730 USA 1.800.458.4141 Main: 1.781.275.3330

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**

STERIS
Isomedix Services

Gamma Process Run ID **179365C**

Product Code	Product Lot Number	Quantity	UOM
GROUP 69	SAMPLE JASON / SAMPLE JASON-0000	1	CS
GROUP 82	140080 / 85174-0000	2	CS
GROUP 82	622014-0602 / 84931-ENDO	1	CS
GROUP 82	B110032-I / 85048-0000	1	CS
GROUP 82	B110522-I / 86408-0000	1	CS

Processing Run Start Date/Time:	01-Nov-2015 01:31:29 am	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	01-Nov-2015 03:25:16 am		

Minimum Specified Dose (kGy):	**27.5**	**Minimum Delivered Dose (kGy):**	**30.1**
Maximum Specified Dose (kGy):	**45.0**	**Maximum Delivered Dose (kGy):**	**37.7**

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Tracy Wild (QS/RC Technician)
Document Content Revision: 1

Signed On 11/2/2015 at 11:07 AM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS Isomedix Services
23 Elizabeth Drive
Chester, NY 10918
Phone: 845-469-4087
Fax: 845-469-7512

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485:2003/2012, and in alignment with EN ANSI/AAMI/ISO 11137:2006. STERIS Isomedix certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC -- Process Run ID 179365C
Date Prepared: 11/2/2015 10:47:31AM

Processing Location: **Chester**

Irradiator / Method: **239, Nordion Cobalt-60 Irradiator #239, Cont Batch**

Carrier	Seq	Coordinate	Batch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Final Dose (kGy)	Comment
1	1	0C1	NR (09/15/2015)	5A3O364003	MX 700989	0.7050	2.748	30.7	
1	2	0C3	NR (09/15/2015)	5A3O364003	MX 700989	0.7742	3.049	30.1	
1	3	0CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8206	3.228	30.2	
1	4	1C1	NR (09/15/2015)	5A3O364003	MX 700989	0.7697	2.877	33.0	
1	5	1CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8630	3.249	32.6	
1	6	TBAEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8840	3.236	34.3	
1	7	TBEEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.7782	2.842	34.5	
2	1	0CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.7542	2.962	30.3	
2	2	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.8315	2.894	37.7	
2	3	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.8871	3.124	36.9	

Minimum Dose for Record (kGy): **30.1**

Maximum Dose for Record (kGy): **37.7**

Last Dosimeter Absorbance Measurement Date/Time: 11/1/2015 4:21:38 AM

Signature Manifest

Prepared By:
Zephoni Rose (Material Handler)
Signed On 11/1/2015 at 4:22 AM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
Tracy Wild (QS/RC Technician)
Signed On 11/2/2015 at 10:47 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

Comment Legend: OUT = Calc Dose Out of Limits; PID = Pre-Irradiated Dosimeter; GRP = Dosimeter Group

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**

STERIS
Isomedix Services

Gamma Process Run ID **179655E**

Product Code	Product Lot Number	Quantity	UOM
GROUP 69	SAMPLE JASON / SAMPLE JASON-0000	1	CS
GROUP 82	B104620-I / 86635-0000	50	CS
GROUP 85	HM00170-I / 86606-0000	1	CS

Processing Run Start Date/Time:	08-Nov-2015 07:22:48 am	Approx. Downtime (hours):	0.09
Processing Run End Date/Time:	08-Nov-2015 09:28:01 am		

Minimum Specified Dose (kGy):	**27.5**	**Minimum Delivered Dose (kGy):**	**30.3**
Maximum Specified Dose (kGy):	**45.0**	**Maximum Delivered Dose (kGy):**	**39.8**

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Tracy Wild (QS/RC Technician)
Document Content Revision: 1

Signed On 11/10/2015 at 3:45 PM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS Isomedix Services
23 Elizabeth Drive
Chester, NY 10918
Phone: 845-469-4087
Fax: 845-469-7512

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485:2003/2012, and in alignment with EN ANSI/AAMI/ISO 11137:2006. STERIS Isomedix certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC – Process Run ID 179655E
Date Prepared: 11/9/2015 12:19:36PM

Processing Location: **Chester**

Irradiator / Method: **239, Nordion Cobalt-60 Irradiator #239, Cont Batch**

Carrier	Seq	Coordinate	Batch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Final Dose (kGy)	Comment
1	1	0C1	NR (09/15/2015)	5A3O364003	MX 700989	0.7962	3.125	30.3	
1	2	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.8975	3.108	38.1	
1	3	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.7923	2.818	36.2	
2	1	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.7922	2.925	33.8	
2	2	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.8764	3.213	34.2	
3	1	0CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8139	3.171	30.7	
3	2	1A5	NR (09/15/2015)	5A3O364003	MX 700989	0.8954	3.032	39.8	
3	3	1E5	NR (09/15/2015)	5A3O364003	MX 700989	0.9176	3.131	39.2	
5	1	0CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.7704	2.963	31.4	
5	2	1A5	NR (09/15/2015)	5A3O364003	MX 700989	0.8998	3.084	38.9	
5	3	1E5	NR (09/15/2015)	5A3O364003	MX 700989	0.9223	3.137	39.5	
6	1	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.8509	3.033	36.1	
6	2	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.8184	2.863	37.4	

Minimum Dose for Record (kGy): **30.3**

Maximum Dose for Record (kGy): **39.8**

Last Dosimeter Absorbance Measurement Date/Time: 11/9/2015 11:27:16 AM

Comment Legend: OUT = Calc Dose Out of Limits; PID = Pre-Irradiated Dosimeter; GRP = Dosimeter Group

9.3 Appendix C: Assembled Flow Cell Certificate: ISO 10993-5 post gamma irradiation

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TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	8/18/2015
Address	174 Nassau Street St. 256 Princeton, New Jersey 08542	**Technical Completion**	8/21/2015
Contact	Dennis Annarelli	**Report Date**	9/1/2015
P.O. Number	2008960	**Final GLP Report**	15-02862-G1

Test Article	UV absorbance sensor	**Ratio**	3 cm^2/mL
Lot/Batch #	See Attachment A	**Vehicle**	Serum–Supplemented (complete) Minimum Essential Medium (MEM)
Study	L929 Neutral Red Uptake Test (1 Concentration) – ISO	**Extraction Conditions**	24 ± 2 hours at 37 ± 1 °C
Comments	Per Sponsor request, the test article was extracted intact and wires were excluded from testing.		

REFERENCES: The study was based upon the following references: ISO 10993–5, 2009, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity. ISO 10993–12, 2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The biological reactivity of a mammalian cell monolayer, L929 mouse fibroblast, in response to the test article extract was determined. The test article extract was prepared as stated above. Positive control (Natural Rubber) and negative control (Negative Control Plastic) articles and an untreated control were prepared to verify the proper functioning of the test system. The test article and control article extracts were used to replace the maintenance medium of the cell culture. The test article extract was tested at the 100% (neat) concentration. All cultures were incubated in, at least, 6 replicates for 24 to 26 hours, at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide (CO_2). The viability of cells following the exposure to the extracts was measured via their capacity to uptake a vital dye, Neutral Red. This dye was added to the cells to be actively incorporated in viable cells. The number of viable cells correlates to the color intensity determined by photometric measurements at 540 nm after extraction.

EVALUATION CRITERIA: The viability of cells exposed to the negative control article and positive control article extracts need to be greater and less than 70% of the untreated control, respectively, to confirm the validity of the assay. The test article meets the requirements of the test if the viability % is greater than or equal to 70% of the untreated control.

RESULTS:

	Untreated Control	Negative Control	Positive Control	Test Article
				100% (neat)
Average OD	0.532	0.571	0.214	0.548
Viability %	100%	107%	40%	103%

CONCLUSION: The test article meets the requirements of the test and is not considered to have a cytotoxic effect.

AUTHORIZED PERSONNEL:

Elizabeth Hogan, B.S.
Quality Assurance

Sruthi Sundaram, Ph.D.
Study Director

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**

STERIS
Isomedix Services

Gamma Process Run ID **75899A**

Product Code	Product Lot Number	Quantity	UOM
GROUP 69	SAMPLE JASON / SAMPLE JASON-0000	1	CS

Processing Run Start Date/Time:	01-Aug-2015 09:52:00 pm	Approx. Downtime (hours):	0.15
Processing Run End Date/Time:	01-Aug-2015 11:27:00 pm		

Minimum Specified Dose (kGy):	**27.5**	**Minimum Delivered Dose (kGy):**	**34.8**
Maximum Specified Dose (kGy):	**45.0**	**Maximum Delivered Dose (kGy):**	**37.8**

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Maria H Greco (QS/RC Technician)
Document Content Revision: 1

Signed On 8/3/2015 at 7:51 AM
UTC / GMT Offset (hh:mm): -4:00

Processing Location:
STERIS Isomedix Services
9 Apollo Drive
Whippany, NJ 07981
Phone: 973-887-2754
Fax: 973-887-6591

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485:2003/2012, and in alignment with EN ANSI/AAMI/ISO 11137:2006. STERIS Isomedix certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC – Process Run ID 75899A
Date Prepared: 8/3/2015 7:49:48AM

Processing Location: **Whippany**

Irradiator / Method: **131, Nordion Cobalt-60 Irradiator #131, ON-STD**

Carrier	Seq	Coordinate	Batch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Final Dose (kGy)	Comment
1	1	2C5	NM (05/27/2015)	4324039	MX 700987	0.8148	2.856	34.8	
1	2	2A5	NM (05/27/2015)	4324039	MX 700987	0.7651	2.602	36.8	
1	3	2E5	NM (05/27/2015)	4324039	MX 700987	0.9126	3.060	37.8	
1	4	TBA5	NM (05/27/2015)	4324039	MX 700987	0.8675	2.926	37.4	
1	5	TBE5	NM (05/27/2015)	4324039	MX 700987	0.8776	2.949	37.6	

Minimum Dose for Record (kGy): **34.8**

Maximum Dose for Record (kGy): **37.8**

Last Dosimeter Absorbance Measurement Date/Time: 8/2/2015 12:33:08 AM

Signature Manifest

Prepared By:
Ronald Slack (Supervisor I)
Signed On 8/2/2015 at 12:33 AM
UTC / GMT Offset (hh:mm): -4:00

Approved By:
Maria H Greco (QS/RC Technician)
Signed On 8/3/2015 at 7:49 AM
UTC / GMT Offset (hh:mm): -4:00

Document Content Revision: 1

Comment Legend: OUT = Calc Dose Out of Limits; PID = Pre-Irradiated Dosimeter; GRP = Dosimeter Group

9.4 Appendix D: Assembled Flow Cell Certificates: Bioburden

Nelson Labs
A Sotera Health company

Sponsor:
Ryan Usgaard
Utah Medical Products, Inc.
7043 Cottonwood Street
Midvale UT 84105

Bioburden Final Report

Study Number: 1471400-S01
Test Article: Part #: SPECPS-N-050
Lot#: 1203390
Qty: 3
Purchase Order: 2017345
Study Received Date: 29 Nov 2021
Test Start Date: 16 Dec 2021
Test Finish Date: 07 Jan 2022
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: STP0036 Rev 15
Customer Specification Sheet (CSS) Number: 201801596 Rev 2
Customer Specification Sheet (CSS) Number: 202200165 Rev 1
Deviation(s): None

Summary: The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in accordance with ANSI/AAMI/ISO 11737-1:2018. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:
Bioburden: When bioburden results are calculated using a validated software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms.

Bioburden Estimate = (Aerobic Average+Fungal Average)×(1/Recovery Efficiency)

Unit Number	Aerobic	Fungal
1	<3	<3
2	<3	<3
3	<3	<3
Averages	<3.0	<3.0
Recovery Efficiency	74.2%	
Bioburden Estimate	8.1	

< = No Organisms Detected
Note: The results are reported as colony forming units per test article.

Matthew R. Shepherd electronically approved — 24 Jan 2022 19:24 (+00:00)
Study Director — Matthew R. Shepherd — Study Completion Date and Time

Nelson Labs
A Sotera Health company

Study Number 1471400-S01
Bioburden Final Report

Inoculated Recovery Efficiency:

Unit Number	CFU Count
4	82
5	94
6	91
Average CFU	89
Average Titer	120
	Recovery Efficiency (%)
RE	74.2

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	137%
Bacillus atrophaeus	130%
Bacillus atrophaeus	118%
Bacillus atrophaeus Average	**129%**

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results.

Procedure:

Inoculum:	*Bacillus atrophaeus*
Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Method:	Manual Shaking
Plating Method:	Membrane Filtration
Agar Medium:	Potato Dextrose Agar Tryptic Soy Agar
Recovery Efficiency:	Inoculated Product Method
Aerobic Bacteria:	Plates were incubated 3 - 7 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 5 - 7 days at 20-25°C, then enumerated.
Inoculated Recovery Efficiency:	Plates were incubated 18 - 168 hrs at 30-35°C, then enumerated.

9.5 Appendix E: Assembled Flow Cell Certificates: Bacteriostasis and Fungistasis Testing

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TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	2/8/2019
Address	174 Nassau Street Ste.256 Princeton, New Jersey 08542	**Technical Completion**	2/13/2019
Contact	Dennis Annarelli	**Report Date**	2/15/2019
P.O. Number	2013094	**Final Non-GLP Report**	19-00365-N1

Test Article	PendoTECH Single Use Pressure Sensor Polysulfone Post Gamma Irradiation (>40KGy)
Lot/Batch #	Not Supplied by Sponsor
Study	Method Suitability Test via Membrane Filtration – USP
Comments	None

REFERENCES: The study was conducted based upon the following references: USP 41, NF 36, 2018. <71> Sterility Tests.

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: Six (6) test articles were supplied by the Sponsor for testing. A quanticult of *Bacillus subtilis* (*B. subtilis*), *Aspergillus brasiliensis* (*A. brasiliensis*, formerly known as *Aspergillus niger*), *Pseudomonas aeruginosa* (*P. aeruginosa*), *Staphylococcus aureus* (*S. aureus*), *Candida albicans* (*C. albicans*), and *Clostridium sporogenes* (*C. sporogenes*) all consisting of 10-100 CFU were used. Cultures were rehydrated according to manufacturer's instructions.

Each test article were individually immersed in 100 mL of sterile Fluid D in a sterile bag. A volume of 98 mL of extract was recovered and aseptically membrane filtered. Following membrane filtration and rinse with 10 mL of sterile Phosphate Buffered Saline (PBS), the filters were directly transferred (one unit per vessel) into 100 mL of sterile Trypticase Soy Broth (TSB) and 100 mL of sterile Fluid Thioglycollate medium (FTM). One TSB vessel was inoculated with *Bacillus subtilis*. One TSB vessel was inoculated with *Candida albicans*. The third TSB vessel was inoculated with *Aspergillus brasiliensis*. One FTM vessel was inoculated with *Pseudomonas aeruginosa*. One FTM vessel was inoculated with *Staphylococcus aureus*. The remaining FTM vessel was inoculated with *Clostridium sporogenes*.

As positive controls, an equivalent number of TSB and FTM vessels were inoculated with the respective organisms. One TSB and one FTM vessel were un-inoculated and served as negative controls. A volume of 20 mL of PBS and 20 mL of Fluid D of the same lot used was membrane filtered and the filters were put in respective containers containing 100 mL of TSB each. All TSB vessels were incubated aerobically at 20-25 °C for 5 days. All FTM vessels except *C. sporogenes* were incubated aerobically at 30-35 °C for 5 days. FTM vessels with *C. sporogenes* were incubated ananerobically at 30-35 °C for 5 days. Growth was visually compared between test and control articles at specific time points.

RESULTS: The growth of each organism was independent of the presence of the test article. Growth was observed for all organisms and test article media conditions in TSB by Day 3. No growth was observed in the negative control, Fluid D, and PBS.

TABLE 1:
Sterility Validation Results – TSB

Day	Growth (+/-) per Medium								
	Organism						Negative Control	Fluid D	PBS
	B. subtilis		*C. albicans*		*A. brasiliensis*				
	With TA	Without TA	With TA	Without TA	With TA	Without TA			
1	W	W	W	W	W	W	W	W	W
2	W	W	W	W	W	W	W	W	W
3	+	+	+	+	+	+	–	–	–
4	+	+	+	+	+	+	–	–	–
5	+	+	+	+	+	+	–	–	–

TA = Test article, W = Weekend, (–) = No Growth, (+) = Growth

TOXIKON

Method Suitability Test via Membrane Filtration – USP
Final Non-GLP Report: 19-00365-N1
Test Article Name: PendoTECH Single Use Pressure Sensor Polysulfone Post Gamma Irradiation (>40KGy)

TABLE 2:
Sterility Validation Results – FTM

Day	Growth (+/-) per Medium								
	Organism						Negative Control	Fluid D	PBS
	C. sporogenes		*S. aureus*		*P. aeruginosa*				
	With TA	Without TA	With TA	Without TA	With TA	Without TA			
1	W	W	W	W	W	W	W	W	W
2	W	W	W	W	W	W	W	W	W
3	+	+	+	+	+	+	–	–	–
4	+	+	+	+	+	+	–	–	–
5	+	+	+	+	+	+	–	–	–

TA = Test article, W = Weekend, (–) = No Growth, (+) = Growth

CONCLUSION: The test articles are considered non–bacteriostatic and non–fungistatic, according to the USP guidelines.

AUTHORIZED PERSONNEL:

John Lugo-Toro, B.S.
Quality Assurance

MBS for
Aparajita Mukherjee, M.S.
Study Director

Certificate Of Processing

STERIS

Prepared for **EMD MILLIPORE – BEDFORD**

Gamma Process Run ID **117005A**

Product Code	Product Lot Number	Quantity	UOM
40-60 SAMPLES Cust Item ID: CAT. NO. CDRF1TN05	0020499769	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRF4HN05	0021039608	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRM8HN05	0022897176	1	CS
40-60 SAMPLES Cust Item ID: 20277484/00123958DR	MGBF620/MGDM180	1	CS
40-60 SAMPLES Cust Item ID: PENDOTECH POLYSULFONE SENSORS	NA	1	CS

PO Number: N1402721

Processing Run Start Date/Time:	20-Jan-2019 10:07:00 pm	Approx. Downtime (hours):	3.82
Processing Run End Date/Time:	21-Jan-2019 04:04:00 am		

Minimum Specified Dose (kGy):	**40.0**	**Minimum Delivered Dose (kGy):**	**42.1**
Maximum Specified Dose (kGy):	**60.0**	**Maximum Delivered Dose (kGy):**	**50.8**

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Francine Maranda (QS & RC Analyst)
Document Content Revision: 1

Signed On 1/21/2019 at 8:48 AM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS
435 Whitney Street
Northborough, MA 01532
Phone: 508-393-9323
Fax: 844-698-9776

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137 or EN ANSI/AAMI/ISO 11135. For items processed with gamma irradiation, STERIS certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.

WI-00034/01354/01369 Last Rev in Rel. 3.6.5.1 Release Date 05-Jun-2017 Page 1 of 1

STERIS

STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for EMD MILLIPORE – BEDFORD
Process Run ID 117005A
Date Prepared: 1/21/2019 8:47:34AM

Processing Location: **Northborough**
Irradiator / Method: **126, Nordion Cobalt-60 Irradiator #126, ON-STD**

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
Final Dose Measurements							
1	1	0C1	0BR600288204	TH0049	0484	28.7	42.1
			0BR600257802	TH0048	0481	13.4	
1	2	TA5	0BR600288439	TH0049	0484	34.4	50.5
			0BR600257878	TH0048	0481	16.1	
1	3	TE5	0BR600288499	TH0049	0484	34.7	50.8
			0BR600257886	TH0048	0481	16.1	

Minimum Dose for Record (kGy): 42.1
Maximum Dose for Record (kGy): 50.8

Signature Manifest

Prepared By:
Baez, Hector (Material Handler)
Signed On 1/21/2019 at 6:23 AM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
Francine Maranda (QS & RC Analyst)
Signed On 1/21/2019 at 8:47 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

WI-08074 Last Rev DMA 2.0.1.0 & RT 3.6.5.1 Release Date: 05-Jun-2017

Page 1 of 1

9.6 Appendix F- Calibration Certificate of pressure gauge used in 8.1

INNOCAL®
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625 East Bunker Court
Vernon Hills, Illinois 60061
PH: 866-466-6225
Fax: 847-327-2993
www.innocalsolutions.com

NIST Traceable
Calibration Report

REPORT NUMBER
769832
Reference Number: **661706**
PO Number: **RANDD**

Pendotech
3490 US Rte 1
Bldg 15 F
Princeton, NJ 08540 United States

Manufacturer:	Druck Inc.	**Calibration Date:**	07/13/2015
Model Number:	DPI 104	**Calibration Due Date:**	07/13/2016
Description:	Pressure, Digital Pressure Indicator	**Condition As Found:**	In Tolerance
Asset Number:	CP91719	**Condition As Left:**	In Tolerance, No adjustment
Serial Number:	3674169		
Procedure:	DS Universal Pressure Gauge-10		

Remarks:
NIST-traceable calibration performed on the unit referenced above in accordance with customer requirements, published specifications and the lab's standard operating procedures. No adjustments were made to the unit.

Standards Utilized

Asset No.	Manufacturer	Model No.	Description	Cal. Date	Due Date
CP05091	DH Instruments Inc.	PPC3-700K A700KS/G100KS	Pressure, -14.7 to 100 psi Calibrator	02/10/2015	02/10/2016

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
Increasing	0.000 psi	0.00		Same		-0.050 to 0.050 psi [EMU 0.00075 psi][TUR 67:1]
|	10.000 psi	10.00		Same		9.950 to 10.050 psi [EMU 0.0012 psi][TUR 41:1]
|	20.000 psi	20.00		Same		19.950 to 20.050 psi [EMU 0.0031 psi][TUR 16:1]
|	30.000 psi	30.00		Same		29.950 to 30.050 psi [EMU 0.0031 psi][TUR 16:1]
|	40.000 psi	40.00		Same		39.950 to 40.050 psi [EMU 0.0040 psi][TUR 12:1]
|	50.000 psi	50.00		Same		49.950 to 50.050 psi [EMU 0.0050 psi][TUR 9.9:1]
|	60.000 psi	60.00		Same		59.950 to 60.050 psi [EMU 0.0060 psi][TUR 8.3:1]
|	70.000 psi	70.00		Same		69.950 to 70.050 psi [EMU 0.0070 psi][TUR 7.1:1]
|	80.000 psi	80.00		Same		79.950 to 80.050 psi [EMU 0.0080 psi][TUR 6.2:1]
|	90.000 psi	90.00		Same		89.950 to 90.050 psi [EMU 0.0090 psi][TUR 5.5:1]
|	100.000 psi	100.00		Same		99.950 to 100.050 psi [EMU 0.010 psi][TUR 5.0:1]
Decreasing	90.000 psi	90.00		Same		89.950 to 90.050 psi [EMU 0.0090 psi][TUR 5.5:1]
|	80.000 psi	80.00		Same		79.950 to 80.050 psi [EMU 0.0080 psi][TUR 6.2:1]
|	70.000 psi	70.00		Same		69.950 to 70.050 psi [EMU 0.0070 psi][TUR 7.1:1]
|	60.000 psi	60.00		Same		59.950 to 60.050 psi [EMU 0.0060 psi][TUR 8.3:1]
|	50.000 psi	50.00		Same		49.950 to 50.050 psi [EMU 0.0050 psi][TUR 9.9:1]
|	40.000 psi	40.00		Same		39.950 to 40.050 psi [EMU 0.0040 psi][TUR 12:1]
|	30.000 psi	30.00		Same		29.950 to 30.050 psi [EMU 0.0031 psi][TUR 16:1]

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Page 1 of 2

9.7 Appendix G- Certificate of Gamma Radiation for Section 8.3

Certificate Of Processing

STERIS

Prepared for **ADVANCED SCIENTIFICS INC**

Gamma Process Run ID **91935A**

Product Code	Product Lot Number	Quantity	UOM
GROUP 69	JASON P SAMP / JASON P-SAMP	1	CS
GROUP 69	NA / JULIE-SAMP	1	CS

Processing Run Start Date/Time:	13-Jan-2018 07:25:00 am	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	13-Jan-2018 08:42:00 am		

Minimum Specified Dose (kGy):	**27.5**	**Minimum Delivered Dose (kGy):**	**30.4**
Maximum Specified Dose (kGy):	**45.0**	**Maximum Delivered Dose (kGy):**	**35.1**

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Caitlin Davies (QS/RC Technician)
Document Content Revision: 1

Signed On 1/13/2018 at 3:57 PM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS
9 Apollo Drive
Whippany, NJ 07981
Phone: 973-887-2754
Fax: 973-887-6591

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

WI-00034/01364/01369 Last Rev in Rel. 3.6.5.1 Release Date: 05-Jan-2017 Page 1 of 1

STERIS

STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for ADVANCED SCIENTIFICS INC
Process Run ID 91935A
Date Prepared: 1/13/2018 3:56:41PM

Processing Location: **Whippany**

Irradiator / Method: **131, Nordion Cobalt-60 Irradiator #131, ON-STD**

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
Final Dose Measurements							
1	1	2C1	0BG592038541	TH0096	0482	31.5	31.5
1	2	2C5	0BG592038836	TH0096	0482	31.1	31.1
1	3	2C8.8	0BG592038532	TH0096	0482	30.4	30.4
1	4	3A5	0BG592038835	TH0096	0482	35.1	35.1
1	5	3E5	0BG592038833	TH0096	0482	34.9	34.9
1	6	TBA5	0BG592038732	TH0096	0482	33.4	33.4
1	7	TBE5	0BG592038830	TH0096	0482	34.3	34.3

Minimum Dose for Record (kGy): 30.4

Maximum Dose for Record (kGy): 35.1

Signature Manifest

Prepared By:
Thomas Meier (Cell Operator)
Signed On 1/13/2018 at 9:00 AM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
Caitlin Davies (QS/RC Technician)
Signed On 1/13/2018 at 3:56 PM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

Certificate Of Processing

STERIS

Prepared for **ADVANCED SCIENTIFICS INC**

Gamma Process Run ID **205239D**

Product Code	Product Lot Number	Quantity	UOM
GROUP 501	B109735-I / 97MNV-0000	10	CS
GROUP 501	B109735-I / 97MNW-0000	10	CS
GROUP 69	JASON P SAMP / JASON P-SAMP	1	CS
GROUP 7	100001926 / 97MSE-0000	5	CS
GROUP 7	B106522-I / 97LRX-0000	1	CS
GROUP 7	B108295-I / 97LXH-0000	22	CS
GROUP 7	B109173-I / 97MCJ-0000	1	CS
GROUP 7	B109174-I / 97MCK-0000	1	CS
GROUP 7	B109344-I / 97K2U-0000	5	CS
GROUP 7	B109606-I / 97MCL-0000	1	CS
GROUP 7	B109606-I / 97MG3-0000	1	CS
GROUP 7	B113538-I / 97LXL-0000	1	CS
GROUP 7	B114444-I / 97MMZ-0000	1	CS
GROUP 7	B114958-I / 97KBX-0000	7	CS

Processing Run Start Date/Time:	22-Jan-2018 08:34:28 am	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	22-Jan-2018 10:34:09 am		

Minimum Specified Dose (kGy):	**27.5**	**Minimum Delivered Dose (kGy):**	**29.0**
Maximum Specified Dose (kGy):	**45.0**	**Maximum Delivered Dose (kGy):**	**42.1**

Product meets Customer specifications, zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Tracy Wild (QS/RC Technician)
Document Content Revision: 1

Signed On 1/23/2018 at 12:44 PM
UTC / GMT Offset (hr:min): -5:00

Processing Location:
STERIS
23 Elizabeth Drive
Chester, NY 10918
Phone: 845-469-4087
Fax: 845-469-7512

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

WI-00034/01354/01389 Last Rev in Rel. 3.6.5.1 Release Date: 05-Jan-2017 Page 1 of 1

STERIS

STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for ADVANCED SCIENTIFICS INC
Process Run ID 205239D
Date Prepared: 1/23/2018 12:17:21PM

Processing Location: **Chester**
Irradiator / Method: **239, Nordion Cobalt-60 Irradiator #239, Cont Batch**

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
		Minimum Dose for Record (kGy):			**29.0**		
		Maximum Dose for Record (kGy):			**42.1**		

Signature Manifest

Prepared By:
James Calone (Material Handler II)
Signed On 1/22/2018 at 12:40 PM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
Tracy Wild (QS/RC Technician)
Signed On 1/23/2018 at 12:17 PM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

WI-00074 Last Rev DMA 2.0.1.0 & RT 3.6.5.1 Release Date: 05-Jun-2017 Page 4 of 4

9.8 Appendix H- Calibration Certificate for Pressure Gauge used in 8.3

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625 East Bunker Court
Vernon Hills, Illinois 60061
PH: 866-466-6225
Fax: 847-327-2993
www.innocalsolutions.com

NIST Traceable
Calibration Report

REPORT NUMBER
1625826

Reference Number: **1392386**
PO Number: **RANDD**

PendoTECH
3490 US Route 1
Building 15F
Princeton, NJ 08540 United States

Manufacturer:	Druck Inc.	**Calibration Date:**	08/27/2020
Model Number:	DPI 104 0-100 PSI	**Calibration Due Date:**	08/27/2021
Description:	Pressure, Digital Gauge, 0-100 PSI	**Condition As Found:**	In Tolerance
Asset Number:	CP91719	**Condition As Left:**	In Tolerance, No adjustment
Serial Number:	3674169		
Procedure:	DS Druck DPI 104 0-100PSI		

Remarks:
NIST-traceable calibration performed on the unit referenced above in accordance with customer requirements, published specifications and the lab's standard operating procedures. No adjustments were made to the unit.

Standards Utilized

Asset No.	Manufacturer	Model No.	Description	Cal. Date	Due Date
CP144957	Fluke Corporation	PM600-G100K	Pressure, Measurement Module 0 - 15PSI	06/02/2020	06/30/2021
CP144959	Fluke Corporation	PM600-A700K	Pressure, Measurement Mod -12.1 -100PSI	06/03/2020	06/30/2021

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
Zero Reference	0.00	0.00		Same		Reference Only
Increasing Pressure Accuracy	10.00 psi	10.00		Same		9.95 to 10.05 psi [EMU 0.0071 psi][TUR 7.1:1]
"	20.00 psi	20.00		Same		19.95 to 20.05 psi [EMU 0.0095 psi][TUR 5.3:1]
"	30.00 psi	30.00		Same		29.95 to 30.05 psi [EMU 0.01 psi][TUR 4.8:1]
"	40.00 psi	40.00		Same		39.95 to 40.05 psi [EMU 0.012 psi][TUR 4.3:1]
"	50.00 psi	50.00		Same		49.95 to 50.05 psi [EMU 0.013 psi][TUR 3.9:1]
"	60.00 psi	60.00		Same		59.95 to 60.05 psi [EMU 0.014 psi][TUR 3.5:1]
"	70.00 psi	70.00		Same		69.95 to 70.05 psi [EMU 0.015 psi][TUR 3.3:1]
"	80.00 psi	80.00		Same		79.95 to 80.05 psi [EMU 0.016 psi][TUR 3.1:1]
"	90.00 psi	90.00		Same		89.95 to 90.05 psi [EMU 0.017 psi][TUR 2.9:1]
"	100.00 psi	99.99		Same		99.95 to 100.05 psi [EMU 0.019 psi][TUR 2.6:1]
Decreasing Pressure Test	90.00 psi	90.00		Same		89.95 to 90.05 psi [EMU 0.017 psi][TUR 2.9:1]
"	80.00 psi	80.00		Same		79.95 to 80.05 psi [EMU 0.016 psi][TUR 3.1:1]
"	70.00 psi	70.00		Same		69.95 to 70.05 psi [EMU 0.015 psi][TUR 3.3:1]
"	60.00 psi	60.00		Same		59.95 to 60.05 psi [EMU 0.014 psi][TUR 3.5:1]
"	50.00 psi	50.00		Same		49.95 to 50.05 psi [EMU 0.013 psi][TUR 3.9:1]
"	40.00 psi	40.00		Same		39.95 to 40.05 psi [EMU 0.012 psi][TUR 4.3:1]
"	30.00 psi	30.00		Same		29.95 to 30.05 psi [EMU 0.01 psi][TUR 4.8:1]

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Page 1 of 2

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
	20.00 psi	20.00		Same		19.95 to 20.05 psi [EMU 0.0095 psi][TUR 5.3:1]
	10.00 psi	10.00		Same		9.95 to 10.05 psi [EMU 0.0071 psi][TUR 7.1:1]
Zero Reference	0.000 psi	0.00		Same		Reference Only

Temperature: 20° C
Humidity: 55% RH
Rpt. No.: 1625826

Calibration Performed By:				Quality Reviewer:	
Gonzalez, Jaime	303	Metrologist	847-327-5322	Szplit, Tony	08/27/2020
Name	ID #	Title	Phone	Name	Date

Report Number: 1625826 *Druck Inc. / DPI 104 0-100 PSI, Pressure, Digital Gauge, 0-100 PSI*

Page 2 of 2

9.9 Appendix I – X-ray Certificate of Processing for section 7.4/8.4

STERIS

Manual Certificate of Processing

Prepared For: PENDOTECH

Processing Run ID: 10834-40001554

Product Code	Product Lot Number	Quantity	UOM
N/A	NA	1	CS

Other Information: Description: Single Use Sensors. PO # 2016692

Processing Run Start Date/Time: 07/14/2021, 7:24AM CST
Processing Run End Date/Time: 08/19/2021, 7:28AM CST
Approximate Downtime (Hours): 0.00

Minimum Specified Dose (kGy):	50.0	**Minimum Delivered Dose (kGy):**	61.8
Maximum Specified Dose (kGy):	70.0	**Maximum Delivered Dose (kGy):**	64.5

A nonconformity occurred during this irradiation run – Reference Customer Disposition.
Reference: NC-23394
Comments: Dose added to meet requested dose range. Dose range within Customer requested dose range.

Latrice Sutherland, 08/23/2021, 07:27AM CST
QA Manager Approval / Date / Time (Print and Sign)

Michael Ezzo 8/23/2021 10:42AM EST
Quality Zone Director Approval / Date / Time (Print and Sign)

Processing Location:	Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used and/or Customer approval.
2500 Commerce Drive Libertyville, IL. 60048 847-247-4782	

WI-01678 Form: 2 Rev: 0 Eff Date: **Oct 19, 2018** Status: **07b. Completed: All Gamma Facilities** **Page 1 of 1**

STERIS Manual Dosimetry Record
(Alanine Dosimetry System)

Prepared For: PENDOTECH
Process Run ID: 10834-40001554
Date and Time Prepared: 08/23/2021 6:55AM

Processing Location:RTC
Irradiator / Method:EBIR-03

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Initial Dose (kGy)	Final Dose (kGy)	Measurement Source
1	1	1	0BX592076386	'0040	11-0186	0.0	62.9	13.1
1	1	1	0BX592026099	'0040	11-0186	0.0	0.0	49.8
1	1	2	0BX592076219	'0040	11-0186	0.0	61.8	12.5
1	1	2	0BX592020042	'0040	11-0186	0.0	0.0	49.3
1	1	3	0BX592076365	'0040	11-0186	0.0	63.8	13.5
1	1	3	0BX592020005	'0040	11-0186	0.0	0.0	50.3
1	1	4	0BX592076319	'0040	11-0186	0.0	61.8	12.8
1	1	4	0BX592020069	'0040	11-0186	0.0	0.0	49.0
1	1	5	0BX592076103	'0040	11-0186	0.0	64.5	13.6
1	1	5	0BX592026490		11-0186	0.0	0.0	50.9

Minimum Dose for Record (kGy): *61.8*
Maximum Dose for Record (kGy): *64.5*

Other Information:	Refer to NC-23394. Measurement Source shows the acutal dose for each dosimeter location, the final dose reports the total dose for both dosimeters for each location. The dose reported on this record is one signnificant figure.

Prepared By Print Name / Title / Sign and Date: Latrice Sutherland, OSEC Manager, [signature] 8-23-21

QA Approved Print Name / Title / Sign and Date: Hailey Mayer, QA Tech I, [signature] 8/23/21

9.10 Appendix J- Calibration Certificate for Pressure Gauge Used in 8.4

INNOCAL®
INNOVATIVE CALIBRATION SOLUTIONS
625 East Bunker Court
Vernon Hills, Illinois 60061
PH: 866-466-6225
Fax: 847-327-2993
www.innocalsolutions.com

NIST Traceable
Calibration Report

REPORT NUMBER
1662895

Reference Number: **1408403**
PO Number: **RANDD**

OK TO use
June
Sept 7, 2021

PendoTECH
3490 US Route 1
Princeton, NJ 08540 United States

Manufacturer:	Digi-Sense	**Calibration Date:**	08/24/2021
Model Number:	68349-06	**Calibration Due Date:**	08/24/2022
Description:	Pressure, Digital Gauge, 0 to 100 psig	**Condition As Found:**	In Tolerance
Asset Number:	CP355333	**Condition As Left:**	In Tolerance, No adjustment
Serial Number:	1912310225		
Procedure:	DS Universal Pressure Gauge-10		

Remarks:
NIST-traceable calibration performed on the unit referenced above in accordance with customer requirements, published specifications and the lab's standard operating procedures. No adjustments were made to the unit.

Standards Utilized

Asset No.	Manufacturer	Model No.	Description	Cal. Date	Due Date
CP144959	Fluke Corporation	PM600-A700K	Pressure, Measurement Mod -12.1 -100PSI	07/08/2021	07/31/2022

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
Increasing	0.000 psi	0.00		Same		-0.250 to 0.250 psi [EMU 0.00058 psi][TUR 428:1]
	10.000 psi	9.98		Same		9.750 to 10.250 psi [EMU 0.0014 psi][TUR 175:1]
	20.000 psi	20.01		Same		19.750 to 20.250 psi [EMU 0.0054 psi][TUR 46:1]
	30.000 psi	30.02		Same		29.750 to 30.250 psi [EMU 0.0059 psi][TUR 42:1]
	40.000 psi	40.02		Same		39.750 to 40.250 psi [EMU 0.0069 psi][TUR 36:1]
	50.000 psi	50.01		Same		49.750 to 50.250 psi [EMU 0.0079 psi][TUR 32:1]
	60.000 psi	60.01		Same		59.750 to 60.250 psi [EMU 0.0089 psi][TUR 28:1]
	70.000 psi	70.02		Same		69.750 to 70.250 psi [EMU 0.0099 psi][TUR 25:1]
	80.000 psi	80.01		Same		79.750 to 80.250 psi [EMU 0.011 psi][TUR 23:1]
	90.000 psi	90.01		Same		89.750 to 90.250 psi [EMU 0.012 psi][TUR 21:1]
	100.000 psi	100.02		Same		99.750 to 100.250 psi [EMU 0.013 psi][TUR 19:1]
Decreasing	90.000 psi	90.02		Same		89.750 to 90.250 psi [EMU 0.012 psi][TUR 21:1]
	80.000 psi	80.02		Same		79.750 to 80.250 psi [EMU 0.011 psi][TUR 23:1]
	70.000 psi	70.02		Same		69.750 to 70.250 psi [EMU 0.0099 psi][TUR 25:1]
	60.000 psi	60.03		Same		59.750 to 60.250 psi [EMU 0.0089 psi][TUR 28:1]
	50.000 psi	50.02		Same		49.750 to 50.250 psi [EMU 0.0079 psi][TUR 32:1]
	40.000 psi	40.02		Same		39.750 to 40.250 psi [EMU 0.0069 psi][TUR 36:1]
	30.000 psi	30.03		Same		29.750 to 30.250 psi [EMU 0.0059 psi][TUR 42:1]
	20.000 psi	20.01		Same		19.750 to 20.250 psi [EMU 0.0054 psi][TUR 46:1]

Cole-Parmer Traceable DIGI-SENSE OAKTON

Page 1 of 2

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
	10.000 psi	9.99		Same		9.750 to 10.250 psi [EMU 0.0014 psi][TUR 175.1]
	0.000 psi	0.00		Same		-0.250 to 0.250 psi [EMU 0.00058 psi][TUR 428.1]

Temperature: 19° C
Humidity: 61% RH
Rpt. No.: 1662895

Calibration Performed By:				Quality Reviewer:	
Fitzsimons, Sean	357	Metrologist	847-327-5305	Alexander, James	08/24/2021
Name	ID #	Title	Phone	Name	Date

Report Number: 1662895

Digi-Sense / 68349-06, Pressure, Digital Gauge, 0 to 100 psig

Cole-Parmer® Traceable® DIGI-SENSE OAKTON®

Page 2 of 2

9.11 Appendix K- Assembled Sensor Certificate: ISO 10993-5 post X-ray irradiation

Nelson Labs.
A Sotera Health company

Sponsor:
Nick Troise
PendoTECH
3490 US-1
Princeton, NJ 08540

MEM Elution GLP Report

Test Article:	PendoTECH Single Use UV/Turbidity Flow Cells Post X-ray Irradiation (> 50kGy)
Purchase Order:	2017882
Study Number:	1496723-S01
Study Received Date:	08 Mar 2022
Test Started Date:	12 Apr 2022
Test Finished Date:	19 Apr 2022
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: STP0032 Rev 11
Deviation(s):	None

Summary: The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. All test method acceptance criteria were met.

Results:
Test Article:

Results Pass/Fail	Scores				Amount Tested / Extraction Solvent Amount
	#1	#2	#3	Average	
Pass	0	0	0	0	Fluid Pathway / 5.6 mL

Controls:

Identification	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount
	#1	#2	#3	Average		
Negative Control - Polypropylene Pellets	0	0	0	0	0.2 g/mL	4 g / 20 mL
Media Control	0	0	0	0	N/A	20 mL
Positive Control - Latex Natural Rubber	4	4	4	4	0.2 g/mL	4 g / 20 mL

Brittany Love electronically approved
Study Director Brittany Love

21 Apr 2022 22:23 (+00:00)
Study Completion Date and Time

STERIS

Manual Certificate of Processing

Prepared For: PENDOTECH

Processing Run ID: 10834-40001554

Product Code	Product Lot Number	Quantity	UOM
N/A	NA	1	CS

Other Information: Description: Single Use Sensors. PO # 2016692

Processing Run Start Date/Time: 07/14/2021, 7:24AM CST
Processing Run End Date/Time: 08/19/2021, 7:28AM CST
Approximate Downtime (Hours): 0.00

Minimum Specified Dose (kGy):	50.0	**Minimum Delivered Dose (kGy):**	61.8
Maximum Specified Dose (kGy):	70.0	**Maximum Delivered Dose (kGy):**	64.5

A nonconformity occurred during this irradiation run – Reference Customer Disposition.
Reference: NC-23394
Comments: Dose added to meet requested dose range. Dose range within Customer requested dose range.

Latrice Sutherland, 08/23/2021, 07:27AM CST
QA Manager Approval / Date / Time (Print and Sign)

Michael Ezzo 8/23/2021 10:42AM EST
Quality Zone Director Approval / Date / Time (Print and Sign)

Processing Location:	
2500 Commerce Drive Libertyville, IL. 60048 847-247-4782	Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used and/or Customer approval.

WI-01678 Form: 2 Rev: 0 Eff Date: Oct 19, 2018 Status: 07b. Completed: All Gamma Facilities Page 1 of 1

STERIS Manual Dosimetry Record
(Alanine Dosimetry System)

Prepared For: PENDOTECH
Process Run ID: 10834-40001554
Date and Time Prepared: 08/23/2021 6:55AM

Processing Location:RTC
Irradiator / Method:EBIR-03

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Initial Dose (kGy)	Final Dose (kGy)	Measurement Source
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1	1	1	0BX592026099	'0040	11-0186	0.0	0.0	49.8
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1	1	2	0BX592020042	'0040	11-0186	0.0	0.0	49.3
1	1	3	0BX592076365	'0040	11-0186	0.0	63.8	13.5
1	1	3	0BX592020005	'0040	11-0186	0.0	0.0	50.3
1	1	4	0BX592076319	'0040	11-0186	0.0	61.8	12.8
1	1	4	0BX592020069	'0040	11-0186	0.0	0.0	49.0
1	1	5	0BX592076103	'0040	11-0186	0.0	64.5	13.6
1	1	5	0BX592026490		11-0186	0.0	0.0	50.9

Minimum Dose for Record (kGy): ***61.8***
Maximum Dose for Record (kGy): ***64.5***

Other Information:	Refer to NC-23394. Measurement Source shows the acutal dose for each dosimeter location, the final dose reports the total dose for both dosimeters for each location. The dose reported on this record is one signnificant figure.

Prepared By Print Name / Title / Sign and Date: Latrice Sutherland, OSEC Manager, [signature] 8-23-21

QA Approved Print Name / Title / Sign and Date: Hailey Mayer, QA Tech I, [signature] 8/23/21