

**INTERNAL PRESSURE AND
THERMAL SHOCK / PRESSURE DIFFERENTIAL TESTING**



B1002-OCC - 100 mL Sterile StarClick Specimen Container

TEST REPORT #: 17-MN10296

TESTING PERFORMED FOR:

STARPLEX SCIENTIFIC, INC.

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TESTING PERFORMED BY:

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September 26, 2017

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OBJECTIVE

To conduct Internal Pressure and Thermal Shock /Pressure Differential testing on the follow design:

- B1002-OCC – 100 mL Sterile StarClick Specimen Container

REGULATORY REFERENCES

TEST	49 CFR ^①	UN ^②	IMDG ^③	ICAO ^④	IATA ^⑤
	October 2016 Edition	19 th Edition	2016 Edition	2017-2018 Edition	58 th Edition
Pressure:	173.196(a)(6) 173.199(b)(4)	P 620(3) P 650(7)(e)	P 620(3) 173.199(b)(4)	PI 620(e) 173.199(b)(4)	PI 620 173.199(b)(4)
Thermal Shock/ Pressure Differential	---	---	---	---	PI 650(a)

① United States Department of Transportation Code of Federal Regulations (CFR) Title 49, Transportation, Parts 100-185

② The United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations (UN – Orange Book)

③ International Maritime Dangerous Goods Code (IMDG)

④ Technical Instructions for the Safe Transport of Dangerous Good by Air (ICAO)


⑤ International Air Transport Association (IATA) Dangerous Goods Regulations

EQUIPMENT

All inspection, measuring and test equipment that can affect product quality is calibrated and adjusted at prescribed intervals, or prior to use, and is traceable to NIST, using ANSI Z540 as an overall guide for calibration certification.

PACKAGING DESCRIPTIONS / COMPONENT DRAWINGS

B1002-OCC – 100 mL Sterile StarClick Specimen Container


CLOSURE		DRAWING
Description:	56 mm Threaded Closure	
Material:	High Density Polyethylene, Orange	
Tare Weight:	6.933 Grams	
Overall Dimensions:		
• Height	0.622"	
• Diameter	2.378"	
Thread Dimensions:		
• T	2.243"	
• E	2.157"	
Markings (QC Audit):	2 SPI "2" HDPE Recycling Symbol	
CONTAINER		
Description:	100 mL StarClick Specimen Container	
Material:	Polypropylene, Natural	
Method of Manufacture:	Injection Molded	
Tare Weight:	10.805 Grams	
Capacity:		
• Rated	100 mL	
• Overflow	111 mL	
Overall Dimensions:		
• Height	2.547"	
• Top Diameter	2.213"	
• Bottom Diameter:	1.927"	
Thread Dimensions:		
• T	2.194"	
• E	2.072"	
Markings (QC Audit):	8 MADE IN USA MFG 08/24/2017 14:36 SPI "5" PP Recycling Symbol	

TEST PROCEDURES AND RESULTS

PRESSURE DIFFERENTIAL TEST

TEST INFORMATION		TEST CRITERIA
SAMPLE SIZE:	3	<ul style="list-style-type: none"> The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi). (§173.196(a)(6))
TEST CONTENTS:	Isopropyl Alcohol	
FILL CAPACITY:	Maximum Capacity	
CLOSURE APPLICATION TORQUE:	30.3 In-Lbs.	
CONDITIONING:	Ambient	
TEST PRESSURE:	28 inHg (95 kPa)	
TEST DURATION:	30 Minutes	
TEST DATE:	September 18, 2017	
TEST EQUIPMENT:	Tenney 6S Vacuum Chamber #: 618 Vacuum Pressure Gauge #: 612 Torque Meter #: 741	

VACUUM TEST SET-UP AND RESULTS

	Sample #	Results	Comments/Observations
	1	PASS	All three samples maintained the 28 inHg test pressure for 30 minutes without leakage.
	2	PASS	
	3	PASS	

THERMAL SHOCK AND PRESSURE DIFFERENTIAL (VACUUM) TESTS

TEST INFORMATION		TEST CRITERIA
SAMPLE SIZE:	3	<ul style="list-style-type: none"> The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa in the range of -40°C to 55°C (-40°F to 131°F) (IATA PI 650)
TEST CONTENTS:	Antifreeze Solution	
FILL CAPACITY:	98% of Overflow Capacity	
CONDITIONING:	-40°C (-40°F) to +55°C (+131°F)	
TEST PRESSURE:	28 inHg (95 kPa)	
CLOSURE APPLICATION TORQUE:	30.3 In-Lbs.	
DURATION:	Thermal Shock: 2 Hours at -40°C (-40°F) 2 Hours at +55°C (+131°F) Pressure Differential: 28 In-Hg (95 kPa) 30 minutes at each condition	
TEST DATE:	September 26, 2017	
TEST EQUIPMENT:	Environmental Chambers #242 & #236 Welch Vacuum Pump #628 Ashcroft Vacuum Pressure Gauge #629 TEN-E Vacuum Chamber #630 Torque Meter #741 Ohaus Gram Scale #137	

*Refer to the following page for temperature recordings.

TEST PROCEDURE

Test #1: (-40°C) Thermal Shock/Pressure Differential

Samples were placed on their sides on a piece of blotting paper in the (-40°C) chamber for 2 hours. If after 2 hours no leakage was evident, a 28 In-Hg vacuum test was performed at (-40°C) for 30 minutes. Following the 30 minute vacuum test samples were evaluated for leakage.

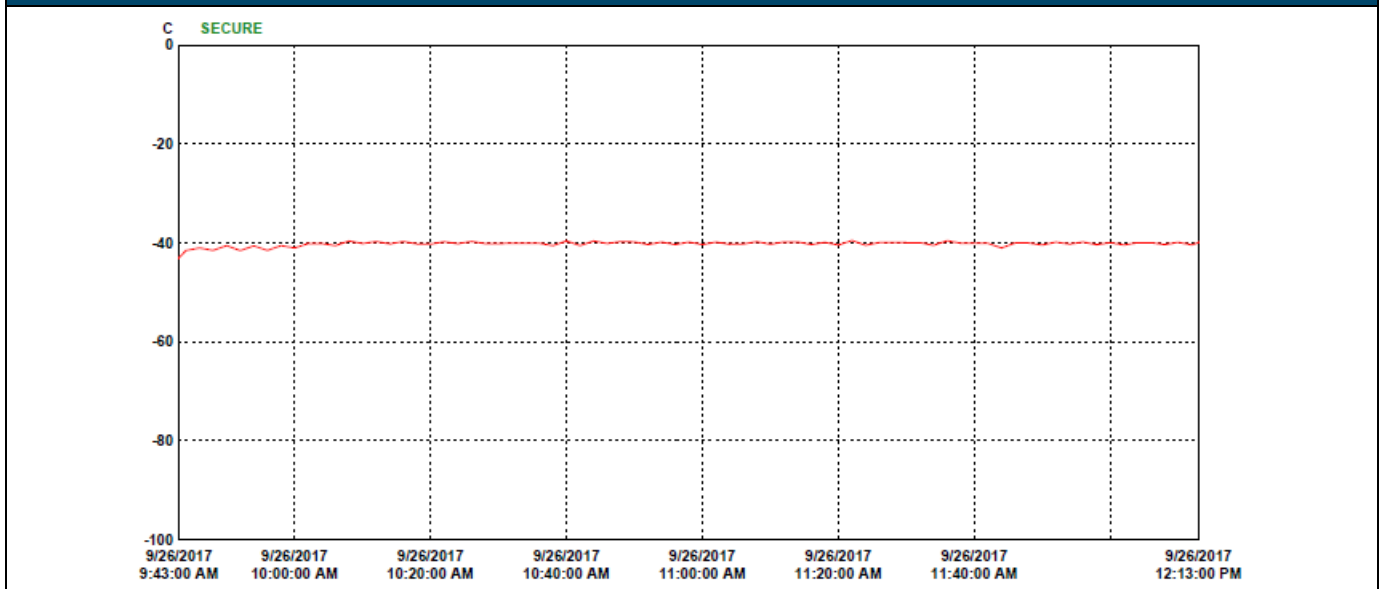
Test #2: (+55°C) Thermal Shock/Pressure Differential

Immediately following thermal shock/pressure differential tests at (-40°C), samples were placed on their sides on a piece of blotting paper in the (+55°C) chamber for 2 hours. If after 2 hours no leakage was evident, a 28 In-Hg vacuum test was performed at (+55°C) for 30 minutes. Following the 30 minute vacuum test samples were evaluated for leakage.

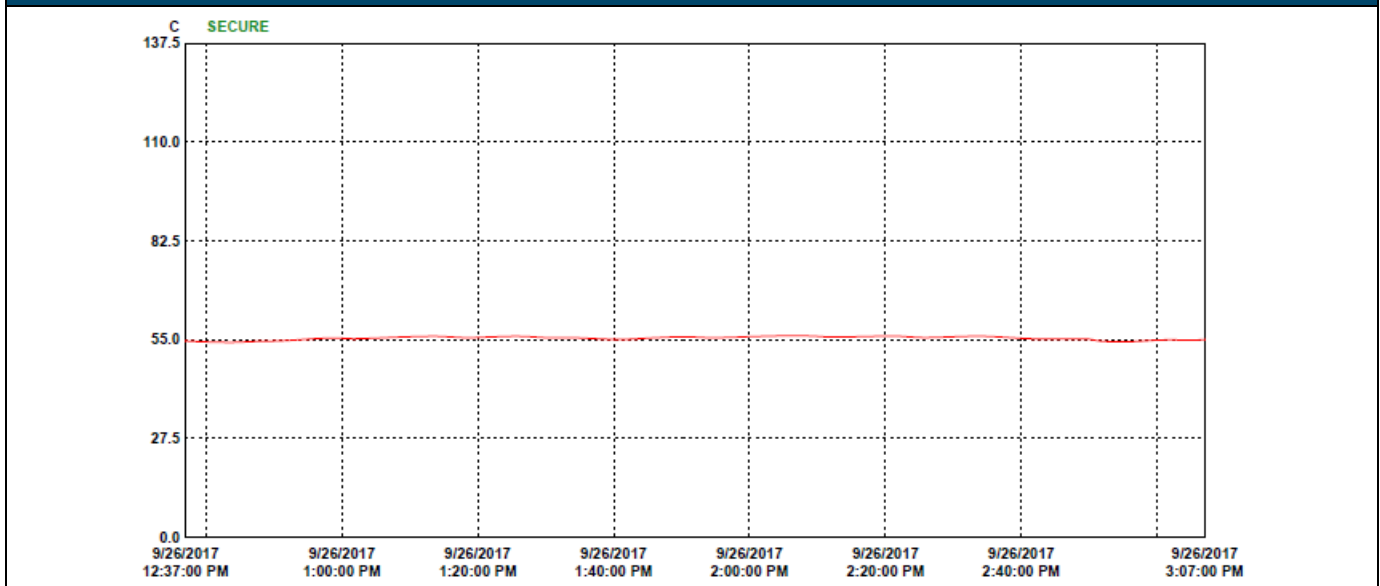
THERMAL SHOCK AND PRESSURE DIFFERENTIAL (VACUUM) TESTS CONTINUED

Test	Chamber ID	Temperature °C	Minimum Duration	Start (Date & Time)	Stop (Date & Time)
1	242	-40°C	2 Hours	9/26/17 @ 9:43 am	9/26/17 @ 12:24 pm
2	236	+55°C	2 Hours	9/26/17 @ 12:37 pm	9/26/17 @ 3:35 pm

-40°C (-40°F) TEMPERATURE DATA

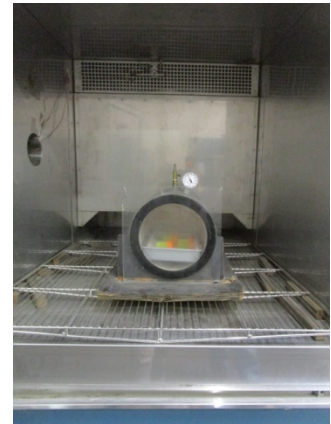


+55°C (+131°F) TEMPERATURE DATA



THERMAL SHOCK AND PRESSURE DIFFERENTIAL (VACUUM) TESTS CONTINUED

THERMAL SHOCK/PRESSURE DIFFERENTIAL TEST SETUP



THERMAL SHOCK/PRESSURE DIFFERENTIAL TEST

Sample ID	Cap Cavity	Vial Cavity	-40°C		+55°C	
			Thermal Shock Test (2 Hours)	28 In-Hg Pressure Differential Test (30 Minutes)	Thermal Shock Test (2 Hours)	28 In-Hg Pressure Differential Test (30 Minutes)
1	1	6	Pass	Pass	Pass	Pass
2	7	7	Pass	Pass	Pass	Pass
3	7	8	Pass	Pass	Pass	Pass

Observation

No leakage of contents following thermal shock/pressure differential test in the temperature range of -40°C to +55°C.

DISCLAIMER OF WARRANTIES

TEN-E PACKAGING SERVICES, INC. certifies that the previously described testing services have been performed in accordance with standard good laboratory practices and the Department of Transportation's Title 49 CFR; 173.196 and 173.199, the International Civil Aviation Organization (ICAO); Technical Instructions for the Safe Transport of Dangerous Goods By Air and the International Air Transport Association (IATA); Dangerous Goods Regulations; P 620 and 650. The results included within this test report relate only to the items tested. **ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY THAT THE PACKAGING TESTED IS MERCHANTABILITY OR FIT FOR A PARTICULAR PURPOSE, ARE DISCLAIMED.** In no event shall TEN-E Packaging Services, Inc. liability exceed the total amount paid by **Starplex Scientific, Inc.** for services rendered.

In the event of future changes to the above referenced test standard, it is the responsibility of **Starplex Scientific, Inc.** to determine whether additional testing or updating of past testing is necessary to verify that the packaging we have tested remains in compliance with those standards.


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