

**PRESSURE DIFFERENTIAL AND
THERMAL SHOCK/PRESSURE DIFFERENTIAL
EVALUATION**



B602-10, V302 and B202-1WNL Vial Variables

TEST REPORT #: 13-1054

TESTING PERFORMED FOR:

STARPLEX SCIENTIFIC, INC.

50A Steinway Boulevard
Etobicoke, ON M9W 6Y3

ATTN: Shirley Walker

TESTING PERFORMED BY:

TEN-E PACKAGING SERVICES, INC.

1666 County Road 74
Newport, MN 55055
Phone: 651-459-0671
Fax: 651-459-1430

February 26, 2013

TABLE OF CONTENTS

OBJECTIVE	2
REGULATORY REFERENCES	2
COMPONENT INFORMATION (TEN-E Packaging Services Quality Control Audit)	3
TEST PROCEDURES AND RESULTS	6
PRESSURE DIFFERENTIAL TEST B202-1WNL (Lot # 1B18).....	6
PRESSURE DIFFERENTIAL TEST V302 (Lot # 2C22)	7
PRESSURE DIFFERENTIAL TEST B602-10 (Lot # 2M12-1).....	8
TEST PROCEDURES AND RESULTS	9
THERMAL SHOCK AND PRESSURE DIFFERENTIAL (VACUUM) TESTS.....	9
DISCLAIMER OF WARRANTIES	14

OBJECTIVE

To conduct Pressure Differential and Thermal Shock/Pressure Differential Testing on the follow design(s):

- B602-10, V302 and B202-1WNL Vial Variables

REGULATORY REFERENCES

TEST	49 CFR ^①	UN ^②	IMDG ^③	ICAO ^④	IATA ^⑤
	October 2011 Edition	17 th Edition	2010 Edition	2011-2012 Edition	53 rd Edition
Pressure:	173.196(a)(6)	P 620(3)	P 620(3)	PI 620(e)	PI 620
Thermal Shock:	173.196(a)(7)	P 620(3)	P 620(3)	PI 620(e)	PI 620
Thermal Shock with Pressure:	---	---	---	---	PI 650

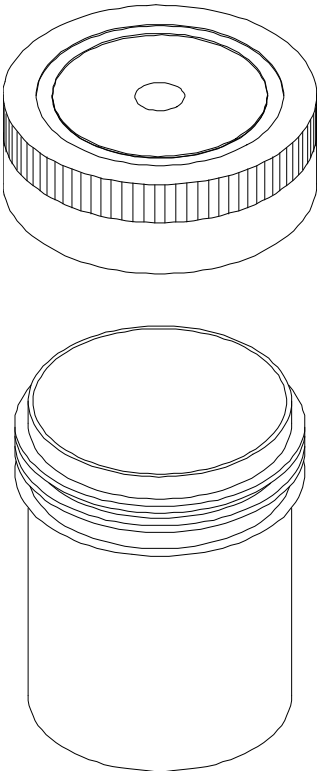
- ① United States Department of Transportation Code of Federal Regulations (CFR) Title 49, Transportation, Parts 100-185
 ② The United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations (UN – Orange Book)
 ③ International Maritime Dangerous Goods Code (IMDG)
 ④ Technical Instructions for the Safe Transport of Dangerous Good by Air (ICAO)
 ⑤ International Air Transport Association (IATA) Dangerous Goods Regulations

EQUIPMENT

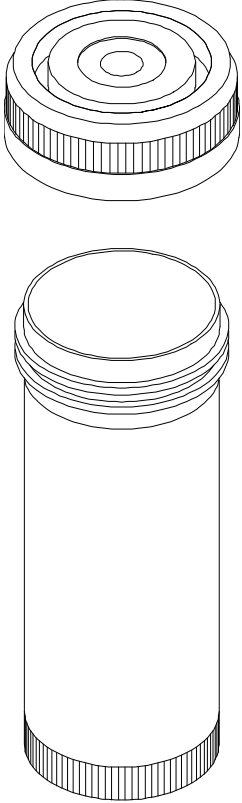
All inspection, measuring and test equipment that can affect product quality is calibrated and adjusted at prescribed intervals, or prior to use, and is traceable to NIST, using ANSI Z540 as an overall guide for calibration certification.

COMPONENT INFORMATION (TEN-E Packaging Services Quality Control Audit)

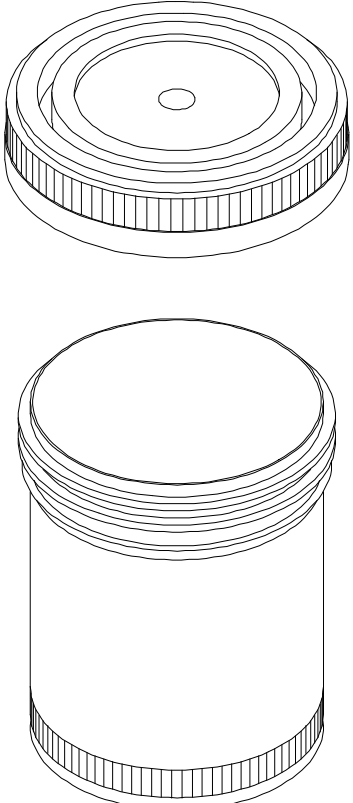
B202-1WNL (Lot #1B18)

CLOSURE		DRAWING
Manufacturer: Starplex Scientific		
Description:	36 mm Threaded Closure with Valve Seal	
Material:	Polypropylene, White	
Tare Weight:	3.099 Grams	
Overall Dimensions:		
• Height	0.492"	
• Diameter	1.536"	
Finish Dimensions:		
• T	1.430"	
• E	1.352"	
Markings (QC Audit):	2	
20 mL PLASTIC VIAL		
Manufacturer: Starplex Scientific		
Description:	20 mL Plastic Vial	
Material/Pigment:	Polypropylene, Natural	
Method of Manufacture:	Injection Molded	
Tare Weight:	5.231 Grams	
Capacity:		
• Rated	20 mL	
• Overflow	28 mL	
Overall Dimensions:		
• Height	1.648"	
• Diameter	1.369"	
Thread Dimensions:		
• T	1.394"	
• E	1.315"	
Markings (QC Audit):	5 20 ML MIN. B FILL	

V302 (Lot # 2C22)

CLOSURE		DRAWING
Manufacturer: Starplex Scientific		
Description:	32 mm Threaded Closure with Valve Seal	
Material:	Polypropylene, White	
Tare Weight:	2.937 Grams	
Overall Dimensions:		
• Height	1.492"	
• Diameter	2.392"	
Finish Dimensions:		
• T	1.282"	
• E	1.212"	
Markings (QC Audit):	4	
30mL PLASTIC VIAL		
Manufacturer: Starplex Scientific		
Description:	30 mL Plastic Vial	
Material/Pigment:	Polypropylene, Natural	
Method of Manufacture:	Injection Molded	
Tare Weight:	8.354 Grams	
Capacity:		
• Rated	30 mL	
• Overflow	42 mL	
Overall Dimensions:		
• Height	3.198"	
• Diameter	1.187"	
Thread Dimensions:		
• T	1.258"	
• E	1.186"	
Markings (QC Audit):	4 30 ML SPI "5" PP Recycling Symbol	

B602-10 (Lot # 2M12)

CLOSURE		DRAWING
Manufacturer: Starplex Scientific		
Description:	47 mm Threaded Closure with Valve Seal	
Material:	Polypropylene, Orange	
Tare Weight:	4.700 Grams	
Overall Dimensions:		
• Height	0.532"	
• Diameter	1.998"	
Finish Dimensions:		
• T	1.879"	
• E	1.806"	
Markings (QC Audit):	4	
60 mL PLASTIC VIAL		
Manufacturer: Starplex Scientific		
Description:	60 mL Plastic Vial	
Material/Pigment:	Polypropylene, Natural	
Method of Manufacture:	Injection Molded	
Tare Weight:	8.647 Grams	
Capacity:		
• Rated	60 mL	
• Overflow	81 mL	
Overall Dimensions:		
• Height	2.314"	
• Diameter	1.819"	
Thread Dimensions:		
• T	1.849"	
• E	1.774"	
Markings (QC Audit):	13 2.OZ MFG 1212182	


TEST PROCEDURES AND RESULTS

PRESSURE DIFFERENTIAL TEST

B202-1WNL (Lot # 1B18)

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:	Water	
FILL CAPACITY:	Maximum Capacity	
CLOSURE APPLICATION:	17 In-Lbs.	
CONDITIONING:	Laboratory Ambient	
TEST PRESSURE:	28 inHg	
TEST DURATION:	30 Minutes	
TEST DATE:	February 26, 2013	
TEST EQUIPMENT:	Tenney Vacuum Chamber #630	

VACUUM TEST SET-UP AND RESULTS


	Sample	Mold No.		Results	Comments/Observations
		Vial	Cap		
	1	4	2	PASS	All three samples maintained the 28 inHg test pressure for 30 minutes without leakage.
	2	1	8	PASS	
	3	7	6	PASS	

PRESSURE DIFFERENTIAL TEST

V302 (Lot # 2C22)

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:	Water	
FILL CAPACITY:	Maximum Capacity	
CLOSURE APPLICATION:	15 In-Lbs.	
CONDITIONING:	Laboratory Ambient	
TEST PRESSURE:	28 inHg	
TEST DURATION:	30 Minutes	
TEST DATE:	February 26, 2013	
TEST EQUIPMENT:	Tenney Vacuum Chamber #630	

VACUUM TEST SET-UP AND RESULTS


	Sample	Mold No.		Results	Comments/Observations
		Vial	Cap		
	1	1	1	PASS	All three samples maintained the 28 inHg test pressure for 30 minutes without leakage.
	2	2	2	PASS	
	3	1	1	PASS	

PRESSURE DIFFERENTIAL TEST

B602-10 (Lot # 2M12-1)

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:	Water	
FILL CAPACITY:	Maximum Capacity	
CLOSURE APPLICATION:	22 In-Lbs.	
CONDITIONING:	Laboratory Ambient	
TEST PRESSURE:	28 inHg	
TEST DURATION:	30 Minutes	
TEST DATE:	February 26, 2013	
TEST EQUIPMENT:	Tenney Vacuum Chamber #630	

VACUUM TEST SET-UP AND RESULTS

	Sample	Mold No.		Results	Comments/Observations
		Vial	Cap		
	1	15	1	PASS	All three samples maintained the 28 inHg test pressure for 30 minutes without leakage.
	2	13	6	PASS	
	3	2	7	PASS	

TEST PROCEDURES AND RESULTS

THERMAL SHOCK AND PRESSURE DIFFERENTIAL (VACUUM) TESTS

TEST INFORMATION		TEST CRITERIA
SAMPLE SIZE:	3 Samples / Variable	<p>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)</p>
TEST CONTENTS:	Anti-freeze Solution	
FILL CAPACITY:	Maximum Capacity	
CLOSURE APPLICATION:	B202-1WNL: 17 In-Lbs. V302: 15 In-Lbs. B602-10: 22 In-Lbs.	
CONDITIONING:	-40°C (-40°F) to +55°C (+131°F)	
TEST PRESSURE:	28 In-Hg (95 kPa)	
TEST DATE:	February 27, 2013	
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 EQUIPMENT:

- Environmental Chamber #236 (Refer to following page for temperature recordings)
- TEN-E Vacuum Chamber #630

TEST PROCEDURES:

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.

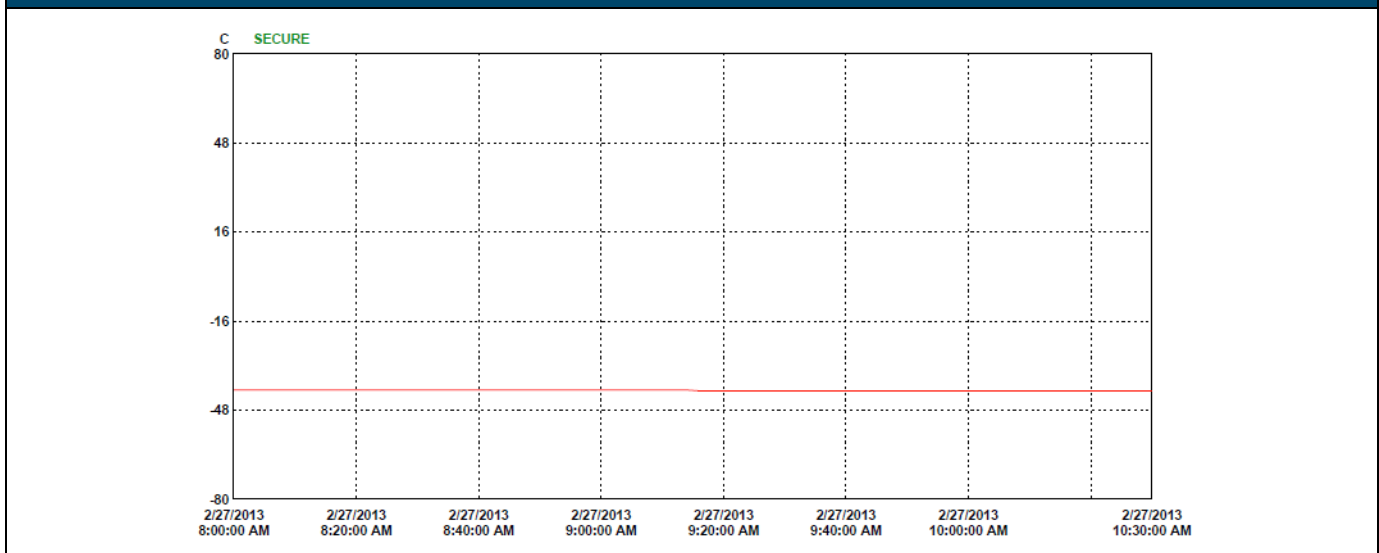
If after 2 hours no leakage was evident, a 28 In-Hg vacuum test was performed at (+55°C) for 30 minutes.

Following the 30 minute vacuum test samples were evaluated for leakage.

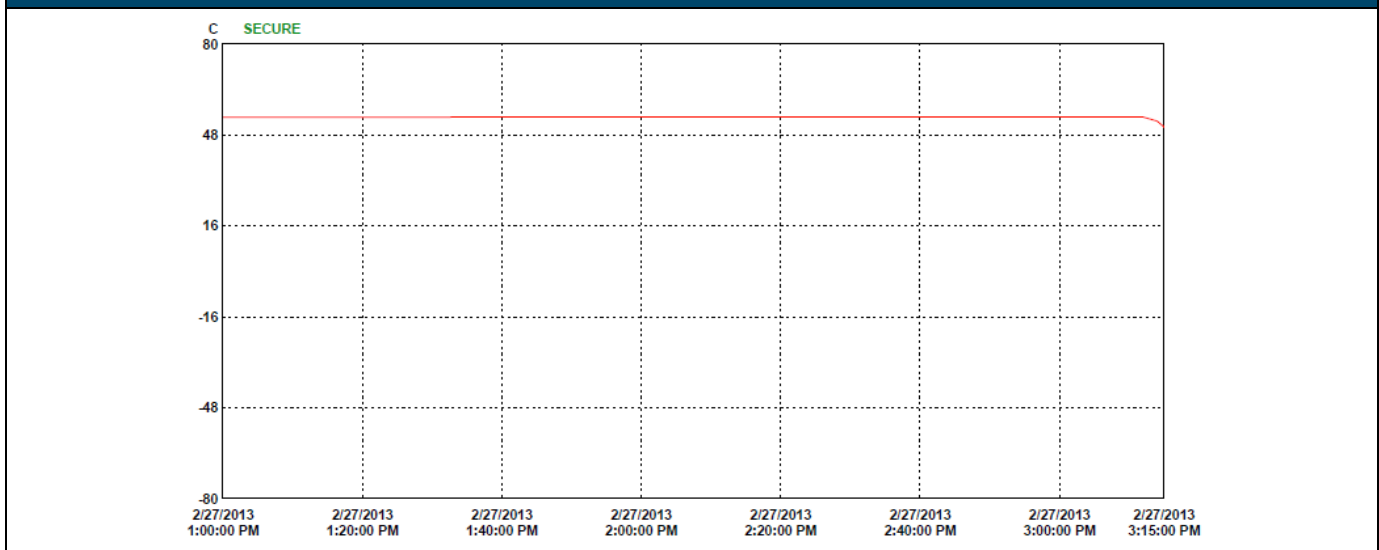
THERMAL SHOCK AND PRESSURE DIFFERENTIAL (VACUUM) TESTS CONTINUED

Test	Chamber ID	Temperature C	Minimum Duration	Start (Date & Time)	Stop (Date & Time)
1	236	-40°C	2 Hours	2/27/13 @ 800	2/27/13 @ 1030
2	236	+55°C	2 Hours	2/27/13 @ 100	2/27/13 @ 315

-40°C (-40°F) TEMPERATURE DATA



+55°C (+131°F) TEMPERATURE DATA



**THERMAL SHOCK AND PRESSURE DIFFERENTIAL (VACUUM) TESTS CONTINUED –
B202-1WNL (Lot # 1B18)**

THERMAL SHOCK/PRESSURE DIFFERENTIAL TEST SETUP



THERMAL SHOCK/PRESSURE DIFFERENTIAL TEST

Sample ID	Vial Mold No.	Cap Mold No.	-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)
4	1	8	Pass	Pass	Pass	Pass
5	5	5	Pass	Pass	Pass	Pass
6	9	4	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.

**THERMAL SHOCK AND PRESSURE DIFFERENTIAL (VACUUM) TESTS CONTINUED –
V302 (Lot # 2C22)**

THERMAL SHOCK/PRESSURE DIFFERENTIAL TEST SETUP



THERMAL SHOCK/PRESSURE DIFFERENTIAL TEST

Sample ID	Vial Mold No.	Cap Mold No.	-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)
4	7	7	Pass	Pass	Pass	Pass
5	8	3	Pass	Pass	Pass	Pass
6	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.

**THERMAL SHOCK AND PRESSURE DIFFERENTIAL (VACUUM) TESTS CONTINUED –
B602-10 (Lot # 2M12-1)**

THERMAL SHOCK/PRESSURE DIFFERENTIAL TEST SETUP



THERMAL SHOCK/PRESSURE DIFFERENTIAL TEST

Sample ID	Vial Mold No.	Cap Mold No.	-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)
4	3	4	Pass	Pass	Pass	Pass
5	15	12	Pass	Pass	Pass	Pass
6	5	1	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, the International Civil Aviation Organization (ICAO); Technical Instructions for the Safe Transport of Dangerous Goods By Air; PI 620 and 650 and the International Air Transport Association (IATA); Dangerous Goods Regulations; PI 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 MERCHANTABLE 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.


Patricia L. Garin
Manager, Technical Services
TEN-E Packaging Services, Inc.
1666 County Road 74
Newport, MN 55055