ANAMA Package & Container Testing Services, Inc.

607 Fayette Avenue, Mamaroneck, NY 10543
Tel: (914) 899-3300 | Fax: (914) 899-3325
info@anamapackagetesting.com | www.anamapackagetesting.com

July 11, 2013

Mr. Thomas Ehrenfellner
Technical Product Manager/Preanalytics
Greiner Bio-One GmbH
Bad Haller Str. 32
A-4550 Kremsmunster Austria

RE: Internal pressure (vacuum) testing of 4.0 ml 13/75 with sep PET blood collection tubes in accordance with the ASTM D4919 Test Standard
Tube ID: Sample A, Item No. 454067, VAC 4.0 ml Z Serum Sep G/A NR REDYE 13x75
P.O. #4500077127
Project #0172-A

Pursuant to your recent request, ANAMA Package & Container Testing Services, Inc. has performed internal pressure (vacuum) testing on Sample A, Item No. 454067, VAC 4.0 ml Z Serum Sep G/A NR REDYE 13x75, PET tubes with sep with Safety Caps, submitted to this laboratory on June 12, 2013. Prior to testing, the plastic tubes were inspected for pre-test damage, then filled with fluid and conditioned to 73 ^{0}F and 50% R.H. for 24 hours. Five (5) fluid filled plastic tubes were then subjected to 95 kPa (0.95 bar, 13.8 lb/in^{2}) pressure differential testing (vacuum) in the range of –40 ^{0}C to +55 ^{0}C (-40 ^{0}F to +130 ^{0}F).

Based on the test results presented herein, we submit that the Sample A, Item No. 454067, VAC 4.0 ml Z Serum Sep G/A NR REDYE 13x75, PET tubes with sep with Safety Caps, described herein and tested on July 9, 2013, in the manner summarized below, pass the tests according to the criteria described in the ASTM D 4919 - Standard Specification For Testing Of Hazardous Material Packagings, Section 12, Pressure Differential Test (IATA, 54th Edition, Section 5, Packing Instructions 602 & 650).

Respectfully submitted,

ANAMA Package & Container Testing Services, Inc.

Anton Cotaj
Director of Technical Services

AC/ac

Description Of The Tested Package

TUBE (Drawings attached)

Type	VACUETTE blood collection tube	
Style	13/75 wide-mouth specimen tube with sep	
Manufacturer	Greiner Bio-One GmbH, Austria	
Item #	454067	
Description	VAC 4.0 ml Z Serum Sep G/A NR REDYE 13x75	
Material of Construction	Transparent PET	
Method of Construction	Extrusion blow molded	
Dimension (mm, OD), D X H	12.81 x 75.69	
Dimension (mm, ID), D X H	10.51 x 74.47	
Minimum Thickness (mm)	Body: 1.15	Bottom: 1.15
Nominal Thickness (mm)	Body: 1.22	Bottom: 1.20
Overflow Capacity	4.69 mL	
Nominal Capacity	4.60 mL	
Net Weight	3.5 ml	
Tare Weight (grams)	4.8 grams (with additive)	
Gross Weight (grams)	11.5 grams (with additive), as tested	
Label	SAMPLE A	
Test Material	Water/Antifreeze Mixture, SG = 0.92	

SAFETY CAP (Drawings attached)

Type	PREM 13/75	
Style	Safety twist cap for PREMIUM tubes	
Manufacturer	Greiner Bio-One GmbH, Austria	
Material of Construction	Red PE	
Method of Construction	Injection blow molded	
Diameter (mm, OD)	Upper: 15.48	Lower: 16.94
Height (mm)	13.80	
Size (mm, ID) – D X H	13.11 x 7.44, lower section only	
Tare Weight (grams)	0.8	
Method of Closure	Vacuum Sealed Friction Fit	

PLUG (Drawings attached)

Type	Friction fit gasket (plug)
Manufacturer	Greiner Bio-One GmbH, Austria
Material of Construction	Gray Brom Butyl/Caoutchouc
Dimension (mm, OD), D X H	13.50 x 10.22
Dimension (mm, ID), D X H	10.73 x 6.15 (lower section only)
Tare Weight (grams)	1.3

STABILISATION RING (Drawings attached)

Type	Inner cap identification ring	
Manufacturer	Greiner Bio-One GmbH, Austria	
Material of Construction	Yellow PP	
Diameter (mm)	Outer: 13.32	Inner: 7.23
Thickness (mm)	0.99	
Tare Weight (grams)	0.012	

Internal Pressure (Vacuum) Test Description and Test Results

Test Method: ASTM D 4919 - Standard Specification For Testing Of Hazardous Material Packagings, Section 12, Pressure Differential Test, Vacuum Testing with Cold & Hot Conditioning (IATA, 54th Edition, Section 5, Packing Instructions 602 & 650
Receptacles Tested: 5
Test Duration: 30 minutes
Test Pressure: -100 kPa

Test Significance and Use:

This test method is conducted in all packagings intended for the transportation of Infectious Substances (Biological Substances Category A, UN2814) or Diagnostic Specimens (Biological Substances Category B, UN3373) in accordance with the International Air Transport Association Dangerous Goods Regulations (IATA), 54th Edition, Section 5, Packing Instructions 602 & 650 respectively.
This test method consists of pressurizing at least three (3) receptacles (primary or secondary packagings) to the test pressure of at least 95 kPa (13.8 lb/in^2) in the range of –40 ^{0}C to +55 ^{0}C (-40 ^{0}F to +130 ^{0}F) and maintained for the specified time (depend on the material of construction of the primary or secondary receptacle).

Test Procedure:

Test receptacles (tubes) were filled for testing with water antifreeze mixture. A 1" long 21-gauge B-D brand 21G1 regular-bevel needle was used to fill the test receptacles (tubes). Filled test receptacles (tubes) were therafter pre-conditioned @ 73 °F (23 °C) & 50% R.H. controlled environment for at least 24 hours. Following the preconditioning, five (5) filled receptacles were placed in a –40 ^{0}C (-40 ^{0}F) controlled environment and maintained for at least four (4) hours. Immediately after the cold environment the tubes were placed in a vacuum chamber and pressurized using a SaveVac 140 Vacuum Pump by gradually increasing partial vacuum. The absorbent blotting paper was placed under the tubes in the chamber to more easily detect the leakage. To provide regulated partial vacuum, Inlet Tube from a Source of Vacuum and Outlet Tube to the Atmosphere was used to apply a gauge pressure slowly (from 30 seconds to 1 minute) to at least 95 kPa (13.8 lb/in^2) and maintained for 30 minutes. The receptacles were observed for signs of leakage, as evidenced by fluid leakage during depressurization or fluid leakage after re-pressurization. Following the 30 minute of vacuum testing, the receptacles were removed from the vacuum chamber, placed on top of the absorbent blotting paper at 73 ^{0}F controlled environment and maintained for at least one (1) hour to be observed for signs of leakage. Then the same receptacles were placed in a 55 ^{0}C (130 ^{0}F) controlled environment for at least four (4) hours, followed by 30 minute vacuum testing to 95 kPa (13.8 lb/in^2) and one (1) hour leakage examination at 73^{0}F controlled environment.

Pass/Fail Criteria:

A receptacle is considered to successfully pass the internal pressure (vacuum) tests if for each sample tested: There is no leakage of liquid from the receptacle.

Test Results:

Test Sample #	Test Level	Time	Results
A1	-100 kPa	2 times, 30 minutes	Pass / There was no evidence of leakage
A2	-100 kPa	2 times, 30 minutes	Pass / There was no evidence of leakage
A3	-100 kPa	2 times, 30 minutes	Pass / There was no evidence of leakage
A4	-100 kPa	2 times, 30 minutes	Pass / There was no evidence of leakage
A5	-100 kPa	2 times, 30 minutes	Pass / There was no evidence of leakage

A - Denotes Tube Sample A