

December 12, 2022

## ▪TEST REPORT▪

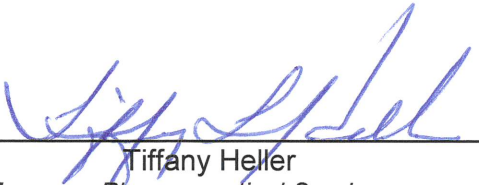
**PN 165757B**

### MICROBIOLOGICAL SERVICES

Prepared For:


Tim Tate  
**USA Gloves**  
11325 Cash Road  
Stafford, TX 77477

Prepared By:

  
Tiffany Heller  
Manager, Pharmaceutical Services

DCN 1176

Approved By:

  
Ana C. Barbur  
Vice President, Analytical & Chemical Services



Cert 225-01, 255-02, 255-03, 255-04

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USA Gloves

Page 2 of 6  
PN 165757B

**SUBJECT:** Viral Penetration Testing per ASTM F1671 on samples submitted by the above company.

**RECEIVED:** One (1) glove type identified by customer as; Blue Nitrile Examination Gloves, Powder-Free, Textured, Single Use Only, Non-Sterile, Ambidextrous, Lot Number 01S081322.

**SUMMARY OF TEST METHOD ASTM F1671:**

Prior to testing, all test and control samples are conditioned in an environmental chamber for 24 h at  $21 \pm 5$  °C and a relative humidity between 30-80%. Samples are then mounted onto the penetration cell chamber and challenged with a suspension of bacteriophage ØX174 at 0 kPa for 5 min followed by a pressure of 13.8 kPa for 1 min and observed over an additional 54 minutes at 0 kPa. After this time, the suspension is removed from the inner chamber, followed by the removal of the outer cover of the penetration cell chamber. Sterile broth is added to the outer chamber and swirled for 1 min before collecting and assaying for the presence of bacteriophage. Assays were performed in the presence of a retaining screen, **Procedure B.** Bacteria used; E. coli; (ATCC 13706), Bacteriophage used; phi X174, (ATCC 13706-B1).

**PROCEDURE B.**

Bacteria used: E coli ATCC 13706, Bacteriophage used: phi- X174, ATCC 13706-B1.

**INTERPRETATION OF RESULTS:**

Test items that exhibit no detectable plaque forming units pass the test. In order for the test results to be valid, the following must be obtained:

- (1) No background counts in any of the airborne contamination controls
- (2) Negative control sample passes the test with no detectable phage counts
- (3) Positive control sample fails the test with the visual observation of a fluid leak or the presence of plaque forming units

**ASTM F1671 VIRAL PENETRATION TEST RESULTS**

Test Article ID: Blue Nitrile Examination Gloves  
 Date received: 08/04/2022  
 Date tested: See Below Tables  
 Test Article Side Tested: Outside  
 Test Article Preparation: Samples were taken from the palm area of the glove  
 Test Article Sealed: Rubber Gaskets  
 Exposure Procedure: B; Retaining Screen  
 Support Screen: Fiberglass Mesh  
 Compatibility Ratio: 1.2  
 Environmental Plate Results: Pass  
 Number Test Articles Tested: 32  
 Number Test Articles Passed: 32

Date Tested: 08/08/2022	Sample Mass (gm)	Average Thickness	Pre-Challenge PFU	Post Challenge PFU	Assay Titer (PFU/ml)	Visual Leak Observation	Test Result
Test Article ID							
Positive Control: Blue Gown	0.50	0.069	$5.8 \times 10^8$	$5.8 \times 10^8$	N/A	Yes	Pass
Negative Control: Silicone Film	21.85	1.996	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #1	0.54	0.067	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #2	0.51	0.065	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #3	0.53	0.066	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #4	0.52	0.071	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #5	0.53	0.069	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #6	0.52	0.073	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #7	0.52	0.065	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #8	0.54	0.065	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #9	0.50	0.061	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #10	0.53	0.067	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass

<sup>a</sup>A value of <1 PFU/ml = plates showing no plaques.

**\*\***TMTC = PFUs that are Too Many To Count

**Note:** The results given in this report relate only to the items tested. This report cannot be reproduced except in full without the written consent of ARDL. This testing was performed at our Robinson Avenue, Barberton Location.



Date Tested: 08/09/2022	Sample Mass (gm)	Average Thickness	Pre-Challenge PFU	Post Challenge PFU	Assay Titer (PFU/ml)	Visual Leak Observation	Test Result
Test Article ID							
Positive Control: Blue Gown	0.49	0.071	$5.8 \times 10^8$	$5.8 \times 10^8$	N/A	Yes	Pass
Negative Control	21.56	1.969	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #11	0.53	0.068	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #12	0.51	0.062	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #13	0.54	0.073	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #14	0.52	0.066	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #15	0.54	0.068	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #16	0.49	0.057	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #17	0.51	0.062	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #18	0.55	0.065	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #19	0.53	0.073	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #20	0.49	0.055	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Date Tested: 08/10/2022	Sample Mass (gm)	Average Thickness	Pre-Challenge PFU	Post Challenge PFU	Assay Titer (PFU/ml)	Visual Leak Observation	Test Result
Test Article ID							
Positive Control: Blue Gown	0.51	0.068	$5.8 \times 10^8$	$5.8 \times 10^8$	N/A	Yes	Pass
Negative Control	22.21	2.022	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #21	0.54	0.065	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #22	0.52	0.064	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #23	0.52	0.060	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #24	0.52	0.066	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #25	0.51	0.065	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #26	0.50	0.065	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #27	0.52	0.065	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #28	0.51	0.067	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #29	0.52	0.070	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #30	0.51	0.066	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #31	0.51	0.063	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass
Sample #32	0.53	0.069	$5.8 \times 10^8$	$5.8 \times 10^8$	<1 <sup>a</sup>	None Seen	Pass

<sup>a</sup>A value of <1 PFU/ml = plates showing no plaques.

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**NOTE:** The Mark ^ is used to designate non-accredited test methods in the body of the report and that any opinions or interpretations of results for these non-accredited tests are outside the scope of this organization's accreditation

**SAMPLES RECEIVED:**

Blue Nitrile Examination Gloves, Powder-Free, Textured, Single Use Only,  
Non-Sterile, Ambidextrous, Lot Number 01S081322



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Page 6 of 6  
PN 165757B

## **APPENDIX**

**Testing Location:** 75 Robinson Ave., Barberton, OH 44203

### **Decision Rules**

**Customer Selected Decision Rule:** Decision Rule 1

Rule 1. This is the way test results have traditionally been reported by ARDL. If ARDL runs a test for you that has pass/fail requirements, ARDL will report the values observed and then state "Pass" or "Fail", based on those values only. By default, ARDL will apply this rule to all Category I tests and those tests which are not on ARDL's Scope of Accreditation.


Rule 2. This rule takes into account the calculated measurement uncertainty of test results generated. Every test and piece of test equipment has an inherent amount of measurement uncertainty associated with it. Rule 2 establishes "Guard Bands", where the measurement uncertainty value is added to the Minimum Passing requirement and is subtracted from the Maximum Passing requirement. The Pass/Fail requirements thus become tighter and customers may be more "Certain" of their Pass/Fail result.

Rule 3. This rule also takes into account measurement uncertainty but does not set up guard bands. Rule 3 may be used when values are reported, but there is no Pass/Fail requirement called out in the test specification. Rule 3 simply states that the measurement uncertainty is reported to the customer, along with the testing result generated, and the customer decides if the results are suitable for their purposes.

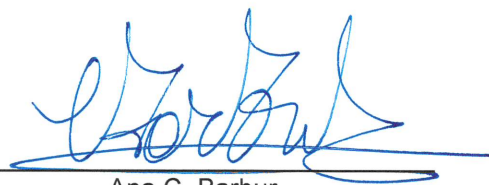
### **REPORT REVISIONS:**

<b><u>DATE</u></b>	<b><u>REVISION #</u></b>	<b><u>DETAILS</u></b>
12/12/2022	N/A	Original Final Report

Prepared By:

  
Tiffany Heller  
Manager, Pharmaceutical Services

Approved By:

  
Ana C. Barbur  
Vice President, Analytical & Chemical Services

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