

Sodium Chloride (NaCl) Aerosol Test Final Report

Test Article: NRC110 Test Sample ID / Lot #
01/O2DB95AG2012
02/O2DB95AG2012
03/O2DB95AG2012
04/O2DB95AG2012
05/O2DB95AG2012
06/O2DB95AG2012
07/O2DB95AG2012
08/O2DB95AG2012
09/O2DB95AG2012
10/O2DB95AG2012
11/O2DB95AG2012
12/O2DB95AG2012
13/O2DB95AG2012
14/O2DB95AG2012
15/O2DB95AG2012
16/O2DB95AG2012
17/O2DB95AG2012
18/O2DB95AG2012
19/O2DB95AG2012
20/O2DB95AG2012

Purchase Order: 0011
Study Number: 1375434-S01
Study Received Date: 23 Dec 2020
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: STP0014 Rev 09
Deviation(s): None

Summary: This procedure was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 and TEB-APR-STP-0059 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized, and passed through the test article at a concentration not exceeding 200 mg/m³. The initial airflow resistance and particle penetration for each respirator was determined.



Natalie Brady electronically approved for
Study Director

Curtis Gerow

25 Jan 2021 23:41 (+00:00)

Study Completion Date and Time

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results: The NIOSH N95 filter efficiency as stated in 42 CFR Part 84.181 is a minimum efficiency for each filter of $\geq 95\%$ ($\leq 5\%$ penetration). The test articles submitted by the sponsor conform to the NIOSH N95 criteria for filter efficiency.

Test Article	Corrected ^a Initial Airflow Resistance (mm H ₂ O)	Maximum Particle Penetration (%)	Filtration Efficiency (%)
01/O2DB95AG2012	5.9	1.48	98.52
02/O2DB95AG2012	5.4	1.17	98.83
03/O2DB95AG2012	5.5	1.38	98.62
04/O2DB95AG2012	5.6	0.175	99.825
05/O2DB95AG2012	5.9	0.283	99.717
06/O2DB95AG2012	5.5	0.206	99.794
07/O2DB95AG2012	6.2	0.277	99.723
08/O2DB95AG2012	5.6	0.182	99.818
09/O2DB95AG2012	5.0	0.344	99.656
10/O2DB95AG2012	5.3	0.172	99.828
11/O2DB95AG2012	5.2	0.236	99.764
12/O2DB95AG2012	4.3	0.082	99.918
13/O2DB95AG2012	3.8	0.035	99.965
14/O2DB95AG2012	4.1	1.66	98.34
15/O2DB95AG2012	4.7	0.108	99.892
16/O2DB95AG2012	3.7	<0.001 ^b	>99.999 ^c
17/O2DB95AG2012	5.2	0.169	99.831
18/O2DB95AG2012	4.5	0.030	99.970
19/O2DB95AG2012	4.4	0.840	99.160
20/O2DB95AG2012	4.4	0.113	99.887

^a The final airflow resistance value for each test article was determined by subtracting out the background resistance from the system.

^b No particle penetration was detected through this test article.

^c There were no detected particles penetrating this filter during testing.

Test Method Acceptance Criteria: The filter tester must pass the “Tester Set Up” procedure. The airflow resistance and particle penetration of the reference material must be within the limits set by the manufacturer.

Filter Test Procedure: Prior to testing, respirators were taken out of their packaging and placed in an environment of $85 \pm 5\%$ relative humidity (RH) and $38 \pm 2.5^\circ\text{C}$ for 25 ± 1 hours.

The filter tester used in testing was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produces a particle size distribution with a count median diameter of 0.075 ± 0.020 microns (μm) and a geometric standard deviation not exceeding $1.86 \mu\text{m}$. The mass median diameter was approximately $0.26 \mu\text{m}$, which is generally accepted as the most penetrating aerosol size. The reservoir was filled with a 2% NaCl solution and the instrument allowed a minimum warm-up time of 30 minutes. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 psi. The NaCl aerosol generator pressure was set to approximately 30 psi and the make-up airflow rate was set to approximately 70 liters per minute (L/min).

The NaCl concentration of the test aerosol was determined in mg/m^3 by a gravimetric method prior to the load test assessment. An entire respirator was mounted on a test fixture, placed into the filter holder, and the NaCl aerosol passed through the outside surface of the test article at a continuous airflow rate of 85 ± 4 L/min. In accordance with NIOSH policy, three respirators were challenged until 200 ± 5 mg of NaCl had contacted each test article. Based upon the load pattern of NIOSH Type 2, the initial penetration reading of the remaining 17 respirators was recorded.