Nelson Labs
A Sotera Health company

Sponsor:
Jaclyn Lautz
iwWatch, LLC
700 Tech Center Pkwy.
Ste. 300
Newport News, VA 23606

# Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators GLP Report

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|---|---|
| Test Article: | Blox Respirator<br>Lot # BLX-F36R-003 |
| Purchase Order: | 00008714 |
| Study Number: | 1404013-S01 |
| Study Received Date: | 31 Mar 2021 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>Salt Lake City, UT 84123 U.S.A. |
| Test Procedure(s): | Standard Test Protocol (STP) Number: STP0145 Rev 05 |
| Deviation(s): | None |

**Summary:** This procedure was performed to evaluate the differential pressure of non-powered air-purifying particulate respirators in accordance with 42 CFR Part 84.180. The air exchange differential or breathability of respirators was measured for inhalation resistance using NIOSH procedure TEB-APR-STP-0007 and exhalation resistance with NIOSH procedure TEB-APR-STP-0003. The differential pressure technique is a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

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.

The inhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial inhalation not exceeding 35 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

The exhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial exhalation not exceeding 25 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

All test method acceptance criteria were met.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

| Christopher Acker electronically approved | 20 Apr 2021 00:22 (+00:00) |
|---|---|
| Study Director Christopher Acker | Study Completion Date and Time |

**Results:**

| Test Article Number | Inhalation Resistance (mm $H_2O$) | Exhalation Resistance (mm $H_2O$) |
|---|---|---|
| 1 | 7.2 | 8.9 |
| 2 | 7.4 | 9.6 |
| 3 | 7.2 | 9.8 |

**Test Method Acceptance Criteria:** The resistance measurement for the reference plate must be within ± 3 standard deviations of the mean established in the control chart.

**Procedure:** A complete respirator was mounted to a test fixture comprised of a metal plate with an approximate 3.5 inch diameter hole in the center to allow airflow to reach the mask. The sample holder was assembled by placing a Plexiglas collar around the test fixture and topping with another metal disc with a 3.5 inch opening in the center. The sample holder is held tightly together with clamps and connected to an air source. The manometer is attached to the sample holder by a connection port on the Plexiglas collar.

Before testing, the manometer was zeroed and the back pressure in the sample holder checked and verified to be acceptable. Resistance measurements were taken with a manometer capable of measuring at least 6 inches of water. For inhalation testing, a negative airflow (vacuum) was applied. For exhalation testing, a positive airflow (compressed air) was used. Airflow was passed through the sample holder at approximately 85 ± 2 liters per minute (L/min).

# Quality Assurance Statement

**Compliance Statement:** The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

| Activity | Date |
|---|---|
| Study Initiation | 02 Apr 2021 |
| Phase Inspected by Quality Assurance: Resistance Measurement | 14 Apr 2021 |
| Audit Results Reported to Study Director | 14 Apr 2021 |
| Audit Results Reported to Management | 15 Apr 2021 |

| Scientists | Title |
|---|---|
| Adrianne Sandall | Supervisor |
| Christopher Acker | Study Director |

**Data Disposition:** The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Bridger James electronically approved
Quality Assurance

19 Apr 2021 23:12 (+00:00)
Date and Time