Nelson Labs
A Sotera Health company

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# MEM Elution GLP Report

| | |
|---|---|
| Test Article: | Lot 001: 50 disposable surgical masks (Blue) LHM-E1 |
| Purchase Order: | M-03122021 |
| Study Number: | 1299031-S01.1 Amended |
| Study Received Date: | 13 May 2020 |
| Study Completion Date: | 28 May 2020 |
| 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: STP0032 Rev 10 |
| Deviation(s): | None |

**Summary:** The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. All test method acceptance criteria were met.

**Results:**
Test Article:

| Dilution | Results Pass/Fail | Scores | | | | Extraction Ratio | Amount Tested / Extraction Solvent Amount |
|---|---|---|---|---|---|---|---|
| | | #1 | #2 | #3 | Average | | |
| Neat | **Pass** | 0 | 0 | 0 | 0 | | |
| 1:2 | **Pass** | 0 | 0 | 0 | 0 | | |
| 1:4 | **Pass** | 0 | 0 | 0 | 0 | 3 $cm^2$/mL | 585 $cm^2$ / 195 mL |
| 1:8 | **Pass** | 0 | 0 | 0 | 0 | | |
| 1:16 | **Pass** | 0 | 0 | 0 | 0 | | |

Note: An additional 10 mL of media was added to account for absorbency.

Danielle Short
Study Director — Danielle M. Short, B.S., SM(NRCM)

30 Jun 2020
Amended Report Date

1299031-S01

Controls:

| Identification | Scores | | | | Extraction Ratio | Amount Tested / Extraction Solvent Amount |
|---|---|---|---|---|---|---|
| | #1 | #2 | #3 | Average | | |
| Negative Control - Polypropylene Pellets | 0 | 0 | 0 | 0 | 0.2 g/mL | 4 g / 20 mL |
| Media Control | 0 | 0 | 0 | 0 | N/A | 20 mL |
| Positive Control - Latex Natural Rubber | 4 | 4 | 4 | 4 | 0.2 g/mL | 4 g / 20 mL |

**Test Method Acceptance Criteria:** The United States Pharmacopeia & National Formulary (USP <87>) states that the test article meets the requirements, or receives a passing score (**Pass**) if the reactivity grade is not greater than grade 2 or a mild reactivity. The ANSI/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade greater than 2 is considered a cytotoxic effect, or a failing score (**Fail**).

Nelson Laboratories acceptance criteria was based upon the negative and media controls receiving "0" reactivity grades and positive controls receiving a 3-4 reactivity grades (moderate to severe). The test was considered valid as the control results were within acceptable parameters.

The cell monolayers were examined microscopically. The wells were scored as to the degree of discernable morphological cytotoxicity on a relative scale of 0 to 4:

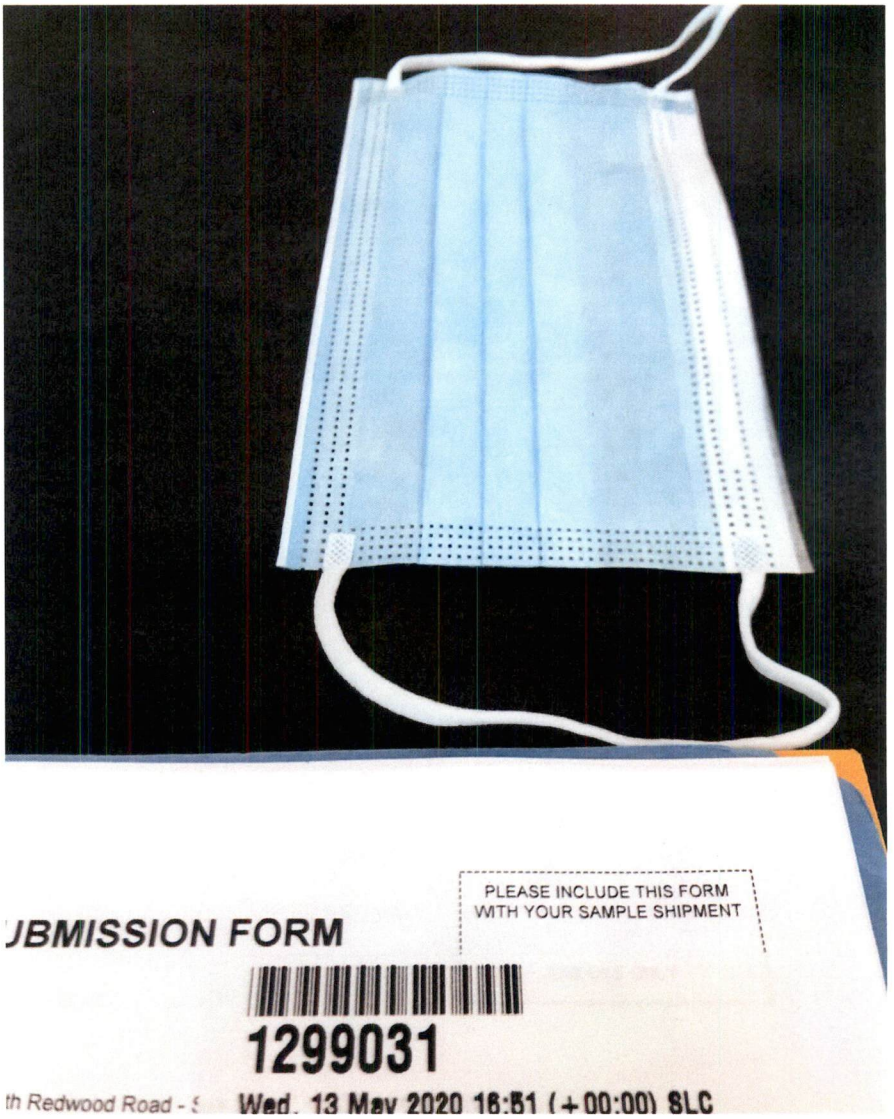
| Conditions of All Cultures | Reactivity | Grade |
|---|---|---|
| No cell lysis, intracytoplasmic granules. | None | 0 |
| Less than or equal to 20% rounding, occasional lysed cells. | Slight | 1 |
| Greater than 20% to less than or equal to 50% rounding, no extensive cell lysis. | Mild | 2 |
| Greater than 50% to less than 70% rounding and lysed cells. | Moderate | 3 |
| Nearly complete destruction of the cell layers. | Severe | 4 |

The results from the three wells were averaged to give a final cytotoxicity score.

**Procedure:** The amount of test material extracted was based on ANSI/AAMI/ISO and USP surface area or weight recommendations. Test articles and controls were extracted in 1X Minimal Essential Media with 5% bovine serum for 24-25 hours at 37 ± 1°C with agitation. Multiple well cell culture plates were seeded with a verified quantity of industry standard L-929 cells (ATCC CCL-1) and incubated until approximately 80% confluent. The test extracts were held at room temperature for less than four hours before testing. The extract fluids were not filtered, centrifuged or manipulated in any way following the extraction process. The test extracts were added to the cell monolayers in triplicate. The cells were incubated at 37 ± 1°C with 5 ± 1% $CO_2$ for 48 ± 3 hours.

| Pre and Post Extract Appearance | | |
|---|---|---|
| Test Article | Pre extract | Clear with no particulates present |
| | Post extract | Clear with no particulates present<br>No color change noted |
| Controls | Pre extract | Clear with no particulates present |
| | Post extract | Clear with no particulates present<br>No color change noted |

**Test Article Preparation:**




**Amendment Justification:** At the request of the sponsor, the test article was changed from "Lot 001" to "Lot 001: 50 disposable surgical masks (Blue) LHM-E1".

# 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 | 20 May 2020 |
| Phase Inspected by Quality Assurance: Cell Exposure | 22 May 2020 |
| Audit Results Reported to Study Director | 26 May 2020 |
| Audit Results Reported to Management | 27 May 2020 |

| Scientists | Title |
|---|---|
| Chad Summers | Supervisor |
| Danielle Short | 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.

Quality Assurance

30 Jun 2020
Date