# Final Report: Test of Hygenix Mask Using MEM Elution

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## Contents

## 1. Report Information

**Report Number:** HYX-M202309045(A)
**Test Method:** MEM Elution
**Standard:** 21 CFR Part 58, U.S. FDA
**Sponsor:** Hygenix Inc.
**Address:** 300 Main Street, Springfield, USA
**Testing Facility:** BioTech Labs
**Facility Address:** 123 Research Ave, BioCity, USA
**Website:** www.biotechlabs.com
**Contact Information:** contact@biotechlabs.com, +1-800-555-1234

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## 2. Quality Assurance Statement

The Quality Assurance Unit inspected/audited this study in compliance with the following GLP (Good Laboratory Practice) regulations:

- **GLP Regulation:** 21 CFR Part 58, U.S. FDA
  The inspections were conducted on the following dates, and the findings were reported to the Study Director and Testing Facility Management:
- **Study Protocol Inspection Date:** 2024-09-10
- **Study Procedure Inspection Date:** 2024-09-12
- **Raw Data Inspection Date:** 2024-09-20
- **Final Report Inspection Date:** 2024-09-21

The final report accurately describes the test methods, and the results are consistent with the raw data.

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## 3. Test and Control Articles

### 3.1 Test Article

- **Name:** Hygenix Mask
- **Manufacturer:** Hygenix Inc.
- **Batch/Lot Number:** HYX-202305001
- **Physical State:** Solid
- **Color:** Blue
- **Size:** 180 x 95 mm
- **Storage Conditions:** Room temperature
- **Intended Use:** To provide respiratory protection in medical settings by filtering particulate matter.

### 3.2 Negative Control Article

- **Name:** Polyethylene Pellets
- **Extraction Ratio:** 3 $cm^2/mL$
- **Physical State:** Solid
- **Color:** White
- **Storage Conditions:** Room temperature
- **Extraction Solvent:** MEM medium with 10% fetal bovine serum (FBS).

### 3.3 Positive Control Article

- **Name:** PVC Plastic
- **Extraction Ratio:** 3 $cm^2/mL$
- **Physical State:** Solid
- **Color:** Clear
- **Extraction Solvent:** MEM medium with 10% FBS.

### 3.4 Media Control

- **Name:** MEM medium with 10% FBS

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## 4. Pre and Post Extract Appearance

- **Pre-Extract Appearance:** Clear and free of particulates.
- **Post-Extract Appearance:** No significant color changes were noted for both the test article and controls.

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## 5. Test System

### 5.1 Cell Line

- **Name:** HeLa Cells, obtained from ATCC (American Type Culture Collection), USA.
- **Justification:** HeLa Cells cells are widely used for cytotoxicity studies due to their sensitivity to cytotoxic extracts.

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## 6. Experimental Design

### 6.1 Preparation of Extracts

- **Extraction Solvent:** MEM medium with 10% fetal bovine serum (FBS).
- **Extraction Conditions:**
  - The test article was extracted at a surface area-to-volume ratio of 3 $cm^2$/mL at 37°C for 72 hours.

### 6.2 Procedure

- Following extraction, the cells were exposed to the test article extract, as well as the positive and negative control extracts, and the media control for 48 hours.
- The test article extract was prepared at concentrations of c("100%", "75%", "50%", "25%").
- The cells were incubated for 24 hours, after which cytotoxicity was assessed by the percentage of cell viability using the MTT assay.
- Cell morphology was observed to evaluate any changes that could indicate cytotoxicity.

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## 7. Results

### 7.1 Acceptance Criteria

| Grade | Criteria |
|---|---|
| 0 - None | No cell lysis observed; intracytoplasmic granules present. |
| 1 - Slight | Less than or equal to 20% rounding of cells with occasional lysed cells. |
| 2 - Mild | Greater than 20% to less than or equal to 50% rounding, with no extensive cell lysis. |
| 3 - Moderate | Greater than 50% rounding with lysed cells. |
| 4 - Severe | Nearly complete destruction of the cell layers. |

The mean reactivity score of the three replicates will be reported using Qualitative Scoring.

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## 9. Record Storage

All raw data and a copy of the final report will be retained in the designated archive.

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## 10. Confidentiality Agreement

All confidentiality statements were agreed upon before the initiation of the study.

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## 12. Deviation Statement

No deviations from the approved study protocol were observed that would affect the validity of the data.

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