The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Bureau of Public Health

Bureau of Health Professions Licensure

239 Causeway Street, Suite 500, Boston, MA 02114

Tel: 617-973-0800

TTY : 617-973-0988

[www.mass.gov/dph/boards](http://www.mass.gov/dph/boards)



**Disclosure of Above Action Level**

MARYLOU SUDDERS

Secretary

MONICA BHAREL, MD, MPH Commissioner

CHARLES D. BAKER

Governor

KARYN E. POLITO

Lieutenant Governor

**Environmental Monitoring (EM) Results**

**Form 2 of 2: Final Reporting Form**

**Pharmacy Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\_\_\_\_\_\_\_\_\_\_\_MA License Number\_\_\_\_\_\_\_\_\_\_\_­­­­­

Pharmacy Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City/Town \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_State\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Zip Code \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Pharmacy Tel. No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Pharmacy Fax No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Manager of Record (MOR) Name (print)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ MOR MA License Number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Pharmacy / MOR Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Within 21 days of Form 1 Initial Reporting Form submission, a signed copy of this form and final repeat EM report must be scanned and emailed to:** [**abnormalresults@MassMail.State.MA.US**](mailto:abnormalresults@MassMail.State.MA.US)

**Specify the name of the pharmacy, town, and state in the subject line.**

**\*All documentation (RCA, CAPA, disclosure forms, etc.) must be kept on site and available for Board inspection.**

|  |  |
| --- | --- |
| **Initial Sampling Date** |  |
| **Repeat Sampling Date** |  |
| **Date/Time Pharmacy Notified of Results** |  |
| **Date Final Repeat EM Report Received by Pharmacy** |  |
| **Results within Action Levels?**  **If no, please use Form 1.** |  |
| **Reporting Laboratory** |  |
| **Root Cause Analysis (RCA) summary** |  |
| **Corrective Action / Preventative Action (CAPA) summary** |  |
| **Date Resumed Standard BUD (if applicable)** |  |
| **Date Resumed Sterile Compounding (if applicable)** |  |

**Non-Viable Air Sample Action Levels per USP <797>:**

|  |  |
| --- | --- |
| **ISO Class 5** | **>3520 particles 0.5 µm or larger per cubic meter of air** |
| **ISO Class 7** | **>352,000 particles 0.5 µm or larger per cubic meter of air** |
| **ISO Class 8** | **>3,520,000 particles 0.5 µm or larger per cubic meter of air** |

**Viable Air Sample Action Levels per USP <797>:**

|  |  |
| --- | --- |
| **ISO Class 5** | **> 1 CFU** |
| **ISO Class 7** | **> 10 CFU** |
| **ISO Class 8** | **> 100 CFU** |
| **Highly pathogenic microorganisms, including gram-negative rods, coagulase positive staphylococcus, and fungi** | > **1 CFU** |

**Viable Surface Sample Action Levels per USP <797>:**

|  |  |
| --- | --- |
| **ISO Class 5** | **> 3 CFU** |
| **ISO Class 7** | **> 5 CFU** |
| **ISO Class 8** | **> 100 CFU** |
| **Highly pathogenic microorganisms, including gram-negative rods, coagulase positive staphylococcus, and fungi** | > **1 CFU** |

**Please direct any questions to:** [**abnormalresults@MassMail.State.MA.US**](mailto:abnormalresults@MassMail.State.MA.US)

**The FAILURE of any Massachusetts pharmacy or pharmacist to make a report required by 247 CMR to the Board within the timeframe stated in 247 CMR will be grounds for discipline under 247 CMR 10.03(q).**

**Attestation**:

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name), of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_(name of pharmacy), attest that all steps for remediation have been completed according to the standards set forth in USP <797> and all classified spaces are in a state of control.

MOR Name (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of MOR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_