



The Commonwealth of Massachusetts
 Executive Office of Health and Human Services
 Bureau of Public Health
 Bureau of Health Professions Licensure
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CHARLES D. BAKER
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 Lieutenant Governor

MARYLOU SUDDERS
 Secretary

MONICA BHAREL, MD, MPH
 Commissioner

**Disclosure of Above Action Level
 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 name (MOR) (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
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.**

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

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: _____ MA License Number: _____

Signature of MOR: _____ Date: _____