



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
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Board of Registration in Pharmacy

Action Level Environmental Monitoring Result Form

Pharmacy Name _____ MA License Number _____
Pharmacy Address _____
City/Town _____ State _____ Zip Code _____
Pharmacy Tel. No. _____ Pharmacy Fax No. _____
Name of Manager of Record (MOR)
(print) _____
MOR MA License Number _____
Pharmacy / MOR Email _____

Within 7 days of notification of AAL result, a signed copy of this form must be scanned and emailed to: AbnormalResults@mass.gov Specify the name of the pharmacy and license number in the subject line. **Date notified of result:** _____

Have there been any other action level reports within the last 60 days? **Yes / No**
If yes, date of report: _____

Confirm that BUDs for compounded preparations dispensed into, within, or from Massachusetts will be limited, or compounding suspended in accordance with [Policy 2023-09: Action Level Environmental Monitoring Results](#) **MOR initials:** _____

If the action level occurred in an **ISO 5 PEC**, provide the date that it was removed from service.
Date: _____

If the pharmacy has ceased all sterile compounding, indicate the effective date: _____

*All documentation (microbiology reports, RCA, CAPA, disclosure forms, etc.) must be kept on site and available upon Board request.

ISO Classification	Positive / Negative Pressure?	Air / Surface Result?	Organism Identification	CFU Count	Non-Viable Particle Count (only report if action level)

See [guidance](#) to help ascertain root cause and develop a remediation plan.

Non-Viable Air Sample Action Levels:

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 (cumulative count):

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 (cumulative count):

ISO Class 5	> 3 CFU
ISO Class 7	> 5 CFU
ISO Class 8	> 50 CFU
Highly pathogenic microorganisms, including gram-negative rods, coagulase positive staphylococcus, and fungi	≥ 1 CFU

Attestation:

I, _____ (MOR), of _____ (pharmacy name), attest that all steps for response and remediation will be completed according to the standards set forth in the current USP <797>, Board regulations and policies (including [Policy 2023-09: Action Level Environmental Monitoring Results](#)), and that all ISO classified spaces shall have repeat environmental sampling results within action levels prior to resuming the facility's standard sterile compounding activities.

MOR Signature: _____ Date: _____