



**Board of Registration in Pharmacy**

**Action Level Environmental Monitoring Result Disclosure**

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](mailto: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:** \_\_\_\_\_

If the action level occurred in an **ISO 5 PEC**, confirm that it has been removed from service.  
**MOR initials:** \_\_\_\_\_

Confirm that BUDs for compounded preparations dispensed into or from Massachusetts will be limited, or compounding suspended in accordance with [Board Policy: Sterile Compounding Pharmacy Response to Above Action Level Environmental Monitoring Results](#)  
**MOR initials:** \_\_\_\_\_

\*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 above action level)

**Guidance to ascertain root cause and develop a remediation plan:**

<https://www.mass.gov/doc/remediation-considerations-for-handling-above-action-level-environmental-monitoring-em-1/download>

**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: Sterile Compounding Pharmacy Response to Above 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: \_\_\_\_\_