

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
250 Washington Street, Boston, MA 02108-4619

Tel: 617-973-0960 TTY: 617-973-0960 www.mass.gov/dph/boards

Board of Registration in Pharmacy

Action Level Environmental Monitoring Result Disclosure

Pharmacy Name	e		MA	A License	Number
Pharmacy Addr	ess		Statesignated Pharmacist-in-		
City/Town			State	Zip C	ode
Pharmacy Tel. 1	No				
Name of Manag	ger of Record	$(MOR) / D\epsilon$	esignated Pharmacist-in-	Charge (P	PIC)
(print)					
MOR / PIC MA	License Nun	nber			
Pharmacy / MO	R / PIC Emai	i1			
Within 1 (one) 1	business day	of receipt of	the microbiology report	<mark>,</mark> a signed	copy of this form
must be scanned	d and emailed	to: Abnorm	nalResults@mass.gov S1	pecify the	name of the
pharmacy and l					
*					
Dute report wa	_				_
Have there heer	n any other ac	tion level re	ports within the last 60 d	love?	
				iays:	
If yes, date of r	ерог с.				
Confirm that RI	IDs for comr	sounded pres	parations dispensed into	within o	r from Massachusetts
Confirm that BUDs for compounded preparations dispensed into, within, or from Massachusetts					
will be limited, or compounding suspended in accordance with <u>Policy 2023-09</u> : <u>Action Level Environmental Monitoring Results</u> MOR/PIC initials:					
Environmental Monting Results MONTIC Illitials.					
If the action lev	el occurred ir	on ISO 5 E	PEC, provide the date that	at it was r	emoved from service
Date:	ci occurred ii.	1 an 150 5 1	EC, provide the date the	ii ii was i	chioved from service.
Datt					
If the pharmac	y has caasad	all starila c	ompounding, indicate the	he effectiv	ve date:
II the pharmae	y nas ccascu	an sterne c	ompounding, maleate the	iic ciiccti	ve date.
ISO	Positive /	Air /	Organism	CFU	Non-Viable Particle
Classification	Negative	Surface	Identification	Count	Count
(e.g., 5, 7, 8)	Pressure?	Result?	required for ISO 5 PECs, ISO 7 buffer rooms, and any action level growth in other ISO classified areas		(only report if action level)

Classification (e.g., 5, 7, 8)	Positive / Negative Pressure?	Air / Surface Result?	Organism Identification required for ISO 5 PECs, ISO 7 buffer rooms, and any action level growth in other ISO classified areas	CFU Count	Non-Viable Particle Count (only report if action level)

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Additional Questions	Yes, No, N/A, or provide requested information
1. If there has been a significant loss of control (>15 CFU) in the ISO 5 PEC, did/will the pharmacy recall any CSP that are within their BUDs, perform adverse event surveillance, contact prescribers, and engage a qualified microbiology professional?	
2. If the action level was associated with non-viable particles in any ISO classified area, did/will compounding be suspended until successfully remediated and all classified areas are recertified?	
3. Did/will the continuity of care plan [as required by 247 CMR 9.19(15)] to meet patient needs be instituted in the event compounding must be suspended?	
4. Have/will remedial cleaning activities been initiated with the appropriate cleaning agents based on the organism(s) identified?	
5. Has/will a risk assessment/risk mitigation plan been initiated to determine whether it is appropriate to compound during remediation in accordance with Policy 2023-09 : Action Level Environmental Monitoring Results?	
6. For action levels identified in ISO Class 5 PECs, was/will all compounding be transitioned to unaffected PECs until proper remediation has been completed?	
7. If only one ISO Class 5 PEC is available for compounding, will BUDs be limited to "immediate use only" until proper remediation has been completed?	
8. For action levels identified in ISO Class 7 Buffer Rooms, will BUDs for all CSPs be limited to 24 hours room temperature or 4 days refrigerated until proper remediation has been completed?	
 9. Until proper remediation has been completed for action levels identified in ISO Class 7 Areas (except buffer rooms) and ISO Class 8 Areas, will BUDs be limited to: a. 24 hours room temperature or 4 days refrigerated if prepared from one or more nonsterile starting component(s); or b. 4 days room temperature or 10 days refrigerated if prepared from sterile starting component(s)? 	Describe:
10. Has repeat environmental monitoring (EM) of the entire affected classified area (air and surface samples) based on the pharmacy's EM sampling plan been scheduled?	Date scheduled:
11. Has a root cause analysis (RCA) investigation been initiated?12. Has a Corrective Action and Preventative Action plan (CAPA) been initiated and actions documented?	
13. Confirm that all documentation (microbiology reports, RCA, CAPA, disclosure forms, etc.) will be kept on site and available upon Board request.	

See guidance to help ascertain root cause and develop a remediation plan.

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Non-Viable Air Sample Action Levels:

Attestation:

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

Viable Surface Sample Action Levels (cumulative count):

ISO Class 5	> 3 CFU
ISO Class 7	> 5 CFU
ISO Class 8	> 50 CFU

I, (MOR / PIC),	of	(pharmacy name), at	ttest
that all steps for response and remediation	n will be completed a	according to the standards set f	orth
in the current USP <797>, Board regula	ations and policies (including Policy 2023-09: Ac	tion
Level Environmental Monitoring Results), and that all affecte	d ISO classified spaces shall h	nave
repeat environmental sampling results	within action levels	prior to resuming the facili	ty's
standard sterile compounding activities.			

MOR/PIC Signature:	Date:

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