

	Document:	Form LAB-007-3-W		Revision:	22
	Title:	Environmental Monitoring – ISO Class 5 Results			
	Effective Date:	10 Feb 2022	Associated Document:	SOP LAB-007-W	
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Product Lot Number:	NDC Number:
Product Name:	
Date of Compounding:	ISO 5 Equipment Number:

Results: (if necessary, multiple pages can be included to document relevant data –include pagination)

Page ____ of ____

N/A Gloved Fingertip and Sleeve Monitoring: Acceptance Criteria = No Growth							Collected By:		
N/A	Compounder Initials	Sample Time	Results				Pass	Action	Documented by (Initials/Date)
			Left Gloved Fingertip	Right Gloved Fingertip	Left Sleeve	Right Sleeve			

N/A Passive Viable Air Monitoring: Acceptance Criteria = No Growth							Collected By:		
N/A	Exposure Start Time	Exposure End Time	Passive Viable Air Total Exposure (Time)	Results (CFU/Plate)			Pass	Action	Documented by (Initials/Date)
				Left	Center	Right			
				N/A	N/A	N/A			
				N/A	N/A	N/A			
				N/A	N/A	N/A			
				N/A	N/A	N/A			

N/A Viable Surface Monitoring: <i>Acceptance Criteria = No Growth</i>					Collected By:		
N/A	Sample ID	Sample Time	Total CFU/Plate	Pass	Action	Documented by (Initials/Date)	
	Left Plate:						
	Center Plate:						
	Right Plate:						

N/A Active Viable Air Monitoring: Acceptance Criteria = No Growth							Collected By:		
N/A	Sample ID	Viable Air EQ Number	Sample Start Time	Total CFU/plate	Most Probable Number (MPN)	Final Results (CFU/m ³)	Pass	Action	Documented by (Initials/Date)

N/A Non-Viable Particulate Monitoring: Acceptance Criteria = <3,520 particles/m³						Collected By:			
N/A	Sample ID	Non-Viable Particle Counter Equipment	Sample Time	Results (0.5µm particles/m ³)		Pass	Alert	Action	Documented by (Initials/Date)

Comments N/A:

N/A: Number of Distinct Morphologies for RS/LS Sample(s): _____

N/A: Number of Distinct Morphologies for RF/LF Sample(s): _____

N/A: Excursion Number: _____

Completed By/Date: _____ Reviewed By/Date: _____