

RECOMMENDED ACTION LEVELS FOR MICROBIAL CONTAMINATION

USP 797 states that the tables of recommended action levels are intended to be used as guidelines only, and "Action levels are determined on the basis of CFU data gathered at each sampling location and trended over time." "Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase-positive *Staphylococcus*, molds, and yeasts)...must be immediately remedied, regardless of CFU count."

(Version USP 40-NF 35)

Action Level for BIOAEROSOL Samples	
CLASSIFICATION	Total CFU per m ³
ISO Class 5	>1
ISO Class 6	>10
ISO Class 7	>10
ISO Class 8 or worse	>100

Action Level for GLOVED FINGERTIP Samples		
Total CFU for both hands		
	Initial Garbing	Subsequent (Post Media Fill)
	>0	>3

Action Level for SURFACE Samples	
CLASSIFICATION	Total CFU per plate, swab, or area sampled
ISO Class 5	>3
ISO Class 6	>5
ISO Class 7	>5
ISO Class 8 or worse	>100

USP <797> Standard Operating Procedure

- **Incubation**
 - Samples are placed in the incubator on the day that they are received in the laboratory.
 - Bacterial agar plates: 30-35°C for 48-72 hours.
 - Fungal agar plates: 20-25°C for 5-7 days.
 - Single plate method agar plates: 30-35°C for 48-72 hours and then 20-25°C for 5-7 additional days.
 - Media fill vials: 20-25°C for 7 days and then 30-35°C for 7 days.
 - Incubator temperatures are monitored 24/7 via a wireless temperature monitoring and alert system.
- **Identification** - species identification performed by MALDI-TOF mass spectrometry.
- **Positive Controls** - performed with the following organisms when requested:
 - *Staphylococcus aureus* ATCC 6538
 - *Pseudomonas aeruginosa* ATCC 9027
 - *Bacillus subtilis* ATCC 6633
 - *Candida albicans* ATCC 10231
 - *Aspergillus brasiliensis* ATCC 16404
- **Accreditation**
 - ISO/IEC 17025:2017 accreditation for bacterial and fungal analysis through the American Industrial Hygiene Association (AIHA-LAP, LLC #103009).