

## 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."

Action Level for BIOAEROSOL TESTING	
CLASSIFICATION	TOTAL CFU/m <sup>3</sup>
ISO Class 5	>1
ISO Class 6	>10
ISO Class 7	>10
ISO Class 8 or worse	>100

Action Level for GLOVED FINGERTIP		
TOTAL CFU/both hands		
	Gowning	Post Fill
	>0	>3

Action Level for SURFACE SAMPLING	
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: 26-30°C for 5-7 days.
  - Single plate method agar plates: 30-35°C for 48-72 hours and then 26-30°C for 5-7 days.
  - Media fill vials: 20-25°C for 7 days and then 30-35°C for 7 days.
  - Cultures are examined daily (Mon – Sat).
  - Incubator temperatures are monitored 24/7 via a wireless temperature monitoring and alert system.
- **Growth Promotion** - performed with the following organisms when requested:
  - *Staphylococcus aureus* ATCC 25923
  - *Pseudomonas aeruginosa* ATCC 9027
  - *Bacillus subtilis* ATCC 6633
  - *Candida albicans* ATCC 10231
  - *Aspergillus brasiliensis* NCPF 2275
- **Accreditation**
  - ISO/IEC 17025:2017 accreditation for bacterial and fungal analysis through the American Industrial Hygiene Association (AIHA-LAP, LLC #103009).