

USP <797> ACTION LEVELS FOR MICROBIAL CONTAMINATION

If levels measured during viable air sampling and/or surface sampling exceed the levels in the tables, an attempt must be made to identify any microorganisms recovered to the genus level with the assistance of a microbiologist.

Version USP NF-2022

Action Levels for BIOAEROSOL Samples	
CLASSIFICATION	Total CFU per m ³
ISO Class 5	>1
ISO Class 7	>10
ISO Class 8	>100

Action Levels for GLOVED FINGERTIP Samples		
Total CFU for both hands		
	After Garbing	After Media Fill
	>0	>3

Action Levels for SURFACE Samples	
CLASSIFICATION	Total CFU per plate, swab, or area sampled
ISO Class 5	>3
ISO Class 7	>5
ISO Class 8	>50

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 no less than 48 hours.
 - Fungal agar plates: 20-25°C for no less than 5 days.
 - Single plate method agar plates: 30-35°C for no less than 48 hours and then 20-25°C for no less than 5 days.
 - Media fill vials: 20-25°C for a minimum of 7 days and then 30-35°C for a minimum of 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 accreditation for bacterial and fungal analysis through the American Association for Laboratory Accreditation (A2LA # 7000.01).