

Final Report

Name:	ABC Pharmacy	Collection Date:	12/05/2023
Address:	1234 Main Street	Receipt Date:	12/06/2023
Phone:	New Town, PA 12345	Analysis Date:	12/14/2023
PO#:	800-123-4567	Report Date:	12/14/2023
Project Name:	25487	Lab #:	12-001234-23
	December Certification		

Media

Media	Manufacturer	Lot #	Exp. Date
CT3P - Tryptic Soy Agar w/ Lecithin & Polysorbate 80	bioMerieux	1010237000	03-30-2024
TSA 3P - Tryptic Soy Agar	bioMerieux	1010183310	08-20-2024

Air Sampler

Sampler	# holes in impaction head
Lighthouse Active Count 100	300
Bioaerosol final results are pore corrected.	

ISO 17025 accreditation - A2LA #7000.01

Samples are in good condition unless otherwise noted. Results relate only to the samples tested as received.

Results are reported as calculated.

For biological data, the first and/or second digit should be considered significant.

This report has been reviewed for accuracy and compliance with ISO17025 Quality Standards prior to release.

Authorization:



Date Generated
12-14-2023 1109

Joelle Miele, Quality Technician

ABC Pharmacy

December Certification

Lab #:12-001234-23

Contact Single Plate - Bacterial & Fungal Counts only

Analytical Method MIC 05

Customer sample numbers below are uniquely identified by prefixing laboratory #12-001234-23

Sample ID	Sample Description	ISO Class	Analytical Sensitivity (CFU/plate)	Bacterial Raw Count	* Fungal Raw Count	Total Microbial Count (CFU/plate)	Identification	Raw Count of IDs	Pass/ OOC	Reason for OOC	Notes
1	BSC #1	5	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
2	C	7	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
3	B	7	1	1	0	1	N/A	N/A	Pass	N/A	N/A
4	BSC #2	5	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
5	A	7	1	1	0	1	N/A	N/A	Pass	N/A	N/A

* Fungus (Yeast/Mold) CFU = Colony forming unit NA = Not applicable OOC = Out of Compliance

ABC Pharmacy

December Certification

Lab #:12-001234-23

Bioaerosol Single Plate - Bacterial & Fungal Counts only

Analytical Method MIC 05

Customer sample numbers below are uniquely identified by prefixing laboratory #12-001234-23

Sample ID	Sample Description	Vol. (L)	ISO Class	Analytical Sensitivity (CFU/m3)	Bacterial Raw Count	* Fungal Raw Count	Total Microbial Count (CFU/m3)	Identification	Raw Count of IDs	Pass/ OOC	Reason for OOC	Notes
1A	BSC #1	1000	5	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
2A	C	1000	7	1	5	0	5	N/A	N/A	Pass	N/A	N/A
3A	BSC #2	1000	5	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
4A	B	1000	7	1	2	0	2	N/A	N/A	Pass	N/A	N/A
5A	A	1000	7	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A

* Fungus (Yeast/Mold) CFU = Colony forming unit NA = Not applicable OOC = Out of Compliance

ABC Pharmacy

December Certification

Lab #:12-001234-23

Media Control Positive Control-Single Plate

Analytical Method MIC 05

Customer sample numbers below are uniquely identified by prefixing laboratory #12-001234-23

Sample ID	Sample Description	Media Type	Media Lot #	Identification	Pass/ OOC	Notes
POS-C	+ Control	CT3P	1010237000	Growth of Aspergillus brasiliensis Growth of Bacillus subtilis Growth of Candida albicans Growth of Pseudomonas aeruginosa Growth of Staphylococcus aureus	Pass	N/A
POS-A	+ Control	TSA 3P	1010183310	Growth of Aspergillus brasiliensis Growth of Bacillus subtilis Growth of Candida albicans Growth of Pseudomonas aeruginosa Growth of Staphylococcus aureus	Pass	N/A

NA = Not applicable OOC = Out of Compliance

Media Control Negative Control-Single Plate

Analytical Method MIC 05

Customer sample numbers below are uniquely identified by prefixing laboratory #12-001234-23

Sample ID	Sample Description	Media Type	Media Lot #	Identification	Pass/ OOC	Notes
NEG-C	- Control	CT3P	1010237000	N/A	Pass	N47
NEG-A	- Control	TSA 3P	1010183310	N/A	Pass	N47

NA = Not applicable OOC = Out of Compliance

N47 = Results are not blank corrected

End of Report

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	
	Initial (Garbing)	Subsequent (Post 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).