U.S. MICRO SOLUTIONS INC.
AN ENVIRONMENTAL MICROBIOLOGY LAB

302 Unity Plaza
Latrobe, PA 15650
Phone: (724) 853-4047
www.usmslab.com

Final Report

Name:	ABC Pharmacy	Collection Date:	12/09/2022
Address:	123 Main Street Stanford, Pa 12345	Receipt Date:	12/10/2022
Phone:	123-456-7890	Analysis Date:	12/19/2022
PO#:	5698-22	Report Date:	12/19/2022
Project Name:	ABC Main Hospital	Lab #:	**12-00123-22**

Media

Media	Manufacturer	Lot #	Exp. Date
CT3P - Tryptic Soy Agar w/ Lecithin & Polysorbate 80	bioMerieux	1009552760	02-28-2023
TSA 3P - Tryptic Soy Agar	bioMerieux	1009470660	07-12-2023

Air Sampler

Sampler	# holes in impaction head
SAS 180	219
Final results are pore corrected	

ISO 17025 accreditation - AIHA-LAP, LLC EMLAP #103009

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: Deanna Kiska

Date Generated
12-19-2022 0912

Deanna L. Kiska, Ph.D.

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Final Report

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ABC Pharmacy | **Main Hospital** | **Lab # 12-00123-22**

Bioaerosol Single Plate - Bacterial & Fungal Counts w/ Genus Identification

Analytical Method MIC 05

Customer sample numbers below are uniquely identified by prefixing laboratory #12-004365-22

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
1	Center of work surface in Left Labconco Clean Bench	1000	5	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
2	Center of work surface in Right Labconco Clean Bench	1000	5	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
3	Center of IV Buffer Room	1000	7	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
5	Center of Anteroom	1000	7	1	11	0	11	Bacillus spp.	11	OOC	Counts Exceed	N/A

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

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Final Report

ABC Pharmacy | **Main Hospital** | **Lab # 12-00123-22**

Contact Single Plate - Bacterial & Fungal Counts w/ Genus Identification

Analytical Method MIC 05

Customer sample numbers below are uniquely identified by prefixing laboratory #12-004365-22

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	Center of work surface in Left Labconco Clean Bench	5	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
2	Center of work surface in Right Labconco Clean Bench	5	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
4	Center of left counter in IV Buffer Room	7	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
6	Center of left counter in Anteroom	7	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
7	Center of right counter in IV Buffer Room	7	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A
8	Center of Right counter Ante Room	7	1	0	0	< 1	N/A	N/A	Pass	N/A	N/A

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ABC Pharmacy **Main Hospital** **Lab # 12-00123-22**

Media Control Positive Control-Single Plate

Analytical Method MIC 05

Customer sample numbers below are uniquely identified by prefixing laboratory #12-004365-22

Sample ID	Sample Description	Media Type	Media Lot #	Identification	Pass/ OOC	Notes
Blank Control	Positive Blank Control	TSA 3P	1009470660	Growth of Aspergillus brasiliensis Growth of Bacillus subtilis Growth of Candida albicans Growth of Pseudomonas aeruginosa Growth of Staphylococcus aureus	Pass	N/A
Blank Control	Positive Blank Control	CT3P	1009552760	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 #12-004365-22

Sample ID	Sample Description	Media Type	Media Lot #	Identification	Pass/ OOC	Notes
Blank Control	Negative Blank Control	TSA 3P	1009470660	N/A	Pass	N47
Blank Control	Negative Blank Control	CT3P	1009552760	N/A	Pass	N47

NA = Not applicable OOC = Out of Compliance

N47 = Results are not blank corrected

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Final Report

ABC Pharmacy **Main Hospital** **Lab # 12-00123-22**

Organism Monograph

Bacillus spp. - Bacillus species are gram-positive, rod-shaped bacteria that are ubiquitous in nature. They form spores that are resistant to heat, desiccation, radiation, and disinfectants. Dissemination of spores via aerosols and dust contributes to contamination of indoor environments.

End of Report

U.S. MICRO-SOLUTIONS INC.
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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).

BIOMÉRIEUX

REF 418140

LOT 1009470660

Certificate of Analysis
Certificat d' Analyse

REF 418140 Irr Tryptic Soy 3P Agar 100PLT

LOT 1009470660 Gélose Trypticase Soja Irradiée 3P 100BTES

2022-07-05 YYYY-MM-DD

2023-07-12 YYYY-MM-DD

Revision : 1

Animal or Human origin / Produit d'origine humaine ou animale

Component / Composant	Source / Origine	Risk Category / Catégorie de	Country / Pays
Bovine / Bovin	Bovine / Bovine	IV	Australia / Australie, New Zealand / Nouvelle-Zélande

Animal Origin Notes

BioMérieux, Inc. screens applicable raw materials to ensure that source regions are not implicated in incidents of bovine spongiform encephalitis (BSE) or transmissible spongiform encephalitis (TSE) in compliance with the FDA's Code of Federal Regulations Title 9 Section 94.18.
Countries of origin for bovine materials in this product are restricted to New Zealand, United States and Australia. Bovine components include beef extract from skeletal muscle and/or casein from milk.
BioMérieux, Inc. inspecte les matières premières applicables afin de s'assurer que les régions d'origine ne sont pas impliquées dans des incidents d'encéphalite spongiforme bovine ou d'encéphalite spongiforme transmissible, conformément au Code of Federal Regulations Title 9 Section 94.18 de la FDA.
Les pays d'origine des composants bovins de ce produit sont restraints à la Nouvelle-Zélande, aux USA et à l'Australie. Les composants bovins contiennent des extraits de boeuf de muscle squelettique et/ou de caséine de lait.

Test(s) / Contrôle(s)	Result(s) / Résultat(s)	Specification(s) / Spécification(s)
Maximum Delivered Dose Dose Delivrée Maximale	14.2 kGy	Dose Range 9.1 - 22.0 kGy Dose 9.1 - 22.0 kGy
Minimum Delivered Dose Dose Delivrée Minimale	10.7 kGy	Dose Range 9.1 - 22.0 kGy Dose 9.1 - 22.0 kGy
Date	6-Jul-22	Irradiation Run Date
Appearance Test Test d'Apparence	Conform / Conforme	Lt - Med. Amber, Clear to Trace Hazy, Firm Gel Ambré Clair à Ambré Moyen, De Clair à Légèrement Opalescent, Gel Ferme
pH	7.5	7.3 ± 0.2 @ 25°C
ASPERGILLUS BRASILIENSIS ATCC 16404	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
BACILLUS SUBTILIS ATCC 6633	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
CANDIDA ALBICANS ATCC 10231	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
ESCHERICHIA COLI ATCC 8739	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
PSEUDOMONAS AERUGINOSA ATCC 9027	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
STAPHYLOCOCCUS AUREUS ATCC 6538	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %

bioMérieux Inc.
1121 North Main Street, Lombard, IL 60148
Tel : 630-628-6055 / 800-634-7656 Fax : 800-657-3053
www.biomerieux-usa.com

BIOMÉRIEUX

REF 418140

LOT 1009470660

bioMérieux, Inc. is certified to ISO 9001 and is compliant with FDA Quality System Regulations (QSR) 21CFR820. This product has met all bioMérieux, Inc. quality standards and has been released for distribution.
Irradiated media is validated to a Sterility Assurance Level (SAL) of 10-5 in unopened/undamaged packages. Sterility is evaluated with minimum incubation time of 5 days at 20-25C and 33-37C.
3P is a registered trademark of bioMérieux, Inc. ATCC is a registered trademark of American Type Culture Collection. Growth promotion testing is compliant to requirements by the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP). Media pH will vary depending on the age of the product and the type of pH meter and probe used.
bioMérieux, Inc. est certifié ISO 9001 et est conforme au FDA Quality System Regulations (QSR) 21CFR820. Ce produit répond aux standards de qualité de bioMérieux, Inc. et a été libéré pour distribution.
Les milieux de culture irradiés sont validés conformément à un niveau de stérilité de 10-5 dans des emballages non ouverts et non endommagés. La stérilité est évaluée avec un temps d'incubation minimum de 5 jours à 20-25C et 33-37C.
3P est une marque déposée d'ioMérieux, Inc. ATCC est une marque déposée d'American Type Culture Collection. Les tests de croissance sont conformes aux exigences de la Pharmacopée des Etats-Unis (USP), de la Pharmacopée Européenne (EP) et de la Pharmacopée Japonaise. Le pH varie avec l'âge du produit et le type de pH-mètre et de sonde utilisés.

Lot accepted on / Lot accepté le:	25-JUL-2022	by / par:	Vikas Kewalramani - Manager, Quality Lombard
			Quality Department / Département Qualité
			Lombard

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BIOMÉRIEUX

REF 418049

LOT 1009552760

Certificate of Analysis
Certificat d' Analyse

REF 418049 Irr Count-Tact 3P Agar 100PLT

LOT 1009552760 Count Tact Irradiées 3P 100BTES

2022-08-30 YYYY-MM-DD

2023-02-28 YYYY-MM-DD

Revision : 1

Animal or Human origin / Produit d'origine humaine ou animale

Component / Composant	Source / Origine	Risk Category / Catégorie de	Country / Pays
Bovine / Bovin	Bovine / Bovine	IV	Australia / Australie, New Zealand / Nouvelle-Zélande, USA / Etats Unis d Amérique

Animal Origin Notes

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Test(s) / Contrôle(s)	Result(s) / Résultat(s)	Specification(s) / Spécification(s)
Maximum Delivered Dose Dose Delivrée Maximale	13.0 kGy	Dose Range 9.1 - 22.0 kGy Dose 9.1 - 22.0 kGy
Minimum Delivered Dose Dose Delivrée Minimale	9.9 kGy	Dose Range 9.1 - 22.0 kGy Dose 9.1 - 22.0 kGy
Date	31-Aug-22	Irradiation Run Date
Appearance Test Test d'Apparence	Conform / Conforme	Lt - Med. Amber, Clear to Trace Hazy, Firm Gel Ambré Clair à Ambré Moyen, De Clair à Légèrement Opalescent, Gel Ferme
pH	7.3	7.3 ± 0.2 @ 25°C
ASPERGILLUS BRASILIENSIS ATCC 16404	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
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PSEUDOMONAS AERUGINOSA ATCC 9027	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
STAPHYLOCOCCUS AUREUS ATCC 6538	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
ESCHERICHIA COLI ATCC 8739	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %

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Lot accepted on / Lot accepté le:	10-OCT-2022	by / par:	Vikas Kewalramani - Manager, Quality Lombard
			Quality Department / Département Qualité
			Lombard

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