

ISO 9001: 2015 NO-801202

Microbial Analysis Report

TSS Training

Service Order: NC-TRAI2451NGA-1

Sampled Date: 03/25/2024

Training Facility

Lab Project ID: 2408500002

Received Date: 03/26/2024

620 Hearst Ave

Report Date: 04/04/2024

Berkeley, CA 94710

Sample ID	Sample Type	Media	ISO Class	CFU Result	Result	Comments
A1	Active Air	TSA Settling Plate	ISO-5	3	OOO	Exceeds Action Limits
A2	Active Air	TSA Settling Plate	ISO-7	1	Acceptable	
A3	Active Air	TSA Settling Plate	ISO-8	0	No Growth	
Air Control	Active Air	TSA Settling Plate	NA	0	No Growth	
S1	Surface	TSA Contact Plate	ISO-5	0	No Growth	
S2	Surface	TSA Contact Plate	ISO-7	0	No Growth	
S3	Surface	TSA Contact Plate	ISO-8	0	No Growth	
Surface Control	Surface	TSA Contact Plate	NA	0	No Growth	

No Growth: No growth of microorganisms. Sample in compliance with USP <797> and CETA CAG-009 guidance documents.

Acceptable: Growth of microorganisms. Sample in compliance with USP <797> and CETA CAG-009 guidance documents.

FIO: For Information Only.

TNTC: Too Numerous to Count.

OOO: Out of Compliance. Unacceptable concentrations. Sample not in compliance with USP <797> and CETA CAG-009 guidance documents.

CFU Result: CFU results are reported as CFU/m³ for all Active Air samples, and CFU/plate for all Surface, Fingertip, and Passive Air samples. TNTC represents a total CFU count that is innumerable. CFU totals are not applicable for Media Fill samples.

TBD: To be determined.

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Sample ID: A1		Active Air		Lab Sample ID: 2408500002-1	
Test: USP <797> 2023 Single Media Dual Incubation ID All Growth Over Limit Plus Pathog				ISO Class: ISO-5	
Condition of sample upon receipt: Media in good condition				Sample Size: 1000 Liters	
Positive Holes: 400				Alert Limit: NA	
Positive Hole Corrected Result: 3 CFU/m³				Action Limit: 1	
Final Result: OOC		Media: TSA Settling Plate		Lot: 123456789	
				Exp.2024-04-30	
Temperature: 30-35 C		Start Date: 03/26/2024		End Date: 03/28/2024	
<u>Organism(s) Isolated</u>	<u>Pathogenic</u>	<u>Raw Count</u>	<u>CFU/m³</u>	<u>% Total</u>	<u>Reservoirs</u>
Staphylococcus aureus	Yes	1	1	33.33%	Human
Staphylococcus epidermidis	No	2	2	66.67%	Human/Env.
Growth:		3	3	100.00%	
Temperature: 20-25 C		Start Date: 03/28/2024		End Date: 04/03/2024	
Total Growth:		3	3	100.00%	

Sample ID: A2		Active Air		Lab Sample ID: 2408500002-2	
Test: USP <797> 2023 Single Media Dual Incubation ID All Growth Over Limit Plus Pathog				ISO Class: ISO-7	
Condition of sample upon receipt: Media in good condition				Sample Size: 1000 Liters	
Positive Holes: 400				Alert Limit: NA	
Positive Hole Corrected Result: 1 CFU/m³				Action Limit: 10	
Final Result: Acceptable		Media: TSA Settling Plate		Lot: 123456789	
				Exp.2024-04-30	
Temperature: 30-35 C		Start Date: 03/26/2024		End Date: 03/28/2024	
Growth:		1	1	100.00%	
Temperature: 20-25 C		Start Date: 03/28/2024		End Date: 04/03/2024	
Total Growth:		1	1	100.00%	

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Sample ID: A3	Active Air	Lab Sample ID: 2408500002-3
Test: USP <797> 2023 Single Media Dual Incubation ID All Growth Over Limit Plus Pathog		ISO Class: ISO-8
Condition of sample upon receipt: Media in good condition		Sample Size: 1000 Liters
Positive Holes: 400		Alert Limit: NA
Positive Hole Corrected Result: 0 CFU/m³		Action Limit: 100
Final Result: No Growth	Media: TSA Settling Plate Lot: 123456789	Exp. 2024-04-30
Temperature: 30-35 C	Start Date: 03/26/2024	End Date: 03/28/2024
Temperature: 20-25 C	Start Date: 03/28/2024	End Date: 04/03/2024

Sample ID: Air Control	Active Air	Lab Sample ID: 2408500002-4
Test: USP <797> 2023 Single Media Dual Incubation ID All Growth Over Limit Plus Pathog		ISO Class: NA
Condition of sample upon receipt: Media in good condition		Sample Size: NA
Positive Holes: 400		Alert Limit: NA
Positive Hole Corrected Result: 0 CFU/m³		Action Limit: NA
Final Result: No Growth	Media: TSA Settling Plate Lot: 123456789	Exp. 2024-04-30
Temperature: 30-35 C	Start Date: 03/26/2024	End Date: 03/28/2024
Temperature: 20-25 C	Start Date: 03/28/2024	End Date: 04/03/2024

Sample ID: S1	Surface	Lab Sample ID: 2408500002-5
Test: USP <797> 2023 Single Media Dual Incubation ID All Growth Over Limit Plus Pathog		ISO Class: ISO-5
Condition of sample upon receipt: Media in good condition		Sample Size: 1 Plate
Positive Holes: NA		Alert Limit: NA
Plate Result: 0 CFU/Plate		Action Limit: 3
Final Result: No Growth	Media: TSA Contact Plate Lot: 123456789	Exp. 2024-04-30
Temperature: 30-35 C	Start Date: 03/26/2024	End Date: 03/28/2024
Temperature: 20-25 C	Start Date: 03/28/2024	End Date: 04/03/2024

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Sample ID: S2	Surface	Lab Sample ID: 2408500002-6
Test: USP <797> 2023 Single Media Dual Incubation ID All Growth Over Limit Plus Pathog		ISO Class: ISO-7
Condition of sample upon receipt: Media in good condition		Sample Size: 1 Plate
Positive Holes: NA		Alert Limit: NA
Plate Result: 0 CFU/Plate		Action Limit: 5
Final Result: No Growth	Media: TSA Contact Plate Lot: 123456789	Exp.2024-04-30
Temperature: 30-35 C	Start Date: 03/26/2024	End Date: 03/28/2024
Temperature: 20-25 C	Start Date: 03/28/2024	End Date: 04/03/2024

Sample ID: S3	Surface	Lab Sample ID: 2408500002-7
Test: USP <797> 2023 Single Media Dual Incubation ID All Growth Over Limit Plus Pathog		ISO Class: ISO-8
Condition of sample upon receipt: Media in good condition		Sample Size: 1 Plate
Positive Holes: NA		Alert Limit: NA
Plate Result: 0 CFU/Plate		Action Limit: 50
Final Result: No Growth	Media: TSA Contact Plate Lot: 123456789	Exp.2024-04-30
Temperature: 30-35 C	Start Date: 03/26/2024	End Date: 03/28/2024
Temperature: 20-25 C	Start Date: 03/28/2024	End Date: 04/03/2024

Sample ID: Surface Control	Surface	Lab Sample ID: 2408500002-8
Test: USP <797> 2023 Single Media Dual Incubation ID All Growth Over Limit Plus Pathog		ISO Class: NA
Condition of sample upon receipt: Media in good condition		Sample Size: NA
Positive Holes: NA		Alert Limit: NA
Plate Result: 0 CFU/Plate		Action Limit: NA
Final Result: No Growth	Media: TSA Contact Plate Lot: 123456789	Exp.2024-04-30
Temperature: 30-35 C	Start Date: 03/26/2024	End Date: 03/28/2024
Temperature: 20-25 C	Start Date: 03/28/2024	End Date: 04/03/2024

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Classifications	Viable Air Sampling Total CFU/m3	Surface Contact CFU/plate	Gloved Fingertip CFU/plate	Gloved Fingertip CFU/plate Gown Validation
ISO Class 5	>1	>3	>3	>0
ISO Class 6	>10	>5	NA	NA
ISO Class 7	>10	>5	NA	NA
ISO Class 8 or Worse	>100	>50	NA	NA

Footnotes and Additional Report Information

1. Testing was performed in compliance with the method or standard indicated. Do not reproduce this report except in full without approval from the laboratory to ensure results are not taken out of context. Laboratory results relate only to the samples tested.
2. All information on this page has undergone quality control assessment including a comprehensive review of field data reported by sampling technician and microbiological lab data.
3. The results in this report are related to this project and these samples only.
4. Controls are unexposed media plates of the same lot submitted for confirmation of media lot sterility.
5. CFU results will populate under the incubation period and temperature range in which they were enumerated. If no CFU data is presented for an incubation regime, no CFUs were recovered from that incubation.
6. Results are reported in CFU/m³ for active air samples. Conversion as appropriate may be required for facility specific criteria application.
7. Viable cultures must be collected using an impaction style sampler for volumetric capture. A sufficient volume of air should be tested at each location to obtain the sensitivity and detection limit necessary for class action levels.
8. Positive hole correction factor is a statistical tool which calculates a probable count from the raw count, considering multiple particles can impact through the same hole of the active air impactor sampling head. For this reason, the raw count may be less than the corrected total.
9. Surface samples are reported per plate. Contact plates range in size from 25-28cm².
10. All contact plates utilized are compliant with USP <797> requirements of neutralizing agents.
11. Media-fill vials are incubated first at 20-25°C for 7 days and then 30-35°C for 7 days, for a minimum total of 14 days per USP <797> requirements. Failure is indicated by visible turbidity in the medium at any time during incubation.
12. Species identification of organisms where noted is performed with a validated MALDI Biotyper Smart CA System.
13. Genus identifications encompass a group of species that are closely related species. These identifications are broader than the specificity of a species ID.
14. Client has two weeks to review and request additional testing; Samples are only retained for two weeks from report date and then discarded.

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15. When microorganism identifications are requested following initial enumeration reporting, expansion/multiplying of organisms may affect which CFUs are able to be identified.
16. Where organisms are identified as non-sporulating fungi, species identification was not possible. Non-sporulating fungi do not produce the necessary spores and/or conidiophores required for species identification.
17. In rare occasions CFUs are unable to be identified due to colony reaching quiescence (dormancy), inability to regrow, etc. The total colony count reported following enumeration (total CFU) may differ from the total identified CFUs in these cases (by the total CFUs that could not be identified).
18. Spreading bacteria (swarming) do not form distinctive colonies on agar plates, instead the bacteria spread/swarm across the surface of the agar. This spreading can inhibit other microorganisms from growing or will grow over an existing CFU.
19. Fungal (mold, yeast, or fungal) colonies can form distinctive colonies, however those distinctive colonies can spread across the agar inhibiting other microorganisms from growing or will grow over an existing CFU.

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Microorganisms Glossary

Organism	Description
Staphylococcus aureus	Staphylococcus aureus is a Gram-positive, round-shaped bacterium and it is a usual member of the microbiota of the body, frequently found in the upper respiratory tract and on the skin. Although S. aureus usually acts as a commensal of the human microbiota it can also become an opportunistic pathogen, being a common cause of skin infections including abscesses, respiratory infections, and food poisoning. Some of the human population are long-term carriers of S. aureus, which can be found as part of the normal skin flora.
Staphylococcus epidermidis	Staphylococcus epidermidis is a Gram-positive bacterium. Staphylococcus epidermidis is a common member of the human epithelial microflora and one of the most frequent nosocomial pathogens. Although S. epidermidis is not usually pathogenic, patients with compromised immune systems are at risk of developing infection. These infections are generally hospital-acquired.

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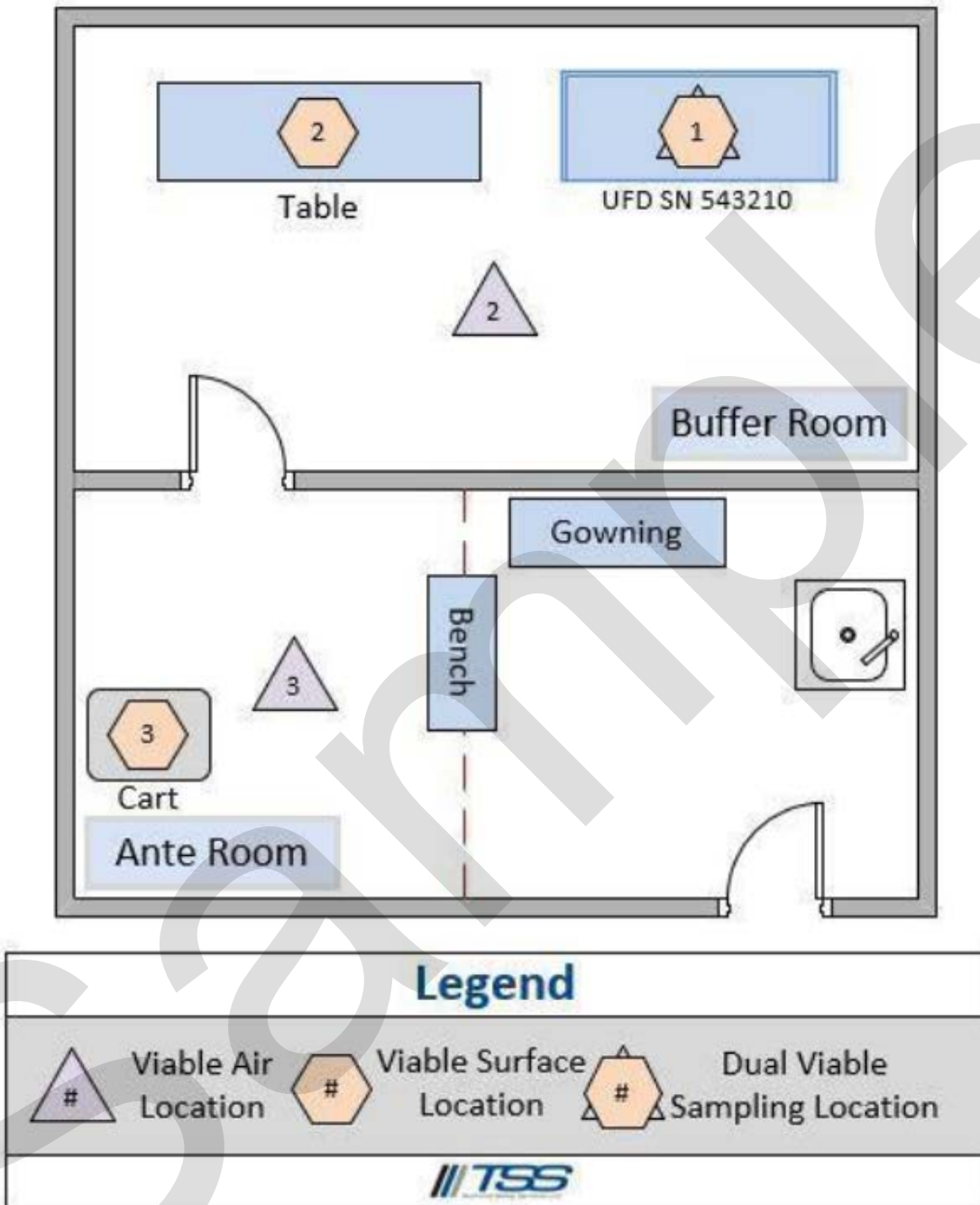
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Definitions	
BI	Biological Indicator
CFU	Colony Forming Unit
CG	Compressed Gas
CNC	Controlled Not Classified
FIO	For Information Only
MALDI-TOF	Matrix Assisted Laser Desorption Ionization-Time of Flight
MEA	Malt Extract Agar
OOC	Out of Compliance
R2A	Reasoner's 2A Agar
SCA	Segregated Compounding Area
SDA	Sabouraud Dextrose Agar
TNTC	Too Numerous To Count
TOC	Total Organic Carbon
TSA	Tryptic Soy Agar

Sample

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Note: Diagram is not to scale.