


Guidance on New TSS USP <797> Microbial Analysis Reports (MAR)

Summary of Results

Each report includes an overall summary and results for each sample collected. Results are indicated based on application of USP <797> criteria determined by the location/ISO classification for the given sample. Samples with CFU total greater than the allotted total in USP <797> will be indicated; as well as samples with identified organisms of concern per USP <797>.



Technical Safety Services, LLC
ISO 9001:2015 NO-801202

620 Hearst Ave. 1
Berkeley, CA 94710
tel: (510) 845-5591
www.techsafety.com

2 **Technical Safety Services, LLC**
Main Office
620 Hearst Avenue
Berkeley, CA 94710

3 **Microbial Analysis Report**
Service Order: NC-NC201076A-1
Lab Project ID: AG20220164721

5 Report Date: 02/21/2020
Collected Date: 02/12/2020
Received Date: 02/13/2020

4 **1st Floor Inpatient RX**

Sample ID	Sample Type	Media	ISO Class	Result	Comments
A-01	Active Air	TSA Settling Plate	ISO-5	OOC	Exceeds Action Limit
A-02	Active Air	TSA Settling Plate	ISO-7	Acceptable	NA
A-03	Active Air	TSA Settling Plate	ISO-8	OOC	Pathogenic Organism Detected
A-04	Active Air	TSA Settling Plate	SCA	No Growth	NA
Control	Active Air	TSA Settling Plate	NA	No Growth	NA
Control	Surface	TSA Contact Plate	NA	No Growth	NA
S-01	Surface	TSA Contact Plate	ISO-5	OOC	Pathogenic Organism Detected
S-02	Surface	TSA Contact Plate	ISO-7	OOC	Pathogenic Organism Detected
S-03	Surface	TSA Contact Plate	ISO-8	Acceptable	NA
S-04	Surface	TSA Contact Plate	SCA	FIO	NA

6

7 **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.
OOC: Out of Compliance. Unacceptable concentrations or presence of actionable microorganisms. Sample not in compliance with USP <797> and CETA CAG-009 guidance documents.


Detailed Guidance

1. TSS office where sampling was scheduled
2. Customer contact information for project
3. TSS Service Order number and Laboratory Project ID for tracking of project
4. Customer Facility Identification
5. Dates for samples collected, received, and report generated.
 - a. Collected Date - date the samples were collected by TSS
 - b. Received Date - date TSS Micro lab accessioned samples for incubation
 - c. Report Date - date the results were input into the report
 - d. Unless noted on the lab report or in the communication from TSS, dates of receipt or reporting have no impact on the validity or quality of the data reported
6. Provides a complete list of all samples included in laboratory report. Included in summary are the following:
 - a. Sample ID
 - b. Sample Type: i.e. air, surface.
 - c. Media Type: i.e. TSA, SDA.
 - d. ISO Class – associated ISO 14644-1 Class
 - e. Result – All results are indicated per color and described in detail per category in the legend beneath the summary table (see description for #7).
 - f. Comments – Additional details to better explain sample accessioning issues and/or out of compliance results.
7. Legend for color coding of results.

Guidance on New TSS USP <797> Microbial Analysis Reports (MAR)

Overview

Following the summary, results are presented in greater detail for every sample collected, broken into the representative first incubation (bacterial) and second incubation (fungal) temperature regime results. Per USP <797>, samples are incubated at 30-35°C for 2-3 days for bacterial growth, and 26-30°C for 5 to 7 days for fungal growth. Dual media sampling will be processed such that the bacteria-selective or general-purpose media (i.e. TSA) is incubated only in the bacterial range; and the fungal-selective media (i.e. MEA, SDA) is incubated only at the fungal range. Dual incubation projects will include a fungal and bacterial result for a single TSA plate.

 ISO 9001:2015 NO-801202 Technical Safety Services, LLC Main Office 620 Hearst Avenue Berkeley, CA 94710	Microbial Analysis Report Service Order: NC-NC201076A-1 Lab Project ID: AG20220164721 1st Floor Inpatient RX	620 Hearst Ave. Berkeley, CA 94710 tel: (510) 845-5591 www.techsafety.com Report Date: 02/21/2020 Collected Date: 02/12/2020 Received Date: 02/13/2020
1 Sample ID: A-01 Test: Pharmacy USP 797 Single Media (Dual Incubation) Condition of sample upon receipt: Media is in good condition. Positive Hole Corrected Result: 6 CFU/m³ Final Result: OOC	Media: TSA Settling Plate Lot: 0123456789-001	Lab Sample ID: 101 Positive Holes: 380 ISO Class: ISO-5 Sample Size: 500 Liters Action Limit: 1 CFU/m ³ Exp. 04/30/2020

Detailed Guidance

1. Detailed description of sample analysis perimeters:

- a. Sample ID** – Corresponds to sampling diagrams and TSS field reports
- b. Lab Sample ID** – TSS Micro lab assigned sample number. For reference only.
- c. Test** – Identifier for procedure completed in TSS Micro lab
- d. Condition of sample upon receipt** – Status of samples on arrival to the laboratory during accessioning. If samples did not meet accessioning criteria (i.e. broken plates) such characteristics are noted upon receipt. Unacceptable sample conditions will be explicitly noted in communication to project contacts at time of notification.
- e. Sample Size** – For air samples equals the total amount of air collected for the given sample. This value is used in determination of the total CFU/m³. For a sample volume of 500L, the raw CFU count is multiplied by 2 to convert the raw count from CFU/500L to CFU/1000L (CFU/m³).
- f. Positive Hole / Positive Hole Corrected Result** – Positive hole correction includes statistical correction factors for Active Air samples to account for the potential of one CFU to follow and impact the same location through the same sampling head hole as another CFU. This result is the final CFU count after positive hole correction factors have

been made; both air and surface samples it is the sum of the first incubation (bacterial) and second incubation (fungal) CFU counts that is applied to the USP <797> limit.

g. Action Limit – Limits of CFU counts per ISO Class designation.

h. Final Result – The final result is given as described in the summary legend; No Growth, Acceptable, FIO, and Out of Compliance (presence of unacceptable organisms or counts exceeding the action limit).

i. Media / Lot – Description of media used, and lot/expiration date shown. For reference only.

Guidance on New TSS USP <797> Microbial Analysis Reports (MAR)

2	Temperature: 30-35 °C	Start Date: 02/13/2020	End Date: 02/15/2020		
	<u>Organism(s) Isolated:</u>	<u>Pathogenic</u>	<u>Raw Count</u>	<u>CFU/m³</u>	<u>% Total</u> <u>Reservoirs</u>
	Coag-negative Staphylococcus species	No	2	4	66.67% Human
	Temperature: 26-30 °C	Start Date: 02/15/2020	End Date: 02/21/2020		
	<u>Organism(s) Isolated:</u>	<u>Pathogenic</u>	<u>Raw Count</u>	<u>CFU/m³</u>	<u>% Total</u> <u>Reservoirs</u>
	Coag-negative Staphylococcus species	No	1	2	33.33% Human
	Total Growth:		3	6	100.00%
	Sample ID: A-02			Lab Sample ID: 102	
	Test: Pharmacy USP 797 Single Media (Dual Incubation)		Positive Holes: 380	ISO Class: ISO-7	
	Condition of sample upon receipt: Media is in good condition.		Sample Size: 500 Liters		
	Positive Hole Corrected Result: 10 CFU/m³		Action Limit: 10 CFU/m ³		
	Final Result: Acceptable	Media: TSA Settling Plate	Lot: 0123456789-001	Exp. 04/30/2020	
	Temperature: 30-35 °C	Start Date: 02/13/2020	End Date: 02/15/2020		
	<u>Organism(s) Isolated:</u>	<u>Pathogenic</u>	<u>Raw Count</u>	<u>CFU/m³</u>	<u>% Total</u> <u>Reservoirs</u>
	Micrococcus species	No	5	10	100.00% Human
	Temperature: 26-30 °C	Start Date: 02/15/2020	End Date: 02/21/2020		
	Sample ID: A-03			Lab Sample ID: 103	
	Test: Pharmacy USP 797 Single Media (Dual Incubation)		Positive Holes: 380	ISO Class: ISO-8	
	Condition of sample upon receipt: Media is in good condition.		Sample Size: 1000 Liters		
	Positive Hole Corrected Result: 1 CFU/m³		Action Limit: 100 CFU/m ³		
	Final Result: OOC	Media: TSA Settling Plate	Lot: 0123456789-001	Exp. 04/30/2020	
	Temperature: 30-35 °C	Start Date: 02/13/2020	End Date: 02/15/2020		
	Temperature: 26-30 °C	Start Date: 02/15/2020	End Date: 02/21/2020		
	<u>Organism(s) Isolated:</u>	<u>Pathogenic</u>	<u>Raw Count</u>	<u>CFU/m³</u>	<u>% Total</u> <u>Reservoirs</u>
	Aspergillus niger	Yes	1	1	100.00% Environment
	Sample ID: A-04			Lab Sample ID: 104	
	Test: Pharmacy USP 797 Single Media (Dual Incubation)		Positive Holes: 380	ISO Class: SCA	
	Condition of sample upon receipt: Media is in good condition.		Sample Size: 1000 Liters		
	Positive Hole Corrected Result: 0 CFU/m³				
	Final Result: No Growth	Media: TSA Settling Plate	Lot: 0123456789-001	Exp. 04/30/2020	
	Temperature: 30-35 °C	Start Date: 02/13/2020	End Date: 02/15/2020		
	Temperature: 26-30 °C	Start Date: 02/15/2020	End Date: 02/21/2020		

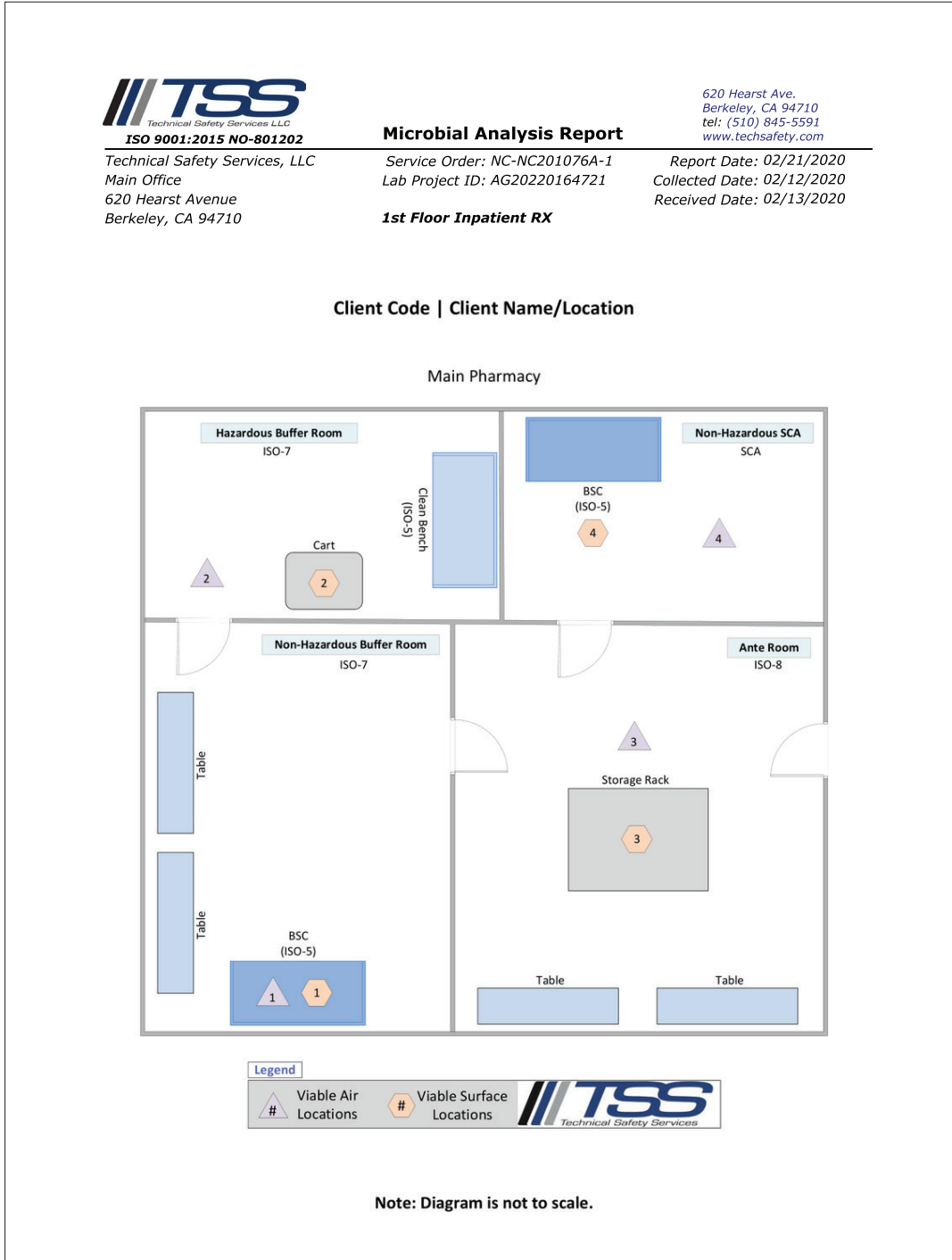
2. Detailed description of incubation results and organism identifications: The values for each identified organism are represented as raw count, converted to CFU/m³ for air samples (as a full m³ was collected this is a 1 to 1 conversion), and % of total CFUs identified for the given line item. Further details of organisms identified are pathogenic based on USP <797> guidance and reservoir sources. The reservoir sources are for information only. All facilities must independently review, analyze, and respond to found microorganisms as required by independent risk assessment. Results are presented specific to the incubation prior to enumeration. In this example, 2 raw CFU were found following 30-35°C incubation, and 1 raw CFU following 26-30°C incubation.

3. If incubation yields a 0 CFU count, nothing will be expanded in incubation columns as shown.

Guidance on New TSS USP <797> Microbial Analysis Reports (MAR)

Overview MAR Diagram

A diagram illustrating the relative location of each sample analyzed in the given MAR will be provided within the report at the time the results are provided. Please see below example.




Guidance on New TSS USP <797> Microbial Analysis Reports (MAR)

Overview MAR Footnotes

Additional information for reference and interpretation of reports will be the final section of the MAR. This information may be used to understand and interpret the acronyms or results presented.

Detailed Guidance for MAR Footnotes

1. Overall guidance for USP <797> ISO classification action limits
2. Microorganism glossary giving brief definitions of organisms identified within the MAR.
3. Signatures of approval from laboratory and data quality personal upon review of MAR. Time/date stamp of review provided for sign-off for each department within TSS.



Technical Safety Services, LLC
ISO 9001:2015 NO-801202

Technical Safety Services, LLC
Main Office
620 Hearst Avenue
Berkeley, CA 94710

620 Hearst Ave.
Berkeley, CA 94710
tel: (510) 845-5591
www.techsafety.com

Microbial Analysis Report

Service Order: NC-NC201076A-1 Report Date: 02/21/2020
Lab Project ID: AG20220164721 Collected Date: 02/12/2020
Received Date: 02/13/2020

1st Floor Inpatient RX

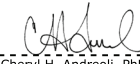
Classification	Viable Air Sampling Total CFU/m ³	Surface Contact CFU/plate	Gloved Fingertip CFU/plate	Gloved Fingertip CFU/plate Gown Validation
ISO Class 5	>1	>3	>3	>0
ISO Class 6	>10	>5	NA	NA
ISO Class 7	>10	>5	NA	NA
ISO Class 8 or Worse	>100	>100	NA	NA

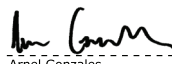
Footnotes and Additional Report Information

1. All contact plates utilized are compliant with USP <797> requirements of neutralizing agents.
2. Controls are unexposed media plates of the same lot submitted for confirmation of media lot sterility.
3. Positive hole correction factor is a statistical tool which calculates a probable count from the total 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.
4. Viable cultures must be collected using an impactation style sampler for volumetric capture. A sufficient volume of air (400 to 1000L) should be tested at each location to obtain the sensitivity and detection limit necessary for class action levels.
5. Surface samples are reported per plate. Contact plates range in size from 25-28cm².
6. Species identification of organisms where noted is performed with a validated MALDI Biotyper Smart CA system.
7. Actionable organisms are defined as any organism deemed highly pathogenic to humans. This includes, but is not limited to; Gram negative rods, coagulase positive Staphylococcus, yeast and molds.
8. Regardless of the number of CFU identified, further corrective actions are required if any pathogenic organisms are identified.
9. 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.

Microorganisms Glossary	
Organism	Description
Aspergillus niger	Aspergillus is one of the most common fungi worldwide, occurring on a large number of substrates. A. niger is typically isolated from soil, seeds, dried fruits, and nuts. It is one of the most commonly reported fungi from indoor environmental samples. This species produces the mycotoxin Ochroatoxin A (OTA) that has been shown to be harmful to some animals, but rarely humans. A. niger has been linked to some human aspergillosis cases.
Micrococcus/Kocuria species	Micrococcus and Kocuria species are gram-positive, spherical bacteria which are widespread in nature and commonly found, along with coagulase-negative Staphylococcus spp., as normal flora on the skin of humans and mammals. They are carried on the skin of most (~96%) people, with M. luteus being the predominant species. Animal and dairy products are considered secondary sources. While these organisms are generally non-pathogenic, they may act as opportunistic pathogens.
Coag-negative Staphylococcus species	Staphylococcus are non spore-forming, gram-positive cocci. Coagulase Negative Staphylococcus species constitute a major part of the normal microbiota of humans.
Micrococcus species	Micrococcus are non-spore-forming, Gram-positive cocci. They are typically non-pathogenic, and considered normal inhabitants of the human body. Micrococci are frequently isolated from air samples and are widespread in nature.
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.

Definitions	
OOC	Out of Compliance
CFU	Colony Forming Unit
CNC	Controlled Not Classified
FIO	For Information Only
MEA	Malt Extract Agar
SCA	Segregated Compounding Area
SDA	Sabouraud Dextrose Agar
TNTC	Too Numerous To Count
TSA	Tryptic Soy Agar


 Cheryl H. Andreoli, PhD 02/21/2020 02:32 PM
 Laboratory Director
 I have reviewed and approve the quality and accuracy of the microbiological data represented.


 Arnel Gonzales 02/21/2020 02:32 PM
 IT and QC Manager
 I have reviewed and approve the quality and accuracy of the testing & certification data represented.