

# Guidance on New TSS USP <1116> Microbial Analysis Reports (MAR)

## Overview MAR Summary of Results

Each report includes an overall summary and results for each sample collected. Results are indicated based on application of USP <1116> criteria determined by the location/ISO classification for the given sample. Samples with CFU total greater than the allotted total by client action/alert limits will be indicated.



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

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

**3 Microbial Analysis Report**

Service Order: NC-NC201077A-1  
Lab Project ID: AG20221145630

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

**4** Report Date: 02/21/2020  
Collected Date: 02/12/2020  
Received Date: 02/13/2020

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

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**6** **No Growth:** No growth of microorganisms.  
**Acceptable:** Growth of microorganisms.  
**FIO:** For Information Only.  
**OOC:** Out of Compliance. Unacceptable concentrations per action limits.

## 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. 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
5. 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.
6. Legend for color coding of results.

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## Overview MAR Detailed Results

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 <1116>, samples are incubated at 30-35°C for 2-3 days for bacterial growth, and 20-25°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.

 <b>ISO 9001:2015 NO-801202</b>	<b>Microbial Analysis Report</b>		620 Hearst Ave. Berkeley, CA 94710 tel: (510) 845-5591 www.techsafety.com
	Technical Safety Services, LLC Main Office 620 Hearst Avenue Berkeley, CA 94710	Service Order: NC-NC201077A-1 Lab Project ID: AG20221145630	Report Date: 02/21/2020 Collected Date: 02/12/2020 Received Date: 02/13/2020
<b>Sample ID: A-01</b>			<b>Lab Sample ID: 201</b>
Test: CER USP 1116 Single Media, Dual Incubation (Dual Incubation)	Condition of sample upon receipt: Media is in good condition.	Positive Holes: 380	ISO Class: ISO-5
<b>Positive Hole Corrected Result: 7 CFU/m<sup>3</sup></b>	Alert Limit: 5 CFU/m <sup>3</sup>	Sample Size: 1000 Liters	
<b>Final Result: ooc</b>	Media: TSA Settling Plate	Lot: 5555555-001	Action Limit: 15 CFU/m <sup>3</sup>
Temperature: 30-35 °C	<b>Start Date: 02/13/2020</b>	<b>End Date: 02/15/2020</b>	
Temperature: 26-30 °C	<b>Start Date: 02/15/2020</b>	<b>End Date: 02/21/2020</b>	
		<u>Raw Count</u>	<u>CFU/m<sup>3</sup></u>
		7	7

## 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/m<sup>3</sup>. 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/m<sup>3</sup>).
- 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.

**j. Detailed description of incubation results:** The values for each identified organism are represented as raw count, converted to CFU/m<sup>3</sup> for air samples (as a full m<sup>3</sup> was collected this is a 1 to 1 conversion) or CFU/plate for the given line item.

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## Microbial Analysis Report

Technical Safety Services, LLC  
Main Office  
620 Hearst Avenue  
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Service Order: NC-NC201077A-1  
Lab Project ID: AG20221145630

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

### Sample ID: A-01

Lab Sample ID: 201

Test: CER USP 1116 Single Media, Dual Incubation (Dual Incubation) Positive Holes: 380 ISO Class: ISO-5  
Condition of sample upon receipt: Media is in good condition. Sample Size: 1000 Liters

Positive Hole Corrected Result: **7 CFU/m<sup>3</sup>** Alert Limit: 5 CFU/m<sup>3</sup> Action Limit: 15 CFU/m<sup>3</sup>

Final Result: **ooc** Media: TSA Settling Plate Lot: 5555555-001 Exp. 04/25/2020

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

Raw Count	CFU/m <sup>3</sup>
7	7

### Sample ID: A-02

Lab Sample ID: 202

Test: CER USP 1116 Single Media, Dual Incubation (Dual Incubation) Positive Holes: 380 ISO Class: ISO-5  
Condition of sample upon receipt: Media is in good condition. Sample Size: 1000 Liters

Positive Hole Corrected Result: **1 CFU/m<sup>3</sup>** Alert Limit: 5 CFU/m<sup>3</sup> Action Limit: 15 CFU/m<sup>3</sup>

Final Result: **Acceptable** Media: TSA Settling Plate Lot: 5555555-001 Exp. 04/25/2020

Temperature: 30-35 °C Start Date: 02/13/2020 End Date: 02/15/2020

Raw Count	CFU/m <sup>3</sup>
1	1

Temperature: 26-30 °C Start Date: 02/15/2020 End Date: 02/21/2020

### Sample ID: A-03

Lab Sample ID: 203

Test: CER USP 1116 Single Media, Dual Incubation (Dual Incubation) Positive Holes: 380 ISO Class: ISO-7  
Condition of sample upon receipt: Media is in good condition. Sample Size: 1000 Liters

Positive Hole Corrected Result: **0 CFU/m<sup>3</sup>** Alert Limit: 10 CFU/m<sup>3</sup> Action Limit: 30 CFU/m<sup>3</sup>

Final Result: **No Growth** Media: TSA Settling Plate Lot: 5555555-001 Exp. 04/25/2020

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

### Sample ID: A-04

Lab Sample ID: 204

Test: CER USP 1116 Single Media, Dual Incubation (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: **0 CFU/m<sup>3</sup>** Alert Limit: 20 CFU/m<sup>3</sup> Action Limit: 50 CFU/m<sup>3</sup>

Final Result: **No Growth** Media: TSA Settling Plate Lot: 5555555-001 Exp. 04/25/2020

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

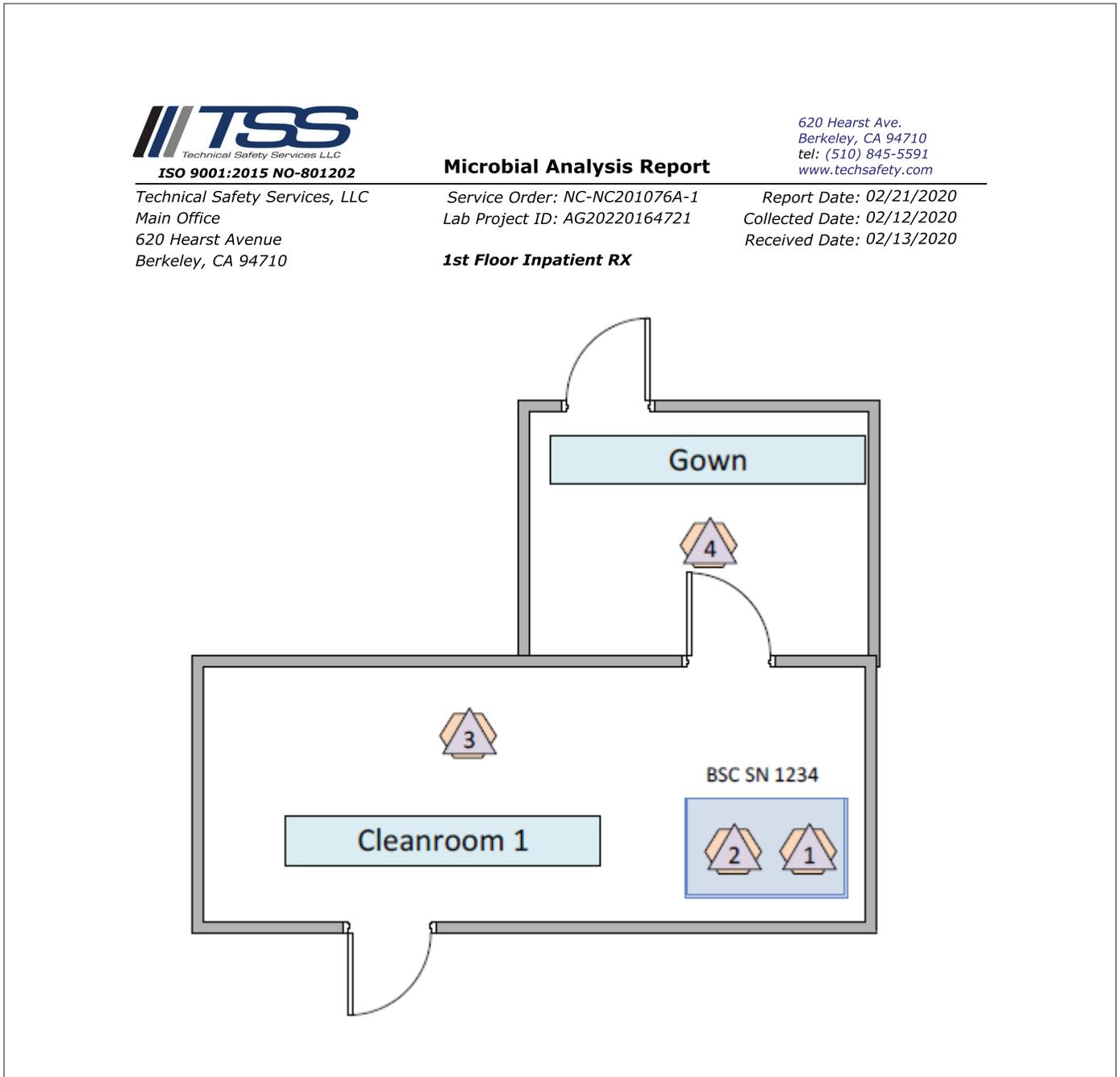
2. If incubation yields a 0 CFU count, nothing will be expanded in incubation columns as shown.



# Guidance on New TSS USP <1116> 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.



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## 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.

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1. Controls are unexposed media plates of the same lot submitted for confirmation of media lot sterility.

2. 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.

3. Results are reported in CFU/m<sup>3</sup> for active air samples. Conversion as appropriate may be required for facility specific criteria application.

4. Surface samples are reported per plate. Contact plates range in size from 25-28cm<sup>2</sup>.

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

 Cheryl H. Andreoli, PhD Laboratory Director I have reviewed and approve the quality and accuracy of the microbiological data represented. 02/21/2020 03:13 PM	 Arnel Gonzales IT and QC Manager I have reviewed and approve the quality and accuracy of the testing & certification data represented. 02/21/2020 03:12 PM
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## Detailed Guidance for MAR Footnotes

1. 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.