ViaScan Analysis
USP <797>

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Inspector:	Mary Sue	Date Collected:	7/29/2020
Project Name:	Little Lamb Pharmacy	Date Received:	7/30/2020
Project Number:	23	Date Reported:	8/13/2020
Assured Bio Identifier:	MS081320-95	Analyst(s):	H. Schmidt

Selected References

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Accreditation

Assured Bio Labs, LLC is accredited by the American Industrial Hygiene Association Laboratory Accreditation Programs, LLC (AIHA-LAP, LLC; Lab ID # 183867) in the Environmental Microbiology accreditation program for "Bacterial and Fungal Culture and Identification by PCR" Fields of Testing as documented by the Scope of Accreditation Certificate and associated Scope. AIHA-LAP, LLC accreditation complies with the ISO/IEC Standard 17025:2005 requirements, but this does not imply ISO certification or registration."

Limitations

Methods of Analysis

Assured Bio Labs, LLC uses the following Standard Operating Procedures for the analysis of samples:
CD 122: Sample Processing for Fungal ViaScan (Culture), CD 125: Sample Processing for Bacterial ViaScan (Culture), CD 117: DNA Sample Preparation, CD 118: Polymerase Chain Reaction, CD 119: Agarose Gel Electrophoresis, CD 120: Agarose Gel Imaging, CD 148: PCR Amplicon Cleanup Using the Omega Bio-Tek E.Z.N.A. Cycle Pure Kit (D6492-01), CD 223: Submitting and Analyzing DNA Sequences, CD 225 Bead Based DNA Extraction

Outlines of USP <797>

U.S. Pharmacopeia (USP) <797> applies to health care institutions, pharmacies, physicians practice facilities, and other facilities in which compound sterile preparations (CSP) are prepared, stored, and dispensed. It provides the practice standards to help ensure that compounded sterile preparations are of high quality.

Air sampling shall be performed at least every 6 months in all ISO (International Organization for Standardization) Class environments. A sufficient volume of air shall be sampled (1,000 liters). Impaction shall be used for volumetric air sampling, settling plates are not sufficient. Counts from air sampling plates are reported as estimated colony forming units (CFU) per cubic meter of air using a positive hole correction formula. The reporting limit(s) and result(s) are calculated based on the sampling information (i.e. collection volume, area, mass, etc.) provided by the customer as noted on the Chain of Custody. The results apply to the sample(s) as received.

Surface sampling performed on a monthly basis at the conclusion of compounding using contact plates (size ranges from 24 to 30 cm^2, standard contact plates have an area of 25 cm^2) or swabs (used for irregular surfaces of equipment) in all ISO classified areas. Results are reported as CFU per plate or swab.

Gloved Fingertip Testing. All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero CFU) before initially being allowed to compound CSPs for human use. Re-evaluation of all compounding personnel shall occur at least bi-annually. Immediately after gowning, the evaluator shall collect a gloved fingertip and thumb sample from both hands. Results should be reported separately as number of CFU per employee per hand (left hand, right hand). The CFU action level for gloved hands will be based on the total number of CFU on both gloves, not per hand.

Media-Fill Testing shall be performed initially before beginning to prepare CSPs and at least bi-annually. It shall be evaluated using sterile fluid bacterial culture media-fill verification. Media-filled tests shall be incubated at 20–25 °C for 7 days, followed by an additional 7 days at 30–35 °C.

Bacterial analysis is perfomed by incubating plates at 30–35 °C for at least 48 hours. Fungal analysis is performed by incubating plates at 20–25 °C for at least 5 days.

For Quality Control purposes two media plates per lot of every media type must be submitted for positive and negative controls.

Reporting Limits

Method Detection Limit: The American Industrial Hygiene Association defines this term in AIHA-LAP, LLC Policy Document – Module 9 as "The minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99 percent probability of being identified, qualitatively or quantitatively measured, and reported to be greater than zero." For solid agar media plates this will always be 1 CFU.

Reporting Limit: The American Industrial Hygiene Association defines this term in AIHA-LAP, LLC Policy Document – Module 9 as "The lowest concentration of analyte in a sample that can be reported with a defined, reproducible level of certainty."

Additional Comments

The analytical data included in this report reflect only the conditions of the material sampled and submitted to the laboratory for analysis at the time of collection. The results included in this report may not be used for past or future environmental conditions. The reporting limit(s) and result(s) are calculated based on the sampling information (i.e. collection volume, area, mass, etc.) provided by the customer as noted on the Chain of Custody. The results apply to the sample(s) as received.

Genus identification is performed using macro- and micro-morphological observation and comparison to relavent literature. In some cases Genus level identification cannot be performed due to indistinct morphological traits typically resulting from a lack of sporulation (e.g. "Sterile Hyphae", "Yeast"). In some cases multiple names may be reported for the same isolate due to taxonomic/nomenclatural uncertainty or the presence of both telomorphic and anamorphic states (e.g. *Aspergillus* (=*Eurotium*)).

Assured Bio Labs, LLC strives to fullly identify any isolates sequenced to the lowest taxomic entity avilable for the orgnaism using specific primers and DNA sequecing methodologies. Unfortunately an isolate cannot always be identified to species based on one or more of the following: PCR inhibition, sequencing inhibition, insufficient genetic resolution, unknown or poorly characterized biodiversity, taxonomic and nomenclatural uncertainty, aberrant and/or atypical strains, etc. A brief description of the identified species may be presented as an interpretive guide and is not intended to be exhaustive or diagnostic. Please consult relevent scientific and medical literature or consultation if required.

Regions amplified for identification may include, but are not limited to, the following: Internal Transcribed Spacer (ITS), Ribosomal Small Subunit (16S/18S/SSU), Ribosomal Large Subunit (25S/28S/LSU), β-Tubulin, Actin, etc. Additional information (including primers used, thermocycling conditions, identification thresholds, raw sequence data, etc.) may be available upon request.

Sample units and reporting limits are as follows unless otherwise noted:

	Unit Sampled	Reporting Limit
Surface Sample	25 cm^2	1 CFU/plate
Air Sample	1000 L	1 CFU/m^3

Incubation conditions are as follows unless otherwise noted

	Incubation Start Date	Incubation End Date	bation Temperature
Bacterial Analysis	7/30/2020	8/3/2020	32.5 ± 2.5 °C
Fungal Analysis	8/3/2020	8/10/2020	22.5 ± 2.5 °C
Media-Fill Analysis	7/30/2020	8/6/2020	22.5 ± 2.5 °C
Media-Fill Analysis	8/6/2020	8/13/2020	32.5 ± 2.5 °C

USP <797> Recommended Action Levels for Microbial Contamination

ISO Class	Air* CFU/m³ of air/plate	Surface (Contact plate) CFU/plate	Gloved Fingertip** CFU/plate	Media-Fill Test
5	>1	>3	>3 (ongoing) >0 (initial)	Presence/Absence
7	>10	>5	N/A	N/A
8 or worse	>100	>100	N/A	N/A

*A sufficient volume of sampled air is 1,000 liters for all ISO Classes.

**Both hands

CFU Count Interpretation

Pass	Compliant - Below action levels established in USP <797>.
Fail	Not Compliant - Above action levels established in USP <797>.
Unclassified	Results not applicable to USP 797.

Quality Control Results

Media Type	Manufacturer	Lot Number	Expiration Date	Reference Cultures	Control Type	Status
TSA w/Lecithin & Tween	Hardy	123456	10/26/2020	*Bacillus subtilis, Pseudomonas aeruginosa, Staphylococcus aureus, Aspergillus brasiliensis, Candida albicans*	Positive	Pass
TSA w/Lecithin & Tween	Hardy	123456	10/26/2020	Uninoculated	Negative	Pass

Test Report Reviewed and Approved By:
John Doe, Ph.D. - Laboratory Manager

Date of Approval: 8/13/2020

Results Summary Table

Sample ID	Test Method	Colony Forming Units	Status	ISO Class
1	Air	<1 CFU/m^3	Pass	5
2	Surface	4 CFU - Bacteria	Fail	5
3 4	Continuing Fingertip	2 CFU - Bacteria	Pass	5
5	Media-Fill Test	No Growth	Pass	5

Assured Bio Identifier: MS081320-95-1
Sample ID: 1
Sample Description: #23 Hood

Sample Type: Single Plate
Test Method: Air
Sample Condition: Intact

	Colony Forming Units Counted	Colony Forming Units/Cubic Meter
Total Bacteria:	None Detected	<1
Total Fungi:	None Detected	<1

Comments: None

Assured Bio Identifier: MS081320-95-2
Sample ID: 2
Sample Description: #23 Hood

Sample Type: Single Plate
Test Method: Surface
Sample Condition: Intact

	Colony Forming Units Counted	Colony Forming Units/Plate
Staphylococcus epidermidis:	4	4
Total Bacteria:	4	4
Total Fungi:	None Detected	<1

Comments: None

Assured Bio Identifier: MS081320-95-3
Sample ID: 3
Sample Description: John Cotton Left Hand

Sample Type: Single Plate
Test Method: Continuing Fingertip
Sample Condition: Intact

	Colony Forming Units Counted	Colony Forming Units/Plate
Micrococcus luteus:	2	2
Total Bacteria:	2	2
Total Fungi:	None Detected	<1

Comments: None

Assured Bio Identifier: MS081320-95-4
Sample ID: 4
Sample Description: John Cotton Right Hand

Sample Type: Single Plate
Test Method: Continuing Fingertip
Sample Condition: Intact

	Colony Forming Units Counted	Colony Forming Units/Plate
Total Bacteria:	None Detected	<1
Total Fungi:	None Detected	<1

Comments: None

Assured Bio Identifier: MS081320-95-5
Sample ID: 5
Sample Description: John Cotton Media Fill

Sample Type: N/A
Test Method: Media-Fill Test
Sample Condition: Intact

Results

Microbial Contamination: None Detected

Comments: None