ViaScan Analysis
USP <797>

228 Midway Lane, Suite B
Oak Ridge, Tennessee 37830
Toll Free: (866) 547-1727
Local: (865) 813-1700
Fax: (865) 813-1705
Email: info@assuredbio.com
www.assuredbio.com

assuredbio™

REVIEWED
by Edward A. Sobek, Ph.D. at 04:25 PM, Sep 17, 2026

Inspector:	sample collector name	**Date Collected**	Sep/01/2026
Project Name:	GFT-MFT Annual	**Date Received:**	Sep/02/2026
Project Number:		**Date Reported:**	Sep/17/2026
Assured Bio Identifier:	internal identifier	**Analyst:**	Chandler Brown

Selected References

United States Pharmacopeiaand National Formulary (USP 43-NF 38). Rockeville, MD: United States Pharmacopeial Convention; 2023. Chapter <797> Sterile Preparations, Revised 2023

CETA Certification Application Guide CAG-011 version 02:2020 Viable Environmental Monitoring for Sterile Compounding Facilities

CETA Certification Application Guide CAG-011 version 01:2021 Gloved Fingertip Testing for Sterile Compounding Personnel

CETA Certification Application Guide CAG-013-2011v3 USP <797> Viable Environmental Sampling & Gowning Evaluation

Alexopoulos, C.J. and C.W. Mims. 1979. *Introductory Mycology, Third Edition*. John Wiley & Sons, New York, New York.

Barron, G.L. 1968. *The Genera of Hyphomycetes from Soil*. Robert E. Krieger Pub. Co., Malabar, Florida.

Ellis, M.B. 1971. *Dematiaceous Hyphomycetes*. CAB International, Wallingford Oxon OX10 8DE, UK.

Ellis, M.B. 1976. More *Dematiaceous Hyphomycetes*. CAB International, Wallingford Oxon OX10 8DE, UK.

Hanlin, R.T. 1990. *Illustrated Genera of Ascomycetes*. APS Press, St. Paul, Minnesota.

Hanlin, R.T. 1998. *Illustrated Genera of Ascomycetes*. II. APS Press, St. Paul, Minnesota.

Hanlin R.T. and M. Ulloa. 1988. *Atlas of Introductory Mycology, Second Edition*. Hunter Textbooks, Inc., Winston-Salem, North Carolina.

Kiffer E. and M. Morelet. 2000. *The Deuteromycetes: Mitosporic Fungi: Classification and Generic Keys*. Science Publishers, Inc., Enfield, New Hampshire.

Macher, J., Ed. 1999. *Bioaerosols: Assessment and Control*. ACGIH, Cincinnati, Ohio.

Morris, E.F. 1963. *The Synnematous Genera of the Fungi Imperfecti*. Western Illinois University Publication, Macomb, Illinois.

Nelson, P.E., Toussoun, T.A. and W.F.O. Marasas. 1983. *Fusarium Species: An Illustrated Manual for Identification*. Pennsylvania State University Press, University Park and London.

Samson R.A., Hoekstra E.S., Frisvad J.C. and O. Filtenborg, Ed. 2002. *Introduction to Food and Airborne Fungi*. Ponsen and Looyen, Wageningen, The Netherlands.

Wistreich G.A. 1997. *Microbiology Laboratory: Fundamentals and Applications*. Prentice Hall, Upper Saddle River, New Jersey.

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 17025:2017 requirements, but this does not imply ISO certification or registration.”

Limitations

ASSURED BIO LABS, LLC MAKES NO WARRANTIES AND EXPRESSLY DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PURPOSE. INSPECTOR ACKNOWLEDGES THAT ASSURED BIO LABS, LLC HAS NOT INSPECTED THE SUBJECT PROPERTY AND THAT THE INSPECTOR IS SOLELY RESPONSIBLE FOR CHOOSING THE LOCATION OF SAMPLE COLLECTION. ASSURED BIO LABS, LLC SHALL NOT BE LIABLE TO INSPECTOR FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OF ANY KIND OR NATURE, INCLUDING, WITHOUT LIMITATION, ANY DAMAGES TO PROPERTY OR PERSONAL INJURY WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT, OR OTHERWISE, EVEN IF ASSURED BIO LABS, LLC HAS BEEN WARNED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE. UNDER NO CIRCUMSTANCES SHALL ASSURED BIO LABS, LLC BE LIABLE FOR DAMAGES UNDER OR ARISING OUT OF THIS REPORT IN AN AMOUNT EXCEEDING THE AMOUNT PAID BY THE INSPECTOR TO ASSURED BIO LABS, LLC FOR THIS ANALYSIS AND REPORT. THIS REPORT IS FOR THE SOLE USE OF THE INSPECTOR AND CREATES NO THIRD PARTY BENEFICIARIES OR RIGHTS HEREUNDER.

Methods of Analysis

Assured Bio Labs, LLC uses the following Standard Operating Procedures for the analysis of samples:
CD 232: Processing and Analysis of USP 797 Samples, 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 monthly in all ISO (International Organization for Standardization) Class environments. A sufficient volume of air shall be sampled (typically 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 at least every 6 months 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.

Personnel competency evaluations. All compounding personnel shall successfully complete an initial garbing competency evaluation and gloved fingertip/thumb sampling procedure (zero CFU) and an Aseptic Manipulation competency evaluation consisting of a Media-Fill Test, Gloved Fingertip Samples, and a Surface Sample of the work area before initially being allowed to compound CSPs for human use. Re-evaluation of all compounding personnel shall occur at least bi-annually.

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 relevant 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 teleomorphic and anamorphic states (e.g. *Aspergillus* (=*Eurotium*)).

Assured Bio Labs, LLC strives to fullly identify any isolates sequenced to the lowest taxonomic entity available for the organism 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 relevant 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.

Abbreviations
SS -Surface Sample
AS -Air Sample
MFT -Media Fill Test
GFTAM -Gloved Fingertip Sample, Aseptic Manipulation
GFTGC -Gloved Fingertip Sample, Garbing Competency

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

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

Incubation conditions are as follows unless otherwise noted:

	Incubation Start Date	Incubation End Date	Incubation Temperature
Bacterial Analysis	09/02/2026 11:20	09/04/2026 11:52	32.5 ± 2.5 °C
Fungal Analysis	09/04/2026 12:04	09/09/2026 14:14	22.5 ± 2.5 °C
Media-Fill Analysis	09/02/2026 11:20	09/09/2026 14:29	22.5 ± 2.5 °C
Media-Fill Analysis	09/09/2026 14:29	09/16/2026 14:42	32.5 ± 2.5 °C

USP <797> Recommended Action Levels for Microbial Contamination

Viable Particle Monitoring			Aseptic Manipulation Competency			Garbing and Glove Hygiene Competency
ISO Class	**Air**	**Surface**	**Gloved Fingertip**	**Surface**	**Media-Fill Test**	**Gloved Fingertip**
	CFU/m^3 of air/plate	CFU/plate	CFU/plate	CFU/plate	Microbial Gorwth	CFU/plate
5	>1	>3	>3	>3	Presence/Absence	>0
7	>10	>5				
8 or worse	>100	>50				

*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 — Above USP <797> or CAG-011-00 action levels or any highly pathogenic organisms regardless of CFU count (Gram-negative rods, coagulase positive staphylococcus, molds and yeasts)

Unclassified — Results not applicable to USP 797 and CAG-011

Quality Control Results

Media Type	Manufacturer	Lot Number	Expiration Date	Reference Cultures	Control Type	Status

Test Report Reviewed and Approved By:
Edward A. Sobek, Ph.D.

Date of Approval: 09/17/2026

Results Summary Table

Sample ID	Test Method	Colony Forming Units	Status	ISO Class
TSA-1, TSA-2	USP <797> Fingertip, Single Plate	<1 CFU	Pass	7
TSA-3, TSA-4	USP <797> Fingertip, Single Plate	<1 CFU	Pass	5
TSA-5	USP <797> Surface, Single Plate	<1 CFU	Pass	5
MFT Bag (Red)	USP <797> Media-Fill Test	None Detected	Pass	5

Assured Bio Identifier: -1
Sample ID: TSA-1
Sample Description: HD-LH
Sample Comments: 7

Sample Type: Single Plate
Test Method: GFT - Garbing, Continuing
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: -2
Sample ID: TSA-2
Sample Description: HD-RH
Sample Comments: 7

Sample Type: Single Plate
Test Method: GFT - Garbing, Continuing
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: -3
Sample ID: TSA-3
Sample Description: HD-LH
Sample Comments: 5

Sample Type: Single Plate
Test Method: GFT - Aseptic Manipulation
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: -4
Sample ID: TSA-4
Sample Description: HD-RH
Sample Comments: 5

Sample Type: Single Plate
Test Method: GFT - Aseptic Manipulation
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: -5
Sample ID: TSA-5
Sample Description: Deck Surface Post HD MFT
Sample Comments: 5

Sample Type: Single Plate
Test Method: Contact Plate
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: -6
Sample ID: MFT Bag (Red)
Sample Description: Chemoteq (Red) MFT Bag
Sample Comments: 5

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

	Results
Microbial Contamination:	None Detected

Comments: None.
