DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	3/2/2026-3/5/2026
	FEI NUMBER 1627497

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hunter D. Conover, Director of Quality

FIRM NAME	STREET ADDRESS
Immuno-Mycologics, Inc	2701 Corporate Centre Dr
CITY, STATE, ZIP CODE, COUNTRY Norman, OK 73069-2901	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Records of risk management activities in product realization were not adequately maintained.

Specifically, your firm's Risk Management SOP, SOP-00038, Rev. 6, effective 05/02/2023, states the risk management file shall provide traceability for risk analysis, evaluation, implementation and verification of risk control measures, and the acceptability of any residual risk with each identified hazard associated with the product. The Risk Management Process SOP, SOP-00038, Rev. 3, effective 10/07/2019, requires the risk management file to be continuously revised as ongoing risk management activities are carried out.

The Risk Management File for the Class II Coccidioides Ab Enzyme Immunoassay (CAB102), Rev. 1, effective 01/14/2020, fails to adequately address potential hazards and risk control measures identified in post market surveillance, such as effects of freeze/thaw cycles, reduced sensitivity, reduced specificity, and reduced stability.

Additionally, your firm was unable to provide evidence of risk analysis documentation, risk evaluation records, or implementation of risk control measure for the Class II Candida Immunodiffusion (ID) Antigen (C50110).

OBSERVATION 2

Design and development changes were not adequately reviewed, verified, validated, and approved before implementation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Yuliana Hernandez-Magana, Investigator X Yuliana Hernandez-Magana Investigator Signed By: YULIANA HERNANDEZ-MAGANA -S Date Signed: 03-05-2026 10:22:29	3/5/2026

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Specifically, your firm's Histoplasma Galactomannan EIA (HGM201) Design Change Report, Study Date(s): (b) (4) through (b) (4) Report Date: (b) (4) has not adequately demonstrated that the new conjugate stabilizer (b) (4) can be used in replacement of the original conjugate stabilizer (b) (4)

Experiment #: 2-8 Design Change Accelerated Stability Verification Study Plan and Report contains failures at the (b) (4) for the Controls and Standard Curve, as well as failures at (b) (4) and (b) (4) for the (b) (4) Urine Results at (b) (4)
(b) (4)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."