

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax: (913)495-5115		DATE(S) OF INSPECTION 4/29/2025-5/7/2025*	
		FEI NUMBER 2128592	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Alok Sharma, Site Lead, Madison, WI			
FIRM NAME Labcorp Early Development Laboratories, Inc.		STREET ADDRESS 3301 Kinsman Blvd	
CITY, STATE, ZIP CODE, COUNTRY Madison, WI 53704-2523		TYPE ESTABLISHMENT INSPECTED GLP	
<p>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.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 The study director failed to assure that all raw data, documentation, protocols, specimens, and final reports were transferred to the archives during or at the close of the study.</p> <p>Specifically, Per regulation, the study director has the overall responsibility for technical conduct of a GLP study, and the transfer of study documentation to archives at the close of the study. In addition, per SOP "****Archive Use and Security**** version: 3.0**** p. 3 of 10****", "****Studies that are claiming compliance to FDA-GLP or EPA-GLP regulations, must transfer all study data into the custody of archives no later than the Study Completion date. ****".</p> <p>Raw data for protocol 8463057 was submitted and archived on 12/19/23 and 1/8/24. The study report for protocol 8463057 was signed by the study director on 1/11/24. The study director failed to ensure the required Quality Control (QC) performance and review of Immunology and Immunotoxicity (I&I) raw data, (b) (4) study closure, and subsequently failed to ensure the submission of this I&I raw data to the (b) (4). QC has not been performed on this data and it was not archived with additional raw study data as required. The I&I data currently remains unsubmitted to the archival unit.</p>			
<p>*DATES OF INSPECTION 4/29/2025(Tue), 4/30/2025(Wed), 5/01/2025(Thu), 5/02/2025(Fri), 5/05/2025(Mon), 5/06/2025(Tue), 5/07/2025(Wed)</p>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Carmen Y Fisher, Investigator		DATE ISSUED 5/7/2025
	<div style="text-align: right;"> Carmen Y Fisher Investigator Signed By: CARMEN Y. FISHER - Date Signed: 05-07-2025 10:20:04 X </div>		

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EMPLOYEE(S) SIGNATURE

Carmen Y Fisher, Investigator

Carmen Y Fisher
Investigator
Signed By: CARMEN Y. FISHER -
Date Signed: 05-07-2025
10:20:04

X

DATE ISSUED

5/7/2025

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."