

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax: (425) 302-0404	DATE(S) OF INSPECTION 1/5/2026-1/8/2026 FEI NUMBER 3023437	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Denise R. Sobolewski, Production Supervisor		
FIRM NAME Solomon Park Research Laboratories, Inc.	STREET ADDRESS 658 S 152nd St	
CITY, STATE, ZIP CODE, COUNTRY Burien, WA 98148-1111	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.		
<i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i>		
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Written MDR procedures have not been developed and implemented. Specifically, Your firm does not have a written procedure for initiating and submitting a Medical Device Report (MDR). This includes formulating the process for evaluating adverse events, documentation of MDR events, and instructions on reporting events in alignment with federal regulations. When asked about Medical Device Reporting, you did not have adequate information or evidence for the understanding of this requirement.		
OBSERVATION 2 The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830. Specifically, Your firm does not adhere to UDI labeling conditions for identified medical devices under the associated regulation. This includes formulating the process for ensuring each medical device bears the UDI within its labeling, and ensuring each UDI is appropriately registered in the UDI database. When asked about UDI labeling affixed to the Lipid Reference Control kit devices, intended for use by medical and biotechnology laboratories for		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Brian R Hendricks, Investigator Brian R Hendricks Investigator Signed By: Brian R. Hendricks Jr - Date Signed: 01-08-2026 132909 X	DATE ISSUED 1/8/2026

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the quality control, calibration, and configuration of clinical testing instruments, you were unable to provide evidence for this requirement. OBSERVATION 3 Procedures that define the responsibility for review and the authority for the disposition of nonconforming product have not been adequately established. Specifically, Your firm does not adhere to the quality system requirement that each manufacturer shall establish procedures that set forth the review and disposition process of nonconforming product. This includes formulating the process for ensuring the disposition of nonconforming product is documented, ensuring the documentation includes the justification for use of nonconforming product, and requiring a signature of the individual(s) authorizing the use. When asked about the governance of dispositions related to nonconforming product, you did not have adequate information or evidence for the understanding of this requirement.			
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Annotations to Observations Observation 1: Observation 2: Observation 3:			
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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."