

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION																												
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160		DATE(S) OF INSPECTION 5/12/2025-5/16/2025 FEINUMBER 3003992026																										
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Laurence De Coninck, Site Manager																												
FIRM NAME Bio-Rad		STREET ADDRESS Route De Cassel																										
CITY, STATE, ZIP CODE, COUNTRY Steenvoorde, 59114 France		TYPE ESTABLISHMENT INSPECTED IVD 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 WE OBSERVED: OBSERVATION 1 There is no documentation of the revalidation of a process performed in response to changes or process deviations. Specifically, risk analysis and design verification have not been completed for a process change you made on 10/26/2023. On this date, you added a (b)(4) step for the (b)(4) of the peptide (b)(4), which is a material component of your Geenius HIV 1/2 Supplemental Assay. A change control was not initiated until 04/01/2025, however, the (b)(4) step was added to the manufacturing protocol, which went live on 03/13/2024. You have manufactured five lots of this peptide since the (b)(4) step was added: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; vertical-align: top;">- Lot</td> <td style="width: 15%; border: 1px solid black; height: 20px;"></td> <td style="width: 35%; vertical-align: top;">manufacture date</td> <td style="width: 15%; border: 1px solid black; height: 20px;"></td> <td style="width: 25%;"></td> </tr> <tr> <td style="vertical-align: top;">- Lot</td> <td style="border: 1px solid black; height: 20px;"></td> <td style="vertical-align: top;">manufacture date</td> <td style="border: 1px solid black; height: 20px;"></td> <td></td> </tr> <tr> <td style="vertical-align: top;">- Lot</td> <td style="border: 1px solid black; height: 20px;"></td> <td style="vertical-align: top;">manufacture date</td> <td style="border: 1px solid black; height: 20px;"></td> <td></td> </tr> <tr> <td style="vertical-align: top;">- Lot</td> <td style="border: 1px solid black; height: 20px;"></td> <td style="vertical-align: top;">manufacture date</td> <td style="border: 1px solid black; height: 20px;"></td> <td></td> </tr> <tr> <td style="vertical-align: top;">- Lot</td> <td style="border: 1px solid black; height: 20px;"></td> <td style="vertical-align: top;">manufacture date</td> <td style="border: 1px solid black; height: 20px;"></td> <td></td> </tr> </table>				- Lot		manufacture date			- Lot		manufacture date			- Lot		manufacture date			- Lot		manufacture date			- Lot		manufacture date		
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Celeta S Covas Investigator X Signed By: Celeta S. Covas -S Date Signed: 05-16-2025 12:02:03 DATE ISSUED 5/16/2025																												
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Celeta S Covas, Investigator Kaarin M Slotte, Investigator Kaarin M Slotte Investigator X Signed By: Kaarin M. Slotte -S Date Signed: 05-16-2025 12:01:29																										

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Annotations to Observations Observation 1: Not annotated			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Celeta S Coves, Investigator Kaarin M Slotte, Investigator		DATE ISSUED 5/16/2025 Kaarin M Slotte Investigator Signed By: Kaarin M. Slotte-S Date Signed: 05-16-2025 1201.29 X

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."