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	1/5/2026-1/13/2026*
	FEI NUMBER 3014515702

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Benjamin L. Treece, Executive VP of Quality and Regulatory Affairs

FIRM NAME	STREET ADDRESS
Nuclein LLC	8305 Cross Park Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Austin, TX 78754-5154	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.

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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary.

Specifically, your firm has failed to adequately investigate complaints received for a Class II medical device intended to aid in the differential diagnosis of SARS-CoV-2, influenza A, and influenza B in humans.

Your firm's Customer Complaint Handling Process, QP-11-001, Ver. 7, effective 10/8/2025, adequately defines a malfunction. However, during a review of your firm's complaint records, it was identified that your firm's Complaint Level 3 Thresholds, QL-0003, Ver. 0, effective 05/01/2025, defines that a device must have an invalid result or error rate above [-] % and the device must have a minimum of [-] runs to indicate that a malfunction may have occurred and for additional investigation to be required.

Since the distribution of the Class II device in February 2025, your firm has received over 40 complaints for invalid results and over 40 complaints for motor related errors. For complaints received by your firm regarding device failures resulting in out-of-box failures, device errors preventing use, and cartridge performance resulting in invalid results, your firm determined that the corresponding device or cartridge did not meet the threshold defined in Complaint Level 3 Thresholds, QL-0003. Therefore, your firm did

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not document the failure of a device to meet its performance specifications as a malfunction and did not conduct any additional investigations.

Additionally, your firm's Medical Device Reporting Process, QP-11-002, Ver. 2, effective 11/21/2024, defines that all events involving distributed medical devices that are associated with death or serious injury, or malfunctions that are likely to cause death or serious injury, must be evaluated. However, your firm does not include documentation to indicate if patient harm occurred as a result of the device failure and documents that the events were not reportable for complaints with a risk of delayed treatment.

OBSERVATION 2

Risk analysis is inadequate.

Specifically, your firm has failed to adequately analyze risk for a Class II medical device associated with the hazard of delayed results and the resulting harm of delayed treatment. Your firm's DASH Rapid PCR System Hazard Analysis, SHA-001, Rev. 9, effective 10/24/2025, defines that each hazard shall be assigned a (b)(4) severity rating based on the potential worst-case consequences of the hazard. Per the procedure, "Death to a patient due to device (e.g., incorrect test result(s) directly responsible for the misdiagnosis and/or inappropriate or delayed medical decisions/actions/treatment resulting in patient death)" is defined as the highest severity with a rating of .

However, your DASH Rapid PCR System Hazard Analysis, Attachment A, Ver. 9, effective 10/24/2025, defines the hazards "Use Error" and "Delay of Results" with the resulting harm as "Delay of Treatment" with a severity rating of . Additionally, during a review of your firm's complaint, service, nonconformance, recall, corrective and preventive action records and corresponding risk assessment records, your firm has documented "Delay of Treatment" with a severity rating of .

Furthermore, your DASH Instrument Design Failure Modes and Effects Analysis, DFMEA-P002-01,

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Ver. 13, effective 10/24/2025, does not include documentation of reasonably foreseeable misuse of the medical device according to ANSI/AAMI/ISO 14971:2019.

OBSERVATION 3

Sampling plans are not based on valid statistical rationale.

Specifically, your firm has failed to sample cartridges in final acceptance testing based on valid statistical rationale. Your firm's Statistical Techniques procedure, QP-06-002, Version 0, effective 07/03/2023, Section 6.6.8.1, states: "(b)(4) (b)(4)." Section 6.6.8.2 states: "(b)(4) (b)(4) (b)(4)".

However, your firm's Finished DASH Cartridge Test Procedure, QCI-06-002, Version 5, effective 11/12/2025, Section 10, defines the following sampling plan without valid statistical rationale:

Negative Assay Results:

- (b)(4)
- (b)(4)

Positive Assay Results:

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- (b)(4)

Additionally, your firm's Final Cartridge QC Protocol Validation, VP-00177, Version 0, effective 10/12/2024, states your statistical rationale as: "(b)(4) (b)(4) (b)(4)." However, during a review of cartridge DHRs for lots [redacted], [redacted], and [redacted], samples are selected for final testing regardless of the cartridge lot size.

***DATES OF INSPECTION**

1/05/2026(Mon), 1/06/2026(Tue), 1/07/2026(Wed), 1/08/2026(Thu), 1/09/2026(Fri), 1/12/2026(Mon), 1/13/2026(Tue)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: 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."