DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/31/2026-4/2/2026
	FEI NUMBER 3011527950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michelle Y. Larmour, President

FIRM NAME	STREET ADDRESS
NEW LIFE DIAGNOSTICS, Inc.	5909 Sea Lion Place, Ste A
CITY, STATE, ZIP CODE, COUNTRY Carlsbad, CA 92010-6607	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.

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

A system to assign unique device identification (UDI) to the medical device was not adequately documented.

Specifically, Class I devices were required to have UDI submitted to the Global Unique Device Identification Database (GUDID) by September 24, 2022. As of this inspection (March 31, 2026), your firm had not completed submission of UDI data to GUDID for its parasitology ELISA test kits.

For example:

• Your firm began preparing GUDID submissions during this inspection but had not completed the submission process as of March 31, 2026. Your firm, New Life Diagnostics, Inc. does not appear in the GUDID database.

• Change Request (b) (4) (dated 10/10/2025) documented UDI labeling implementation. However, the change request contained no risk assessment, and the training plan stated only (b) (4) (b) (4) As of this inspection, employee training had not been completed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jenny L Chisem, Investigator X Jenny L Chisem Investigator Signed By: JENNY L. CHISEM -S Date Signed: 04-02-2026 16:18:14	4/2/2026

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• Review of labels for products shipped in 2025-2026 revealed only one label contains UDI information (Fasciola IgG ELISA Kit Box Label, Lot (b) (4), manufactured December 2, 2025). Labels reviewed that lack UDI include: (b) (4) Strongyloides IgG Lot (b) (4) bag label, (b) (4) Toxocara IgG Lot (b) (4) bag label, and Fasciola IgG Kit Box Label template Revision D.

• Your quality agreement with (b) (4) does not define UDI labeling responsibilities. Neither NLD nor (b) (4) appears in the GUDID database.

OBSERVATION 2

Preventive action to eliminate the causes of potential nonconformities was not adequately determined.

Specifically, your firm failed to establish and maintain procedures for implementing corrective and preventive action. For example:

a) The firm did not initiate CAPA for nonconformances and recurring issues:

• NCR 34 (dated 11/3/2025) documented that two lots of (b) (4) with different expiration dates (Lot (b) (4) expiring 12/2025 and Lot (b) (4) expiring 06/2026) were assigned a single lot number (b) (4) for production use. Production records (Form (b) (4)) from August 13, 2025, through November 3, 2025, contain incorrect expiration dates. Your firm dispositioned this as "Use As-Is" on November 3, 2025. During this inspection (March 31, 2026), the firm provided an undated letter from (b) (4) stating the (b) (4) can be used (b) (4) years past expiration. No CAPA was initiated to investigate root cause or determine which finished device lots were affected.

• NCR 25 (2/14/2024) and Complaint 2024-025 (12/9/2024) both documented 8 of (b) (4) bottles ((b) (4)) with loose caps. No CAPA was initiated to investigate the capping process.

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• Five complaints involving TMB discoloration (2024-002, 2024-010, 2024-021, 2024-026, 2025-008) were closed with no CAPA initiated. Complaint 2024-021 documented the root cause as "undetermined."

b) Review of complaint records from 2024-2025 revealed 2 of 34 complaints (5.9%) resulted in CAPA initiation:

• Five complaints involving labeling and documentation errors (2024-001, 2024-003, 2024-020, 2024-023, 2024-024) resulted in one CAPA (2024-03). CAPA 2024-03 addressed Build Instruction part number errors. Complaint 2024-020 states "this is the third related issue with CoA documentation being sent to (b) (4) A trend is identified," yet no CAPA was initiated.

• Four complaints involving leaking or damaged bottles (2023-02, 2024-025, 2025-003, 2025-006) resulted in one CAPA (2025-01) that addressed packaging for (b) (4) Complaint 2025-006 (dated 9/11/2025) documented loose caps after CAPA 2025-01 was closed on 9/2/2025.

c) Your firm did not document rationale for CAPA decisions. SOP-85-02 Section 3.1 states "If CAPA is not required, the rationale must be documented."

d) Complaint 2024-020 and Complaint 2025-007 both state "a trend is identified." No preventive action was initiated for either complaint.

e) CAPA effectiveness:

• CAPA 2024-03 (7/23/2024) corrective action stated "A review of CRs in the future will take place before approval." Change Request (b) (4) (10/10/2025) contains no risk assessment and an incomplete training plan.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jenny L Chisem, Investigator X Jenny L Chisem Investigator Signed By: JENNY L. CHISEM -S Date Signed: 04-02-2026 16:18:14	4/2/2026

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• CAPA 2024-12 (11/15/2024) corrective action required (b) (4) CAPA status meetings starting 1/15/2025. Management Review dated 1/21/2026 includes action item "Add regular (b) (4) meetings for complaints, CAPAs, NCRs" with due date of 2/1/2026.

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EMPLOYEE(S) SIGNATURE
Jenny L Chisem, Investigator

X Jenny L Chisem
Investigator
Signed By: JENNY L. CHISEM -S
Date Signed: 04-02-2026
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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jenny L Chisem, Investigator	X Jenny L Chisem Investigator Signed By: JENNY L. CHISEM -S Date Signed: 04-02-2026 16:18:14	DATE ISSUED 4/2/2026

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."