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	3/16/2026-3/20/2026
	FEI NUMBER 3018010054

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mindy M. Blackston, Operations, QA, and QMS Manager

FIRM NAME	STREET ADDRESS
Reprolife America, LLC	22751 Professional Dr Ste 220
CITY, STATE, ZIP CODE, COUNTRY Kingwood, TX 77339-6024	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

The significance of the design and development change to function, performance, safety and regulatory requirements for the medical device and its intended use was not determined.

Specifically, your firm has not established procedures to control design and development changes to ensure they are reviewed, verified, validated, as appropriate and approved prior to their implementation. For example:

a) On the third day of the inspection, your Operations, QA, QMS Manager and Production Manager acknowledged that the (b) (4) concentration currently used in manufacturing is different from what was submitted in your 510(k) clearance and that an amendment would need to be submitted to address this discrepancy.
b) Your firm has been manufacturing and distributing product with (b) (4) concentrations that do not match the device's cleared specifications, including lot (b) (4) and (b) (4)

OBSERVATION 2

The quality management system was not documented in accordance with applicable regulatory requirements.

Specifically, your firm failed to establish, implement, maintain and document a quality management system and any requirement, procedure, activity or arrangement to maintain its effectiveness. For example:

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	Elizabeth A Krolczyk, Investigator X Elizabeth A Krolczyk Investigator Signed By: ELIZABETH A. KROLCZYK -S Date Signed: 03-20-2026 11:03:45	3/20/2026

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a)Your firm does not have a documented quality manual.
b)Your firm does not have a documented quality policy.
c)Your firm does not have documented quality objectives.
d)Your firm has not documented procedures for management reviews.
e)Your firm has not conducted management reviews at defined intervals.
f)Your firm does not have a defined management representative.

OBSERVATION 3

Requirements for the work environment, and the procedures to monitor and control the work environment, were not documented where conditions for the work environment can have an adverse effect on product quality.

Specifically, your firm failed to document procedures to monitor and control the work environment in which the Vitrification Solution Sets and Warming Solution Sets are manufactured. For example:

a) Your firm only documents the temperature and humidity of the biosafety cabinet when it is in use, not continuously. Your Operations, QA, QMS Manager acknowledged that your firm is unable to trend this data to ensure consistent environmental conditions.
b) Your firm has not logged temperature and humidity measurements for the ISO Class 7 Cleanroom, which houses the biosafety cabinet used for (b) (4) into (b) (4) vials.
c) Your firm's training signoff sheet does not include the revision in which the employee was trained on.
d) Your firm's cleanroom cleaning log includes entries for (b) (4) and (b) (4) with signatures indicating completion and verification of completion, but procedures defining what these activities entail and how they should be performed do not exist. Your Operations, QA, QMS Manager confirmed that it is unclear what activities are being completed.
e) Your firm did not document contamination control requirements.

OBSERVATION 4

Processes for production and service provision where the resulting output cannot be, or is not, verified by subsequent monitoring or measurement were not validated.

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Specifically, your firm failed to validate processes and document procedures used in production and service provision where the results cannot be verified by subsequent inspection and testing. For example:

a)Your firm does not have documented process validation procedures.
b)Your firm has not defined a process validation lifecycle, revalidation criteria, and ongoing process verification.
c)Your firm has not revalidated since the firm moved to the current location in 2021. Unqualified equipment was used to produce both lots S103124 and U041625.
d)On the second day of the inspection, your Operations, QA, QMS Manager confirmed that the tests described in procedure REPROAM-LAB.2.6, Aseptic Processing, Fingertip Sampling, Environmental Monitoring/Testing, Rev 0, 05/01/2024 have not been performed since 2024. These tests include Environmental Control Testing, Glove Testing, and Media Fill Testing (MFT). Your firm does not have a procedure for MFT.
e)Your firm claimed conformance to ISO 13408-2 2018. However, it was confirmed by your Operations, QA, QMS Manager that a bacterial challenge test has not been performed since 2024.
f)According to procedure REPROAM-LAB.2.6, particle counts should be performed every (b) (4) months. However, your firm's last two documented particle counts were performed on 2/5/2026 and 5/9/2024 exceeding the (b) (4) period.

Despite the lack of environmental monitoring since 2024 and the unqualified equipment, your firm continued to manufacture product and released lot U041625 without documenting deviations or investigating prior to release.

OBSERVATION 5

A design and development file does not include or reference records generated to demonstrate conformity to the requirements for design and development.

Specifically, your firm failed to document a design and development file to ensure that specified requirements are met. For example:

a)Your firm did not document design input requirements for the vitrification and warming solution sets.
b)Your firm did not document design outputs for the vitrification and warming solution sets.

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c)Your firm did not have documented design reviews.
d)On the third day of the inspection, you confirmed that your firm did not establish a design transfer process with your parent company location to ensure that design outputs are suitable for manufacturing at your facility. You stated that you are still using the same recipe for the media that was used before you were acquired by the parent location.

OBSERVATION 6

Medical device files have not been established and maintained.

Specifically, your firm failed to establish and maintain a Medical Device File for the Vitrification Solution Set and the Warming Solution Sets. For example:

a)During the inspection, your Operations, QA, QMS Manager confirmed that your firm does not have a defined Medical Device File that contains or references all documents necessary for manufacturing the Vitrification Solution Set and the Warming Solution Sets.
b)Your firm does not have documented procedures for product distribution.
c)Your firm does not have procedures for measuring and monitoring of product characteristics.

OBSERVATION 7

One or more processes for risk management in product realization have not been documented.

Specifically, your firm failed to establish and maintain risk management documentation to ensure that product manufactured are safe and do not cause patient harm. For example:

a) Your firm does not have risk documentation for media products manufactured.

OBSERVATION 8

Procedures for timely complaint handling have not been documented.

Specifically, your firm failed to document procedures for receiving, reviewing, and evaluating complaints. For example:

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a)Your firm does not have a documented complaint handling procedure.
b)Your firm received a complaint regarding lot U041625 in which there was low egg survival. However, the investigation was inadequate because it:
  a.Did not identify or address that lot U041625 was manufactured without required environmental controls, including swabbing, bacterial challenge testing, glove testing, and media fill validation.
  b.Did not address that lot U041625 was manufactured using an unqualified biosafety cabinet.
  c.Did not initiate a corrective action to address manufacturing deficiencies.

OBSERVATION 9

Procedures for traceability were not documented.

Specifically, your firm failed to document procedures for traceability and identification of your Vitrification Solution Kit and Warming Solution Kits. For example:

a)Your firm does not have documented procedures for product identification.
b)Your firm does not have documented procedures for traceability.
c)Your firm does not have documented procedures for labeling product.

OBSERVATION 10

Corrective action procedures defining the requirements for reviewing nonconformities, determining the causes of nonconformities, evaluating the need for action to ensure that nonconformities do not recur, planning and documenting action needed and implementing such action, verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device and reviewing the effectiveness of corrective action taken have not been documented.

Specifically, your firm failed to establish, implement, and maintain procedures for Corrective Actions and Preventive Actions. For example:

a) Your firm does not have a documented Corrective Action procedure

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b) Your firm does not have a documented Preventive Action Procedure
c) Following your firm's 2026 internal audit, audit findings have not been logged or addressed with corrective actions.
d) Lot U041625 was manufactured without required environmental monitoring and used an unqualified biosafety cabinet. Despite this, the firm did not initiate a Corrective Action to:
   a. Determine why environmental monitoring was not performed since 2024
   b. Prevent the recurrence of product being manufactured without adequate controls and monitoring
   c. Address the unqualified biosafety cabinet and ISO Class 7 Cleanroom.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

Observation 7: Promised to correct

Observation 8: Promised to correct

Observation 9: Promised to correct

Observation 10: 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."