**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 3/24/2026-3/26/2026 |
| | FEI NUMBER<br>3035380687 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Polly Ann Thompson, Quality Assurance Consultant

| FIRM NAME | STREET ADDRESS |
|---|---|
| Targeted Genomics, LLC | 5 Mason |
| CITY, STATE, ZIP CODE, COUNTRY<br>Irvine, CA 92618 | TYPE ESTABLISHMENT INSPECTED<br>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 WE OBSERVED:**

## OBSERVATION 1

A risk-based approach to the control of the appropriate processes needed for the quality management system has not been applied.

Specifically, your firm's procedure, Risk Management Rev. 1 3/1/2026, describes FMEA to be used to systematically evaluate potential failure modes and their impact. Your firm could not provide an FMEA for your Class II GlutenID Genetic Health Risk Test, as required by your procedure.

## OBSERVATION 2

Controls over outsourced processes that affect product conformity to requirements are not proportionate to the risk involved.

Specifically, your firm's procedure, Outsourcing and Purchasing Control Rev. 1 Effective: 3-21-26, defines your process for selection, evaluation, approval, monitoring, and re-evaluation of suppliers and outsourced processes to ensure that purchased products and services conform to specified requirements. Your procedure defines the classification of (b) (4) as any supplier that has direct impact on product quality/safety. (b) (4) suppliers require more stringent qualification and increased monitoring and audits; however, these are not further defined by your procedure. Your procedure does not define requirements such as (b) (4) audit for evaluation or the time intervals for the audit or evaluation of (b) (4) suppliers

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Kevin N Tran, Investigator<br>Richard E Evoy, Investigator<br>X Kevin N Tran Investigator Signed By: 2002406436 Date Signed: 03-26-2026 11:17:52 | 3/26/2026 |

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Firm A provides finished genetic testing kits and distributes them to end users for your firm's GlutenID Genetic Health Risk Test, a Class II genetic variant detection and health risk assessment system. Your firm classified Firm A as a (b) (4) supplier, which has direct impact on product quality and safety. Your firm requires more stringent qualifications and increased monitoring and audits for (b) (4) suppliers; however, your firm only performed an evaluation using your supplier score performance card for Firm A.

As well, the firm's quality agreement with Firm A, signed 3/23/2026, does not fully define their control over the outsourced process of assembling and distributing genetic testing kits, and how the product is meeting device specifications.

Your firm's procedure also requires a supplier qualification form to be filled out for all suppliers, and one was not provided for Firm A. Your firm has been outsourcing kit assembly and distribution to Firm A since 2-1-2026.

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X Richard E Evoy
Investigator
Signed By: RICHARD E. EVOY -S
Date Signed: 03-26-2026 11:21:43

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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<br>Kevin N Tran, Investigator<br>Richard E Evoy, Investigator | X Kevin N Tran Investigator Signed By: 2002406436 Date Signed: 03-26-2026 11:17:52 | DATE ISSUED<br>3/26/2026 |

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."