DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160 orabioinspectionalcorrespondence@fda.hhs.gov	8/28/2023-8/30/2023
	FEI NUMBER 3012094568

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Chorong (NMI) Hahm M.D., Clinical Pathologist

FIRM NAME	STREET ADDRESS
Eone Laboratories	49 Songdong
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Yeonsu, INCHEON, 22014 Korea (the Republic of)	Testing Laboratory

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 I OBSERVED:

OBSERVATION 1

Records were not detailed as necessary to provide a complete history of work performed.

Specifically, the "Microbiology Worksheet" used to document the date of the (b) (4) of media with HCT/P samples, the lot number and expiration date of the media used, as well as the (b) (4) is missing the following:

1. Documentation of (b) (4) sample reading does not provide enough information to verify that the results of each individual sample were observed
2. (b) (4) sample reading is not documented for a total of (b) (4) as required by the "Tissue Culture" procedure. Documentation is missing for (b) (4).
3. Lack of identification of hand written numbers written below the sample list
    a. Example: On 08/10/2023 the numbers (b) (4) were written below the final sample numbered (b) (4) with no other accompanying explanation.
4. The worksheet does not contain documentation of secondary review

Since 2020, your firm has conducted (b) (4) microbiology tests for HCT/P products that are exported into the United States.

THIS IS A REPEATED OSERVATION FROM THE PREVIOUS INSPECTION

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Emily B Camire, Investigator

X Emily B Camire -S
Investigator
Signed By: Emily B. Camire -S
Date Signed: 08-30-2023
14:17:37

DATE ISSUED
8/30/2023

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."