DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Pkwy Alameda CA, 94502 510-337-6700 Industry Information: www.fda.gov/oc/industry	5/5/2025, 5/6/2025
	FEI NUMBER 2974624

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Stephen Smith, Transfusion Services Medical Director

FIRM NAME	STREET ADDRESS
Clinical Laboratories of Hawaii Inc	1190 Waianuenue Ave
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hilo Hawaii 96720	Blood Bank

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) (WE) OBSERVED:

OBSERVATION 1: Failure to maintain storage and distribution records.

Specifically, emergency release records did not include a physician's signature after blood products were issued and left blood bank control.

Your firm's SOP, Emergency Release, CLHA.TRM.02.206.1014.4, approved June 28 2024, states on page 3 that

(b) (4)

I reviewed a sample of your firm's emergency release records, (b) (4) forms, from 2024 and 2025. During my review, I found, out of forty records, three records in October 2024, November 2024, and March 2025 that lacked a physician signature, affecting eight units of O-negative red blood cells (RBCs). While in all three cases the blood products were not transfused to patients, the unit history of every RBC unit reveals the units were issued and left blood bank control.

In 2024 and 2025, your firm conducted a total of (b) (4) emergency releases, according to firm staff.

Reference: 21 CFR 606.160(b)(3)

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Eric Zhu -S Digitally signed by Eric Zhu -S Date: 2025.05.06 13:24:43 -10'00'	Eric Zhu, Investigator	5/6/2025

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 judgement, 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."