DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	4/24/2026-4/28/2026*
	FEI NUMBER 1770152

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Julie Miller, Technical Specialist - Blood Bank

FIRM NAME	STREET ADDRESS
SCL Health Front Range Inc.	8300 W 38th Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wheat Ridge, CO 80033-6005	Hospital 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 OBSERVED:

OBSERVATION 1

Equipment used in the compatibility testing and storage and distribution of blood and blood components is not on a regularly scheduled basis as prescribed in the SOP Manual.

Specifically, The firm failed to maintain documented preventive maintenance records for (b) (4) refrigerators and (b) (4) freezer. The refrigerators are used to store quality control (QC) reagents, antibody panels, typing and crossmatching reagents, blood units for transfusion, and patient samples. Per the manufacturers' manual, these refrigerators require preventive maintenance at a (b) (4) frequency of (b) (4) Similarly, (b) (4) freezer, which is used to store frozen plasma, requires condenser cleaning at a (b) (4) frequency of (b) (4) per the manufacturer's manual. At the time of review, the firm was unable to provide maintenance records for any of these units.

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*DATES OF INSPECTION

4/24/2026(Fri), 4/27/2026(Mon), 4/28/2026(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Deepa E Vadakkan, Investigator X Deepa E Vadakkan Investigator Signed By: DEEPA E. VADAKKAN -S Date Signed: 04-28-2026 14:17:32	4/28/2026

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."