

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0598799	(X3) Date Survey Completed 08/27/2024
Name of Provider or Supplier Fremont Surgery Center	Street Address, City, State 39350 Civic Center Dr, Ste 100, Fremont, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory testing records, the lack of quality control records for the timeframe 2021 to August 20, 2023, and interview with the laboratory administrator/Director of Nursing, it was determined that the laboratory failed to retain QC records for at least two years from date of testing. Findings included: a. California Business and Professions Code (BPC) 1265(J)(2)(A) requires laboratory records to be retained 3 years from date of testing unless a longer retention time is required: (2)(A) Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department. b. See D5441.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number</p>

and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation of the iSTAT handheld analyzer for Chemistry and Hematology, review of laboratory testing records, the lack of records documenting quality control testing, and interview with the laboratory administrator/Director of Nursing, it was determined that the laboratory failed to document all control procedures. Findings included: a. The iSTAT was used to test and report results for the following analytes, as follows: 1. CHEM8+ test cassette: Na (Sodium) CL (Chloride) Glu (Glucose) Creatinine K (Potassium) BUN (Blood Urea Nitrogen) HCT (Hematocrit) HGB (Hemoglobin) Ca (Calcium) TCO2 2. CG4+ test cassette Blood Gases: pH, pCO2, pO2 a. Laboratory test records documented testing patients specimen and reporting results, as follows: Date ID QC records
----- 9/09/21 170952-1 None 12/10/21 130303-8 None 3
/17/22 174197-1 None 7/27/22 123589-5 None 12/13/22 115512-4 None 3/28/23 686
/1 None 5/25/23 33791/1 None b. The laboratory failed to have QC records for the
aforementioned testings. c. The laboratory administrator/Director of Nursing affirmed
(8/27/24 at 12:00 PM) that in accordance with the laboratory's IQCP, quality control
procedures were only performed with each new Lot # of test cassettes received and
not each day of testing; and that the QC records prior to 8/21/23 had been discarded.
d. And thus, the reliability and quality of iSTAT results reported for the timeframe
September 2021 to 8/20/23 could not be assured during this CLIA survey. e. The
laboratory reported 5,006 iSTAT results annually (CMS116 CLIA Application, 8/21
/24). .