Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1099483	03/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Freedom Arthritis	21060 Centre Point Pkwy, Ste A, Santa Clarita, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the surveyor's observation and interview with testing personnel general supervisor (GS) it was determined that the laboratory lacked an eyewash in the testing area. The laboratory failed to observe safety procedures to ensure protection from biohazardous materials. The findings included: 1. On the day of the survey March 5, 2024, at approximately 12:00 p.m. the surveyor observed that the laboratory lacked an eyewash in the area where blood samples are processed. 2. The GS affirmed the lack of an eyewash in the testing area. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 3/4/2024, the laboratory processed, tested, and reported approximately 4,000 samples.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on review of test result reports requested, lack of documentation of calibration records, and interview with the laboratory's general supervisor (GS); it was determined that the laboratory failed to retrieve calibration records for 2022 and 2023.

	The findings included: 1. At the time of the survey on March 5, 2024, at approximately 11:00 a.m. the GS failed to retrieve documentation records requested for the ChroMate ELISA analytic plate. 2. The GS affirmed that calibration records for the years 2022 and 2023 for the ChroMate ELISA analytic plate were not retrievable at the time of the survey. 3. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 4,000 tests annually for which the laboratory was unable to retrieve calibration records for the ELISA analyzer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, lack of documentation, the surveyor's observation, and interview with the general supervisor (GS); it was determined that the laboratory failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's pipettes. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that preventive maintenance and calibration be performed on all equipment and instruments used in the laboratory. 2. The GS confirmed on March 5, 2024, at approximately 11:00 a.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration of pipettes used daily. 3. According to the test volume declared by the laboratory on 3/4/2024 the laboratory performs approximately 4,000 diagnostic immunology tests annually.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures, patient test records review from 9/27/2023 to 2/20/2024, and interview with the general supervisor (GS); it was determined that the laboratory failed to have a policy for turn-around time (TAT) for all tests performed in the laboratory. 1. The laboratory failed to provide TAT of testing for four (4) out of four (4) randomly chosen patients at the time of the survey (March 5, 2024). The laboratory did not provide a TAT policy which may adversely impact patient management. 2. The laboratory GS on March 5, 2024, at approximately 12:00 p.m. affirmed that the laboratory did not have a TAT policy to notify any delay on testing to the physician. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/4/2024, stated that the laboratory performs 4,000 tests annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records, policies and procedures, patients' test results records, quality assessment documentation, and interviews with the laboratory's testing personnel on March 5, 2024; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D3011, D3031, D5429, and D5815.