Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1099483	04/06/2018
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
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) Plan manual, random patient sampling test results, and interview with the technical supervisor/testing personnel, it was determine that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. The findings included: a. The laboratory's QA Plan procedure manual stated, " Goals: The Goal of the QA Plan is to improve reliability, efficient, and quality of laboratory services. The Laboratory has established a QA Review Process which: A. Identifies the reliability and effectiveness of the Laboratory's Policies and Procedures including the Quality Assurance Plan. B. Ensures accurate and reliable patient test results. C. Identifies areas for improvement to the testing process. D. Ensures competency of the Laboratory Staff." b. The laboratory uses patient log and number systems: for three (3) out of eighteen (18) random patient sampling test results reviewed covering period from 11/4/2016 to 3/2/2018, three (3) patients did not match with the laboratory's numbering systems. c. The technical supervisor/testing personnel affirmed (4/6/2018, 1300) that the laboratory failed to identify problem and ensure that the above QA policy and procedure are followed.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) Plan manual, random patient sampling test results, and interview with the technical supervisor/testing personnel, it was determine that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 5891.