

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1099483	(X3) Date Survey Completed 11/13/2020
Name of Provider or Supplier Freedom Arthritis	Street Address, City, State 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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, random patient sample, calibration material and quality control (QC) testing records for the years of 2018, 2019 and 2020, and interview with the laboratory technical consultant (TC) on November 13, 2020 at 12:40 pm, the laboratory failed to perform and document calibration procedures following the manufacturer's test system instructions, using calibration materials provided, and with at least the frequency recommended by the manufacturer for all test procedures. The findings include: 1. The laboratory did not test calibration material, provided by the manufacturer, in each assay as recommended by the manufacturer. Therefore, the accuracy of the patient test results reported can not be assured. a. The laboratory used Theratest ELISA kit for ANA, RF, CCP and ACL panel testing by manual method. Each kit comes with the calibration and control materials. b. The kit manufacturer instructs that the laboratory must include the calibration and control materials in each assay. c. The laboratory did not include the calibration material in each assay. 2. The laboratory TC on November 13, 2020 at 12: 40 pm, affirmed that the laboratory did not include the calibration material in each</p>

assay in order to save money. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/13/2020, stated that the laboratory performs 5,000 tests, annually.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, random patient, QC and calibrator testing records for the years of 2018, 2019 and 2020, and interview with the laboratory TC on November 13, 2020 at 12:40 pm, it was determined that the laboratory director failed to ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. The findings include: See D5437.