

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1091752	(X3) Date Survey Completed 06/21/2018
Name of Provider or Supplier Advanced Arthritis Care Center	Street Address, City, State 3567 Shore Pkwy, 2nd Floor, Brooklyn, NY	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's room temperature logs and confirmed in an interview with the technical consultant, the laboratory failed to follow the manufacturer's required room temperature from January 1, 2017 through survey date. FINDINGS: The technical consultant confirmed on June 21, 2018 at approximately 2:30 PM, the surveyor's findings, that the laboratory recorded the room temperatures from January 1, 2017 through survey date as follows: a. the manufacturer requires a room temperature range of 68-77 F or 20-25 C b. the laboratory used a log sheet for refrigerator temperatures with a range of 35-46F or 2-8C c. the laboratory recorded the room temperature of 24 -26 F for the above time period using the refrigerator temperature log sheets.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that</p>

perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of laboratory's temperature logs, instrument manuals and confirmed in an interview with the technical consultant, the laboratory failed to document corrective action when the room temperature results were recorded on the refrigerator temperature log sheets from January 1, 2017 through survey date. Refer to D5413.