Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0267193	(X3) Date Survey Completed 04/03/2019
Name of Provider or Supplier Arthritis & Osteoporosis Treatment Center Pa	**Street Address, City, State** 2100 Kingsley Ave, Orange Park, FL	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of employee competency records and interview with the Manager, the laboratory failed to perform competency evaluations on 4 out of 4 Testing Personnel (# 2, # 3, # 4, # 5) for Hematology specialty for 2 out of 2 (2017-2019) years reviewed. Findings Included: Review of employee competency records found no competency evaluations performed on Testing Person # 2, # 3, # 4, and # 5 for Hematology specialty from 04/03/17 through 04/03/19. Interview with the Manager confirmed on 04/03/19 at 10:45 AM. that there was no documented competency evaluations for Testing Person #2, # 3, # 4, and # 5.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by:

	Based on record review and interview with the Manager, the laboratory failed to document room temperature and humidity on Cell Dyne -1800 Hematology Analyzer for 2 out of 2 years (2017-2019) reviewed. Findings Included: Review of maintenance records from 04/03/17 through 04/03/19 found no room temperature and humidity documented. Review of Cell Dyne-1800 Hematology Analyzer Manual specifications required an environment for room temperature and humidity. During an interview on 04/03/19 at 10:30 AM, the Manager confirmed that there were no room temperature and humidity recorded.