Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0067411	11/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis Treatment Center	3377 Main St, Springfield, MA	

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
D0000	A CLIA recertification survey was conducted for the laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibration verifications every six months or, as appropriate, as evidenced by the following: a) A

	review of hematology calibration records for calendar years 2018, 2019, and 2020 was performed on 11/4/20 at 10:49 AM. b) The review revealed that calibration verifications of at least 3 points was not performed once every six months complete blood count (CBC) analytes performed on the Beckman Coulter HMX analyzer. Records revealed that calibrations of the analyzer had only been performed once during calendar years 2018, 2019 and 2020 (calibrations performed 5/16/18, 7/9/19, and 1/8/20 respectively). c) General supervisor number one confirmed in an interview on 11/4/20 at 10:58 AM calibrations had not been performed every six months on the hematology analyzer. d) The laboratory performs approximately 9,516 CBCs annually. .
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on record review and interview the technical supervisor failed to ensure the establishment of the laboratory's test performance characteristics and that the verification of the test procedures performed were adequate for accuracy and precision when applicable, prior to implementing a hematology analyzer test procedures for patient testing and reporting: a) A review of validation documentation on 11/4/20 at 11:20 AM for the Sysmex XN 530 hematology analyzer implemented on 10/21/20 was performed. The review revealed that the technical supervisor failed to document a review and approval of all performance specifications that had been completed. There was no documented review of the within and day to day precision studies. b) The technical supervisor confirmed in an interview on 11/4/20 at 12:45 AM that he had not signed off on the precision studies. .