Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0225124	06/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis Specialists Of Winchester	420 West Jubal Early Drive Suite 104, Winchester, VA	

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	An announced CLIA Recertification survey was conducted at the Arthritis Specialists of Winchester on 06/02/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 the review of manufacturer's guidelines, calibration verification records, lack of documentation and interview, the lab failed to follow manufacturer's requirements of performing calibration verification procedures every six months for 24 of 24 months reviewed for the Vitamin D analyte. Dates of record review included 04/01/20 up to 04/01/22. Findings include: 1. Review of the Qualigen FastPack manufacturer's guidelines revealed the following statement, "Every 6 months, verify calibration of the FastPack IP system using the FastPack Vitamin D Method Verification Kit to verify that calibration is accurate to the limits of the reportable range specified by Qualigen, INC." 2. Review of available calibration verification records from 04/01/20 up to 04/01/22 revealed lack of documentation of calibration verification performed after the last calibration verification performed on 04/14/20. The surveyor requested to review additional calibration verification records. The documents were not available for review. 3. An exit interview with the lab director and primary testing personnel on 06/02/22 at 1245 confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), quality control (QC) records, daily patient testing logs and interview, the lab failed to follow the established policy of performing weekly QC procedures for the Vitamin D analyte for three of 104 weeks and reporting 60 patients. Findings include: 1. Review of the P&P revealed an Individualized Quality Control Plan (IQCP) statement, "The lab will perform QC procedures on a weekly basis." 2. Review of weekly QC records and daily patient testing logs for the Vitamin D analyte from 04/01/20 up to 04/30/22 revealed lack of documentation of performance of the weekly QC procedures: 12/15/20- 13 patients reported and 12/17/20- 6 patients reported. 04/22/21- 9 patients reported and 04/23 /21- 7 patients reported. 10/25/21- 7 patients reported, 10/26/21- 6 patients reported, 10/27/21- 7 patients reported and 10/28/21- 5 patients reported. Total of 3 weeks and 60 patients. The surveyor requested to review the QC documents for the above-specified weeks. The documents were not available for review. 3. An exit interview with the lab director and primary testing personnel on 06/02/22 at 1245 confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on the review of quality control records (QC), lack of documentation, daily patient testing logs and interview, the lab failed to perform daily QC procedures for the Beckman Coulter AcTDiff hematology analyzer for three days from 04/01/20 to 04/30/22 and reporting 15 patients. Findings include: 1. Review of the daily QC records and patient testing logs from 04/01/20 to 04/30/22 for the Beckman Coulter AcTDiff hematology analyzer revealed lack of documentation of QC procedures for the following dates: 12/17/20- 11 patients reported, 06/14/21- 3 patients reported, and 06/18/21- 1 patient reported. Total three days and 15 patients. The surveyor requested to review the QC documents for the above-specified dates. The documentation was not available for review. 2. An exit interview with the lab director and primary testing personnel on 06/02/22 at 1245 confirmed the findings.