Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0225124	02/08/2024
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 Arthritis Specialists of Winchester on February 8, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The deficiency cited is as follows:
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's user guide, pipette maintenance records, lack of documentation, and interviews, the laboratory failed to follow the manufacturer's annual calibration maintenance policy for one (1) of 1 positive displacement sample pipettes utilized for Vitamin D patient testing in calendar years 2022 and 2023. Review timeframe: July 2022 until the date of the survey on February 8, 2024. The findings include: 1. During a laboratory tour on February 8, 2024 at approximately 8:30 AM, the surveyor noted one Gilson Microman FXP M100 microliter (ul) pipette, serial number (SN) JD05692, in use for Qualigen FastPack patient sample preparation for Vitamin D testing. The surveyor noted a calibration sticker dated 12/10/21 with a next due date of 12/10/2022. The testing personnel stated "I forgot to send the pipette for calibration. I have the paperwork filled out to send it out today." 2. Review of the Qualigen manufacturer's user guide revealed a

	policy, "Annual Recalibration of the Positive Displacement Sample Pipette" which outlined instructions for pipette calibrations. The policy stated "CLIA requires that the pipette used to collect test samples be checked annually to ensure that it maintains its calibration specification. Proper performance of pipette is critical to obtain accurate results. The pipette included with the FastPack System is a costly piece of equipment that requires periodic recalibration which must be done by a factory certified dealer". 3. Review of the laboratory's pipette maintenance records from July 2022 until the date of the survey on February 8, 2024 revealed a pipette calibration certificate for the Gilson Microman FXP M100 microliter (ul) pipette, SN JD05692, with the statement "Calibrated 12/10/2021. Next due date 12/2022." No additional pipette calibration documentation was observed. The surveyor requested to review additional pipette calibration records. The laboratory provided no further documentation to review. 4. An exit interview with the testing personnel on February 8, 2024, at approximately 11: 00 AM, confirmed the findings.