Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0890671	01/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Shenandoah Oncology, Pc	400 Campus Boulevard - Suite 100, 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 virtual CLIA recertification survey was conducted for Shenandoah Oncology, PC on January 26, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on December 21, 2020 and virtual record review conducted on January 22, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency 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 review of the laboratory's policies and procedures, manufacturer's instructions, equipment maintenance records, and interviews, the laboratory failed to establish maintenance and calibration protocols for pipettes used for dilution of patient specimens for analysis from March 2019 until January 2021. Findings include: 1. During the virtual survey, at approximately 12:40 PM on January 26, 2021, the inspector inquired if pipettes where used in the Chemistry testing area. Testing personnel A (TP A) stated they use pipettes for diluting patient specimens for testing on the TOSOH chemistry analyzer. TP A provided a copy of the manufacturer's instructions for a Eppendorf Reference 2 1-Channel pipette. 2. Review of the manufacturer's instructions for the Eppendorf Reference 2 1-channel pipette revealed the following statement, "Maintenance-Check the performance of your pipettor

	regularly e.g. every 3 months and after every in-house service or maintenance. Calibration-Each pipette has been checked conforming to EN ISO 8655 standards. It is recommended to check the calibration at lease once per year for regularly used pipettes." 3. Review of the laboratory's policies and procedures revealed no policy or procedure for the maintenance and calibration of the Eppendorf Reference 2 1-Channel pipette. The surveyor requested to review written maintenance and calibration protocols for the pipettor. TP A stated they did not have a policy. TP A stated they purchase new pipettes every two years. 4. Review of the laboratory's equipment maintenance records from March 2019 until January 2021 revealed two pipettor "Calibration Reports" for the following pipettors: a. Serial number NF99650 with a report date of 6/6/2018 and received date of 2/6/19 (calibration due 2/2020); b. Serial number P1239755 with a report date of 9/9/2020 and received date of 1/13 /2021 (calibraton current). The inspector requested additional pipette calibration documentation. The laboratory provided no additional documentation to review. 5. In an interview with the Technical Consultant and TP A at 12:45 PM on January 26, 2021, the findings were confirmed.