Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0890671	02/28/2019
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 CLIA initial survey was conducted at Shenandoah Oncology, PC on February 28, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of analyzer validation records, user guide, patient test logs, and an interview, the laboratory director (LD) failed to verify the normal values (reference ranges) for the Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Calcium, Albumin, Alkaline Phosphotase, Alanine Transaminase (ALT), Aspartine Aminotranferase (AST), BUN, Glucose, Total Bilirubin, Direct Bilirubin and Total Protein testing prior to reporting fourteen thousand six hundred ninety-three (14,693) patient results from October 17, 2017 to the date of the survey, February 28, 2019. Findings include: 1. Review of the Horiba Pentra C 400 validation records revealed a new instrument installation occurred on 10/10/17. The inspector noted the validation documentation contained no verification of the Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Calcium, Albumin, Alkaline Phosphotase, Alanine Transaminase (ALT), Aspartine Aminotranferase (AST), BUN, Glucose, Total Bilirubin, Direct Bilirubin and Total Protein patient normal values by the LD for the new Horiba Pentra

	C 400 instrument (Serial Number 707CU-0531). The surveyor requested documentation of the normal range verification. No documentation was provided by the laboratory. 2. Review of the Horiba Pentra 400 User's Guide for new instrument installation revealed the instruction: "The patient reference ranges must be validated by the Lab Director". 3. Review of the patient test log from the laboratory's electronic medical record, Orchard Harvest, revealed the laboratory reported 14,693 patient results from 10/17/17 to the date of the survey on 2/28/19. 4. An interview with the Lab Director and testing personnel A, at approximately 3:00 PM, confirmed the findings listed above.