Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0890671	12/03/2018
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 unannounced, off-cite CLIA proficiency testing (PT) desk review was conducted for Shenandoah Oncology, PC on December 3, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on an off-site desk review of the laboratory's 2017 and 2018 proficiency testing (PT) records, a total of six (6) events, and interview, the laboratory failed to attain a

	score of at least eighty (80) percent of acceptable responses for Chloride in two (2) of three (3) Chemistry testing events resulting in unsuccessful PT performance. See 2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on an off-site desk review of the laboratory's proficiency testing (PT) records and interview, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Chloride in two (2) of three (3) Chemistry testing events resulting in unsuccessful PT performance Findings include: 1. Desk review of the laboratory's 2018 Medical Laboratory Evaluation (MLE) PT records, a total of 3 events, revealed Chloride scores of less than 80% for the following Chemistry events: 2018 2nd event - Chloride score of 20%, 2018 3rd event - Chloride score of 60%, resulting in an unsuccessful PT performance. 2. In a telephone interview with the laboratory manager on December 3, 2018, the findings were confirmed for the PT testing events as outlined above.