

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0890671	(X3) Date Survey Completed 07/13/2023
Name of Provider or Supplier Shenandoah Oncology, Pc	Street Address, City, State 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-site CLIA proficiency testing (PT) desk review was conducted for Shenandoah Oncology, PC on July 13, 2023 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 and include the following condition under 42 CFR part 493 CLIA Regulation: D2016 - 42 CFR. 493.803 Condition: Successful Participation.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on an off-site desk review of the laboratory's 2023 proficiency testing (PT) records, a total of two (2) events, and interview, the laboratory failed to attain a score</p>

of at least eighty (80) percent of acceptable responses for Chloride in two (2) consecutive 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) consecutive Chemistry testing events (2023 Event 1 and 2) resulting in unsuccessful PT performance Findings include: 1. Desk review of the laboratory's 2023 American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) PT records, a total of 2 events, revealed Chloride scores of less than 80% for the following Chemistry events: AAB-MLE 2023 1st event - Chloride score of 20%, AAB-MLE 2023 2nd event - Chloride score of 40%, resulting in an unsuccessful PT performance. 2. In a telephone interview with the laboratory manager on July 13, 2023, at approximately 9:35 AM, the above findings were confirmed.