

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2110804	(X3) Date Survey Completed 08/21/2023
Name of Provider or Supplier Vista Medical Center North Arlington	Street Address, City, State 5335 Langston Blvd, Arlington, 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 CLIA Proficiency Testing (PT) desk review survey was conducted for Vista Medical Center North Arlington on August 21, 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 deficiency cited is as follows and includes the Condition under 42 CFR part 493 CLIA Regulation: D2000-42 CFR. 493.801 Enrollment and Testing of Samples.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CASPER Report 0164S Proficiency Testing (PT) Failure to Re-Enroll Report and CASPER Report 0155, lack of documentation and email, the laboratory failed to enroll in a proficiency testing (PT) program for the Virology /SARS CoV-2 module from January 2023 until August 21, 2023. The findings include: 1. Review of the laboratory's CASPER Report 0164S PT Failure to Re-Enroll Report revealed a lack of documentation of the re-enrollment in a PT program for the specialty of Virology. 2. Review of the laboratory's CASPER Report 0155D Individual Laboratory Profile revealed a lack of documentation of scores for the first and second events in 2023 for Virology. 3. In an email correspondence with the laboratory on August 21, 2023 at 3:07 PM, the laboratory manager confirmed the</p>

findings. The laboratory manager stated in the email that when they tried to enroll in PT for SARS CoV-2 for 2023, the PT program told the laboratory that they could not enroll for the same assay on the same instrument. After receiving the surveyor's email on August 21, 2023, the laboratory manager stated they contacted American Proficiency Institute and were told they could enroll for the SARS CoV-2 module. The laboratory provided a 2023 Order Confirmation with a order date of August 21, 2023 with shipment of samples on 09/18/2023.