

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0667592	(X3) Date Survey Completed 02/09/2021
Name of Provider or Supplier Centra Medical Group - Amherst	Street Address, City, State 115 Ambriar Court, Amherst, 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 Recertification on-site survey was conducted at the Centra Medical Group Amherst on February 9, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on January 21, 2021 with off-site record review of documentation and a follow-up phone conference on February 3, 2021. Specific deficiencies cited are as follows:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation, and interview with the lab director, the lab director or designee failed to review and sign three (3) of 6 attestation statements reviewed. Events of record review include 3 events in 2019 and 3 events in 2020. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) PT records on February 3, 2021 revealed the lack of documentation of the lab director's or designee signature on the attestation statements for the following events: 2019 MLE 2, 2020 MLE A, 2020 MLE B. 2. An interview with the lab director on February 9, 2021 at approximately 10 AM confirmed the findings and the documents were corrected on-site.</p>