

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0231572	(X3) Date Survey Completed 11/20/2020
Name of Provider or Supplier Carilion Clinic Family Medicine - Colonial Ave	Street Address, City, State 3369 Colonial Avenue, Roanoke, 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 Carilion Family Medicine- Colonial AVE on November 20, 2020 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 October 19, 2020 with off-site record review of documentation and a follow-up phone conference on November 13, 2020. Specific deficiencies cited are as follows:
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the technical consultant (TC), the TC failed to perform and document the semi-annual competency assessment for one (1) of 1 new TP. Dates of record review include June 3, 2019 up to November 20, 2020. Findings include: 1. Review of the CMS-209 form revealed that TP A was trained and performing patient testing on June 10, 2019. See attached TP code sheet. 2. Review of TP A records revealed lack of documentation by the TC of performance and review of the semi-annual competency assessment. The review revealed a competency assessment performed June 10, 2019 and June 11, 2020. No other documented competency assessment was available for review upon request. 3. An interview with the TC on November 20, 2020 at approximately 10:30 AM confirmed the findings.</p>