

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2097462	(X3) Date Survey Completed 08/13/2021
Name of Provider or Supplier Carilion Clinic Family Medicine- Oakgrove	Street Address, City, State 1818 Electric Rd, 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 survey was conducted at the Carilion Clinic Family Medicine- Oakgrove on August 13, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), lack of documentation, and interview, the laboratory did not have a P&P for performing competency assessments on testing personnel at the date of the survey on 08/13/21. Findings include: 1. Review of the available P&P's revealed lack of documentation of a policy for performing competency assessments on testing personnel performing patient testing. 2. During an exit interview with the technical consultant on 08/13/21 at approximately 12:00 PM, the documentation was not available for review and the above-specified finding confirmed.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</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 and annual competency assessment for one (1) of 1 new TP. Dates of record review include 06/03/19 up to 08/13/21. Findings include: 1. Review of the CMS-209 form revealed that TP A was trained and performing patient testing on 09/25/19. See attached TP code sheet. 2. Review of TP A's personnel records revealed lack of documentation by the TC of performance and review of the semi-annual and annual competency assessments at the date of survey on 08/13/21. 3. During an exit interview with the TC on 08/13/21 at approximately 12:00 PM, the documentation was not available for review and the above-specified findings confirmed.