

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0937518	(X3) Date Survey Completed 09/28/2021
Name of Provider or Supplier Carilion Clinic Fm- Blacksburg	Street Address, City, State 901 Plantation Road, Blacksburg, 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 FM-Blacksburg on September 28, 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:
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedures (P&P), testing personnel (TP) records, lack of documentation, and interview with the primary TP and technical consultant (TC), the laboratory director failed to follow the established P&P to evaluate and approve the annual competency assessment documents for three (3) of three (3) TP reviewed for the calendar year of 2020. Findings include: 1. Review of the CMS 209 laboratory personnel form revealed TP A, B and C performed patient testing in 2019, 2020 and up to the date of survey on 09/28/21. (See attached TP code sheet.) 2. Review of the P&P "Quality Assurance" revealed the following statement, "Training and competency assessments will be performed annually." 3. Review of TP A, B and C</p>

competency assessment documents revealed the following: Dates of documentation review and assessments recorded as performed for May 2019 through May 2020. The lab director signature of evaluation and approval of the competency assessments recorded as 04/20/21. An interview with the primary TP at approximately 1 PM on 09/28/21 confirmed that the lab director did not review and approve the competency assessments for the above-specified three TP at the date of completion in May 2020.

4. An exit interview with the primary TP and TC on 09/28/21 at approximately 1:30 PM confirmed the findings.