

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0231934	<b>(X3) Date Survey Completed</b> 07/14/2021
<b>Name of Provider or Supplier</b> Carilion Clinic Family Medicine- Radford	<b>Street Address, City, State</b> 701 Randolph Street Suite 120, Radford, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA validation survey was conducted at the Carilion Clinic Family Medicine- Radford on July 14, 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:
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview, the laboratory director failed to ensure that one (1) of 1 new TP had documentation of initial competency assessments prior to performing patient testing procedures in the specialty of Hematology from 07/02/19 and up to the date of survey on 07/14/21. Findings include: 1. Review of CLIA CMS-209 form revealed that TP A was a new TP July 2, 2019 (See attached TP Code Sheet). 2. Review of TP records revealed lack of documentation of an initial competency assessment prior to patient testing procedures by the laboratory director for TP A from 07/02/19 and up to the date of survey on 07/14/21. 3. An exit interview with the the primary TP and technical consultant at approximately 12:00 PM on 07/14/21 confirmed the findings.</p>

**D6053****TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

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.

This STANDARD is not met as evidenced by:

Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, policy and procedures (P&P), and interview, the technical consultant failed to ensure that one (1) of 1 new TP had documentation of a semi-annual competency assessment at the date of survey on 07/14/21. Findings include: 1. Review of CLIA CMS-209 form revealed that TP A was a new TP and had training performed on 07/02/19 (See attached TP Code Sheet). 2. Review of TP records revealed lack of documentation of a semi-annual competency assessment performed by the technical consultant for TP A from 07/02/19 and up to the date of survey on 07/14/21. 3. Review of P&P (signed by lab director as reviewed on 02/11/19) revealed the following: "Quality Assurance Program- Pre-analytical phase a. Documentation of evaluation every six months during the first year of employment then annually thereafter." 4. An exit interview with the the primary TP and technical consultant at approximately 12:00 PM on 07/14/21 confirmed the findings.