

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D1025532	<b>(X3) Date Survey Completed</b> 07/08/2022
<b>Name of Provider or Supplier</b> Carilion Gyn Oncology	<b>Street Address, City, State</b> 1 Riverside Circle - Suite 300, Roanoke, 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 Recertification survey was conducted at the Carilion Gyn Oncology on 07/08/22 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D6063 - 42 C.F.R. 493-803 Condition: Laboratory Testing Personnel.
<b>D6063</b>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available testing personnel records, lack of documentation, and interview the technical consultant, the laboratory failed to provide documentation of education qualifications for one of four laboratory TP performing non-waived testing on the i-STAT hand-held analyzer and the Medonic hematology analyzer from 3/01/22 up to the date of survey on 07/08/22. Refer to D6065.</p>
<b>D6065</b>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a</p>

chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available testing personnel records, lack of documentation, and interview with the technical consultant, the laboratory failed to provide documentation of education qualifications for one of four laboratory TP performing non-waived testing on the i-STAT hand-held analyzer and the Medonic hematology analyzer from 3/01/22 up to the date of survey on 07/08/22. Findings include: 1. Review of the CLIA CMS 209 form revealed four testing personnel listed. 2. Review of the available TP records revealed lack of documentation of the highest level of education for TP A. The inspector requested to review documentation of education for TP A. The documents were not available for review. The training records for TP A revealed documentation of training for the i-STAT hand-held analyzer assaying the Chem 8+ cartridge and the Medonic hematology analyzer assaying complete blood counts (CBC) on 03/01/22. 3. An exit interview with the technical consultant on 07/08/22 at noon confirmed the findings.