

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0231758	(X3) Date Survey Completed 07/16/2025
Name of Provider or Supplier Carilion Clinic Family Medicine - Dublin	Street Address, City, State 118 Broad Street, Dublin, 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	<p>An announced CLIA recertification survey was conducted at Carilion Clinic Family Medicine-Dublin on July 16, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Carilion Clinic Family Medicine-Dublin was not in compliance with the applicable standards under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on a review of procedures, maintenance logs, lack of documentation, observations, and interviews, the laboratory failed to follow their policy to document centrifuge revolutions per minute (RPM) verification checks annually for one centrifuge utilized for urine microscopy sample preparation for one of two years reviewed (survey timeframe June 22, 2023 to July 16, 2025). Findings include: 1. Review of the laboratory's procedure manual revealed a procedure titled Microscopic Examination of Urine that stated "Centrifuge urine for 5 minutes at 1,800-2,000 RPM or 3 minutes at 3,000 RPM." 2. Review of the available maintenance documentation for the timeframe of 6/22/23 - 7/16/25 revealed no records of RPM verifications for the laboratory's McKesson Model 602 Variable Speed Centrifuge. The inspector requested to review centrifuge RPM documentation for the 2 year survey timeframe. No documentation was available for review. The technical consultant (TC) stated on 7</p>

/16/25 at 11:45 AM, "The centrifuge RPM check should be verified annually by the clinical engineering service group. They apply stickers on the centrifuge when completed." 3. The inspector evaluated the McKesson Model 602 centrifuge (Clinical Engineering Serial Tag Number 406061143) located in the urinalysis/specimen processing area for maintenance/inspection tags. The inspector noted on 7/16/25 at 12:30 PM, a sticker located towards the rear of the unit annotating "indicated speeds 2000, 3000, and 4000 verified" (initialed BY, dated June 2024). The inspector noted an additional purple highlighted sticker labeled "GE Healthcare PM next inspection due June 2025". The inspector requested to review RPM check/maintenance record for calendar year 2025. The documentation was not available. 4. An interview with the office manager, lead testing personnel, and TC on 7/16/25 at 1:30 PM confirmed the above findings.