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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>49D0232087     | <b>(X3) Date Survey Completed</b><br><br>07/21/2026 |
| <b>Name of Provider or Supplier</b><br><br>Carilion Family Medicine Parkway                                                | <b>Street Address, City, State</b><br><br>415 South Pollard Street, Vinton, 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| D0000              | An announced CLIA recertification survey was conducted at Carilion Family Medicine - Parkway on July 21, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| D5433              | <p>MAINTENANCE AND FUNCTION CHECKS<br/>CFR(s): 493.1254(b)(1)</p> <p>(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of policies and procedures, equipment maintenance records, and interviews, the laboratory failed to document that the urinalysis centrifuge's revolutions per minute (RPM) calibration protocols ensured reliable urine microscopy results per procedure for 24 of 24 months reviewed (July 17, 2024 through the date of the recertification inspection, July 21, 2026). Findings include: 1. Review of the laboratory's policy and procedure manual revealed a urine microscopy procedure (titled: Urinalysis with Microscopic Exam) which stated, "Fill a urine centrifuge tube with 12 mls well mixed urine. Centrifuge for 5 minutes at 1800-2000 rpms or 3 minutes at 3000 rpm." The inspector noted that the procedure also referenced Clinical Laboratory Diagnosis by Samuel A. Levinson and Robert P. MacFate and Gradwohl's Clinical Laboratory Methods and Diagnosis by Frankel, Sam, and Reitman. The reference methods outlined instructions as, "The sediment is prepared as follows, centrifuge 10-15 mL of urine at 1,500-2,000 rpm for 5 minutes decant supernatant, resuspend the sediment of the remaining 1 ml of urine by tapping the tube gently against countertop and place one drop on a microscope slide for examination." 2. Review of the laboratory's biomedical equipment maintenance records for the review</p> |

timeframe, 7/17/24 to 7/21/26, revealed the following RPM calibration verification recorded for the urinalysis centrifuge (Unico SN 504464) dated: 2/17/25 with speed verified as "expected 3400 RPM, input 3390; 1/23/26 with speed verified as "expected 3400 RPM, input 3395; The inspector requested to review a calibration verification at 1,800-2,000 rpm (per the procedure) or 1,500-2,000 rpm (per procedure's reference). No additional records were available. The inspector inquired regarding the RPM checks outlined above as they were outside the procedure guidelines. The technical consultant (TC) stated on 7/21/26 at 3 PM, "Those RPM checks are outside of the higher RPM option on our procedure and also exceed 10 % variation. We will look at options to use a different centrifuge going forward." 3. An exit interview with the primary testing personnel and TC on 7/21/26 at 3:30 PM confirmed the above findings.