

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D1029091	<b>(X3) Date Survey Completed</b> 11/04/2020
<b>Name of Provider or Supplier</b> Carilion Surgery Center - New River Valley, Llc	<b>Street Address, City, State</b> 2901 Lamb Circle, Christiansburg, 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 unannounced CLIA on-site complaint investigation was conducted at Carilion Surgery Center- New River Surgery, LLC on October 22, 2020 with off-site email communication from October 22, 2020 up to November 4, 2020 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>D1000</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(c)</p> <p>Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), instructions for use (IFU), patient medical charts, employee consent forms, Center for Medicaid and Medicare (CMS) Automated Survey Processing Environment (ASPEN) WEB database WEB-116, and interviews with the charge nurse and lab director, the lab performed testing for twenty-one (21)</p>

employees and four (4) patients utilizing the Healgen Scientific COVID-19 IgG/IgM Rapid Test not authorized under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver between May 22, 2020 and October 20, 2020. The findings include: 1. An interview with charge nurse at approximately 10:30 AM on October 22, 2020 revealed the lab was performing COVID-19 Antibody testing. The charge nurse produced three (3) Healgen COVID-19 IgG/IgM Rapid Test Cassette kits from the administer's office (lot numbers 20024173 and 2003300). The charge nurse stated, "Our management firm ASD in Texas sent the kits to us for testing employees and patients for the surgery center. ASD Management Firm provides surgical procedure oversight that is separate from the Quest lab director." 2. Review of the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 Antibody testing as of October 22, 2020 for the Healgen COVID-19 IgG/IgM Rapid Test (whole blood/serum/plasma) revealed the following statement, "Testing is limited to laboratories certified under the Clinical Laboratory Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests." 3. Review of the IFU for the Healgen COVID-19 IgG/IgM Rapid Test (whole blood/serum/plasma) revealed the following statement, "The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests." 4. At approximately 11:15 AM on October 22, 2020, the inspector observed site staff physically removing the test kits from the test site premises. 5. Confirmation by the lab director via email on October 23, 2020 at approximately 9:23 AM, the review of patient medical charts and employee consent forms and revealed 21 employees and 4 patients tested between May 22, 2020 and October 20, 2020. 6. Review of the laboratory's CMS ASPEN WEB -116 on November 2, 2020 revealed the laboratory possesses a CLIA Certificate of Waiver. In addition, the site administrator listed as the lab director. 7. The lab director confirmed the findings in a phone conference on November 4, 2020 at approximately 11:00 AM.