

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0226114	<b>(X3) Date Survey Completed</b>  09/30/2021
<b>Name of Provider or Supplier</b>  Carilion Clinic Fm -Waynesboro	<b>Street Address, City, State</b>  428 S Magnolia Avenue, Waynesboro, 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 Clinic FM-Waynesboro on September 30, 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>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on interviews, review of manufacturer operator's guide, and patient records, the laboratory failed to have a policy for the collection and processing of an alternative anticoagulant tube type for the analysis of platelet count for one patient on 01/20/20. Findings include: 1. An interview with the primary testing personnel (TP) at approximately 12:00 PM on 09/30/21 revealed the laboratory has practiced an alternative collection and processing sodium citrate anticoagulation tube type for a patient platelet count. The inspector requested to review a policy for the procedure. There was no policy available for review. 2. Review of the Sysmex XN-L Hematology analyzer manufacturer operator's guide revealed the following statement: "4.3 Preparing Sample", "Mix the venous blood with an anticoagulant (EDTA-2k or EDTA-3K). Draw the amount of venous blood that is specified for the amount of EDTA anticoagulant." A call to the Sysmex technical support on 09/30/21 at 1 PM confirmed manufacturer requirements for specimen collection and processing with the EDTA anticoagulant. In addition, the manufacturer did not approve of collection and</p>

processing of specimen with the sodium citrate anticoagulant. 3. During an interview with the primary TP at approximately 1:15 PM, they confirmed that Patient A sample collected with both the EDTA and sodium citrate tube types for comparison of platelet counts on 01/20/20 and that the platelet count reported from EDTA anticoagulant tube type and not the sodium citrate tube type on 01/20/20. In addition, they were not aware that the manufacturer did not approve of the alternative sodium citrate anticoagulant collection and processing for platelet counts. 4. An exit interview with the primary TP and technical consultant at approximately 1:45 PM on 09/30/21 confirmed the findings.