

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0972412	(X3) Date Survey Completed 03/11/2020
Name of Provider or Supplier Carilion Clinic Fm-West Salem	Street Address, City, State 1935 West Main Street, Salem, 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	An announced CLIA Recertification survey was conducted at the Carilion Clinic West Salem on March 11, 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:
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid Services (CMS) 116 form, policy and procedures (P&P), lack of documentation, and interview with the Technical Consultant (TC) and testing personnel, the laboratory failed to implement a mechanism to ensure the accuracy of manually transcribed patient results from instrument printouts into the EPIC electronic health record (EHR) for twenty (20) of 20 months reviewed. Findings include: 1. Review of the laboratory's CMS-116 revealed the laboratory performs Complete Blood Counts (CBC) using the Medonic M-series instrument (serial number 22953). An interview with the TC on 3/11/20 at approximately 11:20 AM revealed manual entry of patient results from the above listed analyzer printouts into the EHR, EPIC. 2. Review of P&P revealed lack of documentation of a procedure or mechanism to detect clerical errors for manually entered test results. Record review from June 1, 2018 and up to February 28, 2020</p>

revealed no documentation of a review of manually transcribed patient test results. 3. An interview with the testing personnel and TC on 3/11/20 at approximately 11:50 AM confirmed the findings.