Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1088542	(X3) Date Survey Completed 01/15/2019
Name of Provider or Supplier Carilion Clinic Dermatology And Mohs Surgery	**Street Address, City, State** 1 Riverside Circle - Suite 300m, Roanoke, 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 Dermatology and Mohs Surgery on January 15, 2019 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:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the tour of laboratory, review of policy and procedure (P&P) manual, and interviews, the laboratory failed to establish a written policy for performing and documenting positive and negative reactivity each day of use for the Leica BOND

	automated Immunohistochemistry (IHC) stainer. Cross Reference D5601. Findings include: 1. Tour of the laboratory and an interview with the primary technical personnel A at approximately 9:20 AM revealed that the laboratory introduced the Leica BOND automated IHC stainer for patient testing in September 2017. 2. Review of the P&P manual revealed no documentation of an established written policy for performing and documenting positive and negative reactivity each day of use the Leica BOND automated IHC stainer. 3. An interview with the laboratory director at approximately 12:00 PM confirmed the above-specified findings.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the tour of laboratory, review of patient testing logs, and interviews, the laboratory failed to document positive and negative reactivity each day of use for twelve (12) of the 12 patient tissue samples using the Leica BOND automated Immunohistochemistry (IHC) stainer. Dates of record review are from September 14, 2017 to date of survey on January 15, 2019. Findings include: 1. Tour of the laboratory and an interview with the primary technical personnel A at approximately 9:20 AM revealed that the laboratory introduced the Leica BOND automated IHC stainer for patient testing in September 2017. 2. Review of the patient testing logs for the stainer revealed the following dates and patients resulted with no documentation of positive and negative reactivity: 09/14/2017: Accession number 17-491, Testing Personnel (TP) B, 09/19/2017: Accession number 17-623, TP A, 11/14/2017: Accession number 17-625, TP B, 11/30/2017: Accession number 17-654, TP B, 01/15/2018: Accession number 18-25, TP B, 02/14/2018: Accession number 18-127, TP A, 05/14/2018: Accession number 18-302, TP B, 05/23/2018: Accession number 18-372, TP A, 06/20/2018: Accession number 18-448, TP A, 07/11/2018: Accession number 18-482, TP A, 07/31/2018: Accession number 18-469, TP B, 11/07/2018: Accession number 18-766, TP A. A total of 12 patients. (See attached TP code sheet) 3. An interview with the laboratory director at approximately 12:00 PM confirmed the above-specified findings.