Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2033489	12/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Valley Skin Specialists	3706 South Main Street - Suite B, Blacksburg, 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 Valley Skin Specialists on December 16, 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:
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), patient histology slides, Mohs surgery maps and an interview with the lab director and primary testing personnel, the lab failed to follow the established P&P for patient labeling of Mohs histopathology tissue slides for one (1) of 5 random samples selected for review. Findings include: 1. Review of P&P "Slide Labeling" (signed by the lab director 8/20/18) revealed the following statement: "Slides are to be labeled with mohs log accession number, patient last name, number of stages will be marked with Roman numeral; stage I, II, III,etc." 2. Review of 5 random tissue slides and corresponding Mohs surgery maps revealed that the last name of Patient A was misspelled on Slide I A (date of test 7/17 /19). 3. An interview with the lab director at approximately 12:10 PM confirmed the findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the review policy and procedures (P&P), patient histology slides, Mohs surgery maps, quality assurance documents, lack of documentation, and an interview with the lab director and primary testing personnel (TP), the lab failed to follow the established P&P for specimen acceptance or rejection and quality assurance corrective actions for one (1) of 1 sample in July 2019. Findings include: 1. Review of the P&P "Specimen Acceptance or Rejection" (signed by the lab director 8/20/18) revealed the following statements: "In the event there is an error in patient or specimen identification, this will be documented on a lab error form and filed in the lab error filed in the lab. The correction will be handled immediately with explanation of how to avoid same error in the future." "Quality Assurance Program" (signed by the lab director 8/20/18) revealed the following statements: "A Corrective Action Form must be completed should any problems occur during testing process. This form must be reviewed by the Laboratory Director." 2. Review of 5 random tissue slides and corresponding Mohs surgery maps revealed that the last name of Patient A was misspelled on Slide I A (date of test 7/17/19). 3. Review of quality assurance document for July 2019 revealed lack of documentation of corrective action for the above-specified event. An interview with the primary TP at approximately 11:50 AM revealed that they did not realize the last name was misspelled and there was no corrective actions. 4. An interview with the lab director at approximately 12:10 PM confirmed the findings.