Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0216260	09/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
University Of Maryland Dermatologists Pa	419 W Redwood Street Suite 260, Baltimore, MD	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on interview with the practice operations director, the laboratory failed to retain the stained slides used for the interpretation of patients who have had Mohs surgery. Findings: 1. The surveyor reviewed the "Patient Log" and selected slides from M18-017, initials AS for review. When Slide M18-017 was found for review the initials were JS. 2. When the rest of the "Patient Log" was reviewed it was determined that the numbers M18-001 through M18-019 had been used in January 2018 and then again in March 2018. 3. At the time of the survey the slides from January 2018, M18-001 through M18-019, could not be located. 4. During the survey on 09/25/18 at 1:00 PM the practice operations director confirmed that the slides from January 2018, M18-001 through M18-019, could not be located. The laboratory did not ensure that the slides used for the interpretation of patients who had Mohs surgery were not saved for the required 2 years.
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: A. Based on review of the procedure manual and interview with the laboratory director, the laboratory did not follow the established policies and procedures for positive identification and integrity of the specimens that were analyzed. Findings: 1. The procedure manual shows an example of how to label the slides. The histotech is required to include the last two digits of the current year followed by the next sequence number for that year. 2. The laboratory director stated that the Mohs ID number should include an "M" for one doctor and a "S" for the other doctor in the practice. This letter should be listed prior to the last two digits of the current year. 3. The surveyor was reviewing the "Patient Log" for 2017 and 2018. From 11/03/17 through 01/26/18 Dr. "S" was listed as the physician. Dr. "S" performed the Mohs surgery and performed the interpretation of the slides labeled M17-267 through M18-019. 4. On 03/05/18 Dr. "M" was listed as the physician. Dr. "M" performed the Mohs surgery and performed the interpretation of the slides labeled M18-001 until the date of the survey. 5. Mohs ID numbers M18-001 through M18-019 were used twice in the same calander year. 6. During the survey on 09/25/18 at 1:00 PM the laboratory director confirmed that there was no written procedure for identify Dr. "M" slides verses Dr. "S" slides and that the Mohs ID numbers M18-001 through M18-019 were used twice in the same calander year.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the laboratory manager, the laboratory did not ensure that the written procedure describing the system used for verifying the accuracy and reliability of interpretation of the histopathology specimens for which proficiency samples are not available was not performed and documented for 2017 and 2018. Findings: 1. The procedure stated that proficiency testing evaluation would be performed twice a year to verify the accuracy of interpretation histopathology specimens. 2. During the survey on 09/25/2018 at 1:00 PM the laboratory manager confirmed that the records that were available did not include documentation of split samples being reviewed by a second Mohs surgeon at part of the proficiency testing program.
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: A. Based on review of the procedure manual and interview with testing personnel, the laboratory director did not provide a written procedure manual covering all aspects of the test procedure. Findings: waiting for email 1. The procedure manual shows an example of how to label the slides. The example shows the identification number (ID) as 13-001. 2. The laboratory director stated that the Mohs ID number should include an "M" for one doctor and a "S" for the other doctor in the practice. This letter should be listed prior to the last two digits of the current year. 3. The procedure manual did not include written instruction for including the letter "M" or "S" as part of the ID number; identifying what the "M" or "S" abbreviation stood for; and using the last two digits of the current year as part of the patient identifying number. 4. During the survey on 09/25/18 at 1:00 PM the laboratory director confirmed that the histotech was not documenting the complete ID number on the Mohs maps to ensure positive patient identification. B. Based on observation, review of the procedure manual and interview with testing personnel, the laboratory director did not provide a written procedure manual covering all aspects of the test procedure. Findings: 1. While in the laboratory the survey observed the medical assistant dropping off a tissue specimen on a piece of blotting paper and another piece of blotting paper that was the map showing where the tissue was taken and had the patients ID label attached. 2. Review of the procedure manual showed that there were no written instructions for patient preparation, specimen collection, labeling, and transportation from the room where the surgery was performed to the laboratory for testing. 3. During the survey on 09/25 /18 at 1:00 PM the laboratory director confirmed that there were no written pre analytical instruction in the procedure manual.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the temperature worksheet and interview with the practice operations director, the laboratory did not define the acceptable limits for the room temperature where testing was being performed. Findings: 1. Review of the temperature worksheet showed that the room temperatureannual evaluations showed that the evaluation for the histotech was not performed and documented in 2017. 2. During the survey on 09/25/18 at 1:00 PM the practice operations director confirmed that the evaluation of the histotech had not been performed in 2017.

D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the evaluation records and interview with the practice operations director, the technical supervisor did not ensure that all testing personnel received an annual competency review. Findings: 1. Review of the annual evaluations showed that the evaluation for the histotech was not performed and documented in 2017. 2. During the survey on 09/25/18 at 1:00 PM the practice operations director confirmed that the evaluation of the histotech had not been performed in 2017.