Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1047946	07/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
University Of Maryland Dermatologists	5890 Waterloo Road, Columbia, 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
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 interview with the laboratory (lab) director, the lab did not have written procedures to At least twice annually, verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. Findings: 1. The lab did not have a written procedure for at least twice annually splitting histology cases with another surgeon to compare technique and microscopic observations; 2. The lab did not have a written procedure to document these split reviews between surgeons; 3. The lab did not have written procedure to recognize discrepant results and corrective actions if needed; and 4. This was confirmed during interview with the lab director on the day of survey.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory (lab) written procedures and interview, the lab director did not approve, sign and date the written procedures for histology procedures performed during MOHS surgery. Findings: 1. The directors review and approval of

	the histology written procedures was not documented. There was no record for showing the directors approval; and 2. This was confirmed with staff during interview on the day of the survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: A. Based on observation and interview with laboratory (lab) staff, the lab did not ensure reagents were not used past expiration. Findings: 1. The lab did not maintain a record of the lot number, expiration date and manufacturer name of stain solutions used for the histology testing performed during MOHS surgery; 2. The histology technician had a record of the hematoxylin stain, but stated that when the stain expires, the record is discarded; 3. The record of the solutions used for staining tissue must be maintained for at least two years; and 4. This was confirmed during interview with lab staff at the time of survey. B. A. Based on observation and interview with laboratory (lab) staff, the lab did not ensure reagents were not deteriorated or of substandard quality. Findings: 1. The lab did not maintain a record of the stain changes for stain solutions used for the histology testing performed during MOHS surgery; and 2. The histology technician stated, during interview on the day of survey, that the stain solutions are changed each week.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the lab did not document quality control checks made on the stain quality for histology stains performed during MOHS surgery. Findings: 1. The lab stains patient tissue with a hematoxylin and eosin stain after the tissue is processed on the slide. The surgeon then performs the microscopic examination of the patients tissue; 2. The record for the patient test has a column for the surgeon to indicate that the staining characteristics reacted in a satisfactory or unsatisfactory manner; and 3. Both surgeons performing the MOHS surgery and microscopic examination of the tissue did not indicate the acceptability of the

	hematoxylin and eosin stain (quality control) on February 9 and 23, 2018, on March 9 and 23, 2018, on April 13, 2018 and May 25, 2018, by initialing the record and indicating if the stain characteristics were "sat" or "unsat".
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: The laboratory (lab) director acting as technical supervisor or technical supervisor identified on the Personnel Report CMS form- 209 did not evaluate and document the performance of individuals responsible for high complexity testing at least annually after the first year of testing. Findings: 1. The technical supervisor as designated on the Personnel Report CMS form- 209 is responsible for assessing the competency of both histology technicians, as the two technicians will perform high complexity tissue grossing on patient specimens. These tissue grossing duties include among other duties the application of the inks (orientation) to the patient tissue; 2. The technician stated that an individual from his company performs competency checks, but this person has not been qualified on the Personnel Report CMS form- 209 to perform these duties, and the competency checks must be performed at the lab performing testing to include observation of performance, review of test records and assessment of problem solving skills; and 3. Any histology technician performing tissue grossing requires competency assessment.