Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0916100	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Cosmetic Surgery & Dermatology Center, Pa	765 Highland Oaks Drive, Suite 100, Winston-Salem, NC	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2017, 2018, and 2019 WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing records and interview with TP (testing personnel) 3/21/19, the laboratory failed to retain all proficiency testing records for at least two years. Findings: 1. The laboratory failed to retain attestation statements signed by the laboratory director and TP for the 2017 SP Micro B2 event, the 2018 SP Micro B2 event, and the 2018 SP Micro B3 event. 2. The laboratory failed to retain the report form used to record responses for the 2018 SP Micro B1, B2, and B3 events. 3. The laboratory failed to retain the graded results for the 2017 SP Micro B2 event and the 2018 SP Micro B3 event. During interview at approximately 10:45 a.m., TP #1 confirmed the records were not retained.
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 laboratory's policies and procedures, review of 2017, 2018, and 2019 pathology verification records, and interview with TP (testing personnel) 3/21/19, the laboratory failed to verify the accuracy of the Mohs histopathology and dermatopathology slides at least twice a year during 2017 and 2018. The laboratory's

	"QUALITY ASSESSMENT PLAN" states "... 4. Proficiency Testing: Mohs lab will participate in the American Society for Mohs Surgery Proficiency Testing Program as needed for Maintenance of Fellow Membership. Records will be maintained in 'ASMS Proficiency' section of Procedure Manual. Histopathology lab will participate in a peer review of twelve cases per year, as well as, consultation/corroboration of dermatopathology with..." Review of 2017, 2018, and 2019 pathology verification records revealed: 1. The laboratory participated in a peer review for 1 case through ASMS (American Society for Mohs Surgery) during 2017 and submitted 12 dermatopathology cases for review by an outside laboratory in May 2017. 2. During 2018, the laboratory submitted 1 case to ASMS for peer review, but the case was unacceptable. There was no documentation of resubmission. During interview at approximately 1:35 p.m., TP #1 confirmed that the laboratory did not resubmit the 2018 peer review case. He stated they attended the ASMS annual meeting instead. He verified they had not performed any other activities to verify the accuracy of the Mohs histopathology and dermatopathology testing during 2017 and 2018.
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: Based on observation and interview with TP (testing personnel) 3/21/19, the laboratory failed to discard supplies that exceeded their expiration dates. Findings: During a tour of the laboratory approximately 12:30 - 12:50 p.m., the surveyor observed the following expired supplies available for use: Mohs Laboratory 1. 1 partial bottle of Gill 2 Hematoxylin (lot #045416, expiration date 9/2017); 2. 1 partial bottle of Eosin - Y Alcoholic 0.25% (lot #046743, expiration date 6/2018); 3. 1 box of Polarstat Plus Frozen Embedding Medium (lot #044033, expiration date 2/2018); 4. 1 box of Dermatophyte Test Medium (lot #1803805, expiration date 2/7/2019). Dermpath Laboratory 1. 1 box of fungus control slides (lot #56547 H, expiration date 1/2019); 2. 3 cubes of 10% Neutral Buffered Formalin (lot #31377, expiration date 7 /2016). During interview at approximately 1:50 p.m., TP #1 stated the formalin was there when he started but it had not been used.
D5819	TEST REPORT CFR(s): 493.1291(j) All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility. This STANDARD is not met as evidenced by: Based on review of 2017, 2018, and 2019 DTM (dermatophyte test medium) fungal culture logs and interview with TP (testing personnel) 3/21/19, the laboratory failed to ensure that all DTM test reports were entered in the EMR (electronic medical records system) to ensure timely accesibility. Review of patient DTM fungal culture logs revealed that 19 patient DTM fungal cultures were performed from 12/1/17 - 2/18/19. During interview at approximately 12:05 p.m., TP #1 stated they recently realized that none of the DTM fungal culture results had been entered in patient charts (EMR)

	since December 2017. He stated they are currently in the process of entering them in the EMR.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing records and interview with TP (testing personnel) 3/21/19, the laboratory director failed to ensure corrective action was taken and documented for all unacceptable proficiency testing results. Review of 2017 and 2018 WSLH proficiency testing records revealed: 1. The laboratory received a score of 40% on the 2017 SP Micro B1 event with no corrective action documented; 2. There were no records available for the 2017 SP Micro B2 event, but the summary report for the 2017 SP Micro B3 event showed a score of 0% for the 2017 SP Micro B2 event. There was no documentation of corrective action; 3. The laboratory received a score of 60% on the 2017 SP Micro B3 event with no corrective action documented. During interview at approximately 10:40 a.m., TP #1 confirmed there was no corrective action documented for the unacceptable results. He stated they usually retest the samples if there is a problem.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan and review of 2016, 2017, 2018, and 2019 laboratory records, the laboratory director failed to ensure that the laboratory's quality assessment program was established and maintained to identify problems and prevent their recurrence. Findings: The laboratory's "QUALITY ASSESSMENT PLAN" states "... Our Quality Assurance reviews will be conducted every 90 days and any deficiencies will be noted and corrective action will be taken. ..." The laboratory failed to have effective mechanisms in place to identify and correct problems identified during the survey in the following areas: 1. Proficiency testing and verification of accuracy - see D3037, D5217, D6092; 2. Expired reagents and supplies - see D5417; 3. Test reports - see D5819; 3. Maintenance - see D6177.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2016, 2017, 2018, and 2019 maintenance logs 3/21/19, the laboratory failed to perform and document maintenance at the frequency specified. Findings: 1. The laboratory's "Equipment Quality Control - Microtome Use Protocol" procedure states "... 3. The moving components on the microtome are oiled, as recommended by the manufacturer, every 3 months. ... 7. Every action is documented on the maintenance record form. ..." Review of maintenance records revealed the oiling of moving components was not documented every 3 months. a. Oiling was documented 3/10/16, but not again until 2/3/17; b. Oiling was documented 3/13/17, but not again until 9/5 /17; c. Oiling was documented 11/7/17, but not again until 3/5/18. 2. The laboratory's "Equipment Quality Control - Automated Fixation, Dehydration, and Infiltration Processor (VIP 1000) Use Protocol" procedure states "... 3. Change carbon filter every 20-40 runs. ... 10. Every action is documented on the maintenance record form. ..." Review of maintenance records revealed the carbon filter change was not documented every 20-40 runs. a. Carbon filter change was documented 8/30/16 and 47 runs later on 3/13/17; b. Carbon filter change was documented 5/7/18. There was no documentation the carbon filter was changed after 5/7/18. There have been 76 runs through 3/21/19. 3. The laboratory's "Equipment Quality Control - Automated Fixation, Dehydration, and Infiltration Processor (VIP 1000) Use Protocol" procedure states "... 4. Hot Water wash is performed every 20-40 runs. (first 4 reagent bottles are replaced with hot water and ran through the processor at one min. per bottle-program #9)... 10. Every action is documented on the maintenance record form. ..." Review of maintenance records revealed the hot water wash was not documented every 20-40 runs. a. Hot water wash was documented 8/30/16 and 47 runs later on 3/13/17; b. Hot water wash was documented 5/7/18. There was no documentation the hot water wash was performed after 5/7/18. There have been 76 runs through 3/21/19.