Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 34D1030592	**(X3) Date Survey Completed** 01/25/2023
Name of Provider or Supplier Piedmont Cosmetic Surgery & Dermatology Center	**Street Address, City, State** 1915 Westpark Drive Suite 108, North Wilkesboro, 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**
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 laboratory documents, review of 2020, 2021, and 2022 peer review records, and interview with the histology technician 1/25/23, the laboratory failed to verify the accuracy of the Mohs histopathology slides at least twice a year during 2021. Review of the laboratory's "QUALITY ASSESSMENT PLAN - Revised 10/2021" revealed "... MOHS: Case submitted for peer review (twice/year ..." Review of a document found in the procedure manual "... PEER REVIEWS STATUS: 2019-2021", dated 10/2021 revealed "... Two 2021 Mohs cases will be sent out in 2021 as an effort to verify the accuracy of the Mohs histopathology in 2021." Review of 2020, 2021, and 2022 peer review records revealed the laboratory sent 2 Mohs cases to an outside laboratory for peer review in 2020 and 2022, but sent only 1 case in 2021. The only 2021 peer review records available were for 1 case sent to an outside laboratory in October 2021. During interview at approximately 10:30 a.m., the histology technician confirmed the laboratory sent only 1 Mohs case for peer review in 2021. This deficiency was cited on previous surveys 11/15/17 and 9/25/19.
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 manufacturer's instructions, review of 2020, 2021, and 2022 temperature and humidity logs, and interview with the histology technician 1/25/23, the laboratory failed to consistently monitor and document the room temperature and humidity in the laboratory during 2021 and 2022 for operation of the Linistat stainer. Findings: Manufacturer's instructions for the Linistat stainer specify operation in an environment of 5-40 degrees Celsius (41-104 degrees Fahrenheit) with a maximum relative humidity of 80% up to 31 degrees Celsius, decreasing linearly to 50% at 40 degrees Celsius. Review of 2020, 2021, and 2022 temperature and humidity logs revealed: 1. No room temperature documented for 12 of 12 months in 2021 and 12 of 12 months in 2022; 2. No humidity documented 8 of 12 months in 2021 (January, February, March, July, August, September, October, November). During interview at approximately 11:00 a.m., the histology technician confirmed that the room temperature and humidity had not been consistently documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of 2 random Mohs histopathology patient test reports (MRN #90660, #16899) and interview with the histology technician 1/25/23, the laboratory's test reports did not indicate the address of the laboratory where the tests were performed. Review of 2 random patient test reports (MRN #90660, #16899) revealed the address of the laboratory's sister facility in another city was listed as the "Surgery Location" in the "Procedure" section of the Mohs operative reports. In addition, the sister facility's address was listed as the laboratory address on the Mohs maps. During interview at approximately 11:30 a.m., the histology technician confirmed the laboratory's address was not indicated on the test reports as the location where testing was performed. She stated the same Mohs maps are used at both the laboratory and the sister facility. This deficiency was cited on the previous survey 9/25/19.
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 2020, 2021, and 2022 laboratory records 1/25/23, the laboratory director failed to ensure the quality assessment program was maintained to assure the quality of laboratory services provided. Review of the laboratory's "QUALITY ASSESSMENT PLAN - Revised 10/2021" revealed "... Our Quality Assurance reviews will be conducted every 90 days and any deficiencies will be noted and corrective action will be taken. ... During our Quality Assessment review, we will check the following: BIOPSIES: ... 4. Ensure that requisition data and data entered into Kareo/Nextech are accurate. MOHS: 1. Case submitted for peer review (twice/year ... 3. All temperatures and daily maintenance records kept. ..." Review of laboratory records revealed the laboratory had documented quality assessment reviews, but the reviews failed to identify problems identified in the following areas during the survey and there was no corrective action documented: 1. Verification of accuracy not performed twice a year for Mohs - see D5217. 2. Room temperature and humidity not consistently documented - see D5413. 3. Test reports did not indicate the laboratory's address - see D5805.