Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2063477	03/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Plastic Surgery & Dermatology Dermlab	1072 X-Ray Drive, Gastonia, 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
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: Based on review of the laboratory's records and procedure manual, the absence of documentation, and interview with the laboratory manager 3/22/22, the laboratory's procedure manual was not current and complete for the testing performed. Findings: 1. The laboratory's procedure manual failed to include a procedure for the verification of accuracy of the microscopic tissue examination performed. At approximately 2 p. m., the laboratory manager confirmed the laboratory did not have a procedure for the biannual verification of accuracy of the testing performed. She stated the pathologist routinely sends out cases for consultation reviews by another dermatopathologist, but

	she needs to work on the procedures for how the reviews are handled. 2. The laboratory's procedure manual failed to include specific corrective action procedures for restaining of slides that are unsatisfactory or the recutting of new slides. Review of the laboratory's stain quality control logs revealed documentation by the pathologist when repeats were needed, but there was no specific step-by-step procedure for how the restaining and recutting process is handled. During interview with the laboratory manager, she confirmed the laboratory needs a better procedure for the restaining and recutting of slides. 3. The laboratory's procedure manual failed to include the laboratory's system for reporting the microscopic tissue examination and diagnostic interpretation into the patient record.
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's records and procedures and interview with the laboratory manager 3/22/22, the laboratory's procedure manual was not approved, signed and dated by the current laboratory director. Findings: Review of laboratory records revealed a change in laboratory director in January 2021 when the laboratory added dermatopathology services. Review of the laboratory's procedures revealed the procedure manual had not been approved and signed by the new laboratory director in 2021. At approximately 2:50 p.m., the laboratory manager stated the laboratory director had reviewed the procedure manual when he started but he failed to document the review.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on the deficiency cited at D6171 and the review of personnel records 3/22/22, the laboratory failed to ensure that 1 of 5 testing personnel(TP #2) met the minimum education requirements for performing high complexity testing.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60

semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with the laboratory manager 3/22/22, the laboratory failed to verify that 1 of 5 testing personnel(TP #2) met the minimum education requirements for performing high complexity testing. Findings: Review of personnel records revealed TP #2 was trained in January 2022 to perform gross tissue examinations. TP #2 had a diploma in Medical Laboratory Technology that was obtained from outside the United States. The personnel records did not include a credential evaluation from a nationally recognized organization to determine

	equivalency of the education to education obtained in the United States. The only other documentation on file for TP #2 was a partial non-credit course transcript and certification from an online histotechnology certificate program and her histotechnician board of certification. During interview at approximately 12 p.m., the laboratory manager confirmed that TP #2 did not have any other education documentation on file. She stated that TP #2 had been performing gross exams in another laboratory but they were unsure whether TP #2 had a foreign credential evaluation performed.