Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0893739	(X3) Date Survey Completed 11/10/2020
Name of Provider or Supplier Piedmont Plastic Surgery And Dermatology-	**Street Address, City, State** 13539 Reese Blvd W, Huntersville, 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 laboratory policies, review of 2018, 2019, and 2020 laboratory records, the absence of records, and interview with the laboratory manager 11/10/20, the laboratory failed to verify the accuracy of Mohs testing and Fungal KOH (potassium hydroxide) and Parasite test at least twice a year. Findings: 1. Review of laboratory policy, "Biannual Proficiency Testing" revealed "Scope/Purpose..The quality assurance program for verifying the accuracy and reliability of the testing results in the Mohs laboratory. Four cases will be randomly selected twice a year for review." Review of proficiency test forms for 2018 and 2019 revealed the laboratory selected cases on the following dates of service: 10/31/18, 11/7/18, 1/9/19, 2/27/19, 3 /11/19, 3/20/19, 7/31/19, 8/5/19, 9/6/19, 9/18/19, 11/6/19, and 11/20/19 but there was no documentation the laboratory verified the accuracy of Mohs testing in 2018, 2019, and 2020. During interview at approximately 9:20am, the laboratory manager confirmed the laboratory failed to verify the accuracy of Mohs testing at least twice a year. She stated the cases were selected in 2018 and 2019, but the laboratory failed to realize the review was never completed. 2. Review of laboratory policy, "Quality Assurance, KOH for Fungus and Parasite Test" revealed "Scope/Purpose...The quality assurance program for verifying the accuracy and reliability of the testing results in the Mohs laboratory. Proficiency testing will be done bi-annually for each physician performing each test, to verify the accuracy and reliability for testing results. This will apply to the Fungal KOH Test and Parasite Test." Review of laboratory records revealed there was no documentation of biannual proficiency testing to verify the accuracy of Fungal KOH test and Parasite test in 2018, 2019, and 2020. During interview at approximately 10:20am, the laboratory manager stated the providers

	should perform biannual proficiency testing for Fungal KOH and Parasite test by reading the slides behind each other, but she could not find the documentation on file.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies, review of 2018, 2019, and 2020 laboratory and personnel records, absence of records, and interview with the laboratory manager 11/10/20, the LD (Laboratory Director) failed to provide overall management and direction for the laboratory. 1. The LD failed to ensure the accuracy of MOHS testing and Fungal KOH and Parasite tests (see D5217). 2. The LD failed to ensure the laboratory's quality assessment program was maintained (see D6094). 3. The LD failed to ensure policies and procedures were established to evaluate the competency of testing personnel who perform Fungal KOH and Parasite tests (see D6103). 4. The LD failed to evaluate the competency of 6 of 6 Testing personnel who perform Fungal KOH and Parasite tests (See D6120).
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 laboratory policies, review of 2018, 2019, and 2020 laboratory records, the absence of records, and interview with laboratory manager 11/10/20, the Laboratory Director failed to maintain the laboratory's quality assessment program (See D5217).
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and personnel records, the absence of records, and interview with the laboratory manager 11/10/20, the LD(Laboratory Director) failed to ensure that policies and procedures were established to evaluate the competency of 6 of 6 TP(testing personnel) who perform Fungal KOH (potassium

	hydroxide) test and Parasite test. Findings: The laboratory policy "Quality Assurance Form for In House Testing" states..."Procedure 1. Each Physician or Physician Assistant has been trained to perform Fungal KOH Test and Parasite Test. 2. There is available to each Physician and Physician Assistant reference material to aid in the interpretation and evaluation of the tests. 3. Proficiency testing is required.....this practice will verify one Fungal KOH and one Parasite Test for each provider performing these test Bi-annually." Review of laboratory policies revealed there was no procedure for how the competency is evaluated and documented for the TP who perform Fungal KOH test and Parasite test. During interview at approximately 11: 30am., the laboratory manager stated the Providers take a quiz and pass around a slide as part of their competency. She confirmed there was no documentation of personnel competency on file for the Providers who perform Fungal KOH test and Parasite test.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel records, the absence of documentation, and interview with the laboratory manager 11/10/20, the Technical Supervisor(Laboratory Director) failed to evaluate 6 of 6 TP(testing personnel)who perform Fungal KOH(potassium hydroxide) test and Parasite test. Findings: Review of personnel records revealed there was no documentation of competency assessments for the TP who perform Fungal KOH test and Parasite test since the laboratory began testing in July 2018. Interview with the laboratory manager at approximately 11:30am confirmed there was no documentation of competency assessments on file for the Providers who perform Fungal KOH test and Parasite test.