

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0243663	(X3) Date Survey Completed 09/22/2021
Name of Provider or Supplier Piedmont Plastic Surgery & Dermatology - Shelby	Street Address, City, State 105 Delta Park Drive, Shelby, 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory policies, review of 2019, 2020, and 2021 laboratory records, the absence of records, and interview with the laboratory manager 9/22/21, 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. The laboratory policy, "Biannual Proficiency Testing" states "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 map forms revealed the verification of accuracy was completed in 2019 but there was no documentation that the laboratory had verified accuracy of Mohs testing in 2020 and 2021. At approximately 1 p.m., the laboratory manager confirmed the laboratory failed to verify accuracy of the Mohs testing in 2020 and 2021. She stated the laboratory selected approximately 14 cases in 2020 and 8 cases in 2021, but failed to send out to another provider to complete the review. 2. The laboratory policy, " Quality Assurance, KOH for Fungus and and Parasite test" states, "II. Procedure...3. Proficiency testing is required in order to meet the standard set by CLIA; this Practice will verify KOH for Fungus and Parasite test. 4. One representative case will be selected for each test, Parasite and KOH for Fungus. 5. The slide for that test will be reviewed by the physician and then verified by another physician in the practice." Review of laboratory records revealed there was no documentation of biannual proficiency testing to verify accuracy of Fungal KOH and Parasite test in 2019, 2020, and 2021. At approximately 12:10 p.m., the laboratory manager confirmed the proficiency testing had not been completed.</p>

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, review of laboratory records, and interview with the laboratory manager 9/22/21, the laboratory failed to discard reagents that had exceeded the expiration date. Findings: During tour of testing area where microscope is located (provider's office) at approximately 10 a.m., the surveyor observed a bottle of KOH (potassium hydroxide), reagent lot number 9220-02 that had exceeded the expiration date of 1/31/21 located beside the microscope, available for use. Review of the In-house Fungal KOH & Parasite test log revealed approximately 25 patients had been tested with the expired reagent since 1/31/21. At approximately 12:45 p.m., the laboratory manager confirmed the KOH reagent was expired and patients had been tested.

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 9/22/21, the Technical Supervisor(Laboratory Director) failed to evaluate 3 of 4 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 TP #2, TP #3, and TP #4 who perform the Fungal KOH and Parasite test in 2019, 2020, and 2021. At approximately 12:10p.m., the laboratory manager confirmed there were no competency assessments on file for the Providers. She stated the clinical director who kept track of the records was no longer employed and she could not locate them.