Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0916100	03/12/2024
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 WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing records and interview with the histotechnician 3/12/24, the laboratory failed to retain all proficiency testing records for at least two years from the date of the proficiency testing event. Findings: 1. Review of WSLH proficiency testing records revealed the laboratory failed to retain the graded results for the following test events: a. 2021 B3 test event b. 2023 B1 and B2 test events. 2. Review of WSLH proficiency testing records revealed the laboratory failed to retain attestation statements signed by the laboratory director as testing personnel for the following test events: a. 2021 B1, B2, and B3 test events b. 2022 B1, B2, and B3 test events c. 2023 B1, B2, and B3 test events. During interview at approximately 11:20 a.m., the histotechnician stated they were unaware the laboratory director needed to sign the attestation statements as both laboratory director and testing personnel.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2021, 2022, and 2023 WSLH proficiency testing records and interview with the histotechnician 3/12/24, the laboratory failed to evaluate ungraded

	and unacceptable results on 4 of 9 proficiency testing events reviewed. Findings: The laboratory failed to evaluate ungraded and unacceptable proficiency testing results on the following events: 1. 2022 B2 test event - no evaluation of ungraded result for sample DM-7. 2. 2022 B3 test event - no evaluation of ungraded result for sample DM-11 and unacceptable result for sample DM-15. 3. 2023 B2 test event - no evaluation of ungraded results for samples DM-6, DM-7, and DM-10. 4. 2023 B3 test event - no evaluation of ungraded result for sample DM-11. During interview at approximately 11:20 a.m., the histotechnician confirmed that the laboratory had not evaluated ungraded and unacceptable results.
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 2021, 2022, and 2023 peer review cases and interview with the histotechnician 3/12/24, the laboratory failed to evaluate the results of 7 of 22 peer review cases used to verify the accuracy of the Mohs dermatopathology cases at least twice a year. Findings: 1. Review of 2022 peer review records revealed results from 2 of 8 cases were not evaluated. The following cases were not evaluated to determine agreement and ensure no corrective action was needed: a. DMS-22-18 b. DMS-22-32 2. Review of 2023 peer review records revealed results from 5 of 6 cases were not evaluated. The following cases were not evaluated to determine agreement and ensure no corrective action was needed: a. DMS-23-129 b. DMS-23-459 c. DMS-23-477 d. DMS-23-592 e. DMS-23-594 During interview at approximately 10:45 a.m., the histotechnician confirmed the peer review cases were not evaluated.
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 policies and procedures and interview with the laboratory director and the histotechnician 3/12/24, the laboratory's procedure manual had not been updated to reflect the laboratory's current practices. Findings: Review of the laboratory's "Quality Assessment Procedures" revealed "... 2. Procedure Manual: The Procedure Manual will be modified as needed to reflect the current practices of the laboratory. ..." Review of the laboratory's procedure manual revealed the procedure manual included procedures that were no longer in use or had not been updated with current information. Examples: 1. An "Ectoparasites" procedure was included in the procedure manual. The procedure did not include a date of discontinuance, but during interview at approximately 10:15 a.m., the laboratory director stated they no longer perform scabies preps. 2. 3. The "Fungal Culture / Dermatophyte Test Medium (DTM)" procedure stated "... Each day that this procedure is performed, a positive and a negative control sample will be analyzed in exactly the same manner as patient samples. ..." The laboratory performs quality control testing on each lot of DTM media, but does not perform quality control testing each day that patients are tested. 2. The "Quality Assessment Plan - Revised 03/2021" stated that the laboratory will participate in peer reviews with an outside laboratory that is no longer utilized by the laboratory. The "QUALITY CONTROL PROCEDURE" STATED "... Slides are sent on-going, no less than twice a year, to another CLIA-certified laboratory ... for confirmation. ..." The laboratory listed in the procedure is no longer utilized by the laboratory for peer reviews. During interview at approximately 10:25 a.m., the histotechnician confirmed they use a different laboratory for peer reviews than the ones listed in the procedures and they use a referee lab not listed in the procedures for discrepant results.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's policies and procedures, review of 2021, 2022, 2023, and 2024 DTM (dermatophyte test medium) quality control records, and interview with the histotechnician 3/12/24, the laboratory failed to check each lot number of DTM media for growth, selectivity, and inhibition as required. Approximately 29 patients were tested from 2/17/21-6/14/23 when DTM quality control was not performed. Findings: Review of the ACU-DTM product insert revealed "... QUALITY CONTROL CLIA requires the end user to perform a minimum of a positive and a negative control on each new lot number or batch purchased. Review of the laboratory's "Fungal Culture / Dermatophyte Test Medium (DTM)" procedure revealed "... To ensure that each new batch, lot, or shipment of DTM provides the expected positive and negative growth and biochemical results during fungal culture, before or at the time of its first use, each new batch, lot, or shipment ... will be tested by culturing with known dermatophyte and the results of these analyses will be recorded..." Review of 2021, 2022, 2023, and 2024 DTM quality control records revealed the laboratory failed to perform and document growth

	checks for lot #D1379-0820 and lot #D1423-0621, in use 2/17/21 - 6/14/23. Approximately 29 patients were tested during this time. During interview at approximately 1:30 p.m., the histotechnician confirmed that there were no records of growth checks for these two lot numbers.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on random review of the laboratory's 2021, 2022, 2023, and 2024 temperature and humidity logs and interview with the histotechnician 3/12/24, the laboratory failed to take and document corrective action for room temperatures outside the acceptable limits. Findings: Random review of the laboratory's 2021, 2022, 2023, and 2024 temperature and humidity logs revealed room temperature in the Dermpath area was outside the acceptable limits of 22-30 degrees Celsius on the following days with no corrective action documented: a. November 2021 - 12 of 16 days (11/1, 11/2, 11/3, 11 /4, 11/8, 11/9, 11/14, 11/15, 11/16, 11/17, 11/29, 11/30); b. December 2022 - 8 of 11 days (12/5, 12/6, 12/7, 12/12, 12/13, 12/14, 12/19, 12/28); c. March 2023 - 13 of 16 days (3/1, 3/2, 3/6, 3/7, 3/8, 3/9, 3/13, 3/14, 3/16, 3/20, 3/21, 3/29, 3/31); d. February 2024 - 7 of 15 days (2/13, 2/21, 2/22, 2/26, 2/27, 2/28, 2/29). During interview at approximately 11:30 a.m., the histotechnician confirmed they had not documented any corrective action for temperatures outside the acceptable limits.
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 4 random patient test reports (chart #3-26-74, #2-6-48, #12-5-42, #44496) and interview with the histotechnician 3/12/24, the laboratory failed to ensure that patient test results were available in the EMR (electronic medical records system) for 3 of 4 patients reviewed (chart #3-26-74, #2-6-48, #12-5-42). Review of patient test reports for chart #3-26-74, #2-6-48, and #12-5-42 revealed each patient had a DTM fungal culture performed. Results were documented on a "Laboratory Test Requisition/Report Form", but were not entered in the EMR used by the laboratory to maintain records of all patient testing. During interview at approximately 2:15 p.m., the histotechnician confirmed that the results were not entered in the EMR.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

	This STANDARD is not met as evidenced by: Based on review of 2021, 2022, and 2023 WSLH proficiency testing records and interview with the histotechnician 3/12/24, the laboratory director failed to ensure 9 of 9 proficiency testing results were reviewed to evaluate the laboratory's performance and identify any problems requiring corrective action. Findings: Based on review of 2021, 2022, and 2023 WSLH proficiency testing records, the laboratory director failed to review and evaluate graded results for the following test events: a. 2021 B1, B2, and B3 test events b. 2022 B1, B2, and B3 test events c. 2023 B1, B2, and B3 test events. During interview at approximately 11:20 a.m., the histotechnician confirmed that the proficiency testing results had not been reviewed by the laboratory director to evaluate the laboratory's performance.
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 policies and procedures and review of 2021, 2022, 2023, and 2024 proficiency testing records, quality control records, personnel records, and patient test reports 3/12/24, the laboratory director failed to ensure the laboratory had an effective system in place to identify and correct problems and prevent their recurrence. Findings: Review of the laboratory's "Quality Assessment Procedures" revealed "To ensure that testing of patient samples and reporting of test results are performedaccurately and in compliance with applicable regulations, the ... Laboratory maintains a Quality Assessment (QA) program that monitors preanalytic, analytic, and postanalytic activities. ... 3 Ongoing Assessment: Each of the laboratory's quality systems will undergo assessment on a regular basis to maintain and improve laboratory performance and services. ..." Review of 2021, 2022, 2023, and 2024 laboratory records revealed the laboratory's quality assessment plan failed to identify problems identified during the survey in the following areas: 1. Proficiency testing (see D3037, D5211, D6091); 2. Analytic systems (see D5403, D5477, D5785); 3. Postanalytic systems (see D5819); 4. Personnel (see D6127).
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the histotechnician 3/12/24, the technical supervisor (laboratory director) failed to perform and document competency evaluations for the histotechnician semiannually during the first year of patient testing. Findings: Review of the laboratory's "Quality Assessment Procedures" revealed "... The competency of Testing Personnel and all staff members will be evaluated and documented by the

	Laboratory Director or an appropriate designated staff member (e.g., Technical Consulatant or Technical Supervisor) to ensure that all laboratory staff maintain their competency in testing and laboratory management functions. ... CLIA regulations for laboratories performing Moderate and High Complexity testing require semiannual performance assessments during the first year and annual assessments thereafter. ..." Review of personnel records revealed the histotechnician was trained during March and April 2021. The histotechnician had a competency evaluation in December 2021, but there was no documentation of another competency evaluation during the histotechnician's first year of testing patient specimens. The histotechnician's next competency evaluation was documented in November 2022. During interview at approximately 9:45 a.m., the histotechnician confirmed she did not have two competency evaluations during her first year of testing patient specimens.