Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2010138	05/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pinski Dermatology & Cosmetic Surgery	374 Larry Power Drive, Bourbonnais, IL	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, patient reports, product operation manual, direct observation, lack of documentation, and interviews with the laboratory representatives; the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings include: 1. The laboratory failed to outline all components of the test procedure for the subspecialty of histopathology. See D5403. 2. The laboratory failed to define and document preventative maintenance (PM) for one of one microscope. See D5433. 3. The laboratory failed to exam and document the quality (intended reactivity) of Hematoxylin and Eosin staining material used for histopathology interpretations. See D5473.
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 policy and procedure manual, lack of documentation, and interviews with laboratory representatives; the laboratory failed to outline all components of the test procedure for the subspecialty of histopathology. Findings include: 1. Review of the laboratory's policy and procedure manual for histopathology interpretations indicated that histopathology slides are, "checked for accuracy in regards to the patient's name, date and site", but failed to include: a. Required control procedures including Hematoxylin and Eosin (H&E) parameters for acceptability; and b. Corrective actions to be taken when H&E quality control (intended reactivity) results fail to meet the laboratory's criteria. 2. On survey date 05 /15/2024, at 09:28 am, the laboratory representatives confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, product operation manual, lack of documentation, and interview with the laboratory representatives; the laboratory failed to define and document preventative maintenance (PM) for one of one microscope, as required per 493.1254. Findings include: 1. Upon a tour of the laboratory on 05/15/2024 at 08:12 am, the surveyor identified a Select Medical Products PSS600R microscope (Serial Number: 20101110) used for histopathology interpretations. 2. Review of the Select Medical Products PSS600R Series Microscope "Operation Manual" revealed, under "Maintenance", "To keep your microscope in top condition for years, we recommend that you have the microscope professionally serviced once a year." 3. Review of the laboratory procedure manual failed to outline the PM methods for the above-mentioned microscope. 4. A lack of documentation revealed no preventative maintenance was documented for the Select Medical Products PSS600R microscope used for histopathology test interpretations from the last date of service, noted on the microscope as 03/12/2020, through the survey date

	of 05/15/2024. 5. On survey date 05/15/2024, at 08:41 am, the laboratory representatives confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: REPEAT DEFICIENCY Based on review of laboratory records, patient reports, lack of documentation, and interviews with the laboratory representatives; the laboratory failed to exam and document the quality control (intended reactivity) of Hematoxylin and Eosin (H&E) staining material used for five of five histopathology interpretations reviewed. Findings include: 1. Review of laboratory records revealed the "Manual for all tissue specimens at Pinski Dermatology and Cosmetic Surgery", failed to outline steps for the examination and documentation of the intended reactivity of the H&E stain utilized for five of five histopathology interpretations reviewed. 2. Review of five of five patient reports revealed a lack of documentation of the examinations for the quality control (intended reactivity) of the H&E stain on the days associated with test interpretations. Patient Accession #: Date of Testing: a. 29024K 09/12/2022 b. 29769K 03/08/2023 c. 30197K 07/13/2023 d. 30699K 11/09/2023 e. 31116K 03/21 /2024 3. On survey date 05/15/2024, at 09:28 am, the laboratory representatives confirmed the above findings.