Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2139348	10/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	2500 S Highland Ave Suite 320, Lombard, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observations; review of laboratory's procedures and records; and interview with the Histology Technician (HT) and Laboratory Director (LD), the laboratory was not constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. Findings: 1. At 9:30 AM on October 8, 2019 the surveyor was escorted to the laboratory, where she observed that the following equipment was in use: a. Microtome b. Stainer c. Slide Storage File Cabinet d. Microscope 2. There was a location above the stainer where an air Filter should be installed but was not installed. 3. The HT told the surveyor that the air filter was not installed, because, "there was not enough space to install it". 4. There were no procedures that described maintenance of the air filter. 5. There was no documentation to show that an air filter was maintained. 6. Observation of the laboratory's equipment revealed that testing personnel used the top of the microtome to place equipment such as slides, slide covers, pens, and permanent markers; and the stainer was propped up on square, plastic, boxes of some sort. 7. At 10:00 AM on October 8, 2019, the LD confirmed the surveyor's findings.
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

	This STANDARD is not met as evidenced by: Based on review of patients' test records; observations; and interview with the Hitstotechnician (HT) and laboratory director (LD), the laboratory failed to ensure confidentiality of patient information throughout all phases of the testing process. Findings: 1. Review of patients test records revealed that patients Mohs maps that contain patients information and test results, were stored in a binder at the reception desk. 2. The Histotechnician told the surveyor that office staff scans patients' Mohs maps into the Electronic Medical Record. After scanning, the Mohs maps are put into a binder and left on the counter of the reception desk. 3. The surveyor observed that there was no lock on the door where patients' Mohs maps are stored. 4. At 11:00 AM on October 8, 2019, the LD confirmed the surveyor's findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (FORM CMS 209); procedures manuals; personnel records; and interview with the laboratory director (LD), the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings: 1. The laboratory listed a total of 3 persons (P1, P2, and P3)) as laboratory personnel who fulfil the following positions in the laboratory: a. P1 = Laboratory Director b. P2 = Clinical Consultant, Technical Supervisor, General Supervisor, and High Complexity Testing Personnel. c. P3 = High Complexity Testing Personnel (processing). 2. Review of laboratory procedures manuals revealed that there were no procedures to show that the laboratory established and followed policies to monitor each individual's competency. 3. Review of personnel records revealed that there was no documentation to show the performance of competency assessments since the last survey in February 2018 for 3 of 3 laboratory personnel. 4. At 11: 00 AM on October 8, 2019, the LD confirmed the surveyor's findings.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of procedures manuals and laboratory records and interview with the laboratory director, the laboratory failed to document the date and time it receives a specimen. Findings: 1. The laboratory procedures manual instructs testing personnel to document the date of specimen receipt; patient information, Mohs Case number, specimen cite location, diagnosis, and Tech initials into a patient testing log. 2. Review of laboratory records revealed that testing personnel used a scheduling page as its documentation for specimen receipt. The scheduling page was also used to note when a patients did not show up for their scheduled appointments. 3. The surveyor asked the HT how patients' specimens were received into the laboratory. 4. The HT told the surveyor that she got a copy of the patients' schedule. She would then

	document when she recieved a specimen on a copy of the patients' schedule. Later, at the end of the day, she typed the specimen receipt page. 5. The surveyor observed that the HT mistakenly documented that a specific case number was given to a patient, but later scratched it out with the words, "accession number not used." 6. The surveyor pointed out that the specimen receipt log should be completed when a specimen is received into the lab, not later. She also told the laboratory director that retyping or completing documentation later, leads to clerical errors. 7. At 11:30 AM, the LD confirmed the surveyor's findings.
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 procedures manuals and interview with the Laboratory Director, the laboratory failed to have a comprehensive procedures manual that includes instruction for preanalytic, analytic, and postanalytic phases of testing. Findings: 1. The laboratory's procedures consisted of 3 incomplete procedures manuals that were not approved by the current Laboratory Director. 2. The procedures did not include the following: a. 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. b. Microscopic examination, including the detection of inadequately prepared slides. c. Control procedures. d. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. e. Limitations in the test methodology, including interfering substances. f. 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. g. Description of the course of action to take if a test system becomes inoperable. 3. At 11:30 AM on October 8, 2019, the Laboratory Director confirmed the surveyor's findings.
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 laboratory procedures manuals, observation, and interview with the Histotechnician (HT) and Laboratory Director (LD), procedures and changes in procedures failed to be approved, signed, and dated by the current Laboratory Director before use. Findings: 1. At 10:00 AM on October 8, 2019 the surveyor requested the laboratory's current procedures manual. 2. The surveyor observed that there were 3 sets of incomplete procedures manuals. 3. The HT told the surveyor that she was in process of updating her procedures. 4. All 3 procedures manuals were not approved, signed, and dated by the current LD. 5. At 11:30 AM on October 8, 2019, the LD confirmed the surveyor's findings.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of presurvey documents and laboratory procedures manuals and interview with the Laboratory Director (LD), the laboratory failed to maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). Findings: 1. Review of CASPER Report 0096D (CLIA Application and Survey Summary) showed that the laboratory performed testing in the subspecialties of Mycology and Histopathology. 2. Review of the laboratory's application (CMS 116) for CLIA Certification collected during the survey of October 8, 2019 reveals that the laboratory is performing testing in, only, the subspecialty of Histopathology. 3. Review of the laboratory's procedures manuals revealed that there was documentation to show the date of discontinuance of Mycology procedures. 4. At 11:30 AM, the LD confirmed the surveyor's findings.
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 records, personnel records, and procedures manuals, and interview with the laboratory director, the laboratory failed to have a director who is responsible for overall management and direction in accordance with 493.1445 of this subpart. Findings: 1. There was no documentation to show that the laboratory established and maintained a quality assessment program. See D tag 6094. 2. There was no documentation to show that competency of personnel was assessed. See D tags 5209 and 6103. 3. A comprehensive procedures manual, approved by the current laboratory director, was not available to all personnel. See D tags 5403 and 6106. 4. The laboratory director did not assign, in writing, responsibilities and duties to each person responsible for Mohs testing. See D tag 6107.

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 observations; review of laboratory procedures and laboratory records, and interview with the laboratory director (LD), the laboratory director failed to ensure that quality assessment (QA)programs are established and maintained to assure the quality of laboratory services provided to identify failures in quality as they occur. Findings: 1. Patients' test records were left out in an unsecured location. See D tag 5201. 2. There laboratory failed to have a comprehensive procedures manual. See D tags 5403. 5407, and 5409. 3. Review of laboratory records revealed, personnel were not following the procedure for logging and accessioning patients' specimens. There was no documentation to show that the failure to follow laboratory procedures was corrected. See D5313 4. There was no documentation to show that the Laboratory Director performed and documented QA of the preanalytic, analytic, and postanalytic laboratory systems. 5. At 11:30 AM on October 8, 2019, the LD confirmed the surveyor's findings.
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 review of the laboratory's procedures manuals and personnel records and interview with the laboratory director, the laboratory director failed to ensure that policies and procedure are established for monitoring the processing of tissue specimens by the Histotechnician. Findings: 1. The laboratory's procedures consisted of 3 incomplete procedures manuals that were not approved by the current Laboratory Director. 2. There was no documentation to show a competency assessment of the Histotechnician since the last survey on February 6, 2018. 3. At 11:30 AM on October 8, 2019, the laboratory director confirmed the surveyor's findings.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manuals, the laboratory director failed

	to ensure that an approved procedure manual is available to personnel responsible for Mohs testing. Findings: 1. There was no comprehensive procedures manual approved by the current laboratory director available for all personnel. See D tag 5403.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manuals and personnel records and interview with the laboratory director, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each identifying which examinations and procedures each individual is authorized to perform, and whether supervisory or director review is required. Findings. 1. There is no documentation to show that the laboratory director assigned specific persons who fulfill the responsibilities and duties of the following positions a. Laboratory Director b. Clinical Consultant c. Technical Supervisor d. General Supervisor e. High Complexity Testing Personnel 2. Review of personnel records show that there was no documentation to show that the laboratory director assigned, in writing, the responsibilities and duties of the following positions: a. b. Clinical Consultant b. Technical Supervisor c. General Supervisor d. High Complexity Testing Personnel 3. At 11:30 AM on October 8, 2019, the laboratory director confirmed the surveyor's findings.