Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2190634	12/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	125 Cool Springs Blvd Suite 210, Franklin, TN	

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
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interviews with the clinic lead and Mohs supervisor, the laboratory failed to have a system in place to investigate and document complaints in 2022. The findings include: 1. Review of the laboratory's procedure manual revealed no policies or procedures in place for documentation and investigation of complaints. 2. Interview with the clinic lead and Mohs supervisor on 12/16/22 at 12:45 pm confirmed the laboratory failed to have a process in place for documentation and investigations of complaints against the laboratory.
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 observation of the laboratory, review of accessioning records and patient test records, the laboratory procedure manual, lack of records, and interview with the clinic lead, the laboratory failed to verify the accuracy of its' histopathology procedures twice a year in 2021 and 2022. The findings include: 1. Observation of the laboratory on 12/16/22 at 8:30 am revealed equipment and reagents in use for

	performing patient testing for histopathology on tissue removed during Mohs surgical procedures. 2. Review of accessioning records and patient test records revealed the first Mohs case was performed on 04/29/21 (case #FTP21-001). Additional randomly selected reviews revealed case number FTP21-041 was performed on 10/13/21, case number FTP22-011 was performed on 04/08/22, and case number FTP22-050 was performed on 11/21/22. Accessioning records indicate approximately 102 patients Mohs surgeries/histopathology procedures have been performed since patient testing began on 04/29/21. 3. Review of the laboratory policy titled "Quality Assurance-Proficiency Testing" revealed that each Mohs surgeon would have six slides from each year -- three from Jan-June and three from July-December pulled at random with review of the cases by another Mohs surgeon to verify diagnosis. 4. There were no records for retrospective case review in 2021 and case reviews were not performed twice in 2022. 5. Interview with the clinic lead on 12/16/22 at 10:30 am confirmed the laboratory failed to follow its' own policy for twice a year verification of accuracy of its' histopathology procedures, resulting in the laboratory failing to verify the accuracy of histopathology procedures twice a year in 2021 and 2022 with patient testing performed.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the first patient Mohs surgery/histopathology records, lack of laboratory records, and interview with the clinic lead and Mohs supervisor, the laboratory's quality assessment process was ineffective in correcting problems with positive patient identification throughout the testing process in 2021 for one of four patient reviewed. The findings include: 1. Review of the first patient Mohs surgery /histopathology testing performed revealed the following: Testing occurred on 04/29 /21. The patient accessioning log had a case number of FTP21-001. The patient Mohs map had a case number recorded of FTP21-003. 2. There were no laboratory records indicating the laboratory identified or corrected the problem with maintaining patient identifiers through the testing process. In addition, there were no records that included monitoring of patient identification throughout the complete testing process in 2021 and 2022. 3. Interview with the clinic lead and Mohs supervisor on 12/16/22 at 12:45 pm confirmed the laboratory's quality assessment process was ineffective in identifying and correcting problems with ensuring positive patient identification throughout the testing process for one of four patients reviewed from 2021 and 2022.
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 of the laboratory, review of patient records, review of accessioning logs, and interview with the clinic lead, the laboratory failed to ensure reagents were not used past their expiration date from 04/01/22 to 12/16/22 with staining for Mohs histopathology procedures performed on approximately 67 patients. The findings include: 1. Observation on 12/16/22 at 8:30 am of the laboratory's flammable storage cabinet revealed StatLab brand Vintage Bluing reagent used in performing staining of tissue removed during MOHS surgery. The lot number observed was 118671 with an expiration date of 2022-03-31. 2. Review of selected Mohs cases revealed patient testing performed for case numbers FTP22-0011 (date of service 04/08/22) and FJT22-050 (date of service 11/21/22) while the expired bluing reagent was in use. 3. Review of the laboratory's accessioning logs since 04/01/22 revealed approximately 67 patients had tissues stained using the expired bluing reagent. 4. Interview with the clinic lead on 12/16/22 at 1 pm confirmed the laboratory performed staining procedures for histopathology using expired bluing agent from 04 /01/22 until the date of the survey on 12/16/22.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) and Aspen Web 116, email communication with the Tennessee State Agency, and email communication with the MOHS supervisor, the laboratory director failed to ensure compliance with 493.51 which requires notification to HHS or designee of changes in director and/or technical supervisor be communicated within 30 days of the change when the laboratory director changed on 09/01/22 and did not notify the State Agency. The findings include: 1. Review of the Form CMS-116 submitted as part of the survey process revealed the name of a laboratory director that was different from the name of the laboratory director as listed in the Aspen Web 116 database. 2. Email communication with the Tennessee State Agency on 12/16/22 at 9: 24 am revealed the State Agency had not received notice of the laboratory director change. 3. Email communication with the MOHS supervisor on 12/20/22 at 10:26 am confirmed the laboratory director failed to ensure the State Agency was notified of the change in laboratory director within 30 days of the change in 2022. According to the email communication the change was effective on 09/01/22.