Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0692360	12/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	6700 N Rochester Road Suite 212, Rochester Hills, MI	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation, record review and interview with the Mohs Technician, the laboratory failed to establish safety procedures to ensure protection from chemical and biohazardous materials for 1 (Mohs Technician) of 1 personnel observed. Findings include: 1. The surveyor observed the Mohs Technician using the Leica CM 1510 cryostat in the laboratory. The Mohs Technician had a bottle of water resting on the cryostat and drank from the bottle while using the cryostat in the laboratory on 12/14 /22 at 9:00 am. 2. A review of the laboratory's safety procedures on 12/14/22 revealed a lack of policy regarding drinking in the laboratory. 3. An interview on 12/14/22 at 9: 00 am with the Mohs Technician confirmed they had been drinking water in the laboratory while using the cryostat.
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 record review and interview with the Mohs Technician, the laboratory failed to verify the accuracy of its Potassium Hydroxide (KOH) and Scabies

	preparation testing for 2 (December 2020 to December 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Quality Assurance- Proficiency Testing" procedure on 12/14/22 revealed a section titled "KOH and Scabies Prep" stating, "Our policy is to have 2 cases of KOH prep and 2 cases of Scabies prep per provider double checked by another physician within the practice per year." 2. A review of the laboratory's verification of accuracy documentation on 12/14/22 revealed a lack of documentation for KOH and Scabies preparation verification of accuracy testing between December 2020 and December 2022. 3. An interview on 12 /14/22 at 10:46 am with the Mohs Technician confirmed the laboratory had no documentation of twice annual verification of accuracy testing from December 2020 to December 2022.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation and interview with the Mohs Technician, the laboratory failed to label staining reagents in the Thermo Scientific Linistat automated staining system with the identity, concentration, and expiration dates for 1 of 1 observation of the laboratory. Findings include: 1. The surveyor toured the laboratory and observed the Thermo Scientific Linistat automated staining system on 12/14/22 at 9:00 am. The wells of the automated staining system were not labeled to show the identity, concentration, and expiration dates for their contents. 2. An interview on 12/14/22 at 11:05 am with the Mohs Technician confirmed the wells were not labeled to indicate the identity, concentration, and expiration dates of their contents.
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: . Based on record review and interview with the Mohs Technician, the laboratory failed to test the hematoxylin and eosin staining materials to ensure predictable staining characteristics at least each date of use for 2 (4/27/22 and 5/25/22) of 11 patient testing dates reviewed. Findings include: 1. A review of the laboratory's "Quality Control Staining" log on 12/14/22 revealed a lack of documentation assessing the hematoxylin and eosin stain quality on 4/27/22 and 5/25/22. 2. A review of patient test records from 4/27/22 and 5/25/22 revealed a total of 3 patients (RHS22-0022 to RHS22-0025) were tested on 4/27/22 and a total of 10 patients (RHS22-0026 to RHS22-0035) were tested on 5/25/22. 3. An interview on 12/14/22 at 11:05 am

	with the Mohs Technician confirmed the laboratory failed to ensure the hematoxylin and eosin stain quality for the patient testing dates listed above.