Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0362431	03/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	1601 Lafayette Rd Ste 100, Crawfordsville, IN	

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
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, the laboratory failed to perform twice annual verification of accuracy for two of three subspecialties reviewed (Mycology-Potassium Hydroxide (KOH) and Histopathology-Mohs Surgery (Mohs)) for 2021. Findings include: 1) Record review indicated only one annual verification of accuracy was performed in 2021 for Histopathology and no twice annual verification of accuracy was performed in 2021 for Mycology. 2) Medical record review indicated the following patients were tested for Histopathology and Mycology in 2021: PT=patient # SCC=Squamous Cell Carcinoma BCC=Basil Cell Carcinoma KOH=Potassium Hydroxide PT Date Result PT#3 12/3/21 Mohs=SCC PT#4 11/19/21 Mohs=BCC PT#5 10/1/21 Mohs=BCC PT#6 9/3/21 Mohs=SCC PT#7 9/28/21 KOH=Neg PT#8 10/28/21 KOH=Neg 3) In interview on 3/16/22 at 1:20 pm, SP-2 (Histology Technician) confirmed twice annual verification of accuracy was not performed in 2021 for Histopathology and Mycology. 4) Total annual test volume for Histopathology is approximately=250 and for Mycology is approximately=40.
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 observation, record review, and interview, the laboratory failed to perform and document maintenance for one of three microscopes used for KOH (Potassium Hydroxide) and Wet Mount examinations. Findings include: 1) On 3/15/22 at 10:30 am, a microscope was observed in the laboratory (Model=EPOI, Serial #=22831). 2) Medical record review indicated the following patients had KOH testing performed in 2021: PT#=patient number PT Date Result (KOH) PT#7 9/28/21 Neg PT#8 10/28/21 Neg 3) In interview on 3/16/22 at 10:30 am, SP-2 (Histology Technician) confirmed the above microscope was used for KOH and Wet Mount examinations and had no maintenance performed nor documented. 4) Total annual test volume for KOH and Wet mounts is approximately=40.