Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2187340	05/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	290 Clear Sky Court, Clarksville, 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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory records and interview with the histotech, the laboratory failed to verify the accuracy of the cryostat temperature recording device in 2020, 2021, and 2022. The finding include: 1. Observation of the laboratory on 05/18/2022 at 9 am revealed a cryostat in use for processing tissue for histopathology procedures, and a thermometer on the counter for monitoring room temperature and humidity. 2. Review of laboratory records revealed an acceptable temperature range of -21 to -30 degrees Celsius for the cryostat, and a room temperature range of 10-30 degrees Celsius. Further review revealed no records were available verifying the accuracy of the cryostat temperature or room temperature recording devices. 3. Interview with the histotech on 05/18/2022 at 11:00 am confirmed the laboratory was recording room temperature using a department store thermometer and recording the temperature of the cryostat with no records verifying the accuracy of the temperature readings in 2020, 2021, and 2022.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f)

	(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Citation number one Based on observation of the laboratory, review of patient data log, document request, and interview with the histotech, the laboratory failed to document reagent lot numbers, dates in use, and expiration dates for chemicals, stains and reagents used for performing histopathology procedures from 08/27/2020 to 05/18 /2022. The findings include: 1. Observation of the laboratory on 05/18/2022 at 9:15 am revealed multiple reagents, chemicals, inks, and stains in use for performing histopathology procedures on tissue removed during MOHS procedures. 2. Review of the patient data log revealed the first patient was reported on 08/27/2020. 3. Request on 05/18/2022 at 11 am for reagent records revealed the laboratory did not retain a reagent log to include all reagents in use from the time patient testing began on 08/27 /2020 until the date of the survey (05/18/2022). 4. Interview with the histotech on 05 /18/2022 at 11:30 am confirmed the laboratory failed to document and retain reagent lot numbers, dates of use, and expiration dates of chemicals, stains, inks and reagents in use for performing histopathology procedures from 08/27/2020 until 05/18/2022. Citation number two Based on observation of the laboratory, review of patient data log, document request, and interview with the histotech, the laboratory failed to document hematoxylin and eosin (H&E) stain quality from 02/25/2021 until 12/16 /2021 with approximately 253 patients tested. The findings include: 1. Observation of the laboratory on 05/18/2022 at 9:15 am revealed multiple reagents and stains in use for performing histopathology procedures on tissue removed during MOHS procedures. 2. Request on 05/18/2022 at 11 am for H&E stain quality assessment records revealed the following: No H&E stain quality assessment records were retained for two of four patients selected (CTP21-0016-date tested 03/11/2021) and (CTP21-0164B-tested 10/07/2021). Further review revealed no documentation of H&E stain quality assessment from 02/25/2021 to 12/16/2021 with approximately 253 patients tested. 4. Interview with the histotech on 05/18/2022 at 11:30 am confirmed the laboratory failed to document H&E stain quality from 02/25/2021 until 12/16 /2021 with approximately 253 patients tested.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, review of laboratory records, and interview with the histotech, the laboratory failed to follow the procedure for quarterly quality assessment activities in 2021. The findings include: 1. Review of the laboratory's procedure titled "Quality Assurance Protocol" revealed that quality assessment activities would be performed quarterly using a quality assurance checklist for documentation. 2. Review of the laboratory's quality assessment documentation revealed no quality assessment activities were documented for 2021. 3. Interview with the histotech on 05/18/2022 at 11 am confirmed there was no quarterly quality

	assessment documentation for the calendar year 2021. She further confirmed patient testing was performed on multiple dates in 2021.