Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0694041	07/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	606 W Pershing Rd Ste E, Decatur, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with a laboratory representative; the laboratory failed to attest to the routine integration of potassium hydroxide (KOH) proficiency testing (PT) samples in 2019. Findings Include: 1. Microbiology proficiency testing records were reviewed for 2019. 2. American Proficiency Institute (API) records for event 2 of 2019 found the laboratory failed to have attestation documentation to the routine integration of KOH samples by the testing personnel and laboratory director. 3. Interview with the laboratory representative on survey date 7-23-2019, at 1:45 pm, confirmed the laboratory failed to attest to the routine integration of KOH PT samples for API PT event 2 in 2019.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with a laboratory representative; the laboratory failed to follow the laboratory's slide labeling procedure

	for Mohs histopathology testing. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure "Mohs Slide Labeling." 2. Review of the "Mohs Slide Labeling" procedure stated for the Decatur, IL office specimen slides will begin with "DT". 3. Review of 22 patient slides for 5 of 5 Mohs cases reviewed found 22 of 22 slides failed to be labeled according to the laboratory procedure. Patient Identification Test Date Slide Quantity P6 06-13-19 8 P7 04-11-19 4 P8 02-14-19 2 P9 10-18-18 4 P10 12-29-17 4 4. Interview with the laboratory representative on 7-23-2019, at 1:45 pm, confirmed the facility failed to follow the slide labeling procedure for Mohs histopathology testing. B. Based on review of laboratory records and interviews with testing personnel #2 (TP#2) and a laboratory representative; the laboratory failed to follow the Mohs histopathology specimen preparation procedure. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure "Mohs Surgery and Specimen Processing Procedure." 2. Review of the "Mohs Surgery and Specimen Processing Procedure" stated Mohs excision and specimen preparation, including the grossing (specifically the inking of the specimen) is performed by the physician. 3. Interview by phone with testing personnel #2, at 12:50 pm, on 7-23-2019, confirmed that the inking of Mohs histopathology specimens is performed by TP#2 and not the Mohs surgeon. 4. Review of 5 of 5 Mohs histopathology cases identified the inking was performed by TP#2. Patient Identification Test Date P6 06-13-19 P7 04-11-19 P8 02-14-19 P9 10-18-18 P10 12-29-17 5. Interview with the laboratory representative on 7-23-2019, at 1:45 pm, confirmed the facility failed to follow the Mohs histopathology surgery and specimen processing procedure.
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: A. Based on direct observation, review of laboratory records, and interview with the laboratory representative; the laboratory failed to perform cryostat maintenance to ensure accurate and reliable test performance for histopathology testing. Findings Include: 1. Direct observation on 7-23-2019, at 11:20 AM, identified an Avantik QS11 cryostat used for Mohs histopathology testing and found it contaminated debris from the cutting of tissue samples though it was not currently in use. 2. Review of the laboratory's "Daily Routine Maintenance" log stated the following: "3. Cryostat will be wiped out with dry gauze to gather excess scrapings, then cleaned appropriately with alcohol." "7. Document that daily maintenance has been completed by initialing daily maintenance log" 3. Review of the laboratory preventative maintenance log, "Daily Routine Maintenance", found the last date of cleaning for the cryostat was on 7-11-2019, its last date of service for Mohs histopathology testing. 4. On survey date 7-23-2018, at 1:45 pm, the laboratory representative confirmed the cryostat had not been cleaned as described in the daily routine maintenance log. B. Based on direct observation, review of laboratory records, and interview with the laboratory representative; the laboratory failed to perform microscope maintenance as required to

	ensure accurate and reliable test performance for mycology and pathology testing. Findings Include: 1. Direct observation on 7-23-2019, at 11:20 AM, identified an Olympus BX41 microscope used for Mohs histopathology and KOH preparation testing, which was not covered. 2. Review of the laboratory's policy and procedure manual identified the log, "Daily Microscope Maintenance". 3. The "Daily Microscope Maintenance" log stated the following: "1.The microscope should be covered at the close of every day." 4. On survey date 7-23-2018, at 1:45 pm, the laboratory representative confirmed no cover was available to cover the microscope as described in the daily routine maintenance log.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, and interview with a laboratory representative; the laboratory failed to perform corrective actions for laboratory room temperature/humidity readings in 2017 through 2019. 1. Review of the laboratory policy and procedure manual identified the log, "Room Temperature /Humidity". 2. Review of the "Room Temperature/Humidity" log for December of 2017 through July of 2019 found the room temperature and humidity readings did not change from 72 degrees Fahrenheit and 44% Humidity over the course of that timeframe. 3. Direct observation of the Extech instruments hygro-thermometer used to track the laboratory room temperature and humidity on 7-23-17 at 1:22 pm had a reading of 69.8 degrees Fahrenheit and 40% humidity. 4. On survey date 07-23-2019, at 1:45 pm, the laboratory representative confirmed no corrective actions were taken as to why room temperature and humidity reading recorded from December of 2017 through July of 2019 were all the same values.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with a laboratory representative; the technical consultant (TC) failed to ensure semi-annual competency assessments were completed for 1 of 1 moderate complexity testing personnel. Findings Include: 1. Review of the laboratory policy, "Annual Personnel Assessment", stated that CLIA guidelines require the semiannual assessment of personnel competency during the first

	year of test performance. 2. Review of competency assessment records for 1 of 1 new moderate complexity testing personnel (testing personnel #2) found only 1 of 2 competency assessments were completed for potassium hydroxide preparations. 3. On survey date 07-23-2019, at 1:45 pm, the laboratory representative confirmed only one competency assessment had been completed for TP#2 in 2018 through the date of survey, 7-23-2019.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory representative; the laboratory director (LD) failed to review 2 of 3 proficiency testing (PT) reports in 2018. Findings Include: 1. American Proficiency Institute (API) PT records for 2017 through 2019 were reviewed. 2. Review of potassium hydroxide preparation PT records found the LD failed to review the following PT events in 2018. a. KOH microscopy event 1 b. KOH microscopy event 2 3. On survey date 7-23-19, at 1:45 pm, the surveyor findings were confirmed by the laboratory representative.