Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0911386	12/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology Brighton	6888 Grand River Avenue, Brighton, 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
D5006	MYCOLOGY CFR(s): 493.1203 If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on document review and interview with the office manager, the laboratory failed to meet the subspecialty of mycology requirements as specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) preparations at least twice annually. Refer to D5217. 2. The laboratory failed to ensure Chlorazol Black E fungal stain used in Potassium Hydroxide (KOH) preparations had not exceeded its expiration date. Refer to D5417.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory failed to assess employee competency for Testing Personnel #1 (TP1) performing Mohs histopathology testing for 2 (December 2017 to December 2019) of 2 years. Findings include: 1. A record review of employee competency records revealed the most recent Mohs histopathology competency assessment for TP1 was performed on 10/18/16. 2.

	A record review of the laboratory's established "Quality Assessment Policy" revealed a section stating, "The quality systems (QA) for Brighton Dermatology Laboratory will be reviewed on an ongoing basis every six months to monitor, assess and when indicated, correct problems identified in all four quality systems stated below using the following documentation page: General Laboratory System (493.1231 to 493.1236) Patient confidentiality, Complaint investigations, Specimen identification and integrity, Communication, Personnel competency and assessment policies." 3. An interview on 12/16/19 at 11:50 with the office manager confirmed TP1 did not have documented competency assessments for Mohs histopathology testing available.
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 office manager, the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) preparations at least twice annually for 2 (December 2017 to December 2019) of 2 years. Findings include: 1. A record review of the laboratory's "KOH Competency Log Sheet", used for twice annual verification of accuracy documentation, revealed it was most recently performed on 1/25/17. 2. An interview on 12/16/19 at 11:45 am with the office manager confirmed the laboratory did not verify accuracy at least twice annually for KOH testing. ***Repeat deficiency from surveys on 7/27/17, 7/29/15, and 8/22/13***
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, record review, and interview with the office manager, the laboratory failed to ensure Chlorazol Black E fungal stain, used in Potassium Hydroxide (KOH) preparations, had not exceeded its expiration date for 77 patient specimens tested after it had been expired. Findings include: 1. An observation by the surveyor on 12/16/19 at 12:07 pm revealed a bottle of Healthlink Chlorazol Black E Fungal Stain, lot number 6349, with the expiration date of 12/14/18. 2. A record review of the laboratory's "KOH Log" sheets, used in recording patient results, revealed 77 patients had been tested since the expiration date. 3. An interview on 12 /16/19 at 12:07 am with the office manager confirmed the laboratory had been using the expired Chlorazol Black E fungal stain on patient specimens.
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 record review and interview with the office manager, the laboratory failed to perform and document microscope and cryostat annual maintenance activities for 2 (December 2017 to December 2019) of 2 years. Findings include: 1. A record review of the laboratory's established "Quality Assurance Program" revealed a section stating, "All equipment within the laboratory will be properly maintained according to the manufacturer's specifications. The Laboratory Director will be responsible for ensuring that all maintenance and repairs will be recorded and maintained by the laboratory personnel and will be reviewed by the Laboratory Director on a periodic basis." 2. A record review of the laboratory's established "Quality Assurance Program" revealed a section titled "Equipment Quality Control for Microscopes" stating, "Grounding check is monitored and recorded yearly." 3. A record review of the laboratory's established "Quality Assurance Program" revealed a section titled "Equipment Quality Control for Cryostats" stating, "Temperature calibration check is done annually and recorded. Preventative maintenance and grounding check are done yearly." 4. A record review of the laboratory's maintenance logs revealed a lack of documentation of required annual maintenance for the following equipment used by the laboratory: a. Leica DM 1000 microscope b. Avantik QS17 cryostat c. Nikon microscope 5. An interview on 12/16/19 at 12:32 pm with the office manager confirmed annual maintenance for the equipment listed above was not performed and documented. ***Repeat deficiency from surveys on 8/22/13 and 9/30/11***
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory director failed to ensure quality assessment programs were maintained to assure the quality of laboratory services for 2 (December 2017 to December 2019) of 2 years. Findings include: 1. A review of the laboratory's established "Quality Assurance Checklist" revealed a lack of completed checklists to assess the quality of laboratory services. 2. A review of the laboratory's established "Quality Assessment Policy" revealed a section stating, "The quality systems (QA) for Brighton Dermatology Laboratory will be reviewed on an ongoing basis every six months to monitor, assess and when indicated, correct problems identified in all four quality systems stated below using the following documentation page." 3. An interview on 12/16/19 at 12:23 pm with the office manager confirmed the laboratory director did not maintain the laboratory's quality assessment programs.