Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1104243	12/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	37605 Pembroke Avenue, Livonia, 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
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 establish policies and procedures to assess employee competency for 2 (December 2019 to December 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of policies for the performance of competency assessments. 2. A review of the laboratory's personnel records revealed a lack of competency assessments for the following personnel listed on the CMS-209 form: a. Testing Personnel #1 was hired August 16, 2021 and had no competency assessments present. b. Testing Personnel #2 was hired July 10, 2012 and had no competency assessments present. c. Testing Personnel #3 was hired September 15, 2021 and had no competency assessments present. 3. An interview on 12/21/21 at 12: 03 pm with the Office Manager confirmed the laboratory did not establish a competency assessment policy. ***This is a repeated deficiency from the 9/24/19 recertification survey***
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and

	rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to properly label slides with the correct case number for 1 (Case LMP20-0052) of 6 patient cases reviewed. Findings include: 1. A review of the laboratory's patient test records revealed LMP20-0052 was a tissue specimen collected from the left superior lateral malar check. 2. The surveyor requested the slides for LMP20-0052 on 12/21/21 at 9:45 am and they were not made available. 3. An interview on 12/21/21 at 10:31 am with the Office Manager revealed slides for case LMP20-0052 were incorrectly labeled as the case LMP20-0049 performed on the same patient, but a different site.
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: . Based on record review and interview with the Office Manager, the laboratory failed to follow its Potassium Hydroxide (KOH) procedure for 1 (Patient #1) of 1 patient receiving testing. Findings include: 1. A review of the laboratory's "KOH Procedure Protocol" revealed a section stating, "Document on the KOH log form the control slide details including Lot# and exp date. If readings of control slide do not coincide, a third provider is brought in to evaluate slides." and "Following examination by the provider, another provider is asked to blindly read the KOH specimen (and control, if applicable) and verify the appropriate presence or absence of spores or hyphae. The results are documented on the KOH log form, as well as entered in the patient's electronic medical record." 2. A review of the laboratory's records revealed a lack of KOH log forms. 3. An interview on 12/21/21 at 12:03 pm with the Office Manager confirmed the laboratory did not follow its KOH testing procedure.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to document temperature and humidity conditions for 4 (August 2021 to December 2021) of 24 months reviewed. Findings include: 1. A review of the laboratory's "Room Temperature/Humidity" logs revealed a lack of documentation of temperature

	and humidity conditions from August 2021 to December 2021. 2. An interview on 12 /21/21 at 12:03 pm with the Office Manager confirmed the laboratory did not have documentation of the temperature and humidity conditions for the dates above.
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 record review and interview with the Office Manager, the laboratory failed to ensure Potassium Hydroxide (KOH) reagent did not exceed its expiration date for 1 (Patient #1) of 1 patient recieving KOH testing. Findings include: 1. A review of patient records revealed Patient #1 had KOH testing performed on a specimen collected from the left superior upper back on 9/20/21. 2. The surveyor observed the laboratory's "Health Link Potassium Hydroxide 10%" bottle with the expiration date of 9/12/21. 3. A review of the laboratory's "KOH Procedure Protocol" revealed a section stating, "Document on the KOH log form the control slide details including Lot# and exp date." 4. An interview on 12/21/21 at 11:36 am with the Office Manager confirmed the laboratory used expired reagent to perform patient KOH testing.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to include the results of testing performed for 1 (Patient #1) of 10 patient test reports reviewed. Findings include: 1. A review of patient test reports revealed Patient #1 had Potassium Hydroxide (KOH) testing performed on 9/20/21. The test report stated, "Examination of the slide showed: +/- results." 2. A review of the laboratory's "KOH Procedure Protocol" revealed a section stating, "Documentation of the presence (POSITIVE) or absence (N EGATIVE) of spores or hyphae is recorded in the patient's chart, along with the site from where the specimen was obtained." 3. An interview on 12/21/21 at 10:45 am with the Office Manager confirmed the patient did not have a result present on the test report.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the Laboratory Director failed to ensure testing personnel received the appropriate training prior to testing patient samples for 1 (Testing Personnel #3) of 3 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel records revealed a lack of documentation of training and competency assessments for Testing Personnel #3 hired on 9/15/21. 2. A review of patient test reports revealed Testing Personnel #3 performed Potassium Hydroxide (KOH) testing on Patient #1 on 9/20/21. 3. An interview on 12/21/21 at 11:17 am with the Office Manager confirmed Testing Personnel #3 did not have documented training prior to testing patients.