Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2056626	10/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	1870 Silver Cross Blvd, Ste 250, New Lenox, 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
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 review of laboratory policies and procedures manuals, laboratory records and interview with the laboratory director; the laboratory failed to verify the accuracy of its Mohs (histopathology) tests. Findings: 1. There are no written procedures that described the laboratory's process for verifying the accuracy of it Mohs testing. 2. There is no documentation to show that the laboratory performed verification procedures of its Mohs testing in 2018 and 2019. 3. During survey date 10/29/13 at 11: 30 AM, the laboratory director confirmed the surveyor's findings.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if

	applicable. This STANDARD is not met as evidenced by: Based on surveyor observation; review of the patient's test records and procedures manual; and interview with the Histotechnician; the laboratory failed to ensure that the requisition solicits the following information: *The patient's name and unique patient identifier. *The sex and age or date of birth of the patient. 1. On October 29, 2019 at 10:30 AM, the surveyor observed 1 of 2 Histotechnicians sectioning tissue specimens for patient #1. 2. A Mohs map accompanied the patients' specimen. 3. There was no unique patient identifier recorded on the Mohs map. 4. The sex and age or date of birth of the patient was not recorded on the Mohs map. 5. Review of the patients test log revealed that the following information was recorded on the log: a. Date b. Accession # c. Medical Record # d. Patient Name e. Diagnosis f. site location g. stage h. block i. # of slides j. # of sections 6. The laboratory's procedures instructed testing personnel to label a map with the patients' name. 7. On October 29, 2019 at 11: 30 AM, the histotechnician confirmed the surveyor's findings.
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 review of policies and procedures manuals, surveyor observation, review of patients' tests records and interview with the laboratory director; the laboratory failed to follow written policies and procedures for the following: *Specimen labeling, including patient name or unique patient identifier and specimen source. * Specimen processing. * Specimen acceptability and rejection. Findings: 1. The surveyor reviewed a procedure titled, "SPECIMEN ACCEPTANCE OR REJECTION." 2. The "SPECIMEN ACCEPTANCE OR REJECTION" policy states the following: "When the specimen is received in the laboratory it must be received accordingly: (1) It must be transported in a secondary container. (2) It must be labeled with the patient's name, date, specimen site, corresponding map with stage number. If the specimen is not received as stated, it will be returned to the nurse or surgeon to complete accurately." 3. On October 29, 2019 at 10:30 AM, the surveyor observed Histotechnician #2 processing a patient's tissue specimen. 4. The specimen container did not include the first and last name of the patient or unique identifier and specimen site. 5. The specimen was not returned to the nurse or surgeon as instructed. 6. On October 29, 2019 at 11:30 AM, the laboratory director confirmed the surveyor's findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manuals, patients' test reports and interview with the Histotechnician; the test report did not indicate the name and address of the laboratory location where the Mohs testing was performed. Findings: 1. There were no procedures that described what information must be included on test reports. 2. Review of 6 patients test reports revealed that patients' Mohs test information was documented on the Mohs map, which is used as the patients' test report. The name AND adress of the laboratory location where Mohs tests were performed was not indicated on the Mohs map. 3. On October 29, 2019 at 11:30 AM, the Histotechnician confirmed the surveyor's findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 observations, review of pre-survey documentation, Laboratory Personnel Report Form (CMS 209), personnel records and interview with the histotechnician; the laboratory director failed to 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 accurate results. Findings: 1. Review of the current CMS 209, signed and dated October 28, 2019, revealed that there was no documentation to show the performance of testing personnel responsible for testing was evaluated at least semiannually during the first year the individual tests patients' specimens for 3 of 3 testing personnel 2. On October 29, 2019 at 11:30 AM, the histotechnician confirmed the surveyor's findings.