Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1040200	02/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	104 N Haven Rd Ste 7, Elmhurst, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observations; review of manufacturer's safety data sheets and procedures manuals; and interview with the laboratory director, the laboratory was not maintained to ensure adequate ventilation when performing histopathology staining processes. Findings include: 1. At 10:00 AM on 02/191/9, the surveyor observed that the laboratory performed cutting and staining of Mohs surgical tissue specimens. 2. The surveyor observed the following equipment in the laboratory: a. stainer b. microtome c. biological flame cabinet that included reagents the laboratory used 3. Review of the laboratory safety data sheets revealed that 3 of the reagents used in the processing and staining of tissue specimens may cause respiratory irritation. 4. Review of the laboratory's procedures manuals revealed, in section titled, "Quality Control Policies and Documentation", under # 10. it states, "Air filter is cleaned as part of maintenance every 6 months." 5. There was no fume hood available when the laboratory performed the processing and staining of tissue specimens in the laboratory. 6. At 12:30 PM on 02/19/19, the laboratory director confirmed the surveyor's findings.
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 the laboratory's procedures manuals, testing records and interview whit the laboratory director; the laboratory failed to verify the accuracy of its histopathology procedures at least twice annually. Findings include: 1. There was no documentation to show that the laboratory verified the accuracy of its histopathology procedures from April 1, 2017 through February 19, 2019. 2. At 12:30 PM on 02/19 /19, 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 procedures manuals, patients' test reports and interview with the laboratory director; the test report did not indicate the test report date. Findings include: 1. Review of the laboratory's procedures manuals revealed that patients' test results were recorded in the electronic medical record (EMR) of the patient. 2. At 12:00 PM on 02/19/19 the surveyor requested a total of 6 patients' test reports for review. There was no record that the test report date was documented on 6 of 6 patients' test reports reviewed. 3. At 12:30 PM on 02/19/19, the laboratory director 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 review of laboratory policies, procedures, personnel records and interview with the laboratory director; the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training and have demonstrated that they can perform all testing operations reliably. Findings include: 1. Review of the laboratory policies and procedures revealed that the laboratory performed histopathology procedures that includes the high complexity Mohs micrographic testing. 2. Review of personnel records revealed that there was no documentation to show the following for 2 of 2 testing personnel processing tissue specimens: a, Highest level of education (Degree/Diploma) b. Documentation of training c. Competency assessment 3. At 12: 30 PM on 02/19/19, the laboratory director confirmed the surveyor's findings.