Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1030241	05/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	1124 Essington Rd, Joliet, 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
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 review of the laboratory records and interview with laboratory personnel; the laboratory failed to establish policies and procedures to assess employee competency for 10 of 10 laboratory positions filled by personnel identified on the CMS-209. Findings Include: 1. Review of the laboratory procedure manual found no policy was established to monitor the competency of 2 of 2 technical consultants (TC), 2 of 2 Technical Supervisors (TS), 4 of 4 Clinical Consultants (CC), and 2 of 2 general supervisors (GS) identified on the CMS-209. 2. On survey date 05-31-2018, at 1:15 pm the laboratory director confirmed that no competency assessment policy was in place to ensure the competency of the above mentioned laboratory personnel.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory personnel; the laboratory failed to outline all components of the potassium hydroxide test procedure. Findings Include: 1. Review of the policy and procedure manual found the procedure, "KOH Procedure Protocol", failed to outline the following required components of a test procedure: a. Control procedures. b. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. c. The laboratory's system for entering results in the patient record and reporting patient results including panic values. f. Description of the course of action to take if a test system becomes inoperable. 2. During survey date 5-31-2018, at 1:15 pm, the above findings were confirmed by the laboratory director.
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 direct observation, laboratory records, and interviews with laboratory personnel; the laboratory used expired potassium hydroxide reagent for 4 of 4 patient test results reviewed in 2018. Findings Include: 1. During tour of laboratory facility on 5-31-2018 with testing personnel (TP) #9, at 12:50 pm, the surveyor observed potassium hydroxide (KOH) reagent that had exceeded the expiration date for patient testing. a. KOH reagent, lot #1705410, expired 2-23-2018. 2. Review of "KOH Log" identified 4 patients tested in March 2018 through May of 2018 with the expired KOH reagent. 3. On survey date 5-31-2018, at 1:15 pm the above findings were confirmed by the laboratory director.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that 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 personnel interviews; the laboratory director failed to ensure 1 of 6 proficiency testing (PT) events in 2016 through 2017 were reviewed by the appropriate staff and identified problems that require corrective action. Findings Include: 1. Review of American Proficiency Institute (API) proficiency testing performance records for KOH preparations found the laboratory failed to review 1 of 6 testing events in 2016 through 2017. 2. Review of API performance summaries found for 2016, event 3, the laboratory scored a 50% for KOH preparations and no corrective action was documented. 3. On survey date 05-31-2018, at 1:15 pm the above findings were confirmed by the laboratory director.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory records and personnel interviews; the technical consultant (TC) failed to ensure annual competency assessments were completed for all testing personnel performing mycology testing. Findings Include: 1. Review of competency assessment records for 2 of 2 testing personnel (TP#4 and TP#5) performing potassium hydroxide preparations found the documented competency assessments in 2017 and 2018 were photocopied competency assessment records performed in 2016. 2. On survey date 5-31-2018, at 1:15 pm, the laboratory director confirmed the competency assessment documents were photocopied assessments from 2016 and no competency assessments had been performed in 2017 and 2018 for TP#4 and TP#5.